INVESTIGATIONS INTO ORTHODONTIC ANCHORAGE

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Volume I of II

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ABSTRACT

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Background and objectives:

The control of anchorage is integral to successful orthodontic treatment. The objective of this research was to undertake three related projects to evaluate methods of increasing anchorage with the aim of adding to orthodontic knowledge and improve methods of treatment delivery.

Methods:

Two Cochrane systematic reviews were undertaken according to the methods published in the Cochrane Handbook for Systematic Reviews of Interventions, version 5.1.0. The influence of functional appliances on tooth position and the extraction decision was performed as a retrospective study using participants from a completed multicentre randomized trial.

Results:

1- Statistically and clinically significant differences were found between the mean values of distal molar movement when surgical anchorage and conventional anchorage were compared.
2- Statistically significant differences were found between the mean values of distal molar movement and mesial upper incisor movement when intraoral distalising appliances and cervical headgear were compared.
3- Fixed and removable functional appliances are equally effective in anchorage preparation. The type of functional appliance and time spent in Phase I treatment influenced the amount of lower incisor proclination.

Conclusions:

1- Surgical anchorage is more effective than headgear without the inherent risks and compliance issues. However, intraoral appliances used in adolescence for distalisation of upper molars do not appear to have any advantages over cervical headgear.
2- Functional appliances reduce the anchorage requirements of a case primarily by reduction of the overjet, both fixed and removable functional appliances are equally effective in obtaining this. However, fixed functional appliances result in greater lower incisor proclination than removable functional appliances.
3- The type of functional appliance (removable or fixed) does not influence the extraction decision, however, this is influenced by overall space requirements.

DECLARATION

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

Safa Jambi

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THE AUTHOR

The author qualified from King Abdul-Aziz University, Jeddah, Saudi Arabia with an honours degree. She then worked as a general dentist in the Ministry of health for two years and then at the prestigious King Faisal Specialist Hospital and Research Center for three years. Following this she completed a three-year specialty Orthodontic programme at the University of Manchester and graduated with distinction. She also has an MOrth degree from the Royal College of Surgeons of Edinburgh. She then started her PhD in Orthodontics at the University of Manchester. This was with the generous support of a full sponsorship from the government of Saudi Arabia.

INTRODUCTION

The purpose of this research is to assess the anchorage potential of three groups of orthodontic appliances; surgical anchorage devices, distal movement appliances and functional appliances.

The importance of controlling orthodontic anchorage in obtaining optimum treatment results has been recognised since the late 1800s. At this time orthodontic headgear was introduced and used extensively, however, it became clear that the use of headgear was not without problems, such as compliance and ocular injuries. As a result, its use has reduced over the last twenty years and orthodontists have investigated several alternatives. Recently, the use of non-compliance devices for surgical anchorage, such as distalising and surgical appliances, has become widespread. In spite of the presence of clinical studies investigating these appliances and devices, their effects have not been subject to critical review. It is also suggested that a functional appliance may be an alternative to headgear due to the type of tooth movements that may result from using these appliances.

Therefore, it is my intention in this thesis to carry out several related projects to investigate the anchorage potential of different groups of appliances, which may help clinicians in making informed decisions when selecting the appliance of choice:

1. A Cochrane systematic review of distal movement appliances.
2. A Cochrane systematic review of surgical anchorage devices.
3. An investigation into anchorage preparation of functional appliances.

This thesis has five main sections. Section 1 is an overall literature review and aims and hypotheses for all three investigations.

Section 2 and 3 reports both systematic reviews. I will start with the Cochrane systematic review into the effectiveness of distal movement of upper molar teeth. This will be

followed by a Cochrane systematic review update that evaluates the effectiveness of surgical anchorage.

Section 4 will outline a study that evaluates the effect of functional appliances on tooth movements in Phase I functional appliance treatment and the extraction decision prior to Phase II.

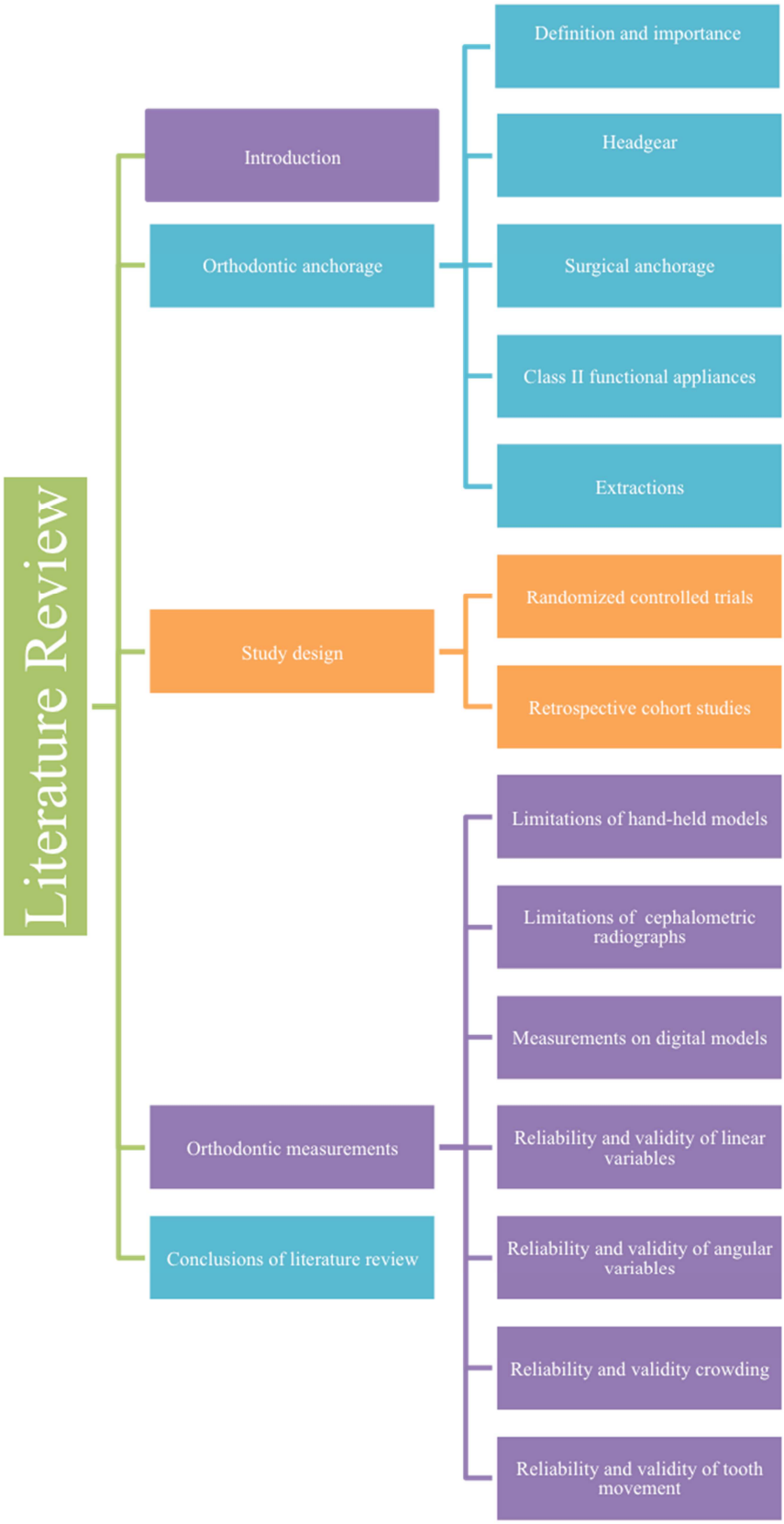
I will then conclude by combining the three investigations together in an overall discussion and concluding commentary in Section 5.

SECTION I: Literature Review, Aims and Hypothesis

1 Literature Review

Figure 1 shows the order in which in which the topics are presented in this review.

Figure 1: A flow chart summarising the main topics discussed in the literature review



1.1 Introduction

Orthodontics is the branch of dentistry concerned with facial growth, the development of the dentition and occlusion, and the diagnosis, interception and treatment of occlusal anomalies. The goal of orthodontic treatment is to improve the person's life by enhancing dental and jaw function and dentofacial aesthetics. This is achieved by obtaining optimal proximal and occlusal contact of teeth (occlusion) within the framework of normal function and physiologic adaptation, acceptable dentofacial aesthetics and self-image and reasonable stability (Graber and Vanarsdal, 1994). Conventional orthodontic treatment is achieved using fixed and removable appliances to achieve a planned end point of treatment.

Orthodontic anchorage is an important concept in orthodontic treatment, and can be reinforced by many types of appliances. Orthodontic headgear has traditionally been considered to be the "gold standard" appliance for reinforcing anchorage. However, an increasing awareness of the drawbacks of headgear, mainly poor patient compliance and serious eye injuries, has led to the development of appliances in which the evidence base supporting their use is incomplete. In addition, it has been suggested that functional appliances which are traditionally used for growth modification, can be used for anchorage preparation.

In this section, the concept of anchorage in orthodontic treatment is reviewed. The definition of anchorage is presented including its relationship to space requirements, extractions and certain appliances, including the potential of using functional appliances for anchorage.

As the effectiveness of some of these appliances has been evaluated by randomized trial methodology (RCT), an account of the bias that can arise in RCTs is given and the potential effect this bias may have on the trial results.

Finally, the important aspect of measurement of variables in orthodontic research is reviewed focusing on the reliability and validity of new measurement methods using computer software and digital models.

1.2 Orthodontic anchorage

1.2.1 Definition and importance

Anchorage in orthodontics can be defined as the resistance to unwanted tooth movement [1]. When an orthodontist/dentist plans treatment they evaluate the anchorage requirement by estimating the amount of space that is needed to correct the malocclusion. Anchorage or space may be obtained by extracting teeth, moving teeth into certain position and/or the use of orthodontic appliances. Achieving anchorage can be obtained by one of the following methods:

1.2.1.1 Maximising the potential of available teeth:

In this method a force is applied between two points (tooth or groups of teeth) and tooth movement is controlled by making one point more resistant to movement than the other. This is done by careful planning of the site of force application. Examples include:

a. Active movement of one tooth versus several “anchor” teeth, for example correcting the centreline by moving one tooth at a time.
b. Teeth of greater resistance to movement are utilized as anchorage for the translation of teeth that have less resistance to movement. A common example of this is closing space by pitting the posterior teeth (greater resistance) against the anterior teeth (less resistance).
c. Increasing the number of teeth in the anchor unit, examples are:
    i. Adding the second molar to the fixed appliance.
    ii. Adding the anterior teeth to reinforce posterior anchorage by bending loops mesial to the first molars.
    iii. Adding teeth from the opposing arch to the anchor unit by utilizing inter-arch elastics.
d. Making movement of anchor teeth more difficult, for example putting a tip-back bend in first molars.

e. Using ankylosed teeth as anchors.

1.2.1.2 Providing an additional form of orthodontic appliance:

The anchorage gained from the previous methods is limited. As a result, it is necessary to reinforce the anchorage with an additional appliance. The most commonly used orthodontic anchorage devices are:

a. Extra oral anchorage (EOA) with headgear
b. Intraoral anchorage with palatal and lingual arches.

1.2.2 Headgear

Headgear is an orthodontic appliance that is used to apply forces to the teeth utilising structures outside the oral cavity. Headgear is usually applied to the first maxillary molar via a tube attached to the molar band. The force necessary to provide extra oral anchorage is 200 to 250 gm applied for 10-12 hours per day [2].

Headgear was first used for anchorage by Kingsley in 1866 to retract upper incisors in an upper premolar extraction case [3]. This was followed by Angle in 1888 and Case in 1907 [3]. In 1953, Kloehn developed the contemporary design of headgear that orthodontists use today [3].

Since then, headgear has been used conventionally when maximum anchorage is required. As a result, it may be considered the “gold standard” for anchorage in orthodontic anchorage.

1.2.2.1 Disadvantages of headgear:

The use of headgear has the following disadvantages or risks:

1. Compliance: From the early days of headgear use, it was clear that substantial compliance was required and failure to wear headgear, for the prescribed amount of time, was recognised [3]. Headgear compliance is measured as the discrepancy between actual hours of wear and reported hours of wear and has been evaluated in several studies. Results of these studies have been discouraging as the actual hours of wearing headgear appear to be much lower than that required [4-6]. For example, Brandao et al in 2006 suggested that patients who had been asked to wear their headgear for 14 hours a day, reported wearing their headgear an average of 13.6 hours a day while the actual hours of wear were only 5.6 hours [4]. Cole [6] and Cureton [5] also found that the reported hours of wear were much less than the actual hours of wearing headgear .
2. Soft tissue injuries: Apart from minor injuries to the surrounding intraoral and extra oral soft tissues, serious ocular injuries have been reported both in Europe and the United States. In some of these instances blindness has resulted as a final result of the injury. Ten eye injuries have been reported in the literature; 2 in the UK, 3 in France, 2 in Italy, 1 in Germany and 2 in the United States [7, 8]. These injuries resulted from one of several factors including dislodgement during sleep, improper removal of headgear or improperly playing with the headgear.
3. Nickel Allergy: A small portion of the population will exhibit sensitivity to the Nickel alloy in facebows [9-11]. Nickel allergies in response to orthodontic appliances are not considered a major health risk.
4. Exacerbation of pre-existing eczema: there has been a case reported in the literature in which an increase in the severity of a pre-existing atopic eczema was observed after headgear wear [12].

It is evident from the problems mentioned that the most significant drawbacks of headgear use are non-compliance and serious eye injuries. Several measures have been taken to overcome these two problems with varying amounts of success.

1.2.2.2 Improving headgear compliance:

Suggestions have been made in the literature to encourage patients to increase the actual number of hours in which headgear is worn; these include the following:

- The use of a headgear calendar [13],
- The use of a headgear timer or electronic monitoring device and informing the patient of its presence [14],
- The use of conscious hypnosis for patient motivation during headgear wear [15],
- Treatment by a defined behavioural model which depends on a schedule for wearing headgear, in addition to parental observations and rewards based on patient compliance. This behavioural model is flexible and will evolve according to the patient's response and needs [16],
- Promoting headgear wear by considering gender differences, making patients more aware of their malocclusions and the effect of treatment [17].

1.2.2.3 Headgear safety mechanisms:

Several features have been added to headgear in an attempt to prevent elastic recoil injuries or unintentional detachment of the headgear. These include:

- Lock mechanisms which prevent release of the facebows from the molar tubes [18],
- Snap-release headgears which prevent elastic recoil of the facebows when an excessive force is used [7],
- Plastic safety straps which attempt to limit the movement of the facebows [7],

- Intraoral elastics to attach the inner bow to the molar tube [7],
- Blunting and smoothening the ends of the facebows to reduce the potential for injury [7].

It has been recommended that at least two of these mechanisms are used simultaneously in addition to clear verbal and written instructions to the patients and parents [19].

In summary, headgear is considered the "gold standard" appliance for providing anchorage. However, in order for it to work effectively, it requires a significant amount of patient cooperation and compliance. There have been many attempts to improve headgear compliance, which is a reflection of the failure to overcome this problem. Finally, there are several safety issues related to headgear, which may discourage patients and orthodontists from its use.

The ideal solution would be to use an anchorage device that provides at least the same anchorage potential as headgear, but requires little or no compliance. This has led to the development of surgical anchorage devices.

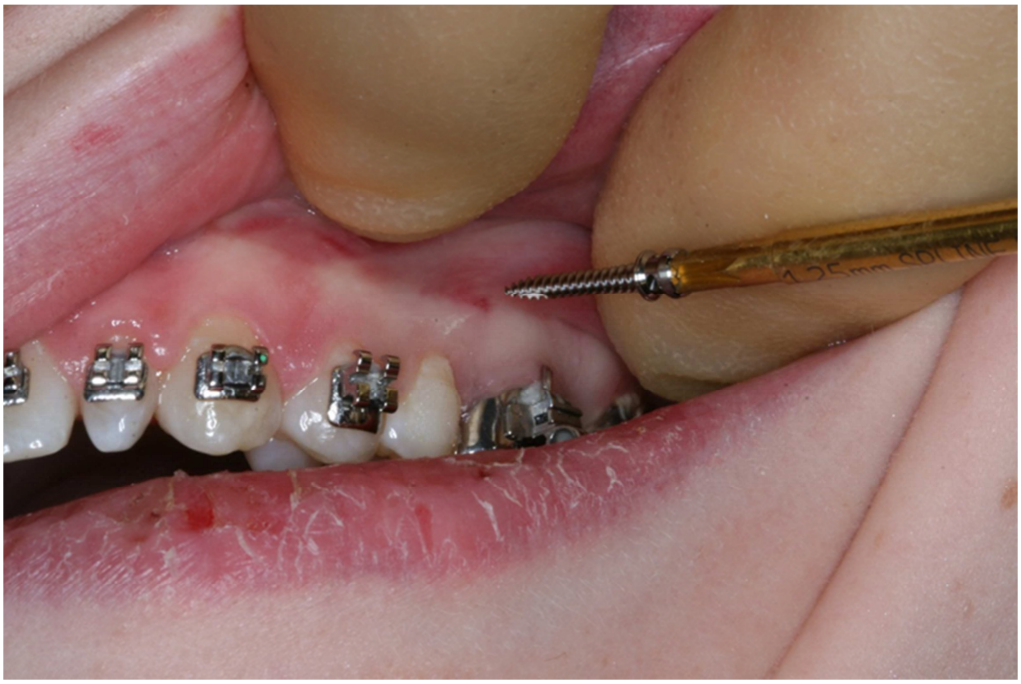
1.2.3 Surgical anchorage

In this thesis I will use the term "surgical anchorage" to denote all types of anchorage devices which are surgically placed in the maxilla or mandible. The use of implants for orthodontic anchorage is a rapidly developing field and appears to be very promising. It has evolved from using conventional restorative implants in the line of the arch to more specialized palatal implants and mini-plates, to mini-screw implants.

Types of surgical anchorage include mini-screw implants, mini-plates and midpalatal implants. The mini-screw implant is a modification of screws used for fixation of

maxillofacial fractures. Although they have varying lengths and diameters, they are generally smaller than maxillofacial fixation screws, hence the term 'mini', (Figure 2). It is also important to distinguish mini-screw implants from midpalatal implants which can be used for orthodontic anchorage, as the latter are endosseous implants and a modification of prosthetic implants, (Figure 3). Mini-plates are small surgical plates that must be surgically screwed to bone under the soft tissue, (Figure 4 and Figure 5).

Figure 2: Insertion and clinical application of a mini-screw implant



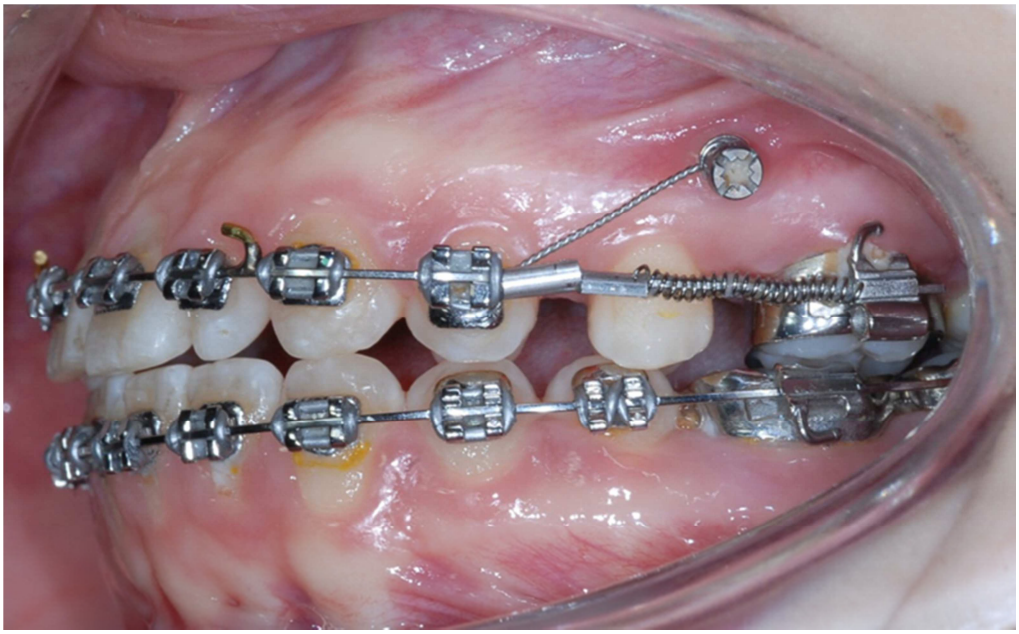


Figure 3: Clinical and radiographic view of a mid-palatal implant

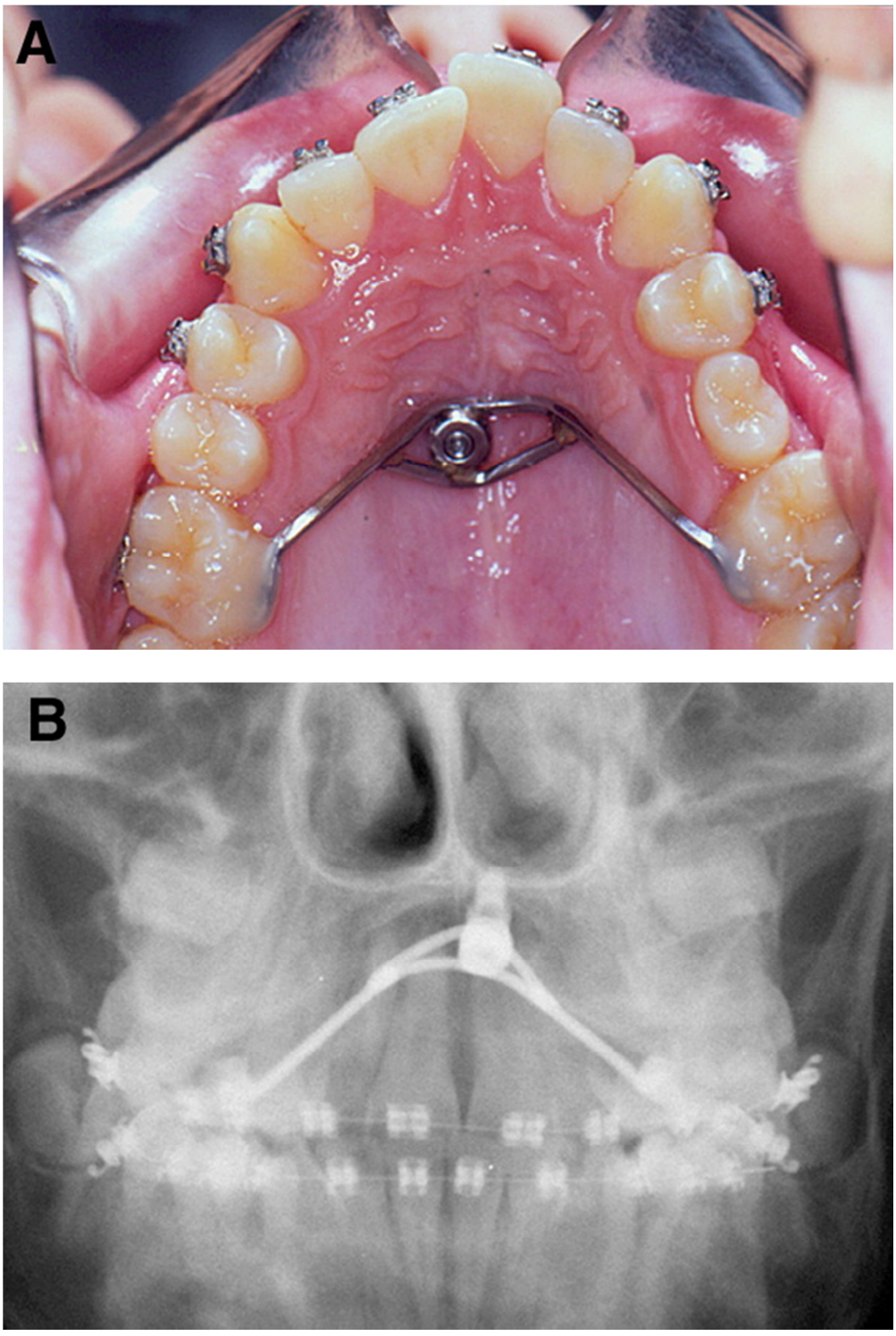


Figure 4: Mini-plates positioned in multiple theoretical locations

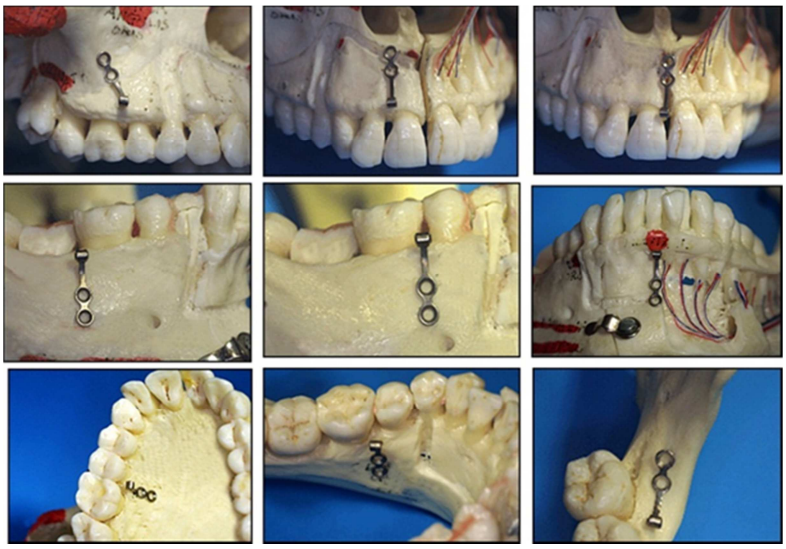
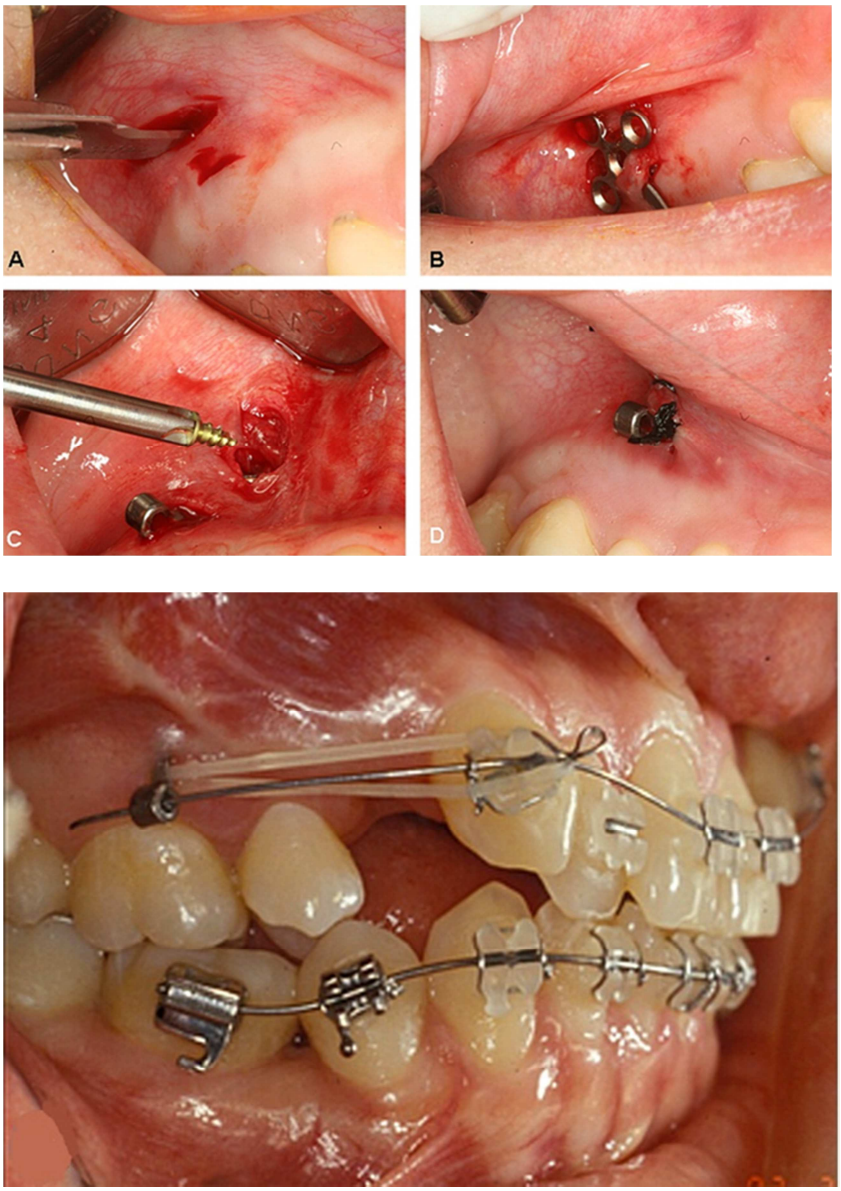


Figure 5: Surgical placement and clinical application of a mini-plate used to reinforce anchorage



Mini-screw implants may provide anchorage reinforcement because of the combination of mechanical retention immediately after insertion (primary stability) and a degree of osseointegration. Mini-plates provide a stable structure fixed to bone for application of forces and midpalatal implants offer stability by osseointegration.

Despite the widespread adoption of this type of technology, there is a dearth of high quality clinical research into their effectiveness. The literature concerning their use is referenced in section III as part of the systematic review.

1.2.4 Class II functional appliances

Functional appliances are orthodontic appliances that utilize the facial and masticatory musculature to produce orthodontic forces. They are commonly used in the treatment of Class II malocclusions. They can either be removable, for example the Clark's Twin Block appliance, or fixed, for example, the Herbst appliance. In the UK, the most popular functional appliance for treating Class II malocclusions is the Twin Block [20].

Functional appliances were developed to treat malocclusions by "growth modification", by encouraging differential growth of the mandible and maxilla. In Class II malocclusions the objective is to encourage growth of the mandible and/or restrain growth of the maxilla. While this theoretical effect of functional appliances is often quoted, the evidence behind these concepts is lacking. Recently, there have been a number of randomized clinical trials evaluating the skeletal effect of functional appliances. These are summarised in a Cochrane systematic review published in 2013 which assessed and analysed outcomes of 17 studies [21].

These studies produce interesting results. When early two-phase treatment with a functional appliance was compared to adolescent one phase treatment (patients who did not receive a functional appliance), there was no difference in the final ANB (MD -0.02°, 95% CI -0.47 to 0.43. P = 0.92). Similarly, when a comparison was made for early treatment between headgear and functional appliances, there was no difference in the final ANB (MD -0.17°, 95% CI -0.67 to 0.34, P = 0.52). When functional appliance treatment was performed in adolescents and compared to untreated controls, there was a statistically significant difference in ANB (MD -2.37°, 95% CI -3.01 to -1.74, P <0.00001); however this was low quality evidence (2 studies, 99 patients).

It was concluded from the results of these trials that the amount of skeletal change (growth modification), from the use of functional appliances is small and is unlikely to be clinically significant. Nevertheless, it is clear that these appliances are very effective in the correction of Class II malocclusion primarily through dentoalveolar movements.

The following effects of Twin Block treatment are clinically useful:

- Enhancing facial appearance [22, 23]
- Distalising upper molars and molar correction [24, 25]
- Reducing the overjet [24-30]
- Proclination of lower incisors [24-26, 28, 30, 31]
- Retroclination of upper incisors [24-26, 28, 30]

A case report using Twin Blocks to treat a Class II division II case suggested that a Twin Block can be used instead of headgear derived anchorage [32]. When we consider the preparation of orthodontic anchorage it is common clinical experience that molar correction and the reduction of the overjet are major factors in reducing the anchorage

requirements of a case. As a result, some clinicians use functional appliances in 'anchorage preparation' with the aim of avoiding dental extractions or other forms of anchorage. A common method of achieving this is by utilizing a 2-phase treatment protocol during adolescence [33]. The first phase of treatment is achieved by using only a functional appliance. This phase usually continues until the overjet and/or molar relationship is corrected. The clinician may then choose to retain the correction obtained by the functional appliance by keeping the functional appliance in place or by using a simple removable appliance [34]. This is immediately followed by a second phase of active fixed orthodontic treatment.

1.2.5 Extraction

As mentioned in the previous section, the anchorage requirements of a case are related to the space available in the upper and lower arches. It is common orthodontic practice to change anchorage requirement by the extraction of teeth [2].

The literature examining factors influencing the extraction decision can be divided into three different methodologies according to the method of study. These are: (i) the studies that directly ask clinicians their "stated reasons" for extraction, (ii) studies that measured the influence of the presence or absence of a cephalometric radiograph on the decision to extract, and (iii) studies that define some patient characteristic, such as cephalometric variables or orthodontic indices, and attempt to identify a correlation between these characteristics and whether or not extractions had been undertaken. I will discuss these studies in the following section:

1.2.5.1 Clinicians stated reasons influencing the extraction decision

Only one study, Baumrind et al, directly asked orthodontists the factors that were related to their decision to extract teeth as part of a course of treatment [35]. In this study full orthodontic records of 72 patients were given to 5 clinical instructors in a University

setting in the USA. They were given a treatment planning form to complete for each patient; included in the form were questions about the extraction decision and the reasons for extraction. The clinicians stated that the most important reasons for extraction were crowding (49%), followed by incisor protrusion in 14% and profile improvement in 8%. Other, less frequent, reasons were 'Concern over Class II severity' and 'concern for post-treatment stability' (5%). No other single reason was stated as the most important reason in more than 2% of the forms. When considering all replies, crowding was cited in 72% of forms, incisor protrusion in 35%, profile improvement in 27% and Class II severity in 15%. No other single reason was stated in more than 9% of forms.

This was a simple cross-sectional study, in which the patient records and the participants were a convenience sample. It does, however, provide some relevant information on the reasons for extraction.

1.2.5.2 Cephalometric radiographs influencing the extraction decision:

There have been several studies that have evaluated the effect of radiographs on the extraction decision. For example, Devereux et al [36] carried out a study in which a group of orthodontists were sent the orthodontic records of 6 patients on a CD, not containing lateral cephalometric radiographs or tracings, and were asked if they would extract teeth (T1). At this point, the orthodontists did not know that they were to be asked to examine the cases again after a washout period. After a period of 8 weeks (T2), the orthodontists were sent the records of the same 6 patients, but the lateral cephalometric radiographs and tracings were included in the records. They were asked again if they would extract teeth. The decisions made by this group (group A) were compared to another group of orthodontists (group B) who had full patient records, including lateral cephalometric radiographs and tracings, at both T1 and T2. It was found that the orthodontists in group

A were 1.7 (95% CI, 1.0-2.8) times more likely to change their extraction decision than those in group B (odds ratio).

In a similar investigation, Nijkamp et al investigated the influence of lateral cephalometric radiographs on the treatment planning decision [37]. This was a crossover design in which diagnostic records of 48 patients were given to 10 orthodontic postgraduates and 4 orthodontists. They were asked to formulate a treatment plan based around a dichotomous decision regarding three treatment options; (i) extraction, (ii) the use of a functional appliance and (iii) the use of rapid maxillary expansion. The diagnostic records at T1 included dental casts, but did not include a lateral cephalometric radiograph. T2 was 1 month later, and included both dental casts and lateral cephalometric radiographs and values. This design was repeated so that at T3, which was one month after T2, only dental casts were included; and at T4, which was one month after T3, dental casts and lateral cephalometric radiographs were included in the diagnostic records. Agreement between the treatment planning decision with and without the lateral cephalometric radiograph was assessed. In order for the treatment plans to agree, decisions about all three treatment options had to be the same. There was no statistically significant difference in the treatment plans between the use of only dental casts or with additional cephalometric information ($P = 0.74$).

Another study by Han et al evaluated the effect of the incremental addition of diagnostic records on the extraction decision [38]. Five orthodontists provided a treatment plan for 57 patients. Orthodontic records were given to each of the five orthodontists in the following order:

1. Session 1: study models only
2. Session 2: study models and facial photographs
3. Session 3: study models, facial photographs, and panoramic radiographs

4. Session 4: study models, facial photographs, panoramic and lateral cephalometric radiographs.

5. Session 5: all the previous records in addition to a lateral cephalometric tracing.

The time interval between each session was 1 month, and the records were re-numbered between sessions. In each session, the orthodontists were asked to select a treatment pathway from a decision tree. The end point of each of the treatment pathway was a decision on whether or not to extract. The treatment planning decisions for each of the orthodontists in session 5 was considered the "gold standard" for that clinician. As a result, the proportion of agreement between the treatment plan in each of the four sessions and the treatment plan in session 5 was obtained. The proportions of agreement between sessions 1, 2, 3, 4 and session 5 were 55%, 55%, 65% and 60% respectively. Therefore,] they concluded that study models alone are adequate for treatment planning, and that the addition of other types of diagnostic records made only a small difference.

These three studies were good quality cross-sectional studies. The randomisation and method of washout were clear strengths of the studies. In addition sample size calculations were undertaken in two of these studies; Devereux et al and Nijkamp et al.

1.2.5.3 Patient characteristics influencing the extraction decision:

The final type of studies evaluating the extraction decision are studies which attempt to identify a correlation between patient characteristics and whether or not extractions had been undertaken. Two studies, Xie et al and Takada et al, used a mathematical model to construct a decision-making Expert System (ES), which could formulate treatment decisions. [39, 40]. ES is a branch of artificial intelligence in which the computer programme simulates the decision-making and working processes of experts and solves

clinical problems. They developed a model in which twenty-five patient characteristics were tested on 180 treated patients [39]. The rate of coincidence between the recommendations given by the optimized model and the actual treatments performed was found to be 100%. The characteristics that influenced the extraction decision were the 'anterior teeth uncovered by incompetent lips' and 'IMPA (L1-MP)'. Another similar study was carried out by Takada et al when they selected 25 patient characteristics and 188 treated patients in their model [40]. The rate of coincidence between the recommendations given by the model and the actual treatment performed was 90.4%. The characteristics mostly influencing the extraction decision were incisor overjet and upper and lower arch length discrepancies.

Heckmann et al investigated the influence of the angulations between the first and second lower molars on panoramic x-rays, on the extraction decision [41]. They used a sample of 30 patients treated by a premolar extraction approach, and a further matched sample of patients treated with a non-extraction approach. Pre- and post-treatment panoramic x-rays were scanned and computer software used to measure the angulations between lower first and second molars. Comparison between the mean angulation of the molars before treatment in the extraction and non-extraction group was not significant.

Li et al compared mean cephalometric parameters and model analysis of Class II division 1 patients who were treated with either an extraction or non-extraction approach [42]. The sample consisted of 81 patients; 42 who had 4 premolar extractions and 39 who had non-extraction treatment. The extraction group had statistically significant greater values for the following parameters; arch length discrepancy, curve of spee, upper incisor tip, Frankfort-mandibular plane angle and lower anterior facial height.

Bishara et al compared patient characteristics of Class II division 1 patients who were treated with either an extraction or non-extraction approach [43]. The sample consisted of 91 patients; 44 had first premolar extractions and 47 who had non-extraction treatment. A statistically significant difference was found between the extraction and non-extraction groups with regards to the following parameters; upper and lower arch length discrepancy, upper and lower lip protrusion in relation to the aesthetic plane in male patients, and the protrusion of the lower lip in female subjects.

These studies were retrospective in nature. There were variations among the studies in the application of inclusion criteria in an attempt to control the characteristics of patients included in the study. Nevertheless, selection bias was inevitably present in these studies. Bias due to periodical changes may also be present due to the retrospective nature of the studies.

In summary, studies evaluating the factors influencing the extraction decision are few in number. They have been carried out by gathering the opinion of clinicians in cross sectional studies or by conducting retrospective investigations on a sample of cases in which teeth were extracted as part of orthodontic treatment. The main deficiencies of the studies were due to inadequate selection and number of the study sample; and bias arising from their retrospective nature.

1.3 Study design:

1.3.1 Randomized controlled trials

A randomized controlled trial (RCT) is a type of clinical investigation that evaluates the safety and efficacy or effectiveness of healthcare services or health technologies. The core concept of an RCT is based around the random allocation of a patient to two or more comparative groups. Importantly, each subject enrolled in the study has an equal opportunity of being allocated to either group through the process of randomization.

Byar et al [44], summed up the advantages of randomization in three major points:

1. 'The randomization procedure prevents bias introduced from the assignment of treatments. This means that the allocation of treatment or control will not depend on selection of patients of a certain kind. It also assumes that all patients eligible for the trial are selected to participate.'
2. 'The randomization procedure produces balanced baseline comparison groups with regards to known and unknown prognostic factors.'
3. 'Randomization ensures the validity of the statistical tests of significance that are used to compare the treatments.'

1.3.1.1 Quality of randomized controlled trials:

When assessing the quality of trials it is necessary to differentiate between the quality of the study and the quality of reporting. . The quality of a study can be defined as 'a set of parameters in the design and conduct of a study that reflects the validity of the outcome, related to the external and internal validity and the statistical model used' [45]. Whereas, the quality of reporting an RCT has been made clear by the adoption of the CONSORT guidelines, it is important to make this distinction because a poorly reported RCT is not necessarily low in quality [46].

An evaluation of the quality assessment of randomized trials suggests that this is far from clear. For example, over 25 ‘quality lists’ have been developed to judge the quality of an RCT [47]. The most transparent method appears to be that used by the Cochrane collaboration which assesses the risk of bias in individual RCTs. Bias in clinical trials may be described as systematic errors that encourage one outcome over others. The potential effect of bias is that investigators may come to incorrect conclusions about the beneficial and/or harmful effects of interventions [47]. The following types of bias will be discussed in some detail; selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias [48].

1.3.1.1.1 Selection bias

Selection bias can arise in the following circumstances; when all eligible participants are not invited or included in the trial, when an allocation sequence is not generated, or when the allocation sequence is easily revealed. The result is that participants allocated to the intervention or control group may not be equal with respect to known or unknown prognostic factors. In other words, the effect of randomization has been removed and the final comparisons may not be valid. A good example of this is when an allocation sequence is concealed in envelopes at the research site. It is possible for the envelopes to be manipulated, for example, by placing them in front of a light to reveal the next allocation. Studies of the effect of selection bias suggest that treatment effects are consistently over- or underestimated [49]. Importantly, inadequate sequence generation and inadequate allocation concealment was found to be associated with larger estimates of treatment effects [50, 51].

1.3.1.1.2 Performance bias

Performance bias (or information bias) occurs when either the participant and/or the operator are not blind to the treatment allocation. In other words, they know which treatment they are receiving. In trials testing the efficacy of drugs, blinding is accomplished by providing a control which is identical to the treatment intervention, but does not contain the active ingredient. In orthodontics however, trials are often conducted to compare devices, or different methods, and it is rarely feasible to blind the patient or operator.

Performance bias is important because if the operator is aware of treatment allocation then it is possible that additional care or procedures may be provided by the operator, if they feel that the subject has been allocated to what they perceive is the "ideal" intervention. For example, an operator may spend more time in an interview or take more care in adjusting an appliance, or give priority to be seen in an emergency clinic. From the patient point of view, they may spend more time in oral hygiene procedures or appliance care. Methodological studies evaluating the effect of double blinding on the treatment effect have had contrasting results; some of these found that research in which double blinding was not reported overestimated the treatment effect in comparison with double blind research, other studies found no association between treatment effect and double blinding [47].

1.3.1.1.3 Detection bias

Detection bias, also referred to as assessment bias, is a type of performance bias which may occur when the outcome assessor is not blind to the treatment intervention. In contrast to blinding of the participant and operator, the assessor can almost always be blind to treatment allocation. If the assessor is not blind to treatment intervention, this may result in excessive care being taken in the measurement of cases with a certain

intervention, and the interpretation of the measurements may be biased. Assessment bias is also related to the type of outcome [47]; if the outcome is more subjective, such as pain assessment, there is more risk of assessment bias. If the outcome is more objective, such as success of mini-implants judged by their mere presence or absence during a course of orthodontic treatment, then assessment bias is less likely to occur.

1.3.1.1.4 Attrition Bias

Attrition bias occurs when subjects enrolled in the study are lost to follow-up. These include patients who drop out of a trial or subjects with protocol deviations. It is important to consider the proportion and reasons for dropouts across trial arms when making judgements on attrition bias. If the reasons for dropouts are related to prognostic factors, adverse events or non-response to treatment, and they are not included in the final analysis, then it is likely that there will be attrition bias, resulting in the treatment effect being overestimated [47]. If the reasons for dropouts are random, for example, the subject moved to a geographical location remote to the trial and was not able to continue treatment, then bias may be minimised.

1.3.1.1.5 Reporting Bias

Reporting bias can occur when all predetermined outcomes are either not reported, or reported differently than predetermined. For example if an outcome, which was predetermined as a secondary outcome, was reported as a primary outcome. In addition, reporting bias can occur if a reported outcome was not predetermined. It can also occur when only statistically significant results are reported. It is difficult to detect reporting bias unless a detailed published protocol is present.

1.3.1.1.6 Other bias

Other bias may be present in studies, such as trials that were stopped early, extreme baseline imbalance, or fraudulent measurements. This may also include issues that are specific to certain studies. For example in a study evaluating the anchorage potential of

two types of anchorage devices, bias may be introduced if one group had en-masse retraction and the other group had tooth by tooth retraction for space closure.

1.3.1.2 CONSORT guidelines

When reporting an RCT, the CONSORT (Consolidated Standards of Reporting Trials) guidelines should be followed. The CONSORT statement was first published in 1996, and updated in 2001. The latest CONSORT statement was published in 2010 and supersedes all previous versions [52]. The CONSORT statement consists of a flow diagram and a checklist. The flow diagram is intended to be used by authors when preparing their publication. It shows the number of subjects in a trial during enrolment, intervention allocation, follow-up, and analysis, (Figure 6). The checklist contains 25 items representing the minimum requirements for reporting the trial in different parts of the publication (title and abstract, introduction, methods, results, discussion, other). It has been shown that these items, if omitted from the report, can lead to biased estimates of the treatment results or hinder the judgment of the reliability of the findings,(Figure 7). The purpose of the CONSORT statement is to improve the reporting of trials, not to provide recommendations on the planning, conduct or statistical analysis of trials. However, it can be used indirectly when planning a trial as it advocates the reporting of all important factors that can bias a trial.

Figure 6: CONSORT 2010 flow diagram (Schulz et al., 2010)

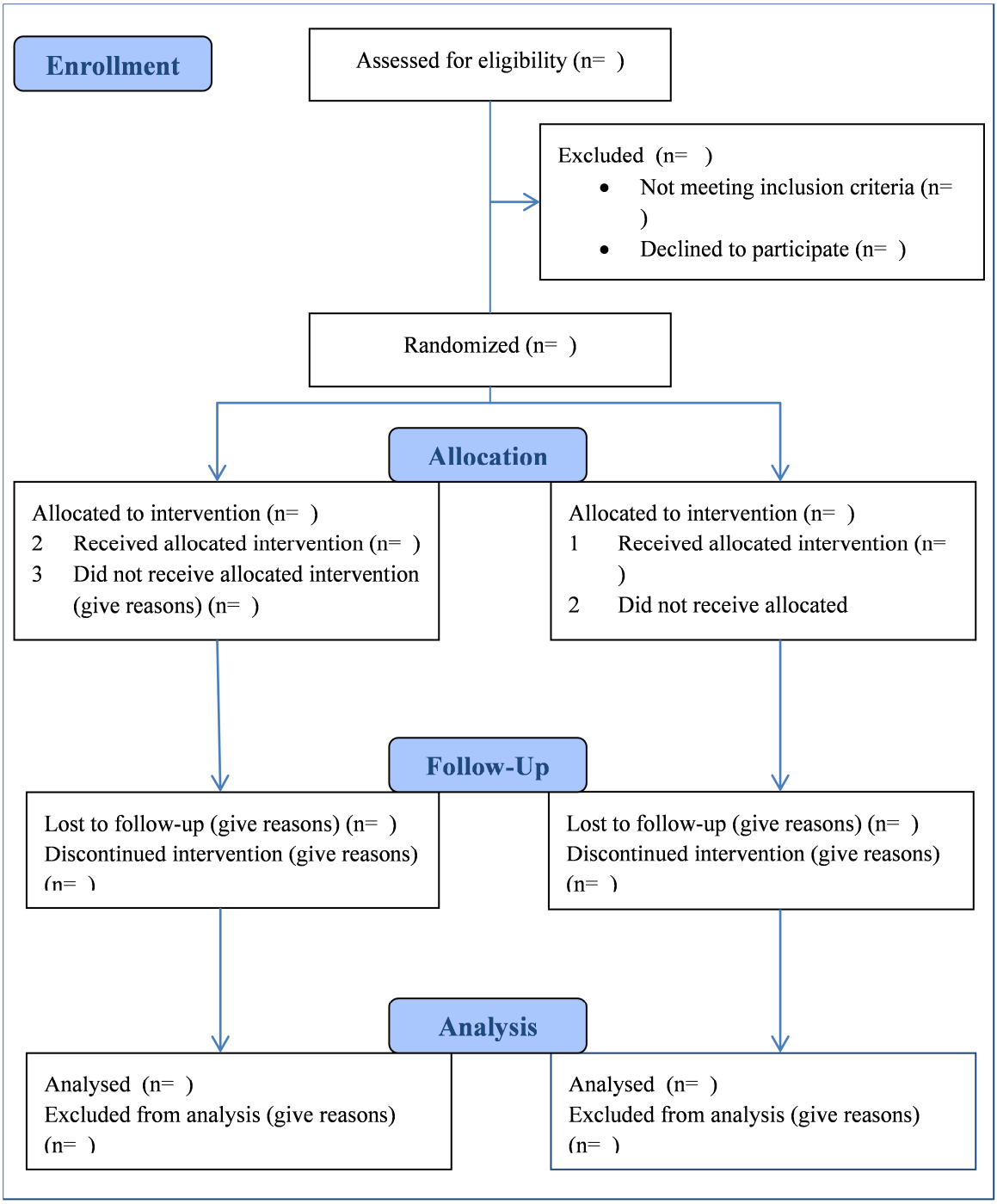


Figure 7: CONSORT checklist, pages 1 and 2

Section/Topic	Item No	Checklist item
Title and Abstract	1a	Identification as a randomised trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)
Introduction		
Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
Methods		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
Randomisation:		
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomisation; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses
Section/Topic	**Item No**	**Checklist item**
Results		
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
	13b	For each group, losses and exclusions after randomisation, together with reasons
Recruitment	14a	Dates defining the periods of recruitment and follow-up
	14b	Why the trial ended or was stopped
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
Discussion		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Generalisability	21	Generalisability (external validity, applicability) of the trial findings

Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
Other information		
Registration	23	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders

1.3.2 Retrospective cohort studies

A retrospective cohort study is a type of epidemiological, observational study in which the medical records of groups of individuals who are alike in many ways but differ by a certain characteristic (for example, children who brush their teeth and those who do not brush) are compared for a particular outcome (such as gum disease) [53]. Retrospective studies rely on adequate information regarding exposure status and outcome being present in patients' records or registries. In retrospective cohorts bias can occur due to periodical changes, recall bias and differential measurement errors. Importantly, selection bias is likely to be present because the exposure to the risk factor cannot be controlled. Recall bias can also occur due to the retrospective nature of the study as participants and records may not recall events that occurred in the past. In addition, events or changes in the condition of the participants over time that may have a bearing on the outcome may not be reported or documented.

The advantages of retrospective cohort study is that it is easy and quick to perform, and may be valuable when assessing rare conditions. It may also be used to generate a question that could be investigated in randomized trials.

1.4 Orthodontic Measurements:

Orthodontic measurements are conventionally made on hand-held models and cephalometric radiographs. Information gained from each of these records is complimentary, and there are limitations to both types of measurements. In addition, it would be desirable to have one source of record capable of measuring all required measurements. With the advent of digital models, many of the shortcomings of conventional orthodontic records can be overcome. The following section will provide a summary on the limitations of hand-held models and cephalometric measurements; and details of 3D techniques of obtaining certain orthodontic measurements.

1.4.1 Limitations of hand-held models

Hand-held physical models are currently the standard for clinical 2 dimensional measurements including linear measurements and measurement of curves. These measurements include variables such as overjet, overbite, intercanine width, arch perimeter and arch-length discrepancy. In addition, information on non-quantitative variables such as canine and molar relationship can be gained from orthodontic models. Occasionally, angular measurements are made on study casts, such as, tooth inclination.

The limitations of physical hand-held models is that it is difficult to obtain angular measurements of anterior and posterior teeth, and it is not possible to superimpose them to view and/or measure tooth movement. In addition, when measurements are made, they are subject to human error; this may not be a problem in a clinical setting, however in a research setting it could be a source of error.

Physical models also require storage space and cannot readily be shared with other professionals.

1.4.2 Limitations of Cephalometric Radiographs

The technique for cephalometric radiography was first introduced in 1931 by Holly Broadbent [54]. Since then, lateral cephalometric radiographs have been and continue to be widely used for both clinical evaluation and research tools. They are used for (i) diagnosis and treatment planning, (ii) to monitor progress of treatment, and (iii) to assess treatment results. In addition to linear measurements, they are used to measure angular variables and also changes in tooth movement, as they can be superimposed. However, molar and canine relationship cannot be obtained accurately from them. In the following section I will give a brief overview of the limitations of cephalometric radiographs by discussing errors which can arise from their use.

1.4.2.1 Projection errors

Errors in projection arise because the x-ray beams used are cone shaped and not parallel, leading to enlargement and distortion of the image [55]. This effects linear measurements more than angular measurements, because angles are not changed by magnification.

1.4.2.2 Positioning errors

The radiographic technique has an apparatus for proper positioning of the head. However, it does not guarantee 100% proper head position, leading to errors. Errors in head positioning lead to a systematic increase in the measurement of angles and decrease in linear measurements [56].

1.4.2.3 Errors in landmark identification

Errors in landmark identification are probably the most problematic and common type of error, because they are the most difficult to overcome. The following reasons have been proposed for occurrence of these types of errors; imprecise definitions of the landmarks

and quality of cephalograms [55, 57]. The precision of landmark identification also depends on the nature of the landmark; if the landmark is on a sharp edge, it is easier to identify than when it is on a gradual curve. It has also been found that the error associated with landmark identification is not uniform. That is to say, the error occurring with different commonly used cephalometric landmarks is different in magnitude and direction. Thus, each cephalometric landmark has its own 'envelope of error' [55].

1.4.2.4 Mechanical errors

Mechanical errors can occur when drawing lines between points and measuring with rulers and protractors. If a digitizing tablet is used errors can occur due to improper stabilization of the radiograph permitting it to move slightly during the digitization process. However, it has been shown that using different positions in a digitizing tablet does not change the envelope of error of a cephalometric landmark [57].

1.4.2.5 Validity and reliability of cephalometric measurements

In addition to all these inherent errors, recent studies have revealed problems with the validity and reliability of measurements in cephalometric radiographs. For example, Gribel compared direct craniometric measurements on dry skulls to their corresponding measurements on lateral cephalometric radiographs [58]. A statistically and clinically significant difference was found with all 12 linear measurements between the direct craniometric measurements and measurements made on lateral cephalometric radiographs. Kamoen et al evaluated intra- and inter-rater reliability for tracing common cephalometric landmarks. They found the difference between landmark identification statistically significant [57]. Moreover, inter-rater differences were greater than intra-rater differences.

To conclude, cephalometric radiographs provide a simple and practical technique for gathering and comparing skeletal and dental measurements. As a result, they remain a vital tool in orthodontic treatment and research, in spite of known shortcomings and limitations.

1.4.3 Measurements on digital models

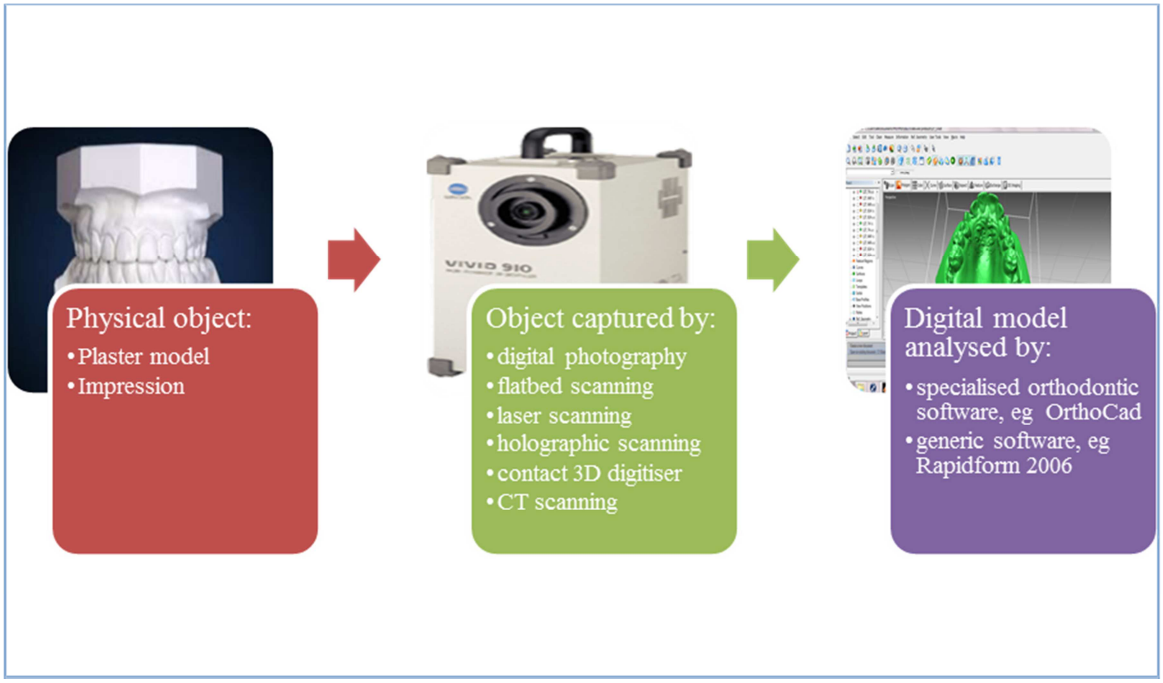
In this section, I will discuss the use of digital models and discuss the measurement methods. A brief description of the digital method will be presented followed by discussing the reliability and validity of the method. I use the term reliability throughout this thesis to describe a method of measurement which consistently produces the same results. The term validity is used in terms of whether the method of measurement actually measures what it purports to measure. In this respect it is the accuracy of the method in obtaining a certain measurement.

1.4.3.1 Definition and formation of digital models

Digitization may be defined as ‘a shorthand phrase that describes the process of making an electronic version of a real world object or event, enabling the object to be stored, displayed and manipulated on a computer, and disseminated over networks and/or the World Wide Web. The physical object is captured by some device such as a scanner, digital camera or recorder, which converts the analogue features of the object to numerical values, enabling them to be 'read' electronically’ [59]. If this definition is considered in relation to orthodontic models, the physical object is the orthodontic study model or impression, which is be captured by digital camera or scanner. The electronic version (the digital model) is then stored in a computer or appropriate storage media. This digital model can be retrieved at any time, and viewing and manipulation occurs by using computer software. The software is either specialised orthodontic software specifically

developed to analyse orthodontic digital models or generic software used to measure any digitised object, (Figure 8).

Figure 8: The formation of digital orthodontic models



In order for digital models to be used for clinical and research purposes, their validity and reliability must be assessed. The following discussion examines the literature addressing validity and reliability of digital models in the measurement of linear and angular orthodontic variables. The validity of arch-length discrepancy will be discussed separately because it involves the measurement of curves. Finally, the literature addressing validity and reliability of measurement of tooth movement on superimposed digital models will be discussed.

Critical appraisal for these studies will be presented using the QUADAS (Quality Assessment of Diagnostic Accuracy Studies) tool as recommended in a systematic review assessing literature reporting validity of measurements on digital models [60]. This

systematic review assessed the literature using the original QUADAS tool [61]; a revised QUADAS tool has since been published and will be used here [62]. The revised tool is a more transparent tool as it requires a judgement on the risk of bias and applicability, and furthermore an explanation of this judgement is required. To help in making the judgements, signalling questions are provided which can be added to if needed, (Table 1).

Table 1: The QUADAS 2 tool

DOMAIN	PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD	FLOW AND TIMING
Description	Describe methods of patient selection: Describe included patients (prior testing, presentation, intended use of index test and setting):	Describe the index test and how it was conducted and interpreted:	Describe the reference standard and how it was conducted and interpreted:	Describe any patients who did not receive the index test(s) and/or reference standard or who were excluded from the 2x2 table (refer to flow diagram): Describe the time interval and any interventions between index test(s) and reference standard:
Signalling questions(yes/no/unclear)	Was a consecutive or random sample of patients enrolled?	Were the index test results interpreted without knowledge of the results of the reference standard?	Is the reference standard likely to correctly classify the target condition?	Was there an appropriate interval between index test(s) and reference standard?
	Was a case-control design avoided?	If a threshold was used, was it pre-specified?	Were the reference standard results interpreted without knowledge of the results of the index test?	Did all patients receive a reference standard?
	Did the study avoid inappropriate exclusions?			Did all patients receive the same reference standard?
				Were all patients included in the analysis?
Risk of bias: High/low/unclear	Could the selection of patients have introduced bias?	Could the conduct or interpretation of the index test have introduced bias?	Could the reference standard, its conduct, or its interpretation have introduced bias?	Could the patient flow have introduced bias?
Concerns regarding applicability: High/low/unclear	Are there concerns that the included patients do not match the review question?	Are there concerns that the index test, its conduct, or interpretation differ from the review question?	Are there concerns that the target condition as defined by the reference standard does not match the review question?	

1.4.4 Reliability and validity of linear variables

The following linear orthodontic variables have been evaluated; overjet, overbite, dental midline deviation, canine and molar relationship, little's irregularity index, PAR index, mesiodistal crown diameter, intercanine and intermolar width, arch length and width, incisor crown height, and ABO grading system. A detailed systematic review has reported results of 17 studies comparing digital models to hand-held physical models [60]. Digital systems and software used included Orthocad, Emodel, C3D builder, Conoprobe, Easy3D Scan, digimodels and cecile 3; the most common being OrthoCad and Emodel. The QUADAS (Quality Assessment of Diagnostic Accuracy Studies) tool was used to assess methodological quality of studies in this review. The main methodological flaw in these studies was related to selection of the sample; clear criteria for including participants (models) in the study were not found. The measurements assessed were tooth size, Bolton ratio, arch length discrepancy, irregularity index, transverse dimensions, inter-arch occlusal features, occlusal indices and miscellaneous linear measurements. The authors of the review concluded that the overall difference between measurements made on digital models and physical models was low and clinically insignificant.

Where intra-rater reliability of overjet measurements was measured by a correlation coefficient, there was high correlation between repeated measurements of the digital model method (0.90 – 0.99) (Table 2). Where the error of the method was reported, this was all under 1 mm except for the Arius 3D software in which the error of the method ranged from 0.32 -1.4mm.

In general, the validity of overjet measurements was acceptable clinically with mean differences ranging from 0.01 to 0.098 mm across different methods of digital model measurement (Table 2).

Molar relationship was measured in one study by quantitatively assessing the anteroposterior relationship of the molars. The method error was 0.2 mm showing high reliability; and the correlation between digital and manual measurements was high (0.989) (Table 2).

Table 2: Reliability and validity of overjet and molar relationship on digital models

Type of tooth movement	Study	Reliability		Validity (agreement with comparison)		
		Error of the method	Intra-rater reliability (correlation coefficient.)	Mean difference	95% limits of agreement	Correlation coefficient
Overjet	Santoro et al [63], n = 76 OrthoCad versus plaster models (Boley gauge)	Not reported	Not reported	0.098	Not reported	Not reported
	Quimby et al [64], n= 50 OrthoCad versus plaster (digital calipers)	Not reported	0.90 or greater	0.45	Not reported	Not reported
	Stevens et al [65], n= 24 Emodel versus plaster (digital caliper)	0.49 (SD 0.31)	0.990	0.01 (SD 0.21)	Not reported	Not reported
	Watanabe-Kanno et al [66], n=15 Cecile 3 versus plaster models (digital calipers)	0.824 (SD 0.15)	0.966	0.31 (SD 0.22	Not reported	Not reported
	Hui Chen et al [67], n=20 Rhinoceros modelling program versus plaster models (digital caliper)	0.18	Not reported	Not reported	Not reported	0.989 ICC
	Asquith et al [68], n = 10 Arius 3D versus plaster models (digital calipers)	Between -1.4 to 0.32	Not reported	-0.07 (SD 0.33)	Not reported	0.998 coefficient of reliability

	Ali et al [69], n = 56 Exelicare software (2D models) versus plaster models	Not reported	0.64 – 0.80 (weighted Kappa statistic)	Not reported	Not reported	0.59 -0.69 (weighted Kappa statistic)
Molar relationship	Hui Chen et al [67], n=20 Rhinoceros modelling program versus plaster models (digital caliper) (quantitative antero-posterior molar relationship)	0.20 mm	Not reported	Not reported	Not reported	0.989 ICC

1.4.5 Reliability and validity of angular variables

The context of angular variables in this section relate to those which can potentially be measured on digital models independent of any other orthodontic record i.e. models are not superimposed on radiographs or photos. These namely include tooth inclination (labio-lingual or bucco-lingual), tooth angulation (mesio-distal), tooth rotation.

This can be achieved in digital models by forming two reference lines; one is the long axis of the tooth and a reference line from which to measure the angulation. The difficulties in making such measurements on digital models arise in forming an adequate reference to measure the angulation/inclination of the teeth. When assessing accuracy, assuming that the digital model/software is the index test, there are problems in choosing the reference test. The software measurements cannot usually be compared to conventional angular variables obtained from lateral cephalometric radiographs. This is because one of the reference lines used in the measurement of the angles on cephalometric radiographs is usually a skeletal reference and cannot be directly replicated on a digital model. In addition, the limitations of cephalometric radiographs previously discussed preclude it from being an ideal reference test. Manual methods are available for measurement of some angular variables; their validity is questionable [70, 71].

Because of the difficulties in obtaining angular measurements in 3D software and of finding an appropriate comparison, studies reporting the validity of angular measurements on 3D digital models are few. Sakurai and Kodaka et al [72, 73] and Sjogren et al [74] assessed the validity of measurements made by 3D software on digital scanned models.

The description and quality assessment of these two studies are presented in Table 3 and Table 4.

According to the QUADAS2 tool (Table 3, Table 4); there is high risk of bias in these two studies mainly due to the improper selection of the sample (Sakurai et al) and selection of reference standards with unknown levels of accuracy. The main concern about applicability was because sample size calculations were not undertaken.

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The reliability and validity of angular measurements is shown in Table 5. In the Sakurai and Kodaka study, crown inclination measurements were presented by tooth (right and left sides averaged). The mean difference between the two methods ranged from 0.0º (95% CI -3.70, 3.70) for the lower first molars to -1.60º (-5.25, 2.05) for the upper second molars and lower first premolars. The mean difference for all upper anterior teeth and premolars was less than 1º; a similar pattern did not exist for the mandibular teeth.

Similarly, in the Sjogren study, angulation and rotation measurements were made twice by two examiners. Mean of the duplicate measurements were used in the analysis. The results were reported for each tooth. The mean difference for rotation between the two methods ranged between 0.3º [95% CI -2.3, 2.9] for the upper left central incisor to 8.1º [5.2, 10.9] for the upper right lateral incisor. Except for the upper right lateral incisor, mandibular mean differences were generally higher than maxillary mean differences. This may suggest that this method is less valid in the lower anterior area which is a common area for imbrication. The mean difference for angulation ranged between 0.1º [-3.9, 4.1] for the upper left lateral incisor to -3.7 [-7.0, -0.4] for the upper right lateral incisor.

In summary, the measurement of tooth inclination, angulation and rotation on digital models has not been extensively researched and validated. The main problem is finding a

reference method for comparisons. Existing studies show acceptable validity for measurement of tooth inclination (labio-lingual or bucco-lingual), with wider variations for rotation and angulation. According to the QUADAS2 tool (Table 3, Table 4); there is high risk of bias in these two studies mainly due to the improper selection of the sample (Sakurai et al) and selection of reference standards with unknown levels of accuracy. The main concern about applicability was because sample size calculations were not undertaken. Therefore their use in clinical and research applications is currently limited. In addition, if widespread use of digital models is planned for measuring tooth angulations in the future, normal values would have to be established to be of diagnostic use.

Table 3: Description and quality assessment of the Kodaka and Sakurai et al study evaluating the accuracy of angular measurements made on digital models

Study	Domains	Patient Selection	Index Test (digital method)	Reference Standard (comparison method)	Flow and Timing
Kodaka 2009 **[73]** , Sakurai 2009 **[72]**	Sample selection and measurements assessed	20 models with normal occlusion, from staff and students at Tokyo dental college, average age 23.6y No sample size calculation Measurement assessed (target condition): • Crown inclination (labial/buccal – lingual) defined as the angle formed by a tangent drawn to the anterior or labial surface of the incisor crowns (FA point) to the perpendicular drawn to occlusal plane	SURFACER software measuring laser scanned models	Ruler and protractor on physical models using Andrews method	• It is assumed that the same models were used for both measurement methods • If the same models weren't used for both measurement methods, it is still unlikely that the time interval between the two models will have an effect leading to a change in the dentition.
	Risk of bias judgement and description (High / Low/ Unclear)	High risk: Not random or consecutive, study selection was based on specific criteria	Low risk: It is unclear if the index test measurements were made without knowledge of the measurements of the reference standard. However this is a computer generated objective measurement, and therefore the impact of bias is low.	High risk: • The accuracy of the reference standard is unknown • It is unclear if the reference standard measurements were made without knowledge of the measurements of the index test	Low risk: All patients received the same reference standard and were included in analysis
	Concerns regarding applicability	High concerns: • No sample size calculation, small sample • There are concerns that the target	Low concern: There are no concerns regarding the conduct or interpretation of the digital	Low concern There are no concerns regarding the definition of	

	(High / Low/ Unclear)	condition (normal occlusion) may be easier to measure than malocclusion.	method.	the target condition. .	

Table 4: Description and quality assessment of the Sjogren et al study evaluating the accuracy of angular measurements made on digital models

Study	Domains	Patient Selection	Index Test (digital method)	Reference Standard (comparison method)	Flow and Timing
Sjogren 2010 **[74]**	Sample selection and measurements assessed	20 consecutive dental casts of patients in early mixed dentition who were participating in a study to examine spontaneous alignment of incisors following extraction of deciduous canines No sample size calculation Measurements assessed (target condition): • Angulation (mesio-distal inclination) and rotation of maxillary and mandibular incisors. • The angulation was defined as the angle between a line bisecting the clinical crown (passing through the centre of the incisal edge) and a line parallel to the occlusal plane • The rotation was defined as the angle between a line formed by extending the line forming the incisal edges and a line formed between defined cusp tips of the molars	• O3DM software programme measuring scanned digital models • measurements were taken by two orthodontists at least two weeks apart • Order of recordings, O3DM, conventional, conventional O3DM	• FACAD 2.2 software measuring digital photographs. • The models were photographed in two orientations; parallel to the occlusal plane (for measurement of rotation) and perpendicular to the occlusal plane with the buccal surface of the tooth in focus (for angular measurements).	• It is assumed that the same models were used for both measurement methods
	Risk of bias judgement and description	Low risk: • consecutive sample, exclusions were appropriate • Lateral incisors which were less than half erupted were not included, another lower incisor (31) was excluded because it was fractured	Low risk: • The index test measurements were made without knowledge of the measurements of the reference standard in the first recordings. • This is a computer generated objective	High risk: • The accuracy of the reference standard is unknown Low risk: • The index test measurements were made without knowledge of the measurements of the reference standard in the first recordings.	Low risk: • It is likely that both models represent the same time for the patient, • All patients were included and received the same reference standard however not

			measurement, and therefore the impact of bias from blinding is low.	• This is a computer generated objective measurement, and therefore the impact of bias from blinding is low.	all teeth had 20 measurements. • The reasons for exclusions were adequate because if lateral teeth are less than half erupted, this may change the angular measurement.
	Concerns regarding applicability	High concerns: • No sample size calculation • Patients in the early mixed dentition commonly have problems with rotation and angulation of teeth. These patients were also enrolled in a study evaluating spontaneous alignment of incisors, so it is assumed that there was an acceptable amount of patients with rotated incisor teeth.	Low concern: There are no concerns regarding the conduct or interpretation of the digital method.	Low concern: There are no concerns in the definition of the target condition.	

Table 5: Reliability and validity of angular variables

Study	Type of tooth movement	Reliability		Validity (agreement with comparison)		
		Error of the method	Intra-rater reliability (correlation coefficient.)	Mean difference[95% confidence intervals]	95% limits of agreement	Correlation coefficient
Sakurai and Kodaka et al 2009 [72, 73] SURFACER software / laser scanned digital models Versus Ruler and protractor on physical models using Andrews method	Crown inclination of all upper and lower teeth	Ranged from 0.15º to 0.25º	0.98	Ranged from 0.00º [-3.70, 3.70] to -1.60º [-5.25, 2.05]	Not reported	Not reported
Sjogen 2010 [74] O3DM software / scanned digital models Versus FACAD 2.2 software/ photographed digital models	Angulation (mesio-distal inclination) of maxillary and mandibular incisors.	Examiner 1 ranged from: 1.1º to 2.7º Examiner 2 ranged from: 1.6 to 2.5º	Not reported	Examiner 1 ranged from: 0.0º [-1.3,1.3] to 1.8 [-0.2, 3.8] Examiner 2 ranged from: -0.2º [-1.3. 1.0] to -3.7 [-7.0, -0.4]	Examiner 1: lowest range -3.8 to 4.8 widest range -10.4 to12.3 Examiner 2: Lowest range -3.5 to 5.7 widest range -12.4 to 12.9	Examiner 1 Ranged from: 0.03 to -0.65 Examiner 2 ranged from: -0.11 to -0.51
	Rotation of maxillary and mandibular	Examiner 1	Not reported	Examiner 1 ranged from:	Examiner 1:	Examiner 1

	incisors.	ranged from: 1.2º to 2.4º Examiner 2 ranged from: 2.1º to 4.0º		-0.3º [-3.0, 2.5] to 3.9º [2.0, 5.8] Examiner 2 ranged from: 0.3º [-2.3, 2.9] to 8.1º [5.2, 10.9]	lowest range -6.5 to 4.7 widest range -7.5 to 14.2 Examiner 2: Lowest range - 2.3 to 8.5 widest range -9.7 to20.5	Ranged from: 0.41 to -0.77 Examiner 2 ranged from: 0.06 to 0.57

1.4.6 Reliability and validity of crowding

The assessment of the amount of crowding or tooth arch discrepancy is basic diagnostic information in orthodontics. Although there is general agreement on what constitutes mild, moderate and severe crowding, there is limited consensus within the orthodontic community on the best way to measure crowding. In this section I will first describe the conventional methods for measuring crowding and the problems associated with these methods. This will be followed by discussing studies in which the reliability of crowding was assessed using digital methods.

1.4.6.1 Conventional methods for crowding measurement:

Several methods have been reported in the literature. These are the visual technique [75], the brass wire technique and its variations [76], adding straight segments of the arch [77], using a catenometer, a mathematical model to calculate arch length [78] and measuring slipped contact points [79].

The visual technique, also referred to as “eyeballing”, involves mentally estimating the amount of overlap of each tooth that is misaligned on a dental model [75]. Adding these together provides an approximation of the amount of total crowding. A variation of this technique is to use a ruler to measure the overlap between the teeth. This method is highly subjective, and therefore does not offer a great deal of reliability. For example, Beazley [75] measured inter-rater reliability for the visual technique, and showed that agreement between two examiners ranged from 2.5 to 5.5 mm.

Other techniques measure the actual difference between the mesiodistal widths of teeth and the arch perimeter. This is referred to as the arch length discrepancy. There have been two main methods to calculate arch length discrepancy:

The first is the brass wire method, first described by Nance in 1947 [77, 80]. The mesiodistal widths of the teeth mesial to the first molars are added together to identify the amount of space needed for the correction of dental crowding. The arch perimeter is then measured by adapting a brass wire around the buccal surfaces of the premolar and anterior teeth and cutting the wire mesial to the first molar. The brass wire is then straightened and measured. This measurement is recorded as the total space available. The arch length discrepancy is then calculated by the following formula:
(total space available) – (total space needed) = arch length discrepancy.

There have been many variations of this method using different diameter brass wires and by changing the points on which the wire is placed. The main problem with this technique is that there is an element of subjectivity in determining the arch form, and therefore, the arch perimeter in the pre-treatment models. This is because the orthodontist must estimate both the optimum position of the teeth and arch form. Furthermore, the final arch form at the end of treatment is dictated by the treatment provided and growth and normal development. As a result, it is difficult for the orthodontist to predict the final arch form, and inaccuracies are introduced. This was illustrated in study by Beazley [75] who found the inter-rater reliability for the brass wire method to range from 5.5 to 12.5 mm. In another study Johal found intra-rater reliability for the brass wire technique less than that of the visual technique [81].

Another method for assessing the arch length discrepancy was described by Lundstrom in 1955. This method uses the same formula as the brass wire technique and the same way of

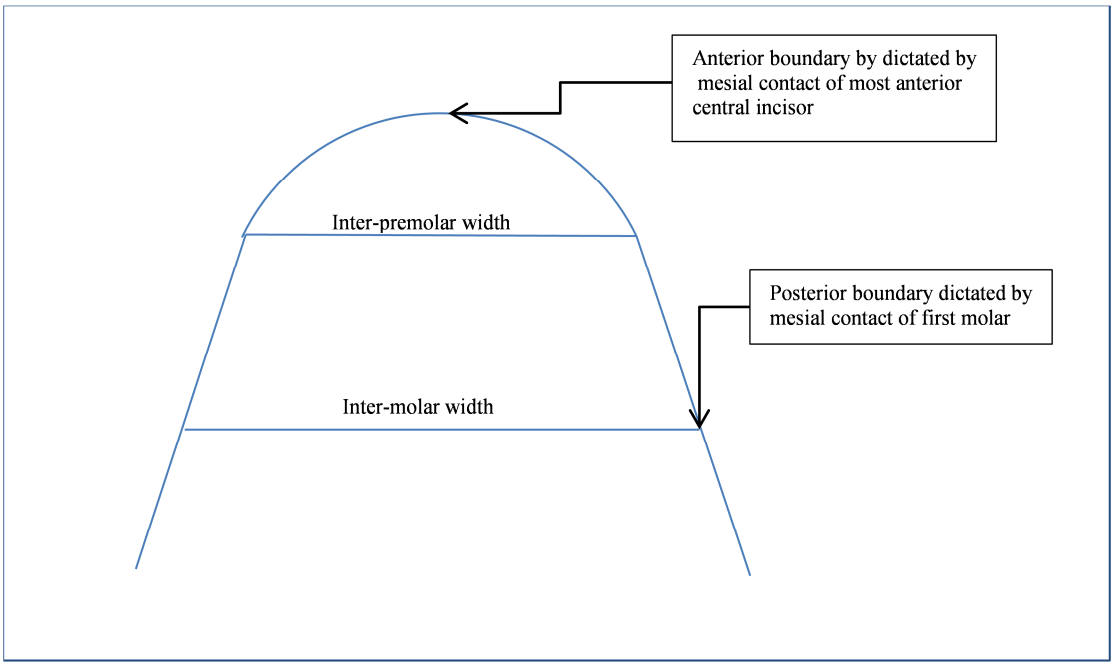
measuring the ‘space needed’. However the ‘space available’ is measured by adding six straight segments from the dental arch. These segments are from the distal of the first molar to the mesial of the ipsilateral second premolar, then to the mesial of the ipsilateral canine, then to the mesial of the ipsilateral central incisor. The same segments are taken from the contra lateral side.

As these segments were straight rather than curved, and the arch form is a curve, the measurement of the arch perimeter in this method is considered less accurate and leads to an underestimation of the available arch perimeter.

In summary, it appears that the measurement of crowding and arch length discrepancy has problems with both the accuracy and reliability of measurements. Several attempts have been made to overcome these problems.

In 1971 Beazley [75] suggested that the main problem in measuring arch length was the prediction of the appropriate arch form. He then devised a method of drawing individualised, reproducible arch forms of patients on graph paper. The individualised arch form took the shape of a Bonwill-Hawley arch form; the anterior curved part of the curve going through the contact points of the anterior teeth, and the two straight ends going through the contact points of the posterior teeth (Figure 9). Then the mesiodistal widths of the teeth anterior to the molars were measured, and the arch length discrepancy calculated. [75].

Figure 9: Individualised curve proposed by Beazley



In 1973, Musich [78] suggested another method for measuring crowding using a catenometer. This method requires the making of a special instrument in which a metal chain was suspended at each end by a Boley gauge to form a catenary curve. This curve was then superimposed on the model so that the ends of the chain coincided with the mesial contact point of the first molars. This chain was then straightened and measured to give the final arch perimeter.

In 1975, Robert Little proposed a valid and reliable method for describing the degree of crowding by measuring “slipped” contact points. He developed Little’s irregularity index and proposed it would be valuable in assessing the degree of initial malrelationship, comparing initial crowding with post-treatment and post-retention results. This was originally developed to measure irregularity of the lower incisor segment because it is a limiting factor in treatment and stability. In this technique there is no need to predict the position of the ideal arch or to measure the arch perimeter. Instead the linear distances between the anatomical contact points of the lower anterior teeth are measured and added

together to give a numerical score. This index has been widely used in research. Because its application is simple and quick, a recent interest for its use in a community setting to predict arch length discrepancy was reported [79]. Bernabe et al evaluated the diagnostic capability of Little's irregularity index in estimated arch length discrepancy. Correlation between Little's irregularity index and arch length discrepancy was statistically significant, and the correlation coefficient was 0.68, indicating moderate correlation.

In 1996, Battagel [81-83] overcame the reliability of the brass wire technique by indirectly measuring the arch perimeter using a computerised mathematical model based on the overlap between the teeth. In this method, tooth widths were measured directly from the study models using a reflex microscope; the computer programme then measured the mesiodistal overlap between adjacent teeth and the total tooth widths. There was no attempt to predict or measure arch form. The crowding was calculated as the total tooth width minus the mesio-distal overlaps between the teeth. The method was found valid and reliable [82, 83]. The reliability was superior to the brass wire and visual technique [81].

This method of calculating the overlap appears to be a workable method using generic software able to calculate at least 2-dimential coordinates. The accuracy and ease of measurement would probably be improved using reliably scanned dental models, rather than a direct measurement by a reflex microscope.

However, in the presence of severe rotations (more than 90 degrees) and labiolingual displacements of teeth, it was suggested that this method was not valid leading to an over- or under-estimation of crowding [83].

In 2000, Kirschen [84, 85] described the Royal London space analysis, which measured crowding as a component of an integrated system of space analysis. In this method

crowding is assessed in relation to an arch form that passes through most of the teeth. The. mesiodistal widths of the misaligned teeth, and a linear segment of the arch related to these teeth are measured with a ruler. The arch length discrepancy is then calculated by subtracting the total mesiodistal widths of the teeth from the total length of the arch segments.

The reliability and validity of the crowding measurements in the Royal London space analysis were assessed by Al-Abdallah et al [86]. The intraclass correlation coefficient (ICC) assessing intra-rater agreement showed high reliability for lower arch crowding and total space requirement; 0.93 (0.83- 0.98) and 0.88 (0.77- 0.95) respectively. The intra-rater reliability for upper arch crowding and space requirement was high to moderate; ICC was 0.85 (0.42- 0.97) and 0.68 (0.21- 0.95) respectively.

The sensitivity and specificity of the Royal London space planning was assessed by Dause et al [87]. In this study, the sensitivity was defined by the accuracy of the analysis in identifying crowding, arch width and arch length reduction that occurs with normal growth and development. The specificity was measured by its accuracy in identifying differential growth of the arches and mesial drift of the buccal segments that occur during normal growth and development. They concluded that the Royal London space planning had good sensitivity but poor specificity. The clinical inference is that it is important to consider differential growth of the dentoalveolar complex and mesial drift of the buccal segment when planning treatment in orthodontics, however, the Royal London space analysis was not effective in identifying these factors.

It is clear from evaluating the literature on the Royal London space analysis that there is still a need for estimation of the arch form, although errors in arch form estimation can be reduced by selecting the arch that passes through most of the teeth.

Furthermore, the analysis does not take into consideration asymmetries including midline deviations. It also does not integrate the overlapping effects of normal growth and development of the dentoalveolar complex into the treatment plan.

Finally, the Royal London space analysis does not evaluate the effect of lower incisor inclination (torque) on the space requirements, only bodily movement (anteroposterior change) and inclination of the upper incisors, and bodily movement of the lower incisors are considered. This may be because the goal of orthodontic treatment is to maintain the inclination of the lower labial segment (Williams, 1986).

From the previous literature, I can conclude the following:

There is not a single method that is both accurate and reliable for the measurement of crowding. Measurements that use straight line to measure the arch perimeter or parts of the arch appear to be inaccurate, and measurements that use curved (arch) measurements are either not reliable or require the use of specialised armamentarium, and/or complicated methods. It appears that Little's irregularity index is a quick and simple technique; but its capability in estimating total arch length discrepancy is limited. The Royal London space analysis is likely to be the optimum method of space calculation as it is not solely confined to the assessment of crowding and includes the other factors which may impact on space requirements.

1.4.6.2 Measurement of crowding on digital models:

Crowding has been measured on digital models by calculating arch length discrepancy. Similar to the conventional methods, there is a potential difficulty in the measurement of

curves on digital models. However the main advantage is the higher reproducibility of measurements obtained using computer software.

Four studies have reported on the measurement of both arch perimeter and mesiodistal tooth widths on digital models. Description, risk of bias and applicability of these studies are presented in Table 6, Table 7, Table 8 and Table 9. Three of these studies used the OrthoCad system as the 'index test' [64, 88, 89], the remaining study used the Teledent software measuring digital models created by scanning plaster models with a holographic sensor [90]. The comparisons or 'reference standards' were plaster models measured by digital calipers. Three studies used a segmental arch method for measuring arch perimeter on both digital and plaster models, and only one study measured the arch perimeter using a curve.

The main drawbacks to study methodology were risk of selection bias in two studies [88, 90], and an inadequate sample size in two studies [89, 90].

The reliability and validity of crowding measurements are presented in Table 10. OrthoCad showed high intra-rater reliability as reported by two studies (correlation coefficient 0.90 -0.99) [64, 88].

The validity of crowding data suggest that using a six segment method (as opposed to four segments) of measuring the arch perimeter component of crowding measurement could result in more comparable measurements between digital models and plaster models [64, 88]. Furthermore, the OrthoCad and Teledent methods appear to have clinically irrelevant differences between the measurements made on digital models and plaster models. [89] [90]. There was no sample size calculation in these two studies and it could be suggested

that these studies lack power. Therefore, it can be concluded that measurement of crowding using a curve method to measure arch perimeter on digital models still require further investigation.

Table 6: Description and quality assessment for the Quimby et al study evaluating the accuracy of arch length discrepancy

Study		PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD	FLOW AND TIMING
Quimby et al 2004 **[64]**	Description: Sample selection and measurements assessed	50 consecutive patients entering orthodontic treatment at a postgraduate orthodontic clinic with the following criteria; a full complement of permanent incisors, canines, and first molars, and all teeth having normal morphology with no visible attrition caries or restorations. A sample size was calculated to demonstrate a difference of 2 mm Measurements: tooth widths and arch perimeter measured using a segmental technique	OrthoCad software measuring digital models formed from scanned alginate impressions using a segmental arch method	Digital callipers measuring plaster models using a segmental arch method	There were no exclusions to the original sample Impressions for both the digital models and the plaster models were taken at the same time.
	Risk of bias description (High/ Low/ \Unclear)	Low risk This was a consecutive sample which avoided inappropriate exclusions	Low risk Although it is unclear if the software measurements were made without knowledge of the results of the digital calliper/plaster models, the final measurements are objective and computer generated so are less likely to be biased.	Low risk There is no gold standard method for the measurement of arch length discrepancy, however digital callipers are likely to produce accurate measurements	Low risk All the patients were included in the analysis and received the same reference standard.
	Concerns regarding applicability (High/ Low/ \Unclear)	Low concerns The study had adequate power and sample size May not be applicable to patients with teeth of less normal morphology.	Low concerns There are no concerns about the conduct of the method. It may be important to note that arch length discrepancy was calculated for upper and lower arches together.	Low concerns There definition of arch length discrepancy in this study is adequate.	

Table 7: Description and quality assessment for the Goonewardene et al study evaluating the accuracy of arch length discrepancy

Study		PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD	FLOW AND TIMING
Goonewardene et al 2008 **[88]**	Description: Sample selection and measurements assessed	A retrospective sample of 30 pre-treatment models of patients in which all teeth were erupted excluding third molars, school age children, teeth had normal crown forms with no interproximal restorations, caries or attrition A sample size was calculated to demonstrate a difference of 0.5 mm Measurements: tooth widths and arch perimeter measured using a six segment technique	OrthoCad software measuring digital models formed from scanned alginate impressions using a six segment arch method	Digital callipers measuring plaster models using a six segment arch method	There were no exclusions to the original sample The same models used for manual measurements were scanned to form the digital models.
	Risk of bias description (High/ Low/ \Unclear)	Unclear Risk • Risk of selection bias due to the retrospective nature of the study, however this is an acceptable study design for a measurement study. • It is unclear if model selection was random or consecutive	Low risk Although the digital calliper measurements were made first, the final measurements are objective and computer generated so are less likely to be biased	Low risk There is no gold standard method for the measurement of arch length discrepancy, however digital callipers are likely to produce accurate measurements	Low risk All the patients were included in the analysis and received the same reference standard.
	Concerns regarding applicability (High/ Low/ \Unclear)	Low concerns The study had adequate power and sample size May not be applicable to patients with teeth of less normal morphology.	Low concerns There are no concerns about the conduct of the method. It may be important to note that arch length discrepancy was calculated for upper and lower arches together.	Low concerns There definition of arch length discrepancy in this study is adequate.	

Table 8: Description and quality assessment of the Leifert et al study evaluating the accuracy of arch length discrepancy

Study		PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD	FLOW AND TIMING
Leifert et al 2009 **[89]**	Description: Sample selection and measurements assessed	25 randomly chosen patients entering orthodontic treatment at a postgraduate orthodontic clinic No sample size calculation. Measurements (target condition): tooth widths and arch perimeter by measuring the curvature around the arch	OrthoCad software measuring digital models formed from scanned alginate impressions using the OrthoCad tools (measurement of the arch perimeter using a software generated curve)	Digital callipers measuring plaster models using the brass wire method	There were no exclusions to the original sample Impressions for both the digital models and the plaster models were taken at the same time.
	Risk of bias description (High/ Low/ \Unclear)	Low risk This was a random sample which avoided inappropriate exclusions	Low risk Although it is unclear if the software measurements were made without knowledge of the results of the digital calliper/plaster models, the final measurements are objective and computer generated so are less likely to be biased.	Low risk There is no gold standard method for the measurement of arch length discrepancy, however digital callipers are likely to produce accurate measurements	Low risk All the patients were included in the analysis and received the same reference standard.
	Concerns regarding applicability (High/ Low/ \Unclear)	High concerns The sample size was not adequate	Low concerns There are no concerns about the conduct of the method. It may be important to note that arch length discrepancy was calculated for upper and lower arches separately	Low concerns There definition of arch length discrepancy in this study is adequate	

Table 9: Description and quality assessment of the Redlich et al study evaluating the accuracy of arch length discrepancy

Study		PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD	FLOW AND TIMING
Redlich et al 2008 **[90]**	Description: Sample selection and measurements assessed	A retrospective sample of 30 patients divided into three equal groups according to degree of crowding; no crowding or spacing, mild crowding, moderate to severe crowding. No sample size calculation. Measurements: tooth widths and arch perimeter using a segmental technique	Teledent software measuring models scanned with a holographic sensor	Digital callipers measuring plaster models using a segmental arch method	There were no exclusions to the original sample The same models used for manual measurements were scanned to form the digital models.
	Risk of bias description (High/ Low/ \Unclear)	Unclear Risk • Risk of selection bias due to the retrospective nature of the study, however this is an acceptable study design for a measurement study. • It is unclear if model selection was random or consecutive	Low risk Although the digital calliper measurements were made first, the final measurements are objective and computer generated so are less likely to be biased	Low risk There is no gold standard method for the measurement of arch length discrepancy, however digital callipers are likely to produce accurate measurements	Low risk All the patients were included in the analysis and received the same reference standard.
	Concerns regarding applicability (High/ Low/ \Unclear)	High concerns The sample size was not adequate	Low concerns There are no concerns about the conduct of the method. It may be important to note that arch length discrepancy was calculated for upper and lower arches separately	Low concerns There definition of arch length discrepancy in this study is adequate	

Table 10: Reliability and validity of crowding measurements in each study

Study	Reliability		Validity (agreement with comparison)		
	Error of the method*	Intra-rater reliability (correlation coefficient.)	Mean difference	95% limits of agreement	Correlation coefficient
Quimby et al 2004 [64] n = 50 OrthoCad versus plaster models (segmental arch, 4 segments)	Not reported	0.90	Maxillary available: 0.54 Maxillary required: 2.23 Mandibular available: 2.88 Mandibular required: 0.212	Not reported	Not reported
Goonewardene et al 2008 [88] n = 50 OrthoCad (6 segment method) versus plaster models (digital calipers) (six segment method)	Not reported	98.65 Maxillary arch 98.60 Mandibular arch	Arch length discrepancy maxilla: 0.17 Arch length discrepancy mandible: 0.26	Not reported	Not reported
Redlich et al 2008 [90] n = 30 Teledent (digital line) versus plaster models (segmental arch, 4 segments)	Not reported	Not reported	Arch length discrepancy maxilla: 1.19 – 2.38 Arch length discrepancy mandible: 0.53 – 3.05	Not reported	Not reported
Redlich et al 2008 [90] n = 30 Teledent (virtual planes) versus plaster models (segmental arch, 4 segments)	Not reported	Not reported	Arch length discrepancy maxilla: 0.14 – 0.55 Arch length discrepancy mandible: 0.15 – 0.74	Not reported	Not reported

Leifert 2009 [89] n = 25 OrthoCad versus plaster models (brass wire)	Not reported	Not reported	Arch length discrepancy maxilla: 0.38 -0.43 Arch length discrepancy mandible: 0.21 – 0.46	Not reported	Not reported

1.4.7 Reliability and validity of tooth movement

The measurement of tooth movement on digital models involves the measurement on superimposed models of translational (bodily) movement (mm) and changes in angular positions of the teeth; i.e. changes in inclination (labio-lingual, bucco-lingual), angulation (mesio-distal) and rotation (degrees).

Assessing the validity of these measurements is a difficult task, as there is no gold standard measurement. Several methods have been used in the literature. One method is to compare digital and radiographic measurements. Another is to consider construct and content validity, in the absence of a gold standard. Construct validity compares the results and interpretation of the digital model method to similar previous research or the expectations of an expert panel. When an expert examines all aspects of the method and it appeared valid to him/her without comparison with the previous research then this is considered content validity.

Another important consideration in studies evaluating the validity of tooth movement on digital models is the landmark for superimposition. The palatal rugae have been established as stable structures by several authors [91-96]. In the mandible, the validity of superimposition on the lingual plate of bone has only been established in one study [97].

There have been few studies on the validity of measuring tooth movement on digital models. These are described in Table 11 to Table 15. Measurements made by Rapidform software were assessed by three investigators [97-99]. These methods were similar in that a common coordinate system was first constructed and that tooth movement was measured on digital models superimposed on palatal rugae or the lingual mandibular cortex.

In addition SCAN 3D software and Imageware 9 software, measuring tooth movement on digital models superimposed on palatal rugae, were investigated [96, 100].

Most of these studies assessed translational movement of selected teeth in one or more planes. Only one of these studies assessed changes in tooth angulation, i.e. change in torque, change in tip and degree of rotation [99].

The quality assessment according to the QUADAS 2 is shown in Table 11 to Table 15. The main risk of bias was related to an undetailed description of the selection process and it was also unclear if the index test and reference standards were measured without the knowledge of the results of the other test. The main concern for applicability was due to small sample sizes.

Table 11: Description and quality assessment of the Mavropoulos et al study evaluating the accuracy of tooth movement measurements

Mavropoulos 2005 **[96]**	Sample selection and measurements assessed	Prospective sample of 10 patients with bilateral class II molar relationships and maxillary second molars (mean age 13.2y) No sample size calculation Measurements (target condition): Vertical and sagittal movement of the molars, second premolars and incisors	• SCAN 3-D software measuring superimposed (palate)scanned digital models • Sagittal movement was measured by constructing centroids for the teeth at baseline and follow-up; the models were superimposed on the palatal rugae and raphe area resulting in a fused hologram which was then projected to the occlusal plane • Vertical measurements a direct measurement of the distance between centroids on the x-axis of the fused hologram	• Digitized superimposed lateral cephalograms • Sagittal and vertical movements were estimated by measuring the distances of the centroid points of the teeth from the pterygoid vertical and the palatal planes respectively	• No exclusions from the samples were mentioned • The radiographs and models were taken at the same time pre-treatment and post treatment
	Risk of bias description (High/ Low/ Unclear)	Unclear Risk • Risk of selection bias due to the retrospective nature of the study, however this is an acceptable study design for a measurement study. • It is unclear if model selection was random or consecutive	Low risk Although it is unclear if the software measurements were made without knowledge of the results manual methods, the final measurements are objective and computer generated so are less likely to be biased.	Unclear risk • There is no gold standard for measuring tooth movement; superimposed cephalometric radiographs are an acceptable current standard. • It is unclear if the reference standard measurements were made without knowledge of the measurements of the index test	Low risk All patients received the reference standard and were included in the analysis
	Concerns regarding applicability (High/ Low/ Unclear)	High risk: • Small sample size, no sample size calculation • No other concerns of applicability	Unclear concern • Sagittal movement, no concerns about the conduct of the method • Vertical movement, it is unclear whether the third dimension of the measurement was eliminated, this could lead to	Low concern	

			overestimated measurements.		

Table 12: Description and quality assessment of the Cha et al study evaluating the accuracy of tooth movement measurements

Study		PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD	FLOW AND TIMING
Cha 2007 **[98]**	Sample selection and measurements assessed	Retrospective sample of 30 patients treated with four premolar extractions in a university dental hospital. No further information on selection of study sample No sample size calculation Measurements (target condition): • Horizontal (mesiodistal) and vertical (intrusion/extrusion) movement of upper molars and incisors	• Rapidform software measuring scanned digital models superimposed on the palate • measurements were made between the midpoints of the incisor edges for the incisors and the mesiobuccal cusp tips of the molars	• Superimposed cephalometric radiographs • a modification of Rickets analysis was used which included formation of in X- and Y- axes similar to that constructed for the digital models	• No exclusions to the original sample were reported. • It is likely that each set of records (pre-treatment and post treatment radiographs and models) were not taken at an interval that would change the condition of the dentition. However this was not explicitly stated, nor can it be controlled for as this was a retrospective investigation.
	Risk of bias description (High/ Low/ Unclear)	Unclear Risk • Risk of selection bias due to the retrospective nature of the study, however this is an acceptable study design for a measurement study. • It is unclear if model selection was random or consecutive	Low risk Although it is unclear if the software measurements were made without knowledge of the results manual methods, the final measurements are objective and computer generated so are less likely to be biased.	Unclear risk • There is no gold standard for measuring tooth movement; superimposed cephalometric radiographs are an acceptable current standard. • It is unclear if the reference standard measurements were made without knowledge of the measurements of the index test	Low risk All patients received the reference standard and were included in the analysis (retrospective study)
	Concerns regarding applicability (High/ Low/	Unclear risks • No sample size calculation • No other concerns of	Low concerns There are no concerns about the conduct of the method.	Low concerns The definition of the target conditions is adequate.	

	Unclear)	applicability.			

Table 13: Description and quality assessment of the Al-Abdallah study evaluating the accuracy of tooth movement measurements

Study		PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD	FLOW AND TIMING
Al-Abdallah 2008 **[99]**	Sample selection and measurements assessed	Retrospective sample of 100 cases Sample size calculation performed Measurements (target condition): • translational movement in three planes of space • change in inclination (torque) of the labial segment • change in rotation • change in tip	• Rapidform software measuring scanned digital models superimposed on the palate • measurements were made from the centres of mass of the crowns of the teeth, which is a more objective computer generated point	The reference standard was different for each type of tooth movement: • Translational movement: construct validity was tested using data from the related clinical trial. • Change in inclination: Tooth Inclination Protractor (TIP) • Change in rotation: Visual assessment on study models by an orthodontic specialist • Change in tip: construct validity was tested using data from the related clinical trial	• No exclusions to the original sample were reported. • Both index test and reference standard were made from the same models, so there is no interval that could have changed the patient condition
	Risk of bias description: (High/ Low/ Unclear)	Unclear Risk • Risk of selection bias due to the retrospective nature of the study, however this is an acceptable study design for a measurement study. • It is unclear if model selection was random or consecutive	Low risk Although it is unclear if the software measurements were made without knowledge of the results manual methods, the final measurements are objective and computer generated so are less likely to be biased.	Unclear risk • Validating the digital method is a difficult task due to absence of gold standard methods to measure tooth movement; different types of validation were used for each type of tooth movement. • It is unclear if the reference standard measurements were made without knowledge of the measurements of the index test	Low risk All patients received the reference standard and were included in the analysis (retrospective study)
	Concerns with applicability (High/ Low/	Low concerns • The study had adequate power	Low concerns There are no concerns about the conduct of	Low concerns The definitions of the target conditions are	

	Unclear	and sample size	the method.	adequate.	

Table 14: Description and quality assessment of the Thiruvenkatachari study evaluating the accuracy of tooth movement measurements

Study		PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD	FLOW AND TIMING
Thiruvenkatachari 2009 **[97]**	Sample selection and measurements assessed	Retrospective sample of 100 cases Sample size calculation performed Measurements (target condition): • translational movement of lower molars and incisors in the sagittal plane (mesiodistal)	• Rapidform software measuring scanned digital models superimposed on the lingual plate of bone • measurements were made from the centres of mass of the crowns of the teeth, which is a more objective computer generated point)	Two reference standards were used: • superimposed lateral cephalometric measurements • construct validity was tested using data from the related clinical trial c	• No exclusions to the original sample were reported. • Both index test and reference standards were collected at the same time from the patients, so there is no interval that could have changed the patient condition
	Risk of bias description: (High/ Low/ Unclear)	Unclear Risk • Risk of selection bias due to the retrospective nature of the study, however this is an acceptable study design for a measurement study. • It is unclear if subject selection was random or consecutive	Low risk Although it is unclear if the software measurements were made without knowledge of the results manual methods, the final measurements are objective and computer generated so are less likely to be biased.	Unclear risk • Validating the digital method is a difficult task due to absence of gold standard methods to measure tooth movement; two different types of validation were used to confirm results • It is unclear if the reference standard measurements were made without knowledge of the measurements of the index test	Low risk All patients received the reference standard and were included in the analysis (retrospective study)
	Concerns regarding applicability (High/ Low/ Unclear)	Low concerns • The study had adequate power and sample size • No other concerns	Low concerns There are no concerns about the conduct of the method.	Low concerns The definition of the target condition is adequate.	

Table 15: Description and quality assessment of the Jang et al study evaluating the accuracy of tooth movement measurements

JANG 2009 **[100]**	Sample selection and measurements assessed	Prospective sample of 10 patients with maxillary protrusion, in which bilateral maxillary premolars were extracted (mean age 20) No sample size calculation Measurements (target condition): Displacement of the central incisors	• Imageware 9 software measuring digital scanned models superimposed on palatal rugae • Measurements were made between the midpoints of the right central incisors	• Imageware 9 software measuring digital scanned models superimposed on registration miniscrews • Measurements were made between the midpoints of the right central incisors	• No exclusions made • Both index test and reference standard were made from the same models, so there is no interval that could have changed the patient condition
	Risk of bias description (High/ Low/ Unclear)	Unclear risk Unclear if it was a random or consecutive sample	Low risk Although it is unclear if the software measurements were made without knowledge of the results manual methods, the final measurements are objective and computer generated so are less likely to be biased.	Unclear risk • There is no gold standard for measuring tooth movement; it is unclear if this is an appropriate reference standard. On the one hand, it is controversial that the registration miniscrews are stable; on the other hand this may be a more accurate method than superimposed cephalograms. • It is unclear if the reference standard measurements were made without knowledge of the measurements of the index test; the final measurements are objective and computer generated so are less likely to be biased.	Low risk All patients received the reference standard and were included in the analysis (retrospective study)
	Concerns regarding applicability (High/ Low/	High risk: • Small sample size, no sample size calculation	Low concerns There are no concerns about the conduct of the method.	Low concerns The definition of the target condition is adequate.	

	Unclear)	• No other concerns			

1.4.7.1 Reliability of tooth movement on digital models

Table 16 shows the values of the error of the method and intra-rater reliability for the methods used to measure tooth movement on digital models.

Both translational movement and changes in angular position of the teeth showed very high repeatability and low errors. This was an expected finding as the software greatly reduces human error.

1.4.7.2 Validity of tooth movement on digital models

Table 16 shows the validity results for the methods used to measure tooth movement on digital models.

In general translational tooth measurements on digital models showed high validity when compared to measurements made on superimposed cephalometric radiographs irrespective of the software used. This finding was reinforced when results and interpretation of measurements made on digital models were compared to results of existing research.

Table 16: Reliability and validity of tooth movement measured on superimposed digital models

Study	Type of tooth movement	Reliability		Validity (agreement with comparison)		
		Error of the method	Intra-rater reliability (correlation coefficient.)	Correlation coefficient	Construct validity	Mean difference
Mavropoulos 2005 [96] n = 10 SCAN 3D software Versus Cephalometric radiographs	Mesio-distal movement of the upper first molars	0.21	Not reported	Not reported	Not reported	0.9 mm
	Mesiodistal movement of the upper second premolars	0.21	Not reported	Not reported	Not reported	1.24 mm
	Mesiodistal movement of the upper incisors	0.16	Not reported	Not reported	Not reported	0.09 mm
	Intrusion/extrusion of upper first molars	0.13	Not reported	Not reported	Not reported	0.08 mm
	Intrusion/extrusion of upper first premolars	0.12	Not reported	Not reported	Not reported	0.15 mm
Cha 2007 [98] n = 30 Rapidform software Versus Cephalometric radiographs	Mesio-distal movement of upper first molars	Not reported	Not reported	0.994	Not reported	0.1 mm
	Mesio-distal movement of upper central incisors	Not reported	Not reported	0.993	Not reported	0.0 mm
	Intrusion/extrusion of upper first molars	Not reported	Not reported	0.932	Not reported	0.1 mm
	Intrusion/extrusion of upper central incisors	Not reported	Not reported	0.990	Not reported	0.1 mm
Al-Abdallah 2008 [99] n = 48 (intra-rater reliability) n = 100 (validity) Rapidform software Versus Cephalometric trial, tooth	Translational movement in three planes of space (mesio-distal, intrusion/extrusion, bucco-lingual) of upper first molars and central incisors	Ranged from -0.004 (SD 0.13) to 0.05 (SD 0.24)	Ranged from 0.922 to 0.993	Not reported	Analysis of data and comparison reinforces the validity of the method	Not reported
	Change in tip of upper first molars and upper central incisors	Ranged from -0.09 (SD 0.65) to	Ranged from 0.929 to 0.987	Not reported	Analysis of data and comparison	Not reported

inclination protractor, visual assessment		-0.25 (SD 0.86)			reinforces the validity of the method	
	Change in torque of upper first molars and central incisors	Ranged from -0.04 (SD 0.52) to 0.11 (SD 0.44),	Ranged from 0.980 to 0.992	Not reported	Analysis of data and comparison reinforces the validity of the method	Not reported
	Change in torque of upper central incisors	Ranged from -0.17 (SD 1.17) to -0.25 (SD 1.00)	Ranged from 0.982 to 0.987	Ranged from 0.888 to 0.897	0.888 to 0.897	Not reported
	Degree of rotation of the upper first molars and central incisors	Ranged from -0.05 (SD 0.49) to -0.18 (SD 0.67)	Ranged from 0.971 to 0.979			
Thiruvenkatachari 2009 [97] n = 48 (reliability) n = 100 (validity) Rapidform software Versus Cephalometric radiographs and cephalometric trial	Mesiodistal movement of lower molars (rt and lt)	-0.063 +/- 0.274, 0.019 +/- 0.289	0.986, 0.990	Not reported	Values and conclusions were similar to those obtained from superimposed lateral cephalometric radiographs in the clinical study	Mean difference 0.3mm (95% CI -0.08, 0.67) Paired t-test was not significant
	Mesiodistal movement of lower incisors	0.018 +/-0.629	0.765	Not reported	Values and conclusions were similar to those obtained from superimposed lateral cephalometric radiographs in the clinical study	Mean difference 0.02 mm (95% CI – 0.43, 0.39) Paired t-test was not significant
Jang 2009 [100] N = 10 Imageware 9 software (models superimposed on palatal rugae)	Displacement of the upper right central incisor	Not reported	0.998	0.99	Not reported	0.08 mm

Versus Imageware 9 (models superimposed on palatal mini-implants)						

In summary, many studies have assessed the reliability and validity of measurements made on digital models. The most common measurements assessed were linear measurements made at one point in time; this was followed by translational movement measured on superimposed digital models. The measurement of angular variables and changes in the angulation of teeth was uncommon.

In general, all methods were highly reliable when the error of the method and intra-rater reliability were assessed. There was also high correlation between these methods and manual methods of comparisons. In many ways this is not unexpected because human error is minimized. The main limitations of the studies were related to sample size and the choice of comparison. Many of the studies had a small sample size and most studies did not report a sample size calculation.

1.5 Conclusions of literature review:

Orthodontic anchorage is an important concept in orthodontics, and is related to the use of additional appliances, the extraction of teeth and the amount of space available.

Headgear is considered the “gold standard” for orthodontic anchorage; nevertheless, its anchorage potential is limited because of poor patient compliance and reports of serious eye injuries. Other appliances such as distal movement appliances and surgical anchorage appliances have been developed, and may be an effective alternative to headgear.

Functional appliances have traditionally been used for growth modification, however, the dento-alveolar effects resulting from a course of functional appliance may alter the anchorage requirements and the decision to extract as part of a course of orthodontic treatment.

Many systems and software have been developed for measuring tooth movement and inter-arch relationship on digital models. These methods have been described for the orthodontic measurements relevant to this investigation, including their reliability and validity. Crowding measurements on digital models is especially problematic; firstly because there is no manual method that is 100% sensitive and thus it is difficult to define a gold standard. Secondly, the validity of crowding has not been evaluated on generic software.

2 Aims and hypothesis

This research had three main parts and had the following aims and hypothesis:

2.1 Part I:

2.1.1 Aims

To assess the effects of orthodontic treatment for distalising upper first molars in children and adolescents.

2.1.2 Null hypothesis

1- There is no statistically significant difference in the mean mesiodistal movement of upper molar teeth and mean mesial movement of anterior teeth between different types of distalising appliances, or between distalising appliances and controls.

2- There is no difference between mean duration of treatment, non-compliance proportion and mean number of attendances between different types of distalising appliances, or between distalising appliances and control.

2.2 Part II:

2.2.1 Aims:

To assess the effects of surgical anchorage compared to conventional anchorage in the prevention of unwanted tooth movement in orthodontic patients

2.2.2 Null Hypothesis

1- There is no statistically significant difference in the mean mesiodistal movement of upper molar teeth between the types of surgical anchorage and other forms of orthodontic anchorage.

2- There is no difference in mean residual overjet, success of the anchorage device, patient perception and acceptability, number of visits, duration of treatment and economic factors between types of surgical anchorage and other forms of orthodontic anchorage.

2.3 Part III:

2.3.1 Aims

1- To assess the intra-rater reliability of 3 dimensional measurements used in this investigation

2- To develop a method for measurement of crowding on digital 3-dimensional models and assess its validity

3- To evaluate the effect of different types of functional appliances on three dimensional tooth movements and interarch relationship in patients with Class II Division I malocclusion

4- To evaluate the influence of types of functional appliance and malocclusion factors on the decision to extract teeth following the initial phase of functional appliance treatment in patients with Class II Division I malocclusion.

2.3.2 Objectives

The objectives were to show the following:

1- There is no difference between repeated measurements when assessing intra-rater reliability for 3 dimensional measurements

2- There is no difference between paired measurements when assessing the validity of the crowding method on digital 3-dimensional models.

3- The type of functional appliance does not have an influence on tooth movement and inter-arch relationship.

4- The type of functional appliance does not influence the decision to extract at the end of functional appliance treatment.

5- Selected malocclusion characteristics (Royal London space analysis pre-treatment, Royal London space analysis post-functional, change in lower incisor torque, molar relationship post-functional) do not influence the decision to extract.

SECTION II: Cochrane Systematic review: Orthodontic treatment for distalising upper first molars in children and adolescents

- **This section provides the exact text of the published review**
- **SJ led this review and her contribution is stated on page 196**

Review information

Review number: 0181

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1 Abstract

1.1 Background

When orthodontic treatment is provided with fixed appliances, it is sometimes necessary to move the upper molar teeth backwards (distalise) to create space or help to overcome anchorage requirements. This can be achieved with the use of extraoral or intraoral appliances. The most common appliance is extraoral headgear, which requires considerable patient co-operation. Further, reports of serious injuries have been published. Intraoral appliances have been developed to overcome such shortcomings. The comparative effects of extraoral and intraoral appliances have not been fully evaluated.

1.2 Objectives

To assess the effects of orthodontic treatment for distalising upper first molars in children and adolescents.

1.3 Search methods

We searched the following electronic databases: the Cochrane Oral Health Group's Trials Register (to 10 December 2012), the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2012, Issue 11), MEDLINE via OVID (1946 to 10 December 2012) and EMBASE via OVID (1980 to 10 December 2012). No restrictions were placed on the language or date of publication when searching the electronic databases.

1.4 Selection criteria

Randomised clinical trials involving the use of removable or fixed orthodontic appliances intended to distalise upper first molars in children and adolescents.

1.5 Data collection and analysis

We used the standard methodological procedures expected by The Cochrane Collaboration. We performed data extraction and assessment of the risk of bias independently and in duplicate. We contacted authors to clarify the inclusion criteria of the studies.

1.6 Main results

Ten studies, reporting data from 354 participants, were included in this review, the majority of which were carried out in a university dental hospital setting. The studies were published between 2005 and 2011 and were conducted in Europe and in Brazil. The age range of participants was from nine to 15 years, with an even distribution of males and females in seven of the studies, and a slight predominance of female patients in three of the studies. The quality of the studies was generally poor; seven studies were at an overall high risk of bias, three studies were at an unclear risk of bias, and we judged no study to be at low risk of bias.

We carried out random-effects meta-analyses as appropriate for the primary clinical outcomes of movement of upper first molars (mm), and loss of anterior anchorage, where there were sufficient data reported in the primary studies. Four studies, involving 159 participants, compared a distalising appliance to an untreated control. Meta-analyses were not undertaken for all primary outcomes due to incomplete reporting of all summary statistics, expected outcomes, and differences between the types of appliances. The degree and direction of molar movement and loss of anterior anchorage varied with the type of appliance. Four studies, involving 150 participants, compared a distalising appliance versus headgear. The mean molar movement for intraoral distalising appliances was -2.20 mm and -1.04 mm for headgear. There was a statistically significant difference in mean distal molar movement (mean difference (MD) -1.45 mm; 95% confidence interval (CI) -

2.74 to -0.15) favouring intraoral appliances compared to headgear (four studies, high or unclear risk of bias, 150 participants analysed). However, a statistically significant difference in mean mesial upper incisor movement (MD 1.82 mm; 95% CI 1.39 to 2.24) and overjet (fixed-effect: MD 1.64 mm; 95% CI 1.26 to 2.02; two studies, unclear risk of bias, 70 participants analysed) favoured headgear, i.e. there was less loss of anterior anchorage with headgear. We reported direct comparisons of intraoral appliances narratively due to the variation in interventions (three studies, high or unclear risk of bias, 93 participants randomised). All appliances were reported to provide some degree of distal movement, and loss of anterior anchorage varied with the type of appliance.

No included studies reported on the incidence of adverse effects (harm, injury), number of attendances or rate of non-compliance.

1.7 Authors' conclusions

It is suggested that intraoral appliances are more effective than headgear in distalising upper first molars. However, this effect is counteracted by loss of anterior anchorage, which was not found to occur with headgear when compared with intraoral distalising appliance in a small number of studies. The number of trials assessing the effects of orthodontic treatment for distilisation is low, and the current evidence is of low or very low quality.

2 Plain language summary

Orthodontic treatment with appliances which move the upper molar teeth backwards

2.1 Review question

The main question addressed by this review is how effective are orthodontic appliances in moving the upper teeth backwards in children and adolescents.

2.2 Background

Orthodontic treatment is a type of dental care that corrects crooked or sticking out teeth by moving the teeth into different positions. When orthodontic treatment is provided with braces it is sometimes necessary to move the upper molar teeth backwards (distalise). This is achieved by special types of braces (appliances) that are placed either before or at the same time as the normal braces. Appliances which move the upper molar teeth backwards can be placed inside the mouth (intraoral appliance) or attached to the back of the head (extraoral appliance). The most commonly used extraoral appliance is headgear. The biggest disadvantage of headgear is that children and adolescents must wear it for prolonged hours during the day. In addition, serious eye injuries have been reported while wearing headgear. As an alternative, several intraoral appliances have been developed. Unfortunately, their effects have not been completely evaluated.

2.3 Study characteristics

This review of existing studies was carried out by the Cochrane Oral Health Group, and the evidence is current as of December 2012. In this review there are 10 studies published between 2005 and 2011 in which a total of 354 children were randomised to receive treatment with a distalising orthodontic appliance and compared to either no treatment, headgear or another distalising appliance. The age range of children in nine of the studies

was from 11 to 15 years, although the children recruited to one study were younger, from nine to 10 years old. Both girls and boys participated in the studies.

Where it was mentioned, the funding was from a university or dental research foundation. The authors did not assess the impact of the funding sources.

2.4 Key results

When intraoral appliances are compared to headgear they will probably move the upper molar teeth backwards more than headgear. However, the use of intraoral appliances was also associated with movement of the upper front teeth when compared to extraoral appliances in four studies. This is an unwanted effect that was not observed with the use of the headgear appliances.

Harm, injury from the appliances and other characteristics of the appliances which may be important to patients were not reported in the studies.

2.5 Quality of the evidence

The evidence presented is generally of low quality. The main shortcomings were related to trial design.

Table 17: Summary of findings: Orthodontic appliance compared to untreated control for distalising first molars

Orthodontic appliance compared to untreated control for distalising first molars						
Patient or population: **children and adolescents undergoing orthodontic treatment** Settings: **university or private orthodontic clinic** Intervention: **orthodontic appliance** Comparison: **untreated control**						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Untreated control	Corresponding risk Orthodontic appliance				
Movement of upper first molars (mm)	Not estimated	Not estimated	Meta-analysis not appropriate	74 (2 studies)	⊕⊕⊖⊖ low[1,2]	No pooled estimate due to different types of appliances (First Class and distalising) used in the studies
Movement of upper incisor teeth (mm)	Not estimated	Not estimated	Meta-analysis not appropriate	74 (2 studies)	⊕⊕⊖⊖ low[1,2]	No pooled estimate due to different types of appliances (First Class and distalising) used in the studies
Change in overjet (mm)	Not estimated	Not estimated	Meta-analysis not appropriate	74 (2 studies)	⊕⊕⊖⊖ low[1,2]	No pooled estimate due to different types of appliances (First Class and distalising) used in the studies
***The basis for the** assumed risk **(e.g. the median control group risk across studies) is provided in footnotes. The** corresponding risk **(and its 95% confidence interval) is based on the assumed risk in the comparison group and the** relative effect **of the intervention (and its 95% CI)** CI: **confidence interval**						
GRADE Working Group grades of evidence High quality: **Further research is very unlikely to change our confidence in the estimate of effect** Moderate quality: **Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate** Low quality: **Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate** Very low quality: **We are very uncertain about the estimate**						

[1]One study at high risk of bias; one study at unclear risk of bias
[2]Evidence based on two studies with a low number of participants

3 Background

3.1 Description of the condition

When orthodontic treatment is provided with braces it is sometimes necessary to move the upper molar teeth backwards (distalise) to create space or help to overcome anchorage requirements. It is crucial to have reliable methods and appliances that can distalise molars in order to plan and treat many malocclusions optimally. However, appliances that claim to provide distal movement can also have adverse or unwanted effects. These are primarily eye injuries [101], minor soft tissue injuries and unwanted tooth movement [102].

3.2 Description of the intervention

Molar distalisation is a phase of comprehensive orthodontic treatment in which the distalisation appliances are inserted prior to or in conjunction with the fixed orthodontic appliance. When the molar teeth have been sufficiently moved in the distal direction, the distalisation appliances are either removed or continued for retention, and the fixed orthodontic appliances are continued until the end of treatment.

Appliances that distalise molars may be categorised as intraoral or extraoral appliances/systems. The most common distalising appliance is extraoral headgear. In the late 1800s, Kingsley and Angle used occipital headgear to move the top front teeth backwards [103]. In the early 1900s, Case was the first orthodontist to use headgear to distalise molar teeth [103]. Several authors [104-110] have reported on the effects that extraoral headgear has on restricting maxillary growth, moving molars distally or both.

Unfortunately, the use of extraoral headgear to move molars distally requires considerable patient co-operation. In order for extraoral headgear to achieve its goal of distal movement, it must be adjusted to apply an appropriate force level, and it must be worn by the patient for the prescribed amount of time. This is usually from 12 to 14 hours per day.

Numerous studies of headgear compliance have shown that patients find this difficult [4-6]. In addition, a number of serious ocular injuries have been reported with external headgear [8]. These injuries occurred through dislodgement during sleep, improper removal or improper use.

Alternative orthodontic appliances and systems which claim to minimise or eliminate the need for patient compliance and which reduce the risk of serious injury have been developed. These are intraoral appliances/systems which are inserted by the orthodontist and remain in the mouth full time. In most instances they can only be removed by the orthodontist. It is stipulated that these can be used to distalise upper molars with minimal patient co-operation because these appliances can only be inserted and removed by the orthodontist. In addition, they are aesthetically more acceptable being less visible than extraoral headgear. A large number of different intraoral appliances and systems which are used to distalise molars have been described in the orthodontic literature. Among the most frequently used in clinical practice are: the pendulum appliance [111], Wilson's arch [112], distal jet appliance [113], Jones Jig appliance [114], First Class appliance [115], repelling magnets [116] and superelastic coil springs [117].

3.3 How the intervention might work

All distalising appliances or systems have two main components. The first component applies a force to the upper first molar teeth, and a second component prevents an unwanted reciprocal force by anchoring the appliance to a structure inside or outside of the mouth. When external headgear is used a force is generated by elastics through the attachment of a facebow to bands cemented to molar teeth. A reciprocal force is prevented by anchoring the facebow to a stable structure which is the back of the head. In order for headgear to achieve its goal of distal movement, it must be adjusted to apply an appropriate force level, and it must be worn by the patient for a prescribed amount of time.

Intraoral appliances work by applying a distal force to the upper molar teeth using springs, coils or wires, against a stable structure inside the mouth which may be the palate, the teeth, any other intraoral structure, or any combination of these. Intraoral appliances can further be divided into two groups according to the arch to which they are anchored; appliances anchored to the palate or teeth (or both) within the maxillary arch such as the pendulum appliance [111], and appliances anchored to teeth or other structure in the mandibular arch (or both) such as the Jasper Jumper [118]. Intraoral appliances are worn full time.

3.4 Why it is important to do this review

Despite the established clinical use of molar distalising devices, there is equivocacy regarding the relative effects of intraoral and extraoral appliances and systems when directly compared or compared to no treatment. For example, an earlier systematic review undertaken on molar distalisation which included trials published between 1988 and 1998 reported that evidence on any specific appliance to move molars distally was inconclusive [119]. Another systematic review, which included both retrospective and prospective comparative studies, concluded that these studies had serious flaws in their quality [120]. An updated systematic review, which includes formal quality assessment to standardised criteria, of the relative effects of orthodontic treatment would be beneficial.

4 Objectives

To assess the effects of orthodontic treatment for distalising upper first molars in children and adolescents.

5 Methods

5.1 Criteria for considering studies for this review

5.1.1 Types of studies

Parallel-group, randomised controlled trials evaluating orthodontic appliances which are intended to move upper first molars distally. Studies reporting clinical evaluation at any point during orthodontic treatment were included. There was no restriction on publication language. Where studies were reported in abstract form we searched the literature for full publication. Due to the nature of the interventions, split-mouth trials were excluded. Trials comparing active intervention with no treatment were included, as were trials directly comparing one active intervention with another.

5.1.2 Types of participants

Children aged 16 years or less, at the start of treatment, who receive orthodontic treatment intended to move the upper molars distally.

Patients with cleft lip and palate, or other craniofacial problems, were excluded.

5.1.3 Types of interventions

- Active interventions: removable or fixed orthodontic appliances intended to distalise upper first molars
- Control: no treatment or another active intervention (removable or fixed orthodontic appliance) intended to distalise upper first molars

5.1.4 Types of outcome measures

5.1.4.1 Primary outcomes

- Movement of upper first molars (measured in mm). Both mesial movement (recorded and reported as a positive value (mm)) and distal movement (recorded and reported as a negative value (mm)) were evaluated.

- Loss of anterior anchorage (measured in mm) reported as either mesial movement of upper incisor teeth or change in overjet.

5.1.4.2 Secondary outcomes

Duration of treatment, non-compliance, number of attendances required to complete treatment.

5.1.4.3 Main outcomes for 'Summary of findings' table

The following outcomes were included the 'Summary of findings' tables: movement of upper first molars, mesial movement of upper incisor teeth and change in overjet.

5.1.4.4 Adverse effects

Injuries associated with headgear, health of gums, damage to the teeth, e.g. tooth decay, root resorption.

5.2 Search methods for identification of studies

5.2.1 Electronic searches

We developed detailed search strategies for each database. Individual search strategies were based on the search strategy developed for MEDLINE (Figure 16), but revised appropriately for each database.

The MEDLINE search used a combination of controlled vocabulary and free-text terms, in conjunction with the Cochrane Highly Sensitive Search Strategy for identifying reports of randomised controlled trials (as published in Box 6.4.c in the Cochrane Handbook for Systematic Reviews of Interventions, version 5.1.0, updated March 2011) [48]. The search of EMBASE was linked to the Cochrane Oral Health Group filters for identifying RCTs.

We searched the following electronic databases:

- Cochrane Oral Health Group's Trials Register (to 10 December 2012) (Figure 17)

- Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2012, Issue 11) (Figure 18);
- MEDLINE via OVID (1946 to 10 December 2012) (Figure 16);
- EMBASE via OVID (1980 to 10 December 2012 (Figure 19).

5.2.2 Language

No restrictions were placed on the language or date of publication when searching the electronic databases.

5.2.3 Searching other resources

5.2.3.1 Handsearching

The following journals have been identified for handsearching for this review. We handsearched journal issues that have not already been searched as part of the Cochrane Oral Health Group's journal handsearching programme:

- American Journal of Orthodontics and Dentofacial Orthopedics (2005 to January 2013)
- The Angle Orthodontist (2007 to January 2013)
- Clinical Implant Dentistry and Related Research (2003 to December 2012)Clinical Oral Implant Research (2001, 2003 to December 2012)
- European Journal of Orthodontics (2006 to December 2012)
- International Journal of Oral and Maxillofacial Implants (2004 to December 2012)
- Journal of Orthodontics (formerly British Journal of Orthodontics) (2008 to December 2012)
- Journal of Dental Research (1999 to 2000, 2004 to January 2013)
- Journal of Dentistry (2004 to December 2012)
- Journal of Clinical Orthodontics (1991 to December 2012)

- Orthodontics and Craniofacial Research (1998 to 2001 Clinical Orthodontics and Research) (2000 to November 2012)
- Seminars in Orthodontics (2005 to December 2012).

We checked the bibliographies of potentially relevant clinical trials for references to trials published outside the handsearched journals. In addition, we checked non-Cochrane systematic reviews for potentially relevant studies.

5.2.3.2 Unpublished studies

We searched trial registries to identify ongoing studies. The most recent search for all trial registries was January 2013. This included the following.

- www.clinicaltrials.gov: The clinical trials.gov website was searched by topic selecting mouth and tooth diseases. We searched all records under 'malocclusion' and 'Malocclusion Angle Class II'. In addition, we conducted a keyword search (Figure 20).
- The IFMPA clinical trials portal (http://clinicaltrials.ifpma.org/clinicaltrials/no_cache/en/clinical-trial-advanced-search/index.htm). This was searched by using the following terms from the 'site language': 'orthodontic procedure' and 'dental braces complication'.
- Current Controlled Trials (isrctn.org). We searched the current controlled trials website by using the key words individually: dental, orthodontic and molar distalisation.

5.3 Data collection and analysis

5.3.1 Selection of studies

We examined the titles and abstracts of the search results to remove obviously irrelevant reports. This was performed by three review authors independently and in duplicate. Disagreements were resolved through discussion.

We retrieved the full text of the potentially relevant reports and examined them for eligibility. There was no restriction by language on the studies to be retrieved. Assessment of eligibility was performed by three review authors independently and in duplicate. We attempted correspondence with investigators to clarify study eligibility where information was unclear or unreported in the primary studies. We made final decisions on study inclusion through discussion.

5.3.2 Data extraction and management

The review authors performed data extraction independently and in duplicate. We used pre-defined data extraction forms to record information on methods, participants, interventions, primary and secondary outcomes and reported results.

5.3.3 Assessment of risk of bias in included studies

We used the Cochrane 'Risk of bias' tool to assess the methodological quality of the studies as described in the Cochrane Handbook for Systematic Reviews of Interventions version 5.1.0 [48]. This was undertaken independently and in duplicate by the review authors as part of the data extraction process. Six specific domains were important for this review: sequence generation, allocation concealment, blinding of outcome assessor, incomplete outcome data, selective outcome reporting and other bias. We gave each domain a judgement of low, high or unclear risk of bias. We did not evaluate blinding of operator and participant as blinding to the intervention was unfeasible in most circumstances.

Following assessment of each domain, we assessed the overall risk of bias for each study. All domains contributed equally to the overall study risk of bias: we considered a study at high risk of bias when at least one domain was judged as high risk of bias; we considered

studies with at least one unclear domain at an unclear risk of bias; we considered studies with all risk of bias domains judged as low as low risk of bias.

5.3.4 Measures of treatment effect

For dichotomous outcomes, the measure of treatment effect was the risk ratio; for continuous outcomes the measure of treatment effect was the mean difference. We calculated 95% confidence intervals alongside the treatment effect. Where insufficient information was reported to enable these effect measures to be calculated we reported summary measures narratively.

5.3.5 Unit of analysis issues

We considered multiplicity of reporting of clinical outcomes at many time points. We extracted the most clinically relevant time point(s).

5.3.6 Dealing with missing data

We recorded missing data due to attrition as reported in the publication. We did not undertake data imputation.

5.3.7 Assessment of heterogeneity

We assessed clinical heterogeneity by examining the type of participants and interventions in each study. We undertook meta-analysis only when studies were of similar comparisons reporting comparable outcome measures. We used the Chi^2 test and I^2 statistic as measures of statistical heterogeneity in random-effects meta-analyses [48].

5.3.8 Data synthesis

We undertook a random-effects meta-analysis when there were more than three studies and data synthesis was clinically and statistically appropriate.

In multi-arm studies with more than two intervention groups, we made only single pair-wise comparisons. We selected the intervention groups relevant to the review objective and the specific meta-analysis. Any additional intervention group which was not used in the review was detailed in the Characteristics of included studies table. In cases where multiple groups were found relevant to the review objective and specific meta-analysis, we combined all relevant intervention groups of the study into a single group, and combined all relevant control groups into a single control group. For continuous outcomes, we combined means and standard deviations using formulae described in the Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [48].

For comparisons where a meta-analysis could not be carried out we provided a narrative reporting of the summary measures and treatment effects. This consisted of the magnitude and direction of the treatment effect and 95% confidence interval, and evaluation of consistency of effect estimate across studies.

We planned sensitivity analysis, restricting comparisons to studies with similar risk of bias.

6 Main results

6.1 Description of studies

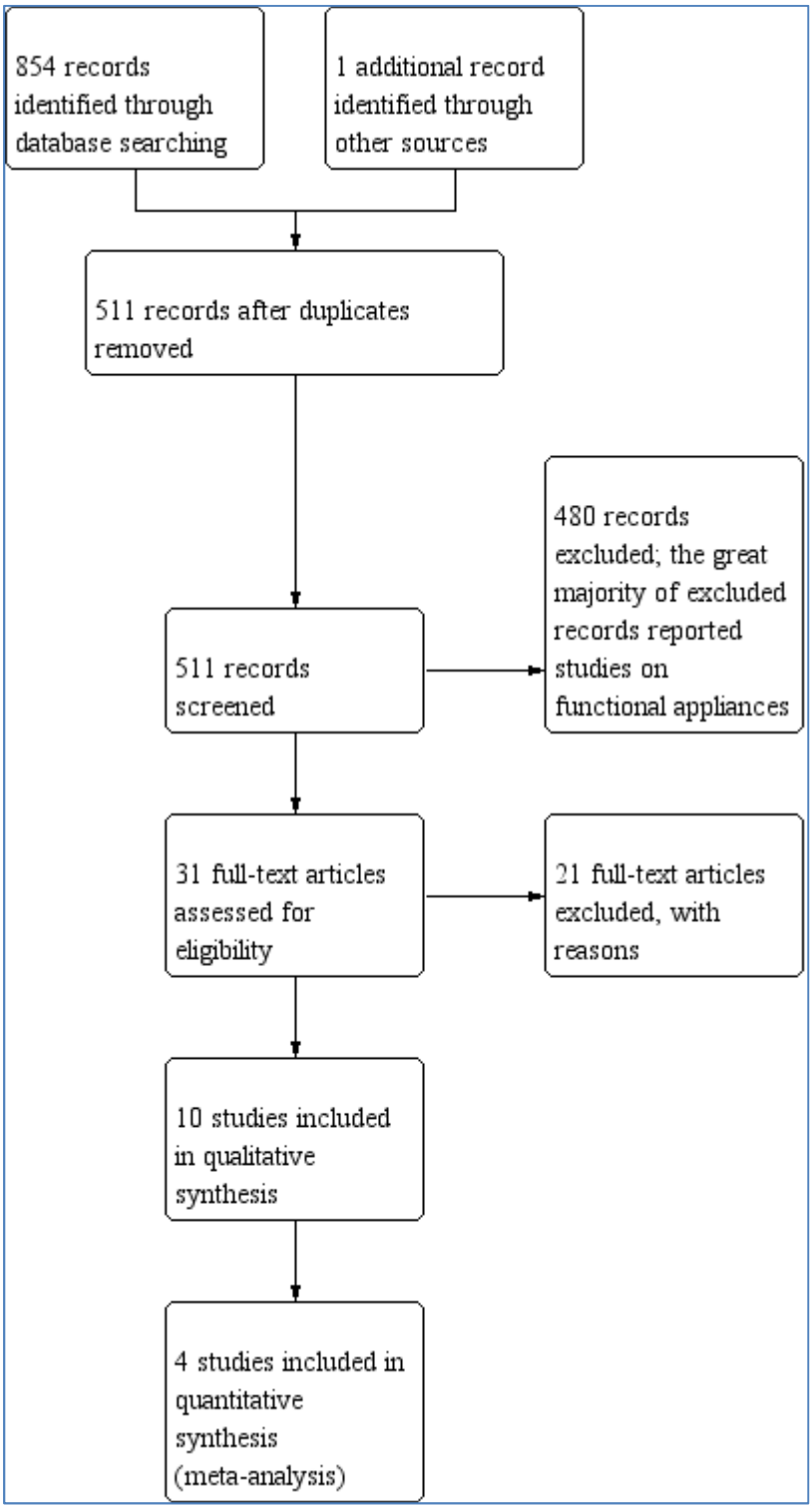
6.1.1 Results of the search

The search was carried out in December 2012. A total of 854 records were identified through database searching and one other potentially relevant study from other sources (see flowchart Figure 10). After duplicates were removed 511 titles and abstracts remained. We discarded 480 records; the great majority of these records reported studies on functional appliances, and those remaining were clearly not relevant. We assessed 31 full-text records for eligibility, of which 21 were excluded and reasons recorded in the

Characteristics of excluded studies table. Ten trials, involving data from 354 analysed participants were included in this review. Seven were two-arm trials; Acar 2010 [121, 122], Altug-Atac 2008 [123], Bondemark 2005 [124], De Oliveira 2007 [125], Papadopoulos 2010 [126], Paul 2002 [127], Toy 2011 [128]. Three were three-arm trials; Armi 2011 (only two interventions were applicable to this review) [129], Baccetti 2008 [130], Karacay 2006 [131]. The included trials were published between 2005 and 2011.

No ongoing studies were identified.

Figure 10: Study flow diagram



6.1.2 Included studies

Summary details are given in the ‘Characteristics of included studies’ section.

6.1.2.1 Characteristics of the trial settings

Nine included trials were conducted in university settings with patients attending a dental clinic, and one (Karacay 2006) was carried out in a military medical academy. Four trials were carried out in Turkey (Acar 2010, Altug-Atac 2008, Karacay 2006, Toy 2011), two were carried out in Italy (Armi 2011, Baccetti 2008) and the remaining four were carried out in Sweden (Bondemark 2005), Brazil (De Oliveira 2007), Greece (Papadopoulos 2010) and the UK (Paul 2002). Eight were single-centre trials and two (Armi 2011, De Oliveira 2007) were carried out in two centres.

The duration of four of the included studies ranged from 6 to 6.5 months (Bondemark 2005, Papadopoulos 2010, Paul 2002, Toy 2011), two studies had a duration of 18 months (Armi 2011, Baccetti 2008) and one study had a duration of 12 weeks (Acar 2010). In two studies (De Oliveira 2007, Karacay 2006), the duration of the study was not stated.

6.1.2.2 Characteristic of participants

The Papadopoulos 2010 trial provided treatment for children with a mean age of 9.2 to 9.7 years. The remaining trials provided treatment to adolescent children; the average age across the trials ranged from 11.45 years to 14.75 years. The gender distribution was comparable in most of the trials (Acar 2010, Armi 2011, Bondemark 2005, De Oliveira 2007, Karacay 2006, Papadopoulos 2010, Paul 2002, Toy 2011). However, there was a slight predominance of female participants in the Altug-Atac 2008 and Baccetti 2008 trials, with the female participants constituting 69% and 61% of the total sample, respectively. The Bondemark 2005 and Paul 2002 trials had a total of 26 and 23 participants, respectively. The remaining trials had a sample ranging from 30 to 69

participants (Acar 2010, Altug-Atac 2008, Armi 2011, Baccetti 2008, De Oliveira 2007, Karacay 2006, Papadopoulos 2010, Toy 2011).

6.1.2.3 Characteristics of the interventions

Four trials included in this review compared intraoral appliances (Karacay 2006, Papadopoulos 2010) or an extraoral appliance (cervical headgear) (Armi 2011, Baccetti 2008) to an untreated control group.

Four of the included trials compared an intraoral distalising appliance to an extraoral appliance (headgear), the Acar 2010 and Toy 2011 trials used the pendulum appliance, the De Oliveira 2007 trial used the Jasper Jumper and the Bondemark 2005 trial used an intraoral appliance with superelastic coils.

Another three studies compared different intraoral appliances; two types of distalisation arches were compared in the Altug-Atac 2008 trial, the Karacay 2006 trial compared Jasper Jumper to the Forsus Nitinol Flat Spring and the Paul 2002 trial compared an upper removable appliance with finger springs to the Jones Jig appliance.

6.1.2.4 Characteristics of the outcomes

The main outcomes reported in the trials were dental and skeletal variables on pretreatment and post-treatment lateral cephalometric radiographs and time needed for distalisation. One study also reported the overall time of treatment (De Oliveira 2007). The number of attendances required to complete treatment and adverse effects were not reported by any of the studies.

Table 18 provides a summary of all of the outcomes relevant to this review as reported by each study.

Table 18: Reported outcomes in included studies which are relevant to this review

Study ID	Movement of molar teeth	Anterior movement of incisor teeth	Overjet	Duration of treatment	Number of attendances	Adverse effects
Acar 2010	Yes	Yes	No	No	No	No
Altug-Atac 2008	Yes	Yes	Yes	Yes	No	No
Armi 2011	Yes	No	No	No	No	No
Baccetti 2008	Yes	No	No	No	No	No
Bondemark 2005	Yes	Yes	Yes	Yes	No	No
De Oliveira 2007	Yes	Yes	No	Yes	No	No
Karacay 2006	Yes	Yes	Yes	Yes	No	No
Papadopoulos 2010	Yes	Yes	Yes	No	No	No
Paul 2002	Yes	No	No	Yes	No	No
Toy 2011	Yes	Yes	Yes	Yes	No	No

6.1.3 Excluded studies

Summary details are given in the 'Characteristics of excluded studies' section.

Twenty-one studies were excluded for the following reasons:

- 13 were not randomised trials: Angelieri 2008 [132], Cetinsahin 2010 [133], Erverdi 1997 [134], Gelgor 2007 [135], Kinzinger 2010 [136], Kucukkeles 2007 [137], Mossaz 2007 [138], Oncag 2007 [139], Sari 2003 [140], Schutze 2007 [141], Taner 2003 [142], Ucem 1998 [143], Uzel 2007 [144].
- four were not relevant to this review because the allocation to treatment groups was not based on the types of distalising appliances as described in the protocol: Kinzinger 2003 [145], Kinzinger 2004 [146], Kinzinger 2005 [147], Kinzinger 2006 [148]
- four did not have relevant intervention(s): Abed 2010 [149]; Kaya 2009 [150], Liu 2009 [151], Silvola 2009 [152].

Kinzinger et al reported several studies evaluating the pendulum appliance, however these were excluded because participants in this study were grouped according to dental maturation stage or the tooth used for anchorage; Kinzinger 2003, Kinzinger 2004, Kinzinger 2005, Kinzinger 2006. In the Kinzinger 2010 studiy, there was no comparative intervention. The Angelieri 2008 study, which compared the pendulum appliance to cervical headgear, was excluded because it was retrospective in nature. The Taner 2003 study compared cervical headgear and pend-x appliance and was excluded because it was not a randomised trial. Correspondence with the author of the Uzel 2007 study confirmed that randomisation was not undertaken.

6.2 Risk of bias in included studies

Summary details are given in the ‘Characteristics of included studies’ section, Figure 11 and Figure 12.

Figure 11: 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study

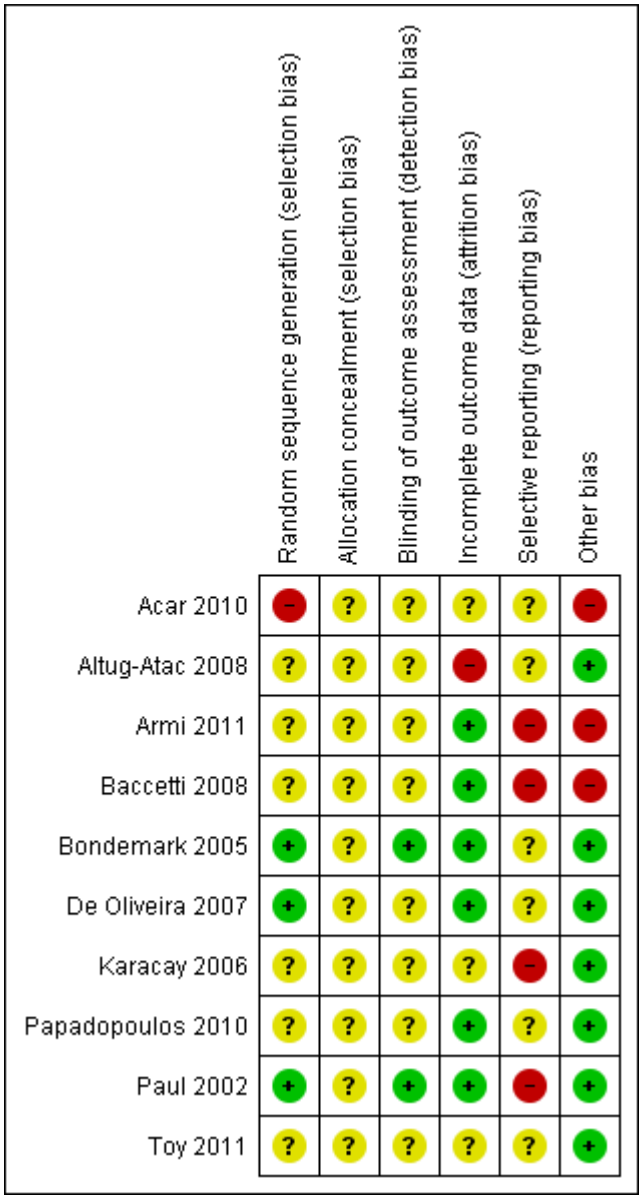
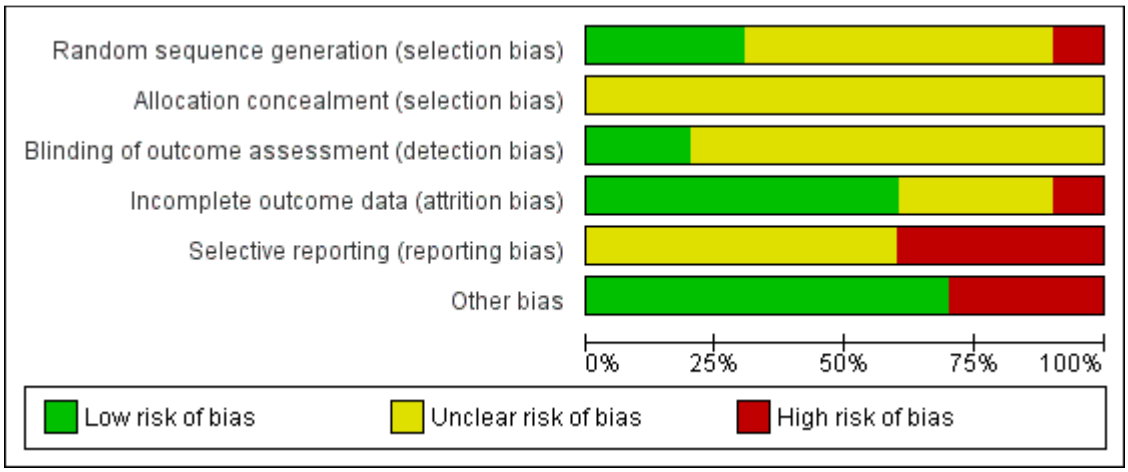


Figure 12: 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies



6.2.1 Allocation (selection bias)

For the domain 'sequence generation', three studies were at a low risk of bias (Bondemark 2005, De Oliveira 2007, Paul 2002), one was at a high risk of bias (Acar 2010) and the remaining six were at unclear risk of bias (Altug-Atac 2008, Armi 2011, Baccetti 2008, Karacay 2006, Papadopoulos 2010, Toy 2011).

Two studies reported the nature of randomisation (Bondemark 2005, Paul 2002), but they did not describe fully the method for generation of the randomisation sequence. In another two studies (Acar 2010, De Oliveira 2007) the authors reported that randomisation was obtained by toss of a coin. The Acar 2010 study was reported in two publications, with conflicting reporting of the method of randomisation. The remaining studies (Altug-Atac 2008, Armi 2011, Baccetti 2008, Karacay 2006, Papadopoulos 2010, Toy 2011) did not report how the randomisation sequence was generated.

Furthermore, none of the included studies reported if and how the allocation sequence was concealed.

6.2.2 Blinding (performance bias and detection bias)

In this domain, there were two studies at low risk of bias (Bondemark 2005, Paul 2002) and the remaining eight studies were at unclear risk of bias.

In all these studies, the interventions were different types of appliances. Therefore it was not possible to blind the operator or participants. However, it may be possible to blind the outcome assessor. Three of the included studies described the method for blinding the outcome assessor (Acar 2010, Bondemark 2005, Paul 2002). In the Acar 2010 study blinding of the outcome assessor was done by evaluating the cephalometric radiographs in a random order. However, it was unclear if the appliances could be seen on the

radiographs and if the assessor was independent. An independent assessor in the Bondemark 2005 study scored and coded the radiographs. In the Paul 2002 study, it was explicitly stated that the outcome assessor was blind to the treatment intervention, but the exact method was not described. The Altug-Atac 2008, Armi 2011, Baccetti 2008, De Oliveira 2007, Karacay 2006, Papadopoulos 2010 and Toy 2011 studies did not state if the outcome assessor was blinded to the treatment allocation.

6.2.3 Incomplete outcome data (attrition bias)

There were six studies with a low risk of bias for this domain (Armi 2011, Baccetti 2008, Bondemark 2005, De Oliveira 2007, Papadopoulos 2010, Paul 2002), one with a high risk of bias (Altug-Atac 2008) and three with an unclear risk of bias (Acar 2010, Karacay 2006, Toy 2011).

All randomised patients were included in the final analysis in two studies (Bondemark 2005, De Oliveira 2007). In the Papadopoulos 2010 and Paul 2002 studies the number of drop-outs was low and the reasons for the drop-outs were explained, therefore we judged them as having low risk of bias. The Armi 2011 and Baccetti 2008 studies also had a small number of drop-outs. The Acar 2010, Karacay 2006 and Toy 2011 studies did not address this domain. In the Altug-Atac 2008 study the high (24%) drop-out rate was due to non co-operation. No further information was given on the nature of non co-operation, however this is an important factor to consider when evaluating orthodontic appliances and is closely linked to compliance. A high drop-out rate due to non co-operation would bias the results towards overestimating the effect of the intervention. Therefore we gave this study a judgement of high risk of bias for this domain.

6.2.4 Selective reporting (reporting bias)

We judged four studies at a high risk of bias (Armi 2011, Baccetti 2008, Karacay 2006, Paul 2002) and judged the remaining six at an unclear risk of bias for this domain.

None of the included trials had published protocols, therefore it is not possible to know for sure if all outcomes were reported. The Armi 2011 and Baccetti 2008 studies had incomplete data reporting, as only the mean distal movement was reported without standard deviations or any other data. The Karacay 2006 study reported the baseline and follow-up data for the molar and incisor teeth position: the difference in means and standard deviations were calculated from these data. In the Paul 2002 study, loss of anterior anchorage was not assessed.

6.2.5 Other potential sources of bias

Seven studies were at a low risk of bias for this domain (Altug-Atac 2008, Bondemark 2005, De Oliveira 2007, Karacay 2006, Papadopoulos 2010, Paul 2002, Toy 2011), and three studies were at a high risk of bias (Acar 2010, Armi 2011, Baccetti 2008).

The Acar 2010 study had errors in reporting data related to the skeletal effects of the intervention. Although these data were not collected as part of this review, this is a potential source of bias in the study as a whole.

The Armi 2011 and Baccetti 2008 studies were reported as two different studies, however the participant characteristics in the control groups in these two studies are very similar. This may be a suggestion that the control group in these two studies was not involved in the randomisation process or that the Armi 2011 study is an extension of the Baccetti 2008 study after more participants were recruited. We contacted the authors of these two studies but no response was received.

6.2.6 Study risk of bias

We assessed the overall risk of bias for each study. We judged the following studies as high risk of bias: Acar 2010, Altug-Atac 2008, Armi 2011, Baccetti 2008, Karacay 2006, Paul 2002. In the Acar 2010 study, there was conflicting evidence in the reports and from the authors' correspondence regarding the randomisation process. In addition there were some errors in the reporting of some skeletal variables. The Altug-Atac 2008 study had a high drop-out rate, and the attrition was due to problems with patient co-operation. The Armi 2011 and Baccetti 2008 studies had incomplete reporting of summary statistics related to an important primary outcome, distal movement. In the Karacay 2006 study there was selective reporting of outcomes as there was no estimate of variability for change by group. We judged the Paul 2002 study at high risk of bias because it did not report an outcome which measures loss of anterior anchorage such as mesial movement of upper incisor teeth or overjet change. This was a primary outcome of this review, and it would be expected to be reported in such a study. The De Oliveira 2007 study did not report all of the summary statistics relating to the duration of distalisation of headgear. However, we did not judge this study at high risk of bias because the duration of overall treatment was reported completely and the duration until distalisation was a secondary outcome in this review.

The remaining four studies were at unclear risk of bias (Bondemark 2005, De Oliveira 2007, Papadopoulos 2010, Toy 2011). In the Bondemark 2005 study, the method of concealment of the allocation sequence was not mentioned and it was unclear if there was selective reporting of outcomes. Similarly the De Oliveira 2007 study did not state how the allocation sequence was concealed and it was unclear if there was selective reporting of outcomes. In addition this study did not address blinding of outcome assessment. In the Papadopoulos 2010 study four risk of bias domains were unclear due to insufficient

information: selection bias (randomisation sequence generation and concealment of the sequence), blinding of outcome assessment and selective reporting of outcomes. There was insufficient information in the Toy 2011 study to permit a judgement on any of the 'Risk of bias' domains.

6.3 Effects of interventions

For the purposes of analysis, the comparisons were as follows.

- Trials that compared a distalising appliance to an untreated control.
- Trials which compared an intraoral appliance to an extraoral appliance.
- Trials which compared two different intraoral appliances.

Table 18 lists the presence or absence of the outcomes reported in the primary studies that are pertinent to this review.

6.3.1 Comparison of a distalising appliance to untreated control

See Summary of findings Table 17.

Four studies with 159 analysed participants compared a distalising appliance to an untreated control (Armi 2011, Baccetti 2008, Karacay 2006, Papadopoulos 2010). The overall quality of studies was low. Both extraoral and intraoral appliances were assessed in these studies: the First Class appliance (Papadopoulos 2010), the Forsus Nitinol Flat Spring and the Jasper Jumper (Karacay 2006), and cervical headgear (Armi 2011, Baccetti 2008). Incomplete reporting of study data in the form of missing standard deviations or expected outcomes meant that a meta-analysis of all four studies could not be undertaken.

6.3.1.1 Primary outcomes

6.3.1.1.1 Movement of upper first molars

Mean difference for distal movement favoured the First Class appliance (mean difference (MD) -4.04 mm; 95% confidence interval (CI) -5.49 to -2.59) and Forsus Spring and Jasper Jumper (groups combined) (MD -1.60 mm; 95% CI -2.20 to -1.00). No pooling was undertaken due to substantial observed heterogeneity (I^2 = 98%). On average there was no distal movement of the upper first molars in the untreated groups due to growth/maturation (0.04 to 0.1 mm mesial movement was reported) (Karacay 2006, Papadopoulos 2010).

The mean amount of distal movement was negligible in two studies with incomplete outcome data that reported that "the average amount of sagittal displacement of the upper first molar ...was close to zero (0.2 mm) whereas it was 2.32 mm in the CG" (Armi 2011) and similarly "the average amount of sagittal displacement of the upper first molar ...was close to zero (0.24 mm), while it was 2.32 mm in the CG" (Baccetti 2008).

Two studies with incomplete outcome data reported that "the amount of mesial movement of the upper first molars was significantly smaller in the HG...groups compared with the CG (P < .01)" (Armi 2011) and similarly "the amount of mesial movement of the upper first molars was significantly less in the EHG when compared with ... the CG (P < .01)" (Baccetti 2008).

6.3.1.1.2 Loss of anterior anchorage

Greater mean loss of anterior anchorage was observed for the First Class appliance over the untreated controls (Papadopoulos 2010), though this was only statistically significant for the difference in overjet (MD 1.18 mm; 95% CI 0.26 to 2.10) and not for mesial movement of anterior teeth (MD 1.32 mm; 95% CI -1.14 to 3.78). Conversely, significant

distal movement of anterior teeth (MD -1.40 mm; 95% CI -2.38 to -0.42) and reduction in overjet (MD -3.55 mm; 95% CI -4.53 to -2.57) was observed with the Forsus and Jasper Jumper (groups combined) interventions (Karacay 2006).

Loss of anterior anchorage was not reported in two studies (Armi 2011, Baccetti 2008).

6.3.1.2 Secondary outcomes and adverse effects

Duration of treatment, non-compliance, number of attendances required to complete treatment and adverse effects were not reported in these studies.

6.3.2 Comparison of intraoral distalising appliances to headgear

See Summary of findings Table 20.

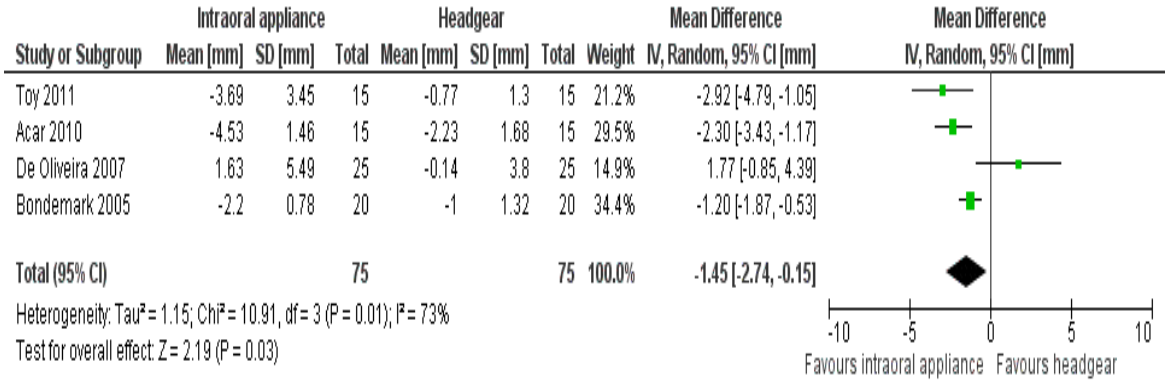
We performed meta-analyses, involving 150 analysed participants, on four studies (Acar 2010, Bondemark 2005, De Oliveira 2007, Toy 2011). The intraoral appliances investigated were the intraoral appliance with superelastic coils (Bondemark 2005), the Jasper Jumper (De Oliveira 2007), the pendulum appliance with K-loops (Acar 2010) and the pendulum appliance with midline screw (Toy 2011).

6.3.2.1 Primary outcomes

6.3.2.1.1 Movement of upper first molars

See Figure 13.

Figure 13: Forest plot of comparison: 2 Intraoral appliance versus headgear, outcome: 2.1 Movement of upper first molar [mm].



The mean molar movement for intraoral distalising appliances was -2.20 mm and -1.04 mm for headgear (distal molar movement).

The meta-analysis showed that there was significantly greater mean distal molar movement for the intraoral appliance group as compared to the headgear group (MD -1.45 mm; 95% CI -2.74 to -0.15). There was substantial heterogeneity though three of the four studies favoured the intraoral appliance (Chi^2 10.91, 3 degrees of freedom (df), P value = 0.01, I^2 = 73%). The high level of heterogeneity can be due to the different types of appliances in the intervention groups. In addition, one of the studies (De Oliveira 2007) reported movement of the upper first molars at the end of active orthodontic treatment, while the remaining four studies reported this outcome at the end of molar distalisation. The overall quality of the studies reporting this outcome was very low.

Removing the high risk of bias study (Acar 2010) did not alter the interpretation (random effect MD -1.01 mm; 95% CI -2.95 to 0.92).

6.3.2.1.2 Loss of anterior anchorage

See Figure 14 and Figure 15.

Figure 14: Forest plot of comparison: 2 Intraoral appliance versus headgear, outcome: 2.2 Movement of upper incisor teeth [mm].

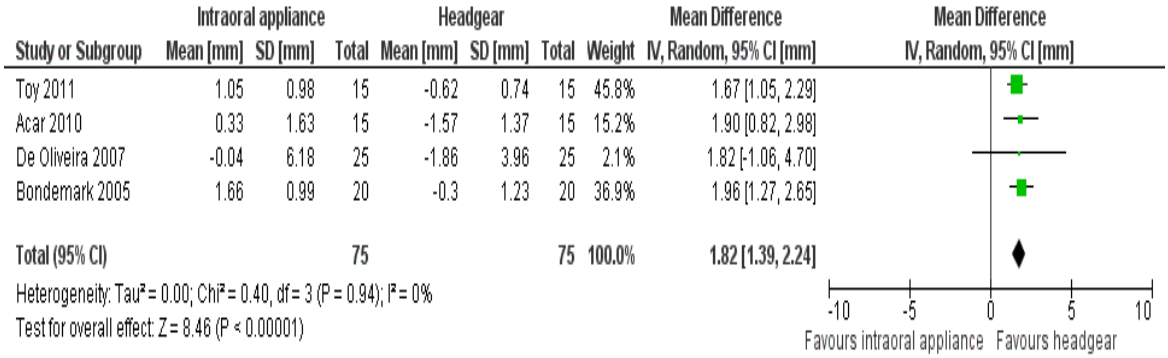
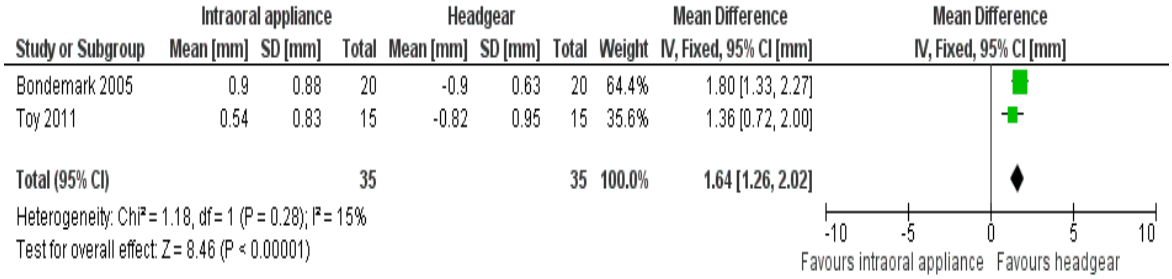


Figure 15: Forest plot of comparison: 2 Intraoral appliance versus headgear, outcome: 2.3 Change in overjet



When the effect on anterior movement of the upper incisors was evaluated there was mean mesial movement reported in three of the four studies of the intraoral appliance, but distal movement in all four of the studies of headgear. The overall quality of the studies was low. There was a statistically significant difference in mean anterior movement in favour of the headgear group (MD 1.82 mm; 95% CI 1.39 to 2.24, Chi^2 0.40, 3 df, P value = 0.94, I^2 = 0%). Removing the high risk of bias study (Acar 2010) did not alter the interpretation (fixed-effect MD 1.80 mm; 95% CI 1.34 to 2.26).

Only two low-quality studies with a total of 70 analysed participants additionally reported the mean change in overjet (Bondemark 2005, Toy 2011), also favouring the headgear

group (MD 1.64 mm; 95% CI 1.26 to 2.02, Chi^2 = 1.18, 1 df, P value = 0.28, I^2 = 15%). The De Oliveira 2007 and Acar 2010 studies did not report the change in overjet.

6.3.2.2 Secondary outcomes and adverse effects

6.3.2.2.1 Duration of treatment

Duration of treatment was reported by three studies, involving 120 analysed participants (Bondemark 2005, De Oliveira 2007, Toy 2011). The Acar 2010 study did not report this outcome.

Table 19 summarises the duration of treatment for the distalising appliances as reported by these three studies:

Table 19: Duration of treatment as reported by the included studies

Study ID	Time point	Appliance	Duration of treatment
Bondemark 2005	End of molar distalisation	Intraoral appliance with superelastic coils	5.2 months (standard deviation (SD) 1)
	End of molar distalisation	Headgear	6.4 months (SD 0.97)
De Oliveira 2007	End of molar distalisation	Jasper Jumper	6 months (range 3 to 12)
	End of molar distalisation	Headgear	8 to 12 months
	End of active orthodontic treatment	Jasper Jumper	1.96 years (range 0.93 to 3.98)
	End of active orthodontic treatment	Headgear	1.88 years (range 0.95 to 3.35)
Toy 2011	End of molar distalisation	Pendulum appliance	4.83 months (SD 0.96)
	Predetermined by a pilot study	Headgear	N/A*

The remaining secondary outcomes and adverse effects were not reported by these studies.

6.3.3 Comparison of two types of intraoral appliances

See Summary of findings Table 21.

Three studies, involving a total of 93 analysed participants directly compared one type of intraoral appliance to another (Altug-Atac 2008, Karacay 2006, Paul 2002). The appliances compared were the three-dimensional bimetric maxillary distalisation arches (3D BMDA) to the modified Begg intraoral distalisation system (MBIDS) (Altug-Atac 2008), the Jasper Jumper to the Forsus Nitinol Flat Spring (Karacay 2006) and the upper removable appliance with finger springs to the Jones Jig appliance (Paul 2002). The quality of the studies was very low according to the GRADE approach. The small number of studies and different intraoral appliances precluded a meta-analysis. However, a comparison between the results of these studies for the following outcomes is provided.

6.3.3.1 Primary outcomes

6.3.3.1.1 Movement of upper first molars

Mean distal movement was achieved by all intraoral appliances in these three studies.

The most clinically significant mean distal molar movement (> 3.3 mm) was achieved with 3D BMDA and the MBIDS in the Altug-Atac 2008 study (MD -0.28 mm; 95% CI -0.63 to 0.07). The Jasper Jumper, Forsus Nitinol Flat Spring upper removable appliance with finger springs and Jones Jig appliance had a mean distal movement ranging from 1.1 mm to 1.9 mm. The distal molar movement statistically favoured the Forsus Nitinol Flat Spring over the Jasper Jumper (MD 0.80 mm; 95% CI 0.12 to 1.48), however it was statistically similar for the removable appliance with finger spring and the Jones Jig (MD -0.13 mm; 95% CI -1.50 to 1.24).

6.3.3.1.2 Loss of anterior anchorage

There was a variation in the direction of movement of the anterior teeth among the appliances, however all the intraoral appliances in this group provided a reduction in the overjet.

A minimal amount of anterior anchorage (< 0.5) was lost with both distalisation arches (Altug-Atac 2008); the mean difference was not statistically significant (MD -0.39 mm; 95% CI -1.43 to 0.65). Distal movement of anterior teeth (-1.4 mm) was observed with both the Jasper Jumper and the Forsus Nitinol (MD 0.50 mm; 95% CI -0.04 to 1.04) (Karacay 2006). The Paul 2002 study did not report this outcome.

6.3.3.2 Secondary outcomes and adverse effects

6.3.3.2.1 Duration of treatment

This outcome was reported by the Altug-Atac 2008 and the Karacay 2006 studies only; the Paul 2002 study did not report this outcome.

Duration of treatment was statistically shorter for the 3D bimetric distalising arch (3.4 months) than for the Modified Begg intraoral distalising system (6.5 months) (MD -3.10; 95% CI -3.49 to -2.71), but similar for the Jasper Jumper (5.23 months) and Forsus Nitinol Flat Spring (5.28 months) (MD -0.05; 95% CI -0.87 to 0.77).

The remaining secondary outcomes and adverse effects were not reported by these studies.

Table 20: Summary of findings: Intraoral appliance compared to headgear for distalising first molars

Intraoral appliance compared to headgear for distalising first molars						
Patient or population: **children and adolescents undergoing orthodontic treatment** Settings: **university or private orthodontic clinic** Intervention: **intraoral appliance** Comparison: **headgear**						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk[1]	Corresponding risk				
	Headgear	Intraoral appliance				
Movement of upper first molars (mm)	The mean movement of upper first molars (mm) in the headgear group was -1.04 mm (distal movement)	The mean movement of upper first molars (mm) in a distal direction for the intraoral appliance group was 1.45 mm more (-2.74 to -0.15)		150 (4 studies)	⊕⊖⊖⊖ very low[2,3]	Movement of the upper first molars in a distal direction is the desired type of tooth movement. This result indicates that the intraoral appliance is superior to headgear for this outcome
Movement of upper incisor teeth (mm)	The mean movement of upper incisor teeth (mm) in the headgear group was -1.09 mm (distal movement)	The mean movement of upper incisor teeth (mm) in a mesial direction for the intraoral appliance group was 1.82 mm more (1.39 to 2.24)		150 (4 studies)	⊕⊕⊖⊖ low[2,4]	Movement of the upper incisor teeth in a mesial direction is an unwanted tooth movement and indicates that the intraoral appliance is inferior to headgear for this outcome
Change in overjet (mm)	The mean loss of anchorage (mm) in the headgear group was -0.86 mm (reduction in overjet)	The mean change (increase) in overjet (mm) in the intraoral appliance group was 1.64 mm more (1.26 to 2.02)		70 (2 studies)	⊕⊕⊖⊖ low[5]	An increase in overjet is unwanted and indicates that the intraoral appliance is inferior to headgear for this outcome
***The basis for the** assumed risk **(e.g. the median control group risk across studies) is provided in footnotes. The** corresponding risk **(and its 95% confidence interval) is based on the assumed risk in the comparison group and the** relative effect **of the intervention (and its 95% CI)** CI: **confidence interval**						
GRADE Working Group grades of evidence High quality: **Further research is very unlikely to change our confidence in the estimate of effect** Moderate quality: **Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate** Low quality: **Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate** Very low quality: **We are very uncertain about the estimate**						

[1]The basis for the assumed risk was the mean of the control groups across studies
[2]Three studies at unclear risk of bias; one study at high risk of bias
[3]Evidence based on the results of four small studies with equivocal results
[4]Evidence based on the results of four studies with a low number of participants
[5] Evidence based on the results of two studies with a low number of participants, at unclear risk of bias

Table 21: Summary of findings: Intraoral appliance compared to other intraoral appliance

Intraoral appliance compared to other intraoral appliance for children and adolescents						
Patient or population: **children and adolescents undergoing orthodontic treatment** Settings: **university or private orthodontic clinic** Intervention: **intraoral appliance** Comparison: **other intraoral appliance**						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Other intraoral appliance	Corresponding risk Intraoral appliance				
Movement of upper first molars (mm)	Not estimated	Not estimated	Meta-analysis not appropriate	93 (3 studies)	⊕⊖⊖⊖ very low[1,2]	No pooled estimate due to different types of appliances used in the studies
Movement of upper incisor teeth (mm)	Not estimated	Not estimated	Meta-analysis not appropriate	70 (2 studies)	⊕⊖⊖⊖ very low[3,4]	No pooled estimate due to different types of appliances used in the studies
Change in overjet (mm)	Not estimated	Not estimated	Meta-analysis not appropriate	70 (2 studies)	⊕⊖⊖⊖ very low[3,4]	No pooled estimate due to different types of appliances used in the studies
***The basis for the** assumed risk **(e.g. the median control group risk across studies) is provided in footnotes. The** corresponding risk **(and its 95% confidence interval) is based on the assumed risk in the comparison group and the** relative effect **of the intervention (and its 95% CI)** CI: **confidence interval**						
GRADE Working Group grades of evidence High quality: **Further research is very unlikely to change our confidence in the estimate of effect** Moderate quality: **Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate** Low quality: **Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate** Very low quality: **We are very uncertain about the estimate**						

[1]Three studies at high risk of bias
[2]Evidence based on the results of three small studies with a low number of participants and equivocal results
[3]Two studies at high risk of bias
[4]Evidence based on the results of two studies with a low number of participants

7 Discussion

7.1 Summary of main results

7.1.1 Comparison of distalising appliance to untreated control

In general, when a distalising appliance is compared to no treatment, a degree of distal molar movement will occur. This is not surprising, as these appliances are mechanically designed to move the molar teeth distally. However, loss of anterior anchorage, which varied according to the type of appliance, may be a limiting factor in the clinical use of these appliances. The First Class appliance showed greater mesial movement and increase in the overjet than the untreated controls. The Forsus Nitinol Flat Spring and Jasper Jumper appear to achieve distal movement of the molars without loss of anterior anchorage. Less anchorage loss was observed with cervical headgear when compared to untreated controls. Therefore a general statement regarding the effect of appliances on anterior anchorage cannot be made here.

7.1.2 Comparison of intraoral distalising appliances to headgear

We found evidence from four trials that orthodontic treatment with intraoral appliances results in greater distal movement of the upper molars when compared to headgear (mean difference (MD) -1.45 mm; 95% confidence interval (CI) -2.74 to -0.15). However, this result is counteracted by greater unwanted mesial movement of the upper incisors with the intraoral appliance when it was compared to headgear (MD 1.82 mm; 95% CI 1.39 to 2.24). In addition, there was a statistically significant increase in the overjet with the intraoral appliance (MD 1.64 mm; 95% CI 1.26 to 2.02). Therefore, it is suggested that there is some evidence that intraoral appliances are more effective than headgear in distalising upper first molars, however they are also associated with loss of anchorage anteriorly.

These results were based on three studies that were assessed as at unclear risk of bias and one study at high risk of bias. Limited evidence from empirical studies confirms that there is a difference in bias between studies that were judged at unclear risk of bias and studies that were judged at high risk of bias [48]. In addition, in the study with high risk of bias in this meta-analysis, the shortcomings were related to a very important risk of bias domain: selection bias. We therefore undertook a sensitivity analysis to exclude this study; the resulting interpretation of the analysis did not change.

It was surprising to find that there was less distal movement with the headgear. This could be attributed to the short duration of the majority of the trials included in the study, and perhaps the intraoral appliances were more efficient in obtaining distal movement. In addition, only one of the included studies reported results after comprehensive treatment with fixed appliances. It would be clinically relevant to know how distalising appliances work in conjunction with or followed by a phase of a fixed orthodontic appliance. Finally, the finding that headgear was less effective than intraoral appliances could in fact be due to poor compliance, an important outcome that was unreported. However, there is uncertainty about the quality of the studies. Therefore these results should be interpreted with caution.

The duration of treatment is an important outcome when considering orthodontic treatment. An appliance which can distalise the molar teeth in a shorter time would be desirable as it will decrease the overall burden of treatment on the patient. All four trials reported the time taken for distalisation, however only one trial also reported the duration of overall treatment. The knowledge of overall treatment time not only gives insight on whether molar distalisation was maintained throughout treatment, but is very likely an important outcome from the patient's perspective. It may be important for patients to know

how long they will be wearing certain appliances, but they are likely to be more interested in how long the overall treatment may take.

These four trials were conducted in three different countries and therefore represent a large general population. However, it is interesting to note that the great majority of these are European countries. This may be due to different clinician and patient values in other parts of the world which may influence compliance with headgear. The use of headgear and compliance may also be a reflection of the fee or payment structure for healthcare providers in various areas around the world. Clinicians and patients living in countries in which orthodontic treatment and the provision of headgear is provided by a national health service with no direct cost to them may exhibit different attitudes to their malocclusion and compliance with treatment in comparison to those living in countries in which the treatment has to paid for directly or through healthcare insurance.

7.1.3 Comparison of two types of intraoral appliances

We did not perform a meta-analysis because there was not a sufficient number of studies comparing the same types of interventions. However, the findings suggest that all types of intraoral appliances provide some degree of distal molar movement. Distal movement with the assessed appliances ranged from 1.3 mm to 3.55 mm. The lower range of distal movement may not be clinically significant, and could be achieved clinically by less complicated techniques such as Class II elastics, bearing in mind that Class II elastics are also subject to a degree of patient compliance. The higher range of the distal movement was achieved by the 3D-BMDA and the MBIDS. The setup of these appliances is more complicated than the other intraoral appliances in this study and they also involve bonding of the maxillary and mandibular arches as part of the system for distalisation.

The anterior movement of the upper central incisors varied with the type of intraoral appliance. A very slight mesial movement of less than 0.5 mm was observed with the 3D-BMDA and the MBIDS, and a distal incisor movement with the Jasper Jumper and the Forsus appliances. Moreover, there was a reduction in the overjet with these appliances. Therefore, it is suggested that in these appliances molar distalisation is not counteracted by a loss of anterior anchorage. However, the trade-off is the use of more complicated appliances, in which the adverse effects on the surrounding oral tissues and the degree of comfort to the patient is unknown. There are limited data on the treatment time associated with these appliances as reported in this review, however there is an insufficient number of studies to allow a judgement on the efficiency of these appliances in providing distal movement.

7.2 Overall completeness and applicability of evidence

The objective of this review was to assess the effects of orthodontic treatment for distalising upper first molars in children and adolescents. Case reports describe a large number of appliances designed to distalise upper first molars, however scientific evidence on their effectiveness is clearly lacking. Studies included in this review report some common distalising appliances, however they are small in number and of low quality. Therefore the studies identified are insufficient to address the objectives of the review. Only suggestions can be made regarding their effects. In addition, important patient-related outcomes such as acceptability and comfort of the appliances have not been addressed.

7.3 Quality of the evidence

See Summary of findings Table 17, Summary of findings Table 20, Summary of findings Table 21, Figure 11 and Figure 12.

All the studies included in this review were of low to very low quality according to the GRADE approach. Despite being randomised controlled trials, they were all downgraded due to low numbers of participants, high risk of bias domains and/or studies yielding equivocal results.

The overall risk of bias of trials in this review ranged from unclear to a high risk of bias. There was a lot of uncertainty in the judgement of bias for the risk of bias domains. It is recognised that this may be due to inadequate reporting of the trials, however the description in the reports and subsequent email correspondence were still unclear and incomplete, and in one instance contradictory. Judgements on the risk of bias were sometimes made after much deliberation and after repeatedly considering the text in the reports and in the e-mail correspondence. The main risk of bias across all studies was due to unclear reporting of how the randomisation sequence was generated and blinded. In particular the method of concealment of the allocation sequence was not addressed in any of the included studies. Blinding of patients and personnel was not considered important in this review because it is not possible to blind the treatment allocation in these trials. However, we did not adopt the same reasoning for outcome assessment, as in most cases the outcome assessor can be blinded to the treatment. For example, this could be done by masking the appliances on the radiographs or the analysis of the radiographs could be performed by a practitioner unaware of the objectives of the trial, or both. In addition, blinding of outcome assessment was considered important due to the nature of the measurements. Measurements of tooth movement are made on a very small scale of millimetres, so that even a low level of detection bias can have a significant effect on the results.

7.4 Potential biases in the review process

There are a small number of low-quality studies in this review and when considering the primary outcome of distal movement of the first molars, the results were not consistent among the studies. There were limitations in the obtaining of information to confirm study methodology and summary data.

We systematically searched the most important electronic resources, in addition to carrying out an extensive handsearch. We searched for unpublished studies in trial databases. Time limitations prevented searching of additional databases and sources which may have potentially led to identifying additional published and unpublished studies.

Finally, we did not conduct an extensive search to identify adverse effects. The identification of adverse effects was limited to known adverse effects which were reported in the randomised studies.

7.5 Agreements and disagreements with other studies or reviews

The results of this review are in agreement with other systematic reviews on the topic with less rigorous methodology. The methodology of these reviews has often involved limited search strategies and a large variation in included study designs including retrospective studies and studies with single interventions. The most common appliances were the pendulum, Nance, Jones Jig and distal jet appliances. The outcomes commonly investigated in these reviews were the distal movement of the molars and loss of anchorage (mesial movement of premolar and anterior teeth). Distalising appliances moved the upper molar distally by a mean of 2.9 mm (95% CI 2.4 to 3.3) [102] and 2.71 mm (standard deviation (SD) 0.79) [120]. In another review the distal molar movement ranged from 1.4 mm (SD 2.06) to 6.1 mm (SD 1.8) across different appliances [153]. Reported anchorage loss was also in agreement with this review. Mean anchorage loss

(mesial movement of premolars, anterior teeth or both) was 1.8 mm (95% CI 1.7 to 2.0) [102] and 1.25 mm (SD 0.74) [120]. The mesial movement of the incisors was also reported, ranging from 0.25 mm (SD 1.09) to 2.30 mm (SD 2.25) [153].

8 Authors' conclusions

8.1 Implications for practice

It is suggested that intraoral appliances are more effective than headgear in distalising upper first molars. However, this effect is counteracted by loss of anterior anchorage, which was not found to occur with headgear when compared with intraoral distalising appliance in a small number of studies. The number of trials assessing the effects of orthodontic treatment for distalisation is low, and the current evidence is of low or very low quality. Some types of intraoral appliances might be associated with a slight amount of distal molar movement without compromising anchorage anteriorly. However, the trade-off is more complicated appliances (for which there are limited data on effectiveness), patient comfort and cost-effectiveness. It is important to acknowledge that the results of this review are based on studies with an unclear to high level of bias.

8.2 Implications for research

This review highlights the importance of appropriately reporting the conduct and results of randomised controlled trials.

Current evidence on the effectiveness of distalising appliances is based on randomised trials in which the level of bias is unknown. Future research should ensure that the allocation sequence is appropriately concealed and further thought should be given to blinding outcome assessment. Trials should be reported according to the Consolidated Standards of Reporting Trials (CONSORT) checklist (CONSORT 2010). It is also advised

that the CONSORT checklist be consulted when planning a trial, along with the SPIRIT checklist for protocols [154].

The samples included in the studies are appropriate in that they are patients of an age that would benefit from these type of appliances. There was variation in the sample sizes used, and a recommendation for future studies would be to perform a sample size calculation prior to undertaking the study. In addition to patients, the study should consider the effects of the operators delivering the interventions. This is especially relevant when determining reasons for non-compliance. Operator values, expertise and attitudes may influence the uptake and degree of compliance of certain interventions. This would most likely be in the form of qualitative research, such as focus groups and in-depth interviews.

Interventions and comparisons should concentrate on distalising appliances that result in the least amount of anterior loss of anchorage, as those found in this review, or by conducting a pilot study, if feasible, on the interventions. In addition to the endpoint of molar distalisation, an overall endpoint of the end of treatment should be considered.

The outcomes considered important for this review were distal movement and loss of anterior anchorage measured by changes in overjet and mesial movement of the anterior teeth. All trials in this review reporting the effect of an intraoral distalising appliance reported these outcomes, except for one trial. In addition, other types of tooth movement were reported in individual trials, such as tipping of the molar teeth. While the CONSORT guidelines can aid in planning the methodology of trials, it does not provide much guidance on selection of outcomes. Future research should include reaching a consensus on the minimal clinically relevant outcomes for specific interventions.

The rationale for developing intraoral appliances for distalising upper molar teeth as an alternative to headgear was the non-compliance and harm associated with using headgear. Understandably, none of these trials measured the compliance associated with the appliances, as it would be difficult to find a single measure of compliance that is common to all appliances. For example 'hours of headgear wear' is a measure of compliance with headgear, but it cannot be used for a pendulum appliance that is fixed inside the mouth and worn full time. However, since the ultimate objective of compliance is the success of treatment, perhaps future research should report the success of the appliances in providing distal movement of molar teeth as a measure of compliance. Success could then be defined according to treatment objectives. For example an appliance would be successful in distal movement if it achieves at least 2 mm distal molar movement with no increase in overjet, or if it achieves at least 3 mm of distal molar movement that is maintained until the end of treatment.

In addition to clinically relevant outcomes, there is a clear lack of studies reporting outcomes which may be important to patients. These are likely to include harm, the degree of comfort of the appliance, the influence on eating, talking or other daily activities, socially acceptability, etc. Qualitative research is indicated to find out which outcomes are important to patients and to give us patient-oriented insight on the reasons for non-compliance.

9 Characteristics of studies

9.1 Characteristics of included studies

Table 22: Characteristics of Acar 2010 study

Acar 2010 **[121, 122]**	
Methods	• Trial design: single-centre RCT (parallel-group) • Location: Baskent University, Turkey • Recruitment period: not stated • Funding source: not stated • Source of participants: patients attending clinic • Study duration: 12 weeks • Time points at which follow-up is reported: 1) start of treatment, 2) end of molar distalisation
Participants	• 30 participants in total, mean age 14.6 years • 15 in pendulum appliance group: mean age 15 years (SD 3.4), 8 males and 7 females • 15 in cervical headgear group: mean age 14.2 years (SD 2.9), 5 males and 10 females • Inclusion criteria 1. Dental Class II malocclusion due to mesial migration of upper first molar 2. Minor arch length discrepancies • Exclusion criteria 1. No vertical or transverse skeletal or dental problem
Interventions	• Comparison 1: Pendulum appliance supported with K-loop buccally 1. Hilger's pendulum appliance was used which exerted a force of 230 g when the springs were activated 90° 2. The K-loop was made from 0.017 X 0.025 inch TMA wire and positioned between the upper first molar and first premolar 3. Patients were recalled every 3 weeks and the K-loop activated every 6 weeks • Comparison 2: Headgear 1. Cervical pull 2. 400 g force was used 3. Patients instructed to wear it for 16 to 20 hours a day
Outcomes	1. Treatment time 2. Skeletal and dental changes assessed from cephalometric radiographs

	3. Dental changes (rotation of molars and premolars) from study models	
Notes	Errors in reported values	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote (from report): "Patients in both groups were matched according to GoGnSN angle and length of treatment" Quote (from correspondence of main report): "patients were allocated to the two treatment groups randomly by coin tossing" Quote (from correspondence of other report of the same study): "the patients were enrolled to the pendulum K-loop first and after completion of a predetermined number of patients (15).... additional 15 patients with dental Class II malocclusion that matched the first group by GoGnSN angle were treated with headgear" Comment: probably not done
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias)	Unclear risk	Quote: "The cephalograms were traced by one investigator in a random order" Comment: it is not mentioned whether the assessor was blinded to the type of treatment; the appliance could have been visible in the radiograph
Incomplete outcome data (attrition bias)	Unclear risk	Total analysed 30 (15 in group 1 and 15 in group 2)
Selective reporting (reporting bias)	Unclear risk	Selective reporting of outcomes: insufficient information to permit judgement
Other bias	High risk	There were errors in the reporting of skeletal variables in the paper

Table 23: Characteristics of the Altug-Atac 2008 study

Altug-Atac 2008 **[123]**	
Methods	• Trial design: single-centre RCT (parallel-group) • Location: Department of Orthodontics, Ankara University, Turkey • Recruitment period: not stated • Funding source: Ankara University Research Foundation • Source of participants: patients attending clinic • Study duration: 6.5 months • Time points at which follow-up is reported: 1) start of treatment, 2) end of distalisation (Class I molars)
Participants	• 38 participants in total, age 12 to 16.58 years • 21 in the distalisation arch group: mean age 14.7 years (SE 1.5), 9 males and 12 females • 17 in the Begg system group: mean age 14.4 years (SE 1.4), 3 males and 14 females • Inclusion criteria 1. Skeletal Class I and II malocclusions and dental Class II relationship on both sides 2. Non-extraction treatment plan 3. SN/GoGn angle less than 40° 4. No/minimal crowding in the mandibular dental arch 5. Erupted maxillary and mandibular second molars in occlusion
Interventions	• Comparison 1: 3-dimensional bimetric maxillary distalisation arches 1. The distalisation arches consist of an upper arch wire with an open coil spring and Class II elastics 2. A full-bonded lower arch was used as an anchorage unit for the Class II elastics 3. Patients were recalled at 10-day intervals and the elastic loads were checked and adjusted at each visit • Comparison 2: modified Begg intraoral distalisation system 1. Maxillary 0.018 inch Australian wire distalisation arch with bilateral double-twisted single vertical loop 2. Full-bonded maxillary and mandibular arches 3. Uprighting springs to activate the mandibular anchorage 4. Class II elastics
Outcomes	1. Primary: treatment time for distalising upper first molars for molar correction 2. Secondary: all skeletal and dental cephalometric

	measurements	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The patients were randomly selected and distributed to the treatment groups" Comment: insufficient information about the sequence generation process to permit judgement
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias)	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias)	High risk	• 50 participants randomised, 38 included in the analysis • 24% (12 participants) drop-out rate due to poor co-operation • Number of exclusion per group not stated; poor co-operation is an important outcome that could influence the results
Selective reporting (reporting bias)	Unclear risk	Selective reporting of outcomes: insufficient information to permit judgement
Other bias	Low risk	Study appears to be free of other sources of bias

Table 24: Characteristics of the Armi 2011 study

Armi 2011 [129]	
Methods	• Trial design: single-centre RCT (parallel-group) • Location: University of Florence and University of Roma, Italy • Recruitment period: not stated • Funding source: not stated • Source of participants: participants enrolled in a prospective study at the department of orthodontics • Study duration: average 18 months • Time points at which follow-up is reported: 1) initial observation, 2) 18 months after initial observation
Participants	• 60 participants in total, mean age 11.51 years • 17 in headgear group: mean age 11.9 years, 9 males and 8 females • 21 in rapid maxillary expansion/headgear group: mean age 11.1 years, 9 males and 12 female • 22 in the untreated control group: mean age 11.6 years, 9 males and 13 females • Inclusion criteria 1. White ancestry 2. Either unilateral or bilateral palatally displaced canines on a panoramic radiograph 3. Dental age older than 8 years and younger than 13 years 4. Skeletal age showing active phases of skeletal growth according to the cervical vertebral maturation method 5. Presence of mild crowding at the maxillary arch and/or molar relation showing Class II tendency • Exclusion criteria 1. Previous orthodontic treatment 2. Craniofacial syndromes, odontomas, cysts, cleft lip and/or palate, sequelae of traumatic injuries to the face, or multiple and/or advanced caries 3. Aplasia or severe hypoplasia of the crown of upper lateral incisors
Interventions	• Comparison 1: Headgear group 1. Cervical pull headgear used alone for 1 year for 12 to 14 hours a day • Comparison 2: Rapid maxillary expansion/headgear group 1. Banded rapid maxillary expander with 7 mm of active expansion

	2. At the end of expansion all patients retained the expander for 6 months 3. Followed by the use of a cervical headgear like the headgear group • Comparison 3: Untreated control group
Outcomes	1. Successful or unsuccessful eruption of the palatally displaced canines 2. Mesiodistal movement of the upper first molars
Notes	1. The main aim of this study was to evaluate the effectiveness of the interventions on the eruption of palatally displaced canines 2. Only 2 of the comparison groups were used in this review because of their relevance: the headgear group and the untreated control group

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "All subjects with PDCs were assigned randomly to one of the following three groups" Comment: insufficient information about the sequence generation process to permit judgement
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias)	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias)	Low risk	• Number randomised: 64 • Drop-outs: 4, not stated in which group • Reason for drop-outs: participants moved from the area or asked to be transferred to other clinicians
Selective reporting (reporting bias)	High risk	• Selective reporting of outcomes: insufficient information to permit judgement • Selective reporting of data: incomplete reporting of the distal movement outcome; means were presented without standard deviations
Other bias	High risk	The control group in this study has very similar characteristics to the Baccetti 2008 study. We

		contacted the authors for clarification but no response was received

Table 25: Characteristics of the Baccetti 2008 study

Baccetti 2008 [130]	
Methods	• Trial design: single-centre RCT (parallel-group) • Location: University of Florence and University of Roma, Italy • Recruitment period: not stated • Funding source: not stated • Source of participants: patients enrolled in a prospective study at the department of orthodontics • Study duration: average 18 months • Time points at which follow-up is reported: 1) initial observation, 2) 18 months after initial observation
Participants	• 69 participants in total • 23 in headgear group: mean age 11.7 years, 8 males and 15 females • 24 in extraction/headgear group: mean age 11.9 years, 10 males and 14 females • 22 in the untreated control group: mean age 11.6 years, 9 males and 13 females • Inclusion criteria 1. White ancestry 2. Either unilateral or bilateral palatally displaced canines on a panoramic radiograph 3. Dental age older than 8 years and younger than 13 years 4. Skeletal age showing active phases of skeletal growth according to the cervical vertebral maturation method • Exclusion criteria 1. Previous orthodontic treatment 2. Craniofacial syndromes, odontomas, cysts, cleft lip and/or palate, sequelae of traumatic injuries to the face, or multiple and/or advanced caries 3. Crowding in the upper arch, as evaluated by means of intraoral inspection 4. Aplasia or severe hypoplasia of the crown of upper lateral incisors
Interventions	3 comparisons in total • Comparison 1: Extraction group 1. Extraction of the primary canine corresponding to the palatally displaced permanent canine was performed • Comparison 2: Extraction/headgear group

	1. Extraction of the primary canine corresponding to the palatally displaced permanent canine was followed by use of a cervical-pull headgear 2. Patients in this group started their headgear therapy in the 3 months after extraction 3. They were instructed to wear the headgear for 12 to 14 hours a day • Comparison 3: Untreated control group
Outcomes	1. Successful or unsuccessful eruption of the palatally displaced canines 2. Mesiodistal movement of the upper first molars
Notes	1. The main aim of this study was to evaluate the effectiveness of the interventions on the eruption of palatally displaced canines 2. Only 2 of the comparison groups were used in this review because of their relevance: the headgear group and the untreated control group

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "All PDC subjects were assigned randomly to one of the following three groups" Comment: insufficient information about the sequence generation process to permit judgement
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias)	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias)	Low risk	• Number randomised: 75 • Drop-outs: 5, not stated in which group, 1 participant not accounted for • Reason for drop-outs: participants moved from the area or asked to be transferred to other clinicians
Selective reporting (reporting bias)	High risk	• Selective reporting of outcomes: insufficient information to permit judgement • Selective reporting of data: incomplete reporting of the distal movement outcome; means were presented

		without standard deviations
Other bias	High risk	The control group in this study has very similar characteristics to the Armi 2011 study. We contacted the authors for clarification but no response was received

Table 26: Characteristics of the Bondemark 2005 study

Bondemark 2005 [124]	
Methods	• Trial design: single-centre RCT (parallel-group) • Location: Malmo University, Sweden • Recruitment period: not stated • Funding source: Swedish Dental Society and Skane County Council, Sweden • Source of participants: patients attending clinic in Malmo • Study duration: 6.5 months • Time points at which follow-up is reported: 1) start of treatment, 2) end of molar correction
Participants	• 40 participants in total, mean age 11.45 years • 20 in the intraoral appliance group: mean age 11.4 years (SD 1.37), 10 males and 10 females • 20 in the extraoral appliance group: mean age 11.5 years (SD 1.25), 8 males and 12 females • Inclusion criteria 1. No orthodontic treatment before distalisation 2. A non-extraction treatment plan 3. Maxillary first permanent molars in occlusion and no erupted second permanent molars 4. Class II molar relationship, defined by at least end-to-end molar relationship
Interventions	• Comparison 1: Intraoral appliance with superelastic coils 1. Bands on upper first molars and first and second premolars 2. 1.1 mm tube soldered to the lingual of the molar band 3. A Nance acrylic button was soldered to the appliance • Comparison 2: Headgear 1. Cervical pull 2. 400 g force was used for the first 2 weeks and 500 g afterwards 3. Patient instructed to wear appliance at least 12 hours a day 4. Patients recalled every 5 weeks
Outcomes	• Treatment time to achieve molar correction • Distal movement and tipping of maxillary first permanent molars • Anterior movement and inclination of maxillary central incisors, i.e. anchorage loss • Movement of mandibular first permanent molars • Movement and inclination of mandibular central incisors

	• Skeletal changes of maxilla and mandible • Bite opening effect
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A restricted randomisation method was used in blocks of 10"
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias)	Low risk	Quote: "the cephalograms were scored and coded by an independent person unaware of the group allocation"
Incomplete outcome data (attrition bias)	Low risk	• Number randomised 40, number included in the analysis 40 • No drop-outs
Selective reporting (reporting bias)	Unclear risk	• Selective reporting of outcomes: insufficient information to permit judgement
Other bias	Low risk	Study appears to be free of other sources of bias

Table 27: Characteristics of the De Oliveira 2007 study

De Oliveira 2007 [125]	
Methods	• Trial design: 2-centre RCT (parallel-group) • Location: University of Sao Paulo, Brazil; Lavras Dental School, Brazil • Recruitment period: not stated • Funding source: research submitted as partial fulfilment of MSc degree • Source of participants: patients attending clinic at university • Study duration: not stated • Time points at which follow-up is reported: 1) start of treatment, 2) removal of fixed orthodontic appliance
Participants	• 50 participants in total, mean age 11.45 years • 25 in the Jasper Jumper group: mean age 11.86 years (range, 9.45 to 14.94), 13 males and 12 females • 25 in the cervical headgear group: mean age 12.29 years (range, 9.95 to 15.24), 13 males and 12 females • Inclusion criteria 1. Angle Class II molar relationship 2. Class II division 1 with no subdivision malocclusion 3. Early permanent dentition with all permanent first molars, and first and second premolars • Exclusion criteria 1. No craniofacial syndrome or systemic disease 2. No tooth agenesis or missing permanent teeth
Interventions	• Comparison 1: Jasper Jumper 1. Jasper Jumpers attached to the maxillary and mandibular arches, in conjunction with: 2. Standard edgewise appliance with a 0.022 inch slot 3. Transpalatal arch in the maxilla • Comparison 2: Cervical headgear 1. Cervical headgear exerting 150 to 300 g of force on each side with an average wear of 14 to 16 hours per day 2. Standard edgewise appliance with a 0.022 inch slot
Outcomes	Skeletal and dentoalveolar measurements on initial and final cephalometric radiographs
Notes	There was also an untreated control group in the study, but it was not involved in the randomisation process
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote (from correspondence): "The randomization process was performed as follows: the patients were placed into one of the groups by the use of a coin-toss"
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias)	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias)	Low risk	All randomised patients were included in the final analysis
Selective reporting (reporting bias)	Unclear risk	• Selective reporting of outcomes: insufficient information to permit judgement • Selective reporting of data: the duration of treatment to distalise the molar teeth was reported as a range; this is a secondary outcome of this review
Other bias	Low risk	Study appears to be free of other sources of bias

Table 28: Characteristics of the Karacay 2006 study

Karacay 2006 [131]	
Methods	• Trial design: RCT (parallel-group) • Location: Gulhane Military Medical Academy, Ankara, Turkey • Recruitment period: not stated • Funding source: not stated • Source of participants: patients attending clinic • Study duration: not stated • Time points at which follow-up is reported: 1) attachment of distalising appliance, 2) end of molar correction
Participants	• 48 participants in total, mean age 13.8 years • 16 in the Forsus Nitinol Flat Spring group: mean age 13.6 years (SD 1.2), 9 males and 7 females • 16 in the Jasper Jumper group: mean age 14.0 years (SD 1.9), 10 males and 6 females • 16 in the control group: mean age 13.8 years (SD 1.4), gender distribution not stated
Interventions	• Comparison 1: Forsus Nitinol Flat Spring (FNFS) 1. Size determined by adding 12 mm to the distance between the mesial edge of the headgear tube and the distal edge of the mandibular canine bracket when the patient was in centric occlusion 2. Attached to headgear tube of maxillary molar and auxiliary arch in mandible between canine and first premolar brackets 3. Patients recalled every 3 weeks • Comparison 2: Jasper Jumper (JJ) 1. Size determined by adding 12 mm to the distance between the mesial edge of the headgear tube and the distal edge of the mandibular canine bracket when the patient was in centric occlusion 2. Attached to headgear tube of maxillary molar and auxiliary arch in mandible between canine and first premolar brackets 3. Patients recalled every 3 weeks • Comparison 3: Untreated control
Outcomes	• Skeletal and dentoalveolar measurements on initial and final cephalometric radiographs • Inter-molar and inter-canine widths on study models
Notes	
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The patients were randomly divided into three groups" Comment: insufficient information about the sequence generation process to permit judgement
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias)	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias)	Unclear risk	• 48 patients were included in the analysis • Number of drop-outs not addressed
Selective reporting (reporting bias)	High risk	Selective reporting of outcome data: no estimate of variability for change by group
Other bias	Low risk	Study appears to be free of other sources of bias

Table 29: Characteristics of the Papadopoulos 2010 study

Papadopoulos 2010 [126]	
Methods	• Trial design: single-centre RCT (parallel-group) • Location: Department of Orthodontics, Aristotle University of Thessaloniki, Greece • Recruitment period: not stated • Funding source: none • Source of participants: patients attending clinic • Study duration: 6.5 months • Time points at which follow-up is reported: 1) start of distalisation, 2) end of distalisation
Participants	• 26 participants in total, age 7.1 to 11.9 years • 15 in the First Class appliance group: mean age 9.2 years (range: 7.6 to 10.8), 8 males and 7 females • 11 in the 'no treatment' group: mean age 9.7 years (range: 7.1 to 11.9), 5 males and 6 females • Inclusion criteria 1. Bilateral Class II molar relationship (quarter to 1 molar cusp) • Exclusion criteria 1. Past orthodontic treatment 2. Crossbites 3. Severe carious lesions 4. Poor oral hygiene 5. Mobility of the maxillary deciduous molars 6. Flat palate 7. Ectopic maxillary canines 8. Anterior open bites 9. Vertical growth pattern 10. Tongue habits
Interventions	• Comparison 1: First Class appliance 1. Banded first molars and second premolars or second primary molars 2. 2 buccally positioned activation screws 3. 2 palatally positioned open nickel-titanium coil springs 4. Buccal and palatal tubes 5. Large modified Nance button • Comparison 2: Untreated control
Outcomes	Cephalometric and dental cast variables
Notes	

Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "They were randomized into 2 groups" Comment: insufficient information about the sequence generation process to permit judgement
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias)	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias)	Low risk	27 randomised, 1 dropped out because of broken appliance
Selective reporting (reporting bias)	Unclear risk	Selective reporting of outcomes: insufficient information to permit judgement
Other bias	Low risk	Study appears to be free of other sources of bias

Table 30: Characteristics of the Paul 2002 study

Paul 2002 [127]	
Methods	• Trial design: single-centre RCT (parallel-group) • Location: University Dental Hospital, Manchester • Recruitment period: not stated • Funding source: none • Source of participants: patients referred for treatment • Study duration: 6 months • Time points at which follow-up is reported: 1) start of distalisation, 2) end of distalisation
Participants	• 23 participants in total, age 10 to 16 years • 12 in the removable appliance group: mean age 13.5 years (SD 1.58) • 11 in the Begg system group: mean age 14.75 years (SD 1.75) • Inclusion criteria 1. Patient 10 to 16 years old at start of treatment 2. Upper second premolars present and erupted (required for the Jones Jig)
Interventions	• Comparison 1: Upper removable appliance 1. Adam's cribs on upper first premolars 2. Southend clasp on the upper central incisor 3. Occlusal stops on the upper canine 4. Palatal finger springs to distalise the molars • Comparison 2: Jones Jig 1. Bands on the upper second premolars 2. Nance palatal arch 3. The jig main frame attached to headgear slot on molar bands 4. Niti coil spring
Outcomes	Primary outcomes 1. Changes in the position of upper first molar in terms of • distal movement • distal tipping • disto-palatal rotation (molar straightening) Secondary outcomes 1. Mesial movement of the upper first premolars (loss of anchorage)

	2. Reported discomfort	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A restricted randomisation method was used in blocks of 12"
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias)	Low risk	Quote: "the examiner measuring the models was blind until all the data were recorded"
Incomplete outcome data (attrition bias)	Low risk	• Number randomised: 27, number evaluated: 23 • 15% drop-out rate: 1. URA (2) (reasons: repeated breakage and did not attend after fit) 2. Jones Jig (2) (reasons: treatment plan changed and patient did not want treatment)
Selective reporting (reporting bias)	High risk	• Selective reporting of outcomes: insufficient information to permit judgement • Selective reporting of data: there were no data on loss of anterior anchorage; this is an important outcome that is expected to be reported
Other bias	Low risk	Study appears to be free of other sources of bias

Table 31: Characteristics of the Toy 2011 study

Toy 2011 [128]	
Methods	• Trial design: single-centre RCT (parallel-group) • Location: Hacettepe University, Turkey • Recruitment period: not stated • Funding source: not stated • Source of participants: patients referred to orthodontic clinic • Study duration: 6.4 months • Time points at which follow-up is reported: 1) start of treatment, 2) end of molar distalisation or in the case of the headgear group, after 4.96 +/- 0.35 months
Participants	• 30 participants in total, mean age 11.59 • 15 in the intraoral pendulum appliance group: mean age 11.45 years (SD 1.54), 6 males and 9 females • 15 in the cervical headgear group: mean age 11.72 years (SD 1.24), 5 males and 10 females • Inclusion criteria 1. Skeletal Class I malocclusion with bilateral Class II molars 2. Radiographic confirmation that at least one-third of the roots of the unerupted maxillary second molars had developed 3. A non-extraction treatment plan 4. Good oral hygiene 5. No or minimal crowding in the mandibular dental arch 6. No signs of temporomandibular joint disorder
Interventions	• Comparison 1: Intraoral pendulum appliance with a midline expansion screw 1. Palatal acrylic button anchored to the maxillary first and second premolars with bonded occlusal rests 2. A midline screw and bilateral 0.032 inch TMA cantilever springs were inserted into lingual sheaths on the first molar bands 3. Springs were initially activated 90° 4. Participants were monitored at 3-week intervals 5. Participants were instructed to turn the expansion screw a quarter turn once a week • Comparison 2: Headgear group 1. Cervical pull headgear 2. Activated to deliver a force of 500 g 3. Participants were instructed to wear the appliance for 12 to 14 hours per day 4. Participants were monitored at 3-week intervals

Outcomes	1. Mesiodistal movement of the upper first molars 2. Anterior movement of upper incisor 3. Overjet 4. Other cephalometric variables	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The subjects were randomly allocated to ..." Comment: insufficient information about the sequence generation process to permit judgement
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias)	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias)	Unclear risk	• 30 patients were included in the analysis • Number of drop-outs not addressed
Selective reporting (reporting bias)	Unclear risk	• Selective reporting of outcomes: insufficient information to permit judgement
Other bias	Low risk	Study appears to be free of other sources of bias

9.2 Characteristics of excluded studies

Table 32: Excluded studies with reasons

Study	Reason for exclusion
Abed 2010 **[149]**	Did not involve treatment with a distalising appliance; outcomes are not relevant; retrospective study
Angelieri 2008 **[132]**	Retrospective study
Cetinsahin 2010 **[133]**	Not a randomised trial; patient allocation depended on anchorage need. Did not involve treatment with a distalising appliance
Erverdi 1997 **[134]**	Not a randomised trial
Gelgor 2007 **[135]**	Not a randomised trial
Kaya 2009 **[150]**	Did not involve treatment with a distalising appliance
Kinzinger 2003 **[145]**	Not relevant; participants in this study were grouped according to dental maturation stage
Kinzinger 2004 **[146]**	Not relevant; participants in this study were grouped according to second and third molar maturation stage
Kinzinger 2005 **[147]**	Not relevant; participants in this study were grouped according to the tooth used for anchorage
Kinzinger 2006 **[148]**	Not relevant; participants in this study were grouped according to dental maturation stage
Kinzinger 2010 **[136]**	No comparison intervention
Kucukkeles 2007 **[137]**	Not a randomised trial
Liu 2009 **[151]**	Did not involve treatment with a distalising appliance; all patients over 16 years of age
Mossaz 2007 **[138]**	Not a randomised trial, patients chose their intervention
Oncag 2007 **[139]**	Not a randomised trial
Sari 2003 **[140]**	Not a randomised trial
Schutze 2007 **[141]**	Not a randomised trial
Silvola 2009 **[152]**	The comparative intervention was not relevant to this review
Taner 2003 **[142]**	Not a randomised trial
Ucem 1998 **[143]**	Not a randomised trial

Uzel 2007 **[144]**	Correspondence with author confirmed it was not randomised

10 Data and analyses

Table 33: Data and analysis: Appliance versus untreated control

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Movement of upper first molars [mm]	2		Mean Difference (IV, Fixed, 95% CI [mm])	Subtotals only
1.1.1 First Class appliance versus untreated controls	1	26	Mean Difference (IV, Fixed, 95% CI [mm])	-4.04 [-5.49, -2.59]
1.1.2 Distalising appliance (Forsus and Jasper Jumper) versus untreated control	1	48	Mean Difference (IV, Fixed, 95% CI [mm])	-1.60 [-2.20, -1.00]
1.2 Movement of upper incisor teeth [mm]	2		Mean Difference (IV, Fixed, 95% CI [mm])	Subtotals only
1.2.1 First Class appliance versus untreated controls	1	26	Mean Difference (IV, Fixed, 95% CI [mm])	1.32 [-1.14, 3.78]
1.2.2 Distalising appliance (Forsus and Jasper Jumper) versus untreated control	1	48	Mean Difference (IV, Fixed, 95% CI [mm])	-1.40 [-2.38, -0.42]
1.3 Loss of anchorage (overjet mm) [mm]	2		Mean Difference (IV, Fixed, 95% CI [mm])	Subtotals only
1.3.1 First Class appliance versus untreated controls	1	26	Mean Difference (IV, Fixed, 95% CI [mm])	1.18 [0.26, 2.10]
1.3.2 Distalising appliance (Forsus and Jasper Jumper) versus untreated control	1	48	Mean Difference (IV, Fixed, 95% CI [mm])	-3.55 [-4.53, -2.57]

Table 34: Data and analysis: Intraoral appliance versus headgear

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
2.1 Movement of upper first molar [mm]	4	150	Mean Difference (IV, Random, 95% CI [mm])	-1.45 [-2.74, -0.15]
2.2 Movement of upper incisor teeth [mm]	4	150	Mean Difference (IV, Random, 95% CI [mm])	1.82 [1.39, 2.24]
2.3 Change in overjet [mm]	2	70	Mean Difference (IV, Fixed, 95% CI [mm])	1.64 [1.26, 2.02]

Table 35: Data and analysis: Intraoral appliance versus other intraoral appliance

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
3.1 Movement of upper first molars [mm]	3		Mean Difference (IV, Fixed, 95% CI [mm])	Subtotals only
3.1.1 Three-dimensional bimetric distalising arch versus modified Begg intraoral distalising system	1	38	Mean Difference (IV, Fixed, 95% CI [mm])	-0.28 [-0.63, 0.07]
3.1.2 Jasper Jumper versus Forsus Nitinol Flat Spring	1	32	Mean Difference (IV, Fixed, 95% CI [mm])	0.80 [0.12, 1.48]
3.1.3 Upper removable appliance with finger springs versus Jones Jig appliance	1	23	Mean Difference (IV, Fixed, 95% CI [mm])	-0.13 [-1.50, 1.24]
3.2 Movement of upper incisor teeth [mm]	2		Mean Difference (IV, Fixed, 95% CI [mm])	Subtotals only
3.2.1 Three-dimensional bimetric distalising arch versus modified Begg intraoral distalising system	1	38	Mean Difference (IV, Fixed, 95% CI [mm])	-0.39 [-1.43, 0.65]
3.2.2 Jasper Jumper versus Forsus Nitinol Flat Spring	1	32	Mean Difference (IV, Fixed, 95% CI [mm])	0.00 [-0.80, 0.80]
3.3 Loss of anchorage (overjet) [mm]	2		Mean Difference (IV, Fixed, 95% CI [mm])	Subtotals only
3.3.1 Three-dimensional dimetric distalising arch	1	38	Mean Difference (IV, Fixed, 95% CI [mm])	-0.43 [-0.74, -0.12]

versus modified Begg intraoral distalising system				
3.3.2 Jasper Jumper versus Forsus Nitinol Flat Spring	1	32	Mean Difference (IV, Fixed, 95% CI [mm])	0.50 [-0.04, 1.04]
3.4 Duration of treatment	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.4.1 Three-dimensional bimetric distalising arch versus modified Begg intraoral distalising system	1	38	Mean Difference (IV, Fixed, 95% CI)	-3.10 [-3.49, -2.71]
3.4.2 Jasper Jumper versus Forsus Nitinol Flat Spring	1	32	Mean Difference (IV, Fixed, 95% CI)	-0.05 [-0.87, 0.77]

11 Search Strategies

Figure 16: MEDLINE (OVID) search strategy

1. Malocclusion, Angle Class II/
2. "Class II" AND (Angle$ OR malocclusion$ OR bite$)
3. (("distal molar movement") OR (distal$ adj4 molar$))
4. or/1-3
5. exp Orthodontic appliances, Functional/
6. exp Orthodontic appliances, Removable/
7. ((extraoral or extra-oral or "extra oral") adj4 appliance$)
8. ("head gear" or headgear or head-gear)
9. ((intraoral or intra-oral or "intra oral") adj4 appliance$)
10. ("pendulum appliance$" or "Wilson's arch$" or "distal jet appliance$" or Jones or "jig appliance$" or "repelling magnets" or (super elastic adj3 spring$) or (super-elastic adj3 spring$) or ("super elastic" adj3 spring$) or Herbst or Frankel or Bass or Harvold).ti,ab.
11. or/5-10
12. 4 AND 11

The above subject search was linked to the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the *Cochrane Handbook for Systematic Reviews of Interventions*, Version 5.1.0 [updated March 2011].

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

Figure 17: The Cochrane Oral Health Group's Trials Register search strategy

This search was done in the Cochrane Oral Health Group's Trials Register via the Cochrane Register of Studies using the search strategy below:

#1 (("class II" AND (Angle* or malocclusion* or bite*))) AND (INREGISTER)
#2 (("class 2" AND (Angle* or malocclusion* or bite*))) AND (INREGISTER)
#3 (("class two" AND (Angle* or malocclusion* or bite*))) AND (INREGISTER)
#4 ((distal and molar)) AND (INREGISTER)
#5 (#1 or #2 or #3 or #4) AND (INREGISTER)
#6 (orthodontic*) AND (INREGISTER)
#7 ((extraoral or extra-oral or "extra oral" or headgear or head-gear or "head gear" or intraoral or intra-oral or "intra oral" or "pendulum appliance*" or "wilson* arch*" or "distal jet appliance*" or Jones or "jig appliance*" or "repelling magent*" or "superelastic spring*" or "super-elastic spring*" or "super elastic spring*" or Herbst or Frankel or Bass or Harvold)) AND (INREGISTER)
#8 (#6 or #7) AND (INREGISTER)
#9 (#5 and #8) AND (INREGISTER)

Previous searches for this review were conducted in the Cochrane Oral Health Group's Trials Register using the ProCite software and the search strategy below:

((orthodontic* or extraoral or extra-oral or "extra oral" or headgear or head-gear or "head gear" or intraoral or intra-oral or "intra oral" or "pendulum appliance*" or "wilson* arch*" or "distal jet appliance*" or Jones or "jig appliance*" or "repelling magent*" or "superelastic spring*" or "super-elastic spring*" or "super elastic spring*" or Herbst or Frankel or Bass or Harvold) AND ((angle* or malocclusion* or bite*) AND ("class two" or "class II" or "class 2")))

Figure 18: Cochrane Central Register of Controlled Trials (CENTRAL) search strategy

#1 MeSH descriptor Malocclusion, Angle Class II this term only
#2 ("Class II" in All Text and (Angle* in All Text or malocclusion* in All Text or bite* in All Text))
#3 "distal molar movement" in All Text
#4 (distal* in All Text near/4 molar* in All Text)
#5 (#1 or #2 or #3 or #4)
#6 MeSH descriptor Orthodontic Appliances, Functional explode all trees
#7 MeSH descriptor Orthodontic Appliances, Removable explode all trees
#8 ((extraoral in All Text or extra-oral in All Text or "extra oral" in All Text) and appliance* in All Text)
#9 ("head gear" in All Text or headgear in All Text or head-gear in All Text)
#10 ((intraoral in All Text or intra-oral in All Text or "intra oral" in All Text) and appliance* in All Text)
#11 ("pendulum appliance*" in Title, Abstract or Keywords or "Wilson* arch*" in Title, Abstract or Keywords or "distal jet appliance*" in Title, Abstract or Keywords or Jones in Title, Abstract or Keywords or "jig appliance*" in Title, Abstract or Keywords or "repelling magnet*" in Title, Abstract or Keywords or "superelastic spring*" in Title, Abstract or Keywords or "super-elastic spring*" in Title, Abstract or Keywords or "super elastic spring*" in Title, Abstract or Keywords or Herbst in Title, Abstract or Keywords or Frankel in Title, Abstract or Keywords or Bass in Title, Abstract or Keywords or Harvold in Title, Abstract or Keywords)
#12 (#6 or #7 or #8 or #9 or #10 or #11)
#13 (#5 and #12)

Figure 19: EMBASE (OVID) search strategy

1. Malocclusion, Angle Class II/
2. "Class II" AND (Angle$ OR malocclusion$ OR bite$)
3. (("distal molar movement") OR (distal$ adj4 molar$))
4. or/1-3
5. exp Orthodontic appliances, Functional/
6. exp Orthodontic appliances, Removable/
7. ((extraoral or extra-oral or "extra oral") adj4 appliance$)
8. ("head gear" or headgear or head-gear)
9. ((intraoral or intra-oral or "intra oral") adj4 appliance$)
10. ("pendulum appliance$" or "Wilson's arch$" or "distal jet appliance$" or Jones or "jig appliance$" or "repelling magnets" or (superelastic adj3 spring$) or (super-elastic adj3 spring$) or ("super elastic" adj3 spring$) or Herbst or Frankel or Bass or Harvold).ti,ab.
11. or/5-10
12. 4 AND 11

The above subject search was linked to the Cochrane Oral Health Group filter for identifying RCTs in EMBASE via OVID:

1. random$.ti,ab.2. factorial$.ti,ab.
3. (crossover$ or cross over$ or cross-over$).ti,ab.
4. placebo$.ti,ab.
5. (doubl$ adj blind$).ti,ab.
6. (singl$ adj blind$).ti,ab.
7. assign$.ti,ab.
8. allocat$.ti,ab.
9. volunteer$.ti,ab.
10. CROSSOVER PROCEDURE.sh.
11. DOUBLE-BLIND PROCEDURE.sh.
12. RANDOMIZED CONTROLLED TRIAL.sh.
13. SINGLE BLIND PROCEDURE.sh.
14. or/1-13
15. ANIMAL/ or NONHUMAN/ or ANIMAL EXPERIMENT/
16. HUMAN/
17. 16 and 15
18. 15 not 17
19. 14 not 18

Figure 20: Clinicaltrials.gov search strategy

An advanced search using the following 'search terms' and 'conditions':

Class II OR Class 2 OR distalise OR distal AND movement OR distal AND molar OR orthodontic OR headgear OR distal AND jet OR pendulum OR wilson AND arch OR Jones AND jig OR repelling AND magnet OR superelastic AND spring | orthodontic OR Malocclusion OR Class II

12 Acknowledgements

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13 Contributions of authors

- Development of the protocol: Safa Jambi (SJ), Kevin O'Brien (KOB), Badri Thiruvenkatachari (BT), Tanya Walsh (TW).
- Examination of titles and abstracts: SJ, BT, KOB.
- Retrieval of full-text reports: SJ.
- Examination of full-text reports and final decisions on study inclusion: SJ, BT, KOB.
- Development of data collection forms: SJ, BT.
- Data extraction and management: SJ, BT, TW, KOB.
- Risk of bias assessment: SJ, BT, TW, KOB.
- Data synthesis: SJ, BT, TW.
- Writing the review: SJ supervised by TW, KOB.

14 Declarations of interest

- One of the authors of this review, Kevin O'Brien, was involved as an author in one of the included studies (Paul 2002). Decisions on study inclusion, data extraction and management for the Paul 2002 study were performed independently of this author.
- Safa Jambi: no interests to declare.
- Badri Thiruvenkatachari: no interests to declare.
- Tanya Walsh: no interests to declare.

15 Differences between protocol and review

15.1 Changes from the protocol

- Interventions assessing functional appliances were included in the protocol but not in the review. The rationale for this change was that studies in which functional appliances were used did not have the same treatment objective as studies which were specifically intended for distal movement of molars.
- The handsearched journals were expanded to also include the following journals: Clinical Implant Dentistry and Related Research Clinical Oral Implant Research International Journal of Oral and Maxillofacial Implants Journal of Dentistry.

15.2 Methods not implemented

The following outcomes were not assessed because they were not reported by any of the included studies.

- Number of attendances required to complete treatment.
- Non-compliance rate of intervention.
- Adverse effects, including headgear injuries, health of gingiva and damage to teeth.

16 Sources of support

16.1 Internal sources

- The University of Manchester, UKManchester Academic Health Sciences Centre (MAHSC), UK
- The Cochrane Oral Health Group is supported by MAHSC and the NIHR Manchester Biomedical Research Centre.

16.2 External sources

- The Ministry of Higher Education/Taiba University, Saudi Arabia
- This review was undertaken as part of a PhD at the University of Manchester and funded by the government of Saudi Arabia.
- Cochrane Oral Health Group Global Alliance, UK

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- Disclaimer:The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR, NHS or the Department of Health.

SECTION III: Cochrane Systematic Review Update: Reinforcement of anchorage during orthodontic brace treatment with implants or other surgical methods

- **This is the final submitted text of the review.**
- **Safa Jambi led the review and her contribution is stated on page 299**.

Review information

Review number: 0061

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What's new:

18 December 2013 New citation: conclusions changed:

- Substantial update with different authors, inclusion criteria, search strategy, citations and conclusions.
- 14 new studies were added to the single study in the last published version of

1 Abstract

1.1 Background

The term anchorage in orthodontic treatment refers to methods of controlling unwanted tooth movement. This is provided either by anchor sites within the mouth, such as the teeth and the palate or from outside the mouth (headgear). Recently, new methods of providing anchorage have been developed using orthodontic implants which are surgically inserted into the bone in the mouth, this is termed surgical anchorage. This is an update of a Cochrane review first published in 2008.

1.2 Objectives

To assess the effects of surgical anchorage techniques in the prevention of unwanted tooth movement in patients undergoing orthodontic treatment. The secondary objective was to assess the effects of different surgical anchorage techniques.

1.3 Search methods

We searched the Cochrane Oral Health Group's Trials Register (to 28 October 2013), CENTRAL (to Issue 9, 2013), MEDLINE (1946 to 28 October 2013) and EMBASE (1980 to 28 October 2013). We hand searched key international orthodontic and dental journals, and searched trial databases ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform for ongoing and unpublished studies.

1.4 Selection criteria

Randomised controlled trials comparing surgical anchorage with conventional anchorage in orthodontic patients. Trials comparing two types of surgical anchorage were also included.

1.5 Data collection and analysis

At least two review authors independently and in duplicate extracted data and carried out risk of bias assessments. We contacted study authors to clarify aspects of study design and conduct and obtain unreported data.

1.6 Main results

Fourteen new studies were added in this update resulting in a total of fifteen studies reporting data from 561 randomised patients. The studies were conducted in Europe, India, China, South Korea and USA. The age range of patients was commonly restricted to adolescents or young adults; however the participants of two studies were from a much wider age range (12 to 54 years). The distribution of males and females was similar in seven studies, with a predominance of female patients in seven studies.

Eight studies were assessed at overall high risk of bias; six studies at unclear risk of bias; one study at low risk of bias.

Ten studies with 407 randomised and 390 analysed patients compared surgical anchorage with conventional anchorage for the primary outcome of mesiodistal movement of upper first molars. We carried out a random effect meta-analysis for the seven studies that fully reported this outcome. There was strong evidence of an effect of surgical anchorage on this outcome compared with conventional anchorage; surgical anchorage was more effective in the reinforcement of anchorage by 1.68mm (95% CI -2.27mm to -1.09mm) (moderate quality of evidence; 1 study overall high risk of bias, 5 studies unclear risk of bias, one study low risk of bias, 308 participants analysed). This result should be interpreted with some caution however as there was a substantial degree of heterogeneity for this comparison. Information on patient reported outcomes such as pain and acceptability was limited and inconclusive.

No included studies reported adverse effects.

1.7 Authors' conclusions

There is moderate quality evidence that reinforcement of anchorage is more effective with surgical anchorage than conventional anchorage. While surgical anchorage is not associated with the inherent risks and compliance issues related to extraoral headgear, none of the included studies reported on harms of surgical or conventional anchorage.

2 Plain language summary

Reinforcement of anchorage during orthodontic brace treatment with implants or other surgical methods

2.1 Review Question

Researchers in the Oral Health group of the Cochrane Collaboration reviewed the evidence about the effects of implants and other surgical methods in preventing unwanted tooth movement in people undergoing orthodontic brace treatment.

2.2 Background

Orthodontic treatment is a type of dental care that corrects crooked or sticking out teeth by moving the teeth into ideal positions. Teeth are straightened by application of a force by a brace. This force has an opposite reaction force, which may cause unwanted tooth movement. In most cases it is necessary to control these reaction forces in order to achieve the best results from treatment. This is known as anchorage control. Recently, special types of devices have been used inside the mouth to help orthodontists control anchorage. These are small implants or pins inserted into the bone that require a simple surgical procedure. They are placed either before or at the same time as the normal braces. These types of devices have become increasing popular; however their effects have not been completely evaluated.

2.3 Study Characteristics

This is an update to an existing review which described one study. Further research published up to October 2013 was examined; fourteen studies were added. A total of 15 studies, reporting information from 561 patients, were included in this update. Most of these studies were conducted in University settings. The studies were conducted in Europe, India, China, South Korea and USA. All participants in the studies needed a

course of orthodontic treatment with additional anchorage control. Children, adults, male and female participants were included.

2.4 Key Results

When surgical anchorage devices are compared to conventional anchorage devices, they are better in providing orthodontic anchorage. There is limited reported information on patient reported outcomes such as pain and acceptability, and no reported information on adverse events.

2.5 Quality of the Evidence

The quality of the evidence for the important outcomes in this review ranged from moderate to low quality. The main shortcomings from all of the studies were related to issues with study design and implementation, and inadequate reporting of the study methods and outcomes.

Table 36: Summary of findings table

Surgical anchorage compared to conventional anchorage for patients undergoing orthodontic treatment						
Patient or population: **patients undergoing orthodontic treatment** Settings: **orthodontic clinics in University settings or specialist practice** Intervention: **surgical anchorage** Comparison: **conventional anchorage**						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Conventional anchorage	Corresponding risk Surgical anchorage				
Mesiodistal movement of the upper first permanent molar	The mean mesiodistal movement of the upper first permanent molar ranged across control groups from 1.47mm to 3.22mm	The mean mesiodistal movement of the upper first permanent molar in the intervention groups was 1.68 mm lower (2.27 to 1.09 lower)		308 (7 studies)	⊕⊕⊕⊖ moderate[1, 2]	Lower scores indicates less movement (greater reinforcement of anchorage). A change of 1.5 mm or greater is clinically important.
Duration of overall treatment (years)	The mean duration of overall treatment (years) ranged across control groups from 2.23 years to 2.75 years	The mean duration of overall treatment (years) in the intervention groups was 0.15 lower (0.37 lower to 0.07 higher)		111 (3 studies)	⊕⊕⊕⊖ moderate[3,4]	Lower scores indicate a shorted duration of overall treatment.
Duration of space closure (days)	The mean duration of overall treatment (days) ranged across control groups from 181 days to 298.2 days	The mean duration of overall treatment (days) in the intervention groups was 12 lower (72 lower to 47 higher)		80 (3 studies)	⊕⊕⊖⊖ low[3,5]	Lower scores indicate a shorted duration of overall treatment.
Adverse events						This outcome was unreported in all included studies.
***The basis for the** assumed risk **(e.g. the median control group risk across studies) is provided in footnotes. The** corresponding risk **(and its 95% confidence interval) is based on the assumed risk in the comparison group and the** relative effect **of the intervention (and its 95% CI).** CI: **Confidence interval;** OR: **Odds ratio;**						
GRADE Working Group grades of evidence High quality: **Further research is very unlikely to change our confidence in the estimate of effect.** Moderate quality: **Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.** Low quality: **Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.** Very low quality: **We are very uncertain about the estimate.**						

[1] Seven studies at overall high (1), unclear (5) and low (1) overall risk of bias. Substantial heterogeneity I^2 78% though mean difference (MD) of 6/7 studies in favour of surgical intervention.
[2] Outcome incompletely reported in two additional studies at overall high risk of bias (both studies reported in favour of surgical anchorage) and not reported in one study at overall high risk of bias.
[3] Small studies likely underpowered; imprecision of result.
[4] Two studies at overall unclear risk of bias; one study at low risk of bias. Negligible heterogeneity I^2 0%.
[5] One study at overall high risk of bias; two studies at unclear risk of bias. Moderate heterogeneity I^2 45%.

3 Background

3.1 Description of the condition

Anchorage in orthodontics is defined as the prevention of unwanted tooth movement. Traditionally this may be provided from anchor sites within the mouth (intraoral anchorage) or from outside the mouth (extraoral anchorage). Intraoral anchor sites include teeth or other oral structures. Extraoral anchorage is achieved with headgear, using the back of the head or the neck.

Intraoral anchorage can be supplemented by securing teeth together by means of metal wires, such as transpalatal arches or lingual arches. Anchorage may also be supplemented by using elastic traction to the opposing arch. This is termed intermaxillary anchorage [2].

While extra-oral anchorage may be a more effective method of preventing anchor tooth movement than intra oral methods, there are concerns about patient compliance with headgear [5] and issues over patient safety. For example, Samuels has described a range of soft tissue and eye injuries associated with headgear. In a few cases this has resulted in the loss of an eye [101, 155, 156]. A related Cochrane systematic review has assessed the effects of conventional distalising appliances developed to overcome the limitations of headgear [157].

Another method of reinforcing anchorage using surgical techniques has been developed. For example, Gainsforth and Higley suggested the use of metallic screws as anchors as long ago as 1945 [158]. Melsen experimented with anchorage from wires passed through the zygomatic arch in cases where posterior teeth were absent or of poor quality [159]. A recent development has been the modification of dental implants in which devices are surgically inserted into the alveolar bone where they become osseointegrated [160]. This

new technique could have an important role in orthodontic treatment as it may offer the possibility of circumventing most of the shortcomings of traditional anchorage methods.

3.2 Description of the intervention

All surgical techniques for reinforcing anchorage use the bone as the anchor site, which is considered a solid stable structure. Types of surgical anchorage include mini-screw implants, mini-plates and mid-palatal implants. The mini-screw implant is a modification of screws used for fixation of maxillofacial fractures. Although they have varying lengths and diameters, they are generally smaller than maxillofacial fixation screws, hence the term 'mini'. Another type of implant is placed in the bone in the middle of the palate, these are called mid-palatal implants.

Both these types of implants can be placed by the orthodontist or the oral surgeon. The anchorage device can be placed either before the start of treatment, at the beginning or during the space closure phase of treatment.

3.3 How the intervention might work

As the surgical anchorage device is fixed to the bone it is proposed that they provide a stable point from which anchorage can be provided.

3.4 Why it is important to do this review

Many children and adolescents present for orthodontic treatment with crooked or prominent of the teeth. Treatment to align the teeth in these situations is conventionally provided using fixed orthodontic appliances with the extraction of teeth and the use of either an intra- or extra-oral appliance to provide support to the molar teeth (reinforcing anchorage) as the fixed appliance aligns the anterior teeth.

The two most common methods of providing this anchorage reinforcement have been headgear and palatal arches. Recently the use of surgical anchorage has become increasingly popular with what may be considered to be lack of high level evidence to underpin its use.

The potential advantages of surgical anchorage over conventional anchorage reinforcement are as follows:

1. active compliance by the wearer is eliminated
2. surgical appliances are not associated with the injuries that can result from conventional wearing conventional anchorage appliances
3. absolute anchorage may be provided

4 Objectives

The primary objective of this review was to assess the effects of surgical anchorage compared to conventional anchorage in the prevention of unwanted tooth movement in orthodontic patients, by evaluating the mesiodistal movement of upper first molar teeth. A secondary objective was to compare the effects of one type of surgical anchorage with another.

5 Methods

5.1 Criteria for considering studies for this review

5.1.1 Types of studies

We included parallel group, randomised controlled trials in which surgically assisted anchorage reinforcement techniques during orthodontic treatment were used. There was no restriction on publication language. Where studies were reported in abstract form, the literature was searched for full publication. Split mouth trials were excluded because the nature of orthodontic treatment precludes both sides of the mouth from being independent of each other.

5.1.2 Types of participants

Patients of any age undergoing orthodontic treatment with fixed appliances and requiring surgical or conventional anchorage.

5.1.3 Types of interventions

Mid-palatal implants, onplants, mini screw implants, spider screws, titanium plates and zygomatic wires were considered under the term surgically assisted means of reinforcing anchorage.

The control group included patients with anchorage supported by conventional means including headgear, chin caps, face masks, transpalatal arches (including Nance buttons), lingual arches and interarch elastics.

We also included studies comparing two methods of surgically assisted anchorage.

5.1.4 Types of outcome measures

The primary outcome measure was the mesiodistal movement of upper first molars (mm). The secondary outcome measures were residual overjet, success/failure of the anchorage device, duration of active treatment, duration of space closure, number of visits, patient perception (pain and discomfort), acceptability of the anchorage device, adverse effects and economic factors.

5.2 Search methods for identification of studies

5.2.1 Electronic searches

We searched the following electronic databases:

- Cochrane Oral Health Group Trials Register (to 28 October 2013) (Figure 28);
- Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library, 2013, Issue 9) (Figure 29);
- MEDLINE via OVID (1946 to 28 October 2013) (Figure 27); EMBASE via OVID (1980 to 28 October 2013) (Figure 30).

No restrictions were placed on the language or date of publication when searching the electronic databases.

Detailed search strategies were developed for each database. Individual search strategies were based on the search strategy developed for MEDLINE (Figure 27), but revised appropriately for each database. The MEDLINE search used a combination of controlled vocabulary and free text terms, in conjunction with the Cochrane Highly Sensitive Search Strategy for identifying reports of randomised controlled trials (as published in Box 6.4.c in the Cochrane Handbook for Systematic Reviews of Interventions, version 5.1.0, updated March 2011) [48]. The search of EMBASE was linked to the Cochrane Oral Health Group filters for identifying RCTs.

5.2.2 Searching other resources

5.2.2.1 Handsearching

The following journals have been identified for handsearching for this review. Journal issues that have not already been searched as part of the Cochrane Oral Health Group's journal handsearching programme were handsearched:

- American Journal of Orthodontics and Dentofacial Orthopedics 2005-January 2013
- Angle Orthodontist 2007-January 2013
- Clinical Implant Dentistry and Related Research 2003-December 2012
- Clinical Oral Implant Research 2001, 2003- December 2012
- European Journal of Orthodontics 2006- December 2012
- International Journal of Oral and Maxillofacial Implants 2004-December 2012
- Journal of Orthodontics (formerly British Journal of Orthodontics) 2008- December 2012
- Journal of Dental Research 1999-2000, 2004- January 2013
- Journal of Dentistry 2004- December 2012
- Journal of Clinical Orthodontics 1991- December 2012
- Orthodontics and Craniofacial Research (1998 to 2001 Clinical Orthodontics and Research) 2000- November 2012
- Seminars in Orthodontics 2005-December 2012

5.2.2.2 Grey literature and trial registries

In addition to contacting authors, we looked for unpublished studies by searching abstracts and conference proceedings. We also approached manufacturers of implant products used in orthodontics and asked them to provide us with information concerning unpublished or ongoing studies.

We also checked the bibliographies of potentially relevant clinical trials for references to trials published outside the handsearched journals. In addition, non-Cochrane systematic reviews were checked for potentially relevant studies.

Trial registries were searched to identify ongoing studies. The most recent search for all trial registries was January 2013. These included the following:

- www.clinicaltrials.gov: The clinical trials.gov web site was searched by topic selecting mouth and tooth diseases. All records under 'malocclusion' and 'Malocclusion Angle Class II' were searched. In addition, a keyword search was conducted (Figure 31).
- the IFMPA clinical trials portal (http://clinicaltrials.ifpma.org/clinicaltrials/no_cache/en/clinical-trial-advanced-search/index.htm). This was searched by using the following terms from the 'site language': 'orthodontic procedure' and 'dental braces complication'.
- The current controlled trials web site (isrctn.org) was searched by using the following key words individually; dental, orthodontic, mini-implant, mini-screw implant, surgical anchorage and headgear.

5.3 Data collection and analysis

5.3.1 Selection of studies

At least two review authors independently examined the titles and abstracts of identified studies; any report that was clearly not relevant was excluded. We retrieved full text documents of potentially relevant studies and assessed them for eligibility according to the criteria for considering studies for this review. We resolved any disagreements by open discussion, occasionally arbitrated by an independent assessor. If information was unclear on study eligibility in study reports, we contacted the study investigators. Final decisions on study inclusion were made through discussion.

There was no language restrictions on the studies to be retrieved. Where the report was in a language other than English, a translation was sought.

5.3.2 Data extraction and management

We developed and piloted a more detailed data extraction form for use in this update. It contained information on methods, participants, interventions, primary and secondary outcomes and reported results. Data extraction was performed independently and in duplicate by three review authors. One form was used as the master form and any additions added to it as appropriate. We resolved disagreements by discussion.

When we found that there was incomplete reporting of data, we contacted the study authors in an attempt to obtain this data.

5.3.3 Assessment of risk of bias in included studies

We used the Cochrane risk of bias tool to assess the potential bias of the studies. This was done independently and in duplicate by two review authors as part of the data extraction process. We investigated six specific domains: sequence generation, allocation concealment, blinding of outcome assessor, incomplete outcome data, selective outcome reporting and ‘other issues with bias’. Blinding of patients and operators was considered unfeasible due to the nature of interventions, however there was potential for assessment and detection bias.

Selective reporting considered both selective reporting of outcomes and selective reporting of study data. Where the primary outcome of this review was not reported but could reasonably have been expected to be recorded and reported then the study was judged to be a high risk of bias for this domain. Where the protocol of the primary study was not available then the study was judged to be of unclear risk of bias because of the uncertainty in reporting all intended outcomes. Selective reporting of study data such as incomplete reporting of summary statistics was considered high risk only in relation to the

primary outcome. The overall judgement of risk of bias in this domain was given according to the highest risk of bias available.

For each study, each domain was assessed as being of low, high or unclear risk of bias as described in the Cochrane Handbook for Systematic Reviews of Intervention version 5.1.0 [48]. Additional information provided by authors of the primary studies was taken in to account where appropriate. A risk of bias table was completed for each included study. These results were also presented graphically.

5.3.4 Measures of treatment effect

For dichotomous outcomes, the estimate of effect expressed as risk ratios (RR); for continuous outcomes the measure of treatment effect was expressed as the mean difference. 95% confidence intervals (95% CIs) were calculated alongside the effect estimate. Where insufficient information was reported to enable these effect measures to be calculated a narrative report of the summary measures were provided.

5.3.5 Unit of analysis issues

When we identified the reporting of outcomes at multiple time points, the most common and/or clinically relevant time point was extracted.

5.3.6 Dealing with missing data

Where data were not available in the printed report, or where the data were unclear, we contacted the corresponding author of the study to obtain the missing data. No studies were excluded on the basis of missing data and no imputations for missing data were carried out.

5.3.7 Assessment of heterogeneity

Clinical heterogeneity was assessed on the basis of the participants and interventions in each study. A meta-analysis was undertaken when there were studies of sufficient similarities of participant, interventions and outcomes. Statistical heterogeneity was assessed using the Chi^2 test for heterogeneity ($p < 0.1$) and the I^2 statistic.

5.3.8 Data synthesis

We carried out a random-effects meta-analysis when there were more than three studies and pooling of the data was clinically and statistically appropriate. In meta-analyses with two or three studies, a fixed-effects model was undertaken.

In multi-arm studies with more than two intervention groups, only single pair-wise comparisons were made. When we identified studies with multiple groups all relevant intervention and control groups were combined into a single intervention or control group respectively. For continuous outcomes, we combined means and standard deviations using formulae described in the Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [48]. For dichotomous outcomes the number of events and total number of participants were added together for each of the intervention and control groups.

For comparisons where a meta-analysis could not be carried out, we provided a narrative reporting of the summary measures and treatment effects.

We undertook a meta-analysis comparing all types of surgical anchorage to all types of conventional anchorage for the planned outcomes found in the studies. In addition, subgroup analysis was carried out to investigate the effects of different types of surgical anchorage appliances compared to conventional anchorage.

A summary of findings table was developed for the primary outcomes of this review using GRADE profiler software. The quality of the evidence was assessed with reference to the overall risk of bias of the included studies, the directness of the evidence, the inconsistency of the results, the precision of the estimates, the risk of publication bias, the magnitude of the effect. The quality of the evidence for the primary outcomes of mesiodistal movement, duration of overall treatment and adverse events was categorised as high, moderate, low or very low.

6 Main results

6.1 Description of studies

6.1.1 Results of the search

The initial search strategy for the original review was undertaken in November 2004. One-hundred-and fifty-seven records were identified of which 147 were rejected after examination of the title and abstract. Ten studies were selected for more detailed evaluation of the full publication. None fulfilled the criteria for inclusion. One trial, Chesterfiled 2007 [161], meeting the inclusion criteria was identified through personal contact with the authors whilst the review was in preparation.

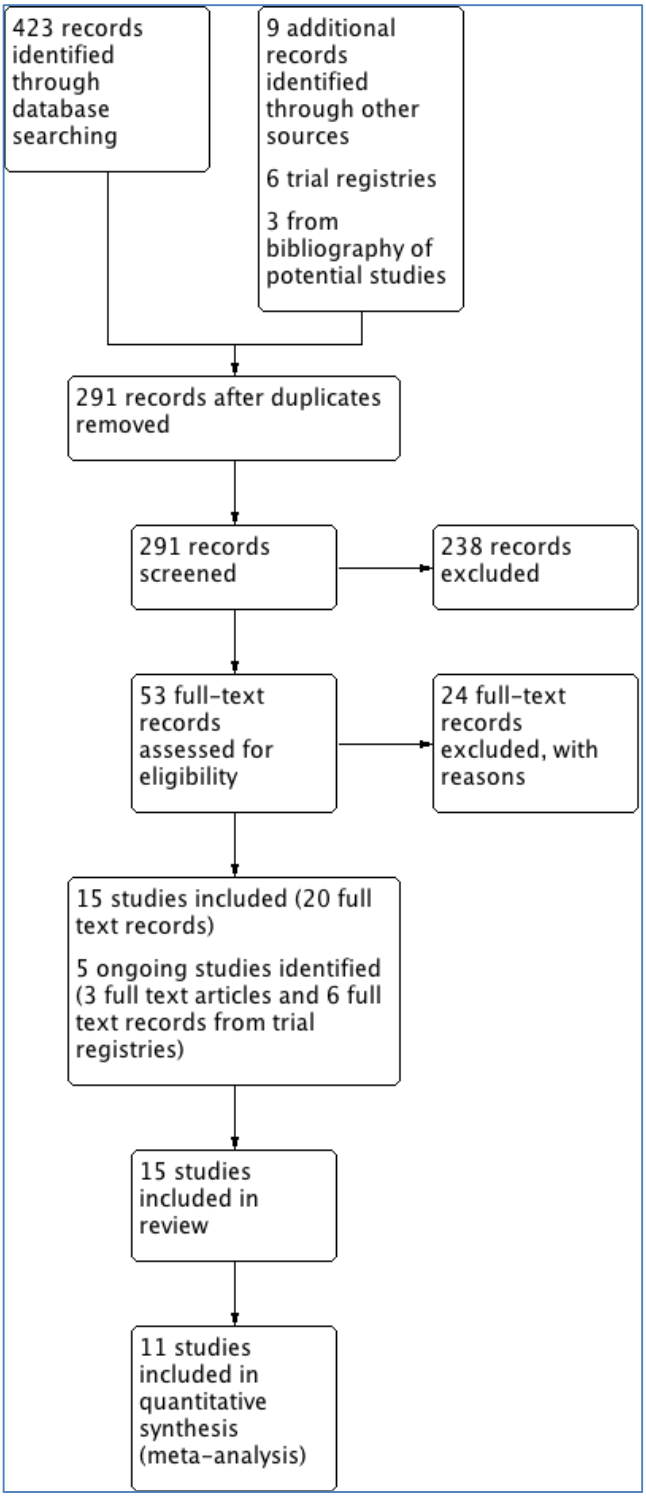
The search was last updated in October 2013, and the results are presented graphically (Figure 21). We identified a total of 423 records from electronic resources and 9 from other resources. After removing duplicates, 291 records remained of which 238 were excluded after examination of the title and abstract. Most of these were excluded because the interventions were clearly not relevant or the studies were not randomised controlled trials.

We assessed 53 full text records for eligibility. Fifteen studies, involving data from 543 analysed participants were included in this review; 13 were two-arm studies, one three arm study (Turkoz 2011 [162]) and one four-arm study (Feldmann 2007 [163-166]).

Five ongoing studies were identified; Bearn 2008 (ISRCTN29710460 , UKCRN ID 7460), Biavati/ Migliorati 2011 (ClinicalTrials.gov NCT01717417), Jung 2007 (ISRCTN97142521), Miller 2009 (ClinicalTrials.gov NCT01025141), Sandler 2008 (ClinicalTrials.gov NCT00995436).

We contacted the corresponding authors of five studies to enquire about issues relating to study eligibility. In four studies, replies indicated that the allocation of interventions in the studies was not random; there was no reply from the author of the fifth study.

Figure 21: Study flow diagram



6.1.2 Included studies

The last published version of this review included one study (Chesterfield 2007) which compared mid-palatal implants versus headgear in patients with Class II Division 1 malocclusions deemed to have an 'absolute anchorage' requirement. This study with 47 participants analysed was assessed as low risk of bias. This update has added fourteen studies. A total of fifteen studies with 561 ranodmised patients (543 analysed patients) were included in this update. Summary details of the studies included in this review are given in the 'Characteristics of included studies' section.

6.1.2.1 Characteristics of the trial settings

Thirteen trials were conducted in University settings or training hospitals with patients attending a dental clinic. The Lehnen 2011 study was conducted in a specialist orthodontic practice, and the setting of the Maddalone 2010 study was not stated. Seven trials were carried out in European countries (Borsos 2008, Borsos 2012, Chesterfield 2007, Feldmann 2007, Lehnen 2011, Maddalone 2010, Turkoz 2011), three were carried out in India (Basha 2010, Sharma 2012, Upadhyay 2008), three in China (Liu 2009, Ma 2008, Shi 2008, one in south Korea (Bechtold 2013) and one in the USA (Jackson 2008). Fourteen studies were single centre trials and one (Chesterfield 2007) was carried out in two centres.

6.1.2.2 Characteristic of participants

Seven studies recruited adolescent children (Borsos 2008, Borsos 2012, Chesterfield 2007, Feldmann 2007, Lehnen 2011, Sharma 2012, Turkoz 2011); six studies recruited young adults (Basha 2010, Bechtold 2013, Liu 2009, Ma 2008, Upadhyay 2008, Shi 2008). Two

studies included adults up to the age of 48 years (Jackson 2008) and 54 years (Maddalone 2010).

The gender distribution was comparable in most of the trials (Borsos 2008, Borsos 2012, Feldmann 2007, Jackson 2008, Lehnen 2011, Ma 2008). However, there was a clear predominance of female participants in five studies (Bechtold 2013, Chesterfield 2007, Liu 2009, Shi 2008, Sharma 2012) and two studies recruited only female participants (Basha 2010, Upadhyay 2008). The gender distribution was not reported in one study (Maddalone 2010).

6.1.2.3 Characteristics of the interventions

Ten studies compared surgical anchorage to conventional anchorage; three studies compared midpalatal implants to conventional anchorage (Borsos 2012, Chesterfield 2007, Feldmann 2007), and seven studies compared mini-screw implants to conventional anchorage (Basha 2010, Liu 2009, Ma 2008, Maddalone 2010, Sharma 2012, Shi 2008, Upadhyay 2008).

The direct comparisons of surgical interventions were early and delayed loading of the same mini-screw implants (Borsos 2008, Jackson 2008); pre-drilling and self-drilling mini-screw implants (Lehnen 2011, Turkoz 2011); single and dual mini-screw implants (Bechtold 2013).

6.1.2.4 Characteristics of the outcomes

Table 37 provides a summary of all of the outcomes relevant to this review as reported by each study.

Table 37: Outcomes found in each of the included studies

	Basha 2010	Bechtold 2013*	Borsos 2008*	Borsos 2012	Chesterfield 2007	Feldmann 2007	Jackson 2008*	Lehnen 2011*	Liu 2009	Ma 2008	Maddalone 2010	Sharma 2012	Shi 2008	Upadhyay 2008
Mesial movement of upper first molar	yes	yes	no	yes	yes	yes	no	no	yes	no	yes	yes	yes	yes
Residual overjet at the end of treatment	no	no	no	no	no	no	no	no	no	no	no	no	no	no
Success/failure of anchorage device	yes	yes	yes	no	yes	yes	yes	no	no	no	yes	no	no	yes
Duration of active treatment	no	no	no	no	yes	no	no	no	yes	no	no	no	no	no
Duration of space closure	yes	yes	no	yes	no	no	no	no	no	no	no	no	no	yes
Number of visits	no	no	no	no	yes	no	no	no	no	no	no	no	no	no
Patient perception (pain/discomfort)	no	no	no	no	yes	yes	no	yes	no	no	no	no	no	no
Acceptability	no	no	no	no	no	yes	no	no	no	no	no	no	no	no
Adverse effects	no	no	no	no	no	no	no	no	no	no	no	no	no	no
Economic factors	no	no	no	no	no	no	no	no	no	no	no	no	no	no

*These studies compared 2 types of surgical anchorage

6.1.2.4.1 Studies comparing surgical anchorage to conventional anchorage

The primary outcome for this comparison was the movement of the upper first molar in a mesial or distal direction. This was measured at different time points:

- when anchorage reinforcement was no longer needed (Chesterfield 2007)

- at the end of levelling and alignment and at the end of space closure (including and excluding the levelling and alignment phase) (Feldmann 2007)
- from the start of treatment to the end of space closure (Sharma 2012)
- at the end of space closure (not including levelling and alignment) (Basha 2010, Borsos 2012, Upadhyay 2008)
- at the start and end of active orthodontic treatment (Borsos 2012, Liu 2009, Shi 2008)
- from the beginning of space closure to four months later (Maddalone 2010).

All studies measured molar movement on lateral cephalometric radiographs except for the Maddalone 2010 study, in which molar movement was measured clinically using the head of the mini-screw implant as a reference point.

No studies reported on residual overjet at the end of treatment.

Treatment 'success' was reported in five studies (Chesterfield 2007, Feldmann 2007, Basha 2010, Maddalone 2010, Upadhyay 2008); duration was reported in five studies (duration of the course of orthodontic treatment (Borsos 2012, Chesterfield 2007, Liu 2009) or space closure (Basha 2010, Borsos 2011, Upadhyay 2008)). Number of visits was reported in one study (Chesterfield 2007).

Two studies (Chesterfield 2007, Feldmann 2007) reported on patient perception in terms of pain and discomfort.

No studies reported on adverse effects and economic evaluation.

One study (Ma 2008) did not report any of the outcomes of interest to this review.

6.1.2.4.2 Studies comparing two types of surgical anchorage

One study (Bechtold 2013) reported on the primary outcome of movement of the upper first molar in a mesial or distal direction. No studies reported on the residual overjet at the end of treatment.

Four studies reported on the success of the anchorage device as defined by histologic bone-implant contact (Borsos 2008) and implant stability (Bechtold 2013, Jackson 2008, Turkoz 2011).

One study reported on duration (space closure (Bechtold 2013)). No studies reported on the number of visits.

Patient perception was reported in one study (Lehnen 2011).

Acceptability, economic factors and adverse effects were not reported in any of the studies.

6.1.3 Excluded studies

Summary details are given in the 'Characteristics of excluded studies' section. After examination of full text records we excluded 24 records.

- not truly randomised or not RCT (confirmed following contact with the authors
- surgical anchorage was not included as an intervention (n=6)

- randomisation doesn’t occur between two types of surgical anchorage (n=2)
- split mouth study (Garfinkle 2008) (n=1)
- trial with a single arm (n=1)
- no fixed appliance in the duration of the trial (Schatzle 2009) (n=1)

6.1.4 Studies awaiting classification

No studies are awaiting classification.

6.1.5 Ongoing studies

Summary details are given in the ‘Characteristics of ongoing studies’ section.

We identified five ongoing studies; four studies are comparing surgical anchorage to conventional anchorage (Bearn 2008, Biavati/ Migliorati 2011, Miller 2009, Sandler 2008), and one is comparing two types of surgical anchorage (early and delayed loading of Ortho-system type II implants) (Jung 2007). The number of participants recruited ranges from 45 to 124. All studies are recruiting males and females; one study is recruiting adolescents from 12 to 17 years only (Sandler 2008), two studies are recruiting growing and non-growing participants (Biavati/ Migliorati 2011, Miller 2009); the age of participants in the remaining trials is not stated. Two are three-arm trials comparing mini-screw implants to headgear and transpalatal arches (Bearn 2008, Sandler 2008), and the remaining are two-arm trials comparing mini-screw implants to conventional anchorage. Four of these studies will measure anchorage loss as a primary outcome, it isn't clear if the remaining study will measure this outcome as part of assessing treatment efficacy (Miller 2009). Secondary outcomes include success of anchorage device, PAR index, ABO scores, patient perception, treatment process, soft tissue health, root resorption, bone quality, amount of extraction space closure, angle classification of canines and parallelism of the dental axis.

6.2 Risk of bias in included studies

The overall risk of bias assessments for all the included studies are shown in Figure 22 and Figure 23.

Figure 22: Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

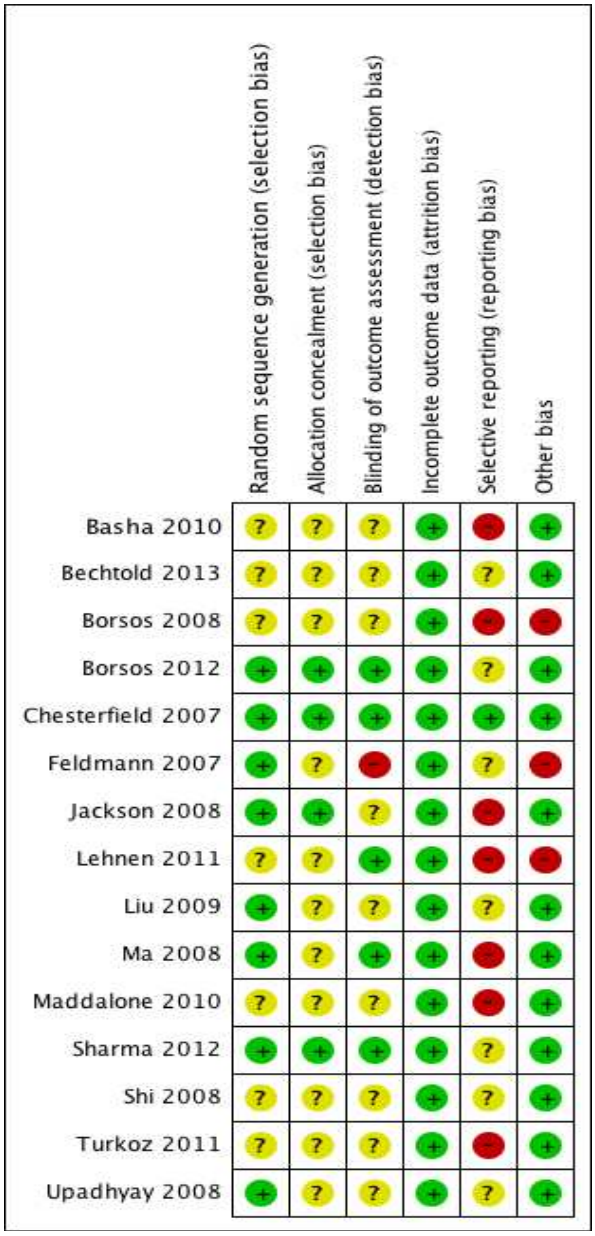
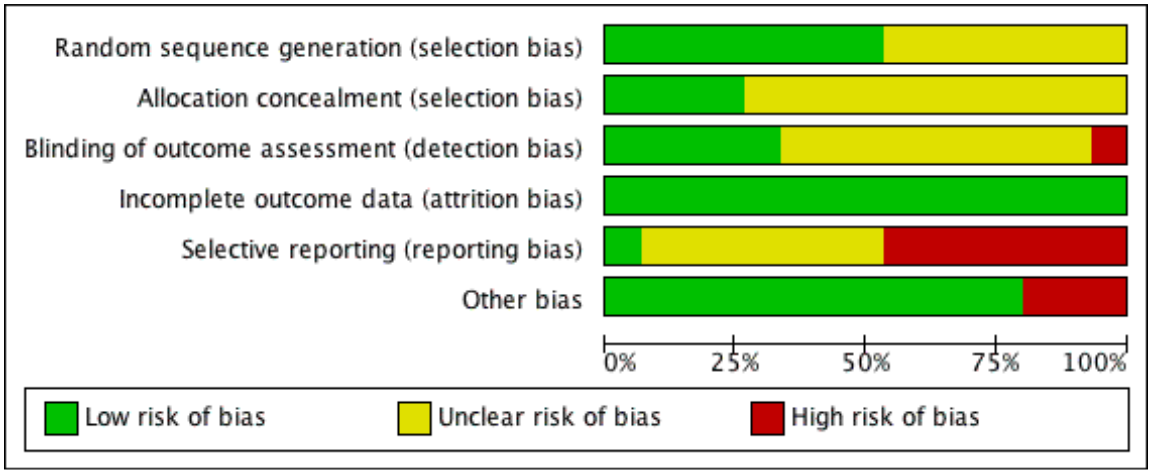


Figure 23: Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Eight studies (Basha 2010, Borsos 2008, Feldmann 2007, Jackson 2008, Lehnen 2011, Ma 2008, Maddalone 2010, Turkoz 2011) were assessed at high risk of bias overall and in six studies (Bechtold 2013, Borsos 2012, Liu 2009, Sharma 2012, Shi 2008, Upadhyay 2008) the overall risk of bias was unclear. One study (Chesterfield 2007) was assessed at overall low risk of bias.

6.2.1 Allocation (selection bias)

Four studies clearly reported the method of sequence generation and allocation concealment (Borsos 2012, Jackson 2008, Chesterfield 2007, Sharma 2012) and were assessed at low risk of selection bias. Four studies clearly reported the method of random sequence generation but allocation concealment was unclear (Feldmann 2007, Liu 2009, Ma 2008, Upadhyay 2008). In seven studies methods of both random sequence generation and allocation concealment were unclear, and these studies were assessed at unclear risk of selection bias.

6.2.2 Blinding (performance bias and detection bias)

It is not always possible to blind the clinician and the patient to the intervention in studies assessing the effects of orthodontic appliances. It is sometimes possible to carry out blinded outcome assessment. We assessed five studies at low risk of detection bias (study level), where the implant type was concealed or obscured (Borsos 2012, Chesterfield 2007, Shrama 2012) and assessment of outcome was carried out by individuals not associated with the study (Chesterfield 2007, Ma 2008, Lehnen 2011, Sharma 2012).

We assessed one study (Feldmann 2007) at high risk of detection bias as the orthodontic appliances were clearly visible in the radiographs being measured.

We assessed nine studies at unclear risk of detection bias due to lack of reporting of methods taken to ensure blinded outcome assessment (Basha 2010, Bechtold 2013, Borsos 2008, Jackson 2008, Liu 2009, Maddalone 2010, Shi 2008, Turkoz 2011) or it was unclear if there was an attempt to mask the intervention on the radiographs (Upadhyay 2008).

6.2.3 Incomplete outcome data (attrition bias)

This domain was assessed on a study level. All fifteen studies were at low risk of attrition bias because either all randomised patients were accounted for or there were a small number of dropouts.

All randomised patients were accounted for in the analysis in nine studies (Basha 2010, Bechtold 2013, Borsos 2008, Borsos 2012, Lehnen 2011, Liu 2009, Ma 2008, Maddalone 2010, Sharma 2012). In six studies the number of post randomisation drop outs was small and/or unrelated to the intervention or the outcome (Jackson 2008, Chesterfield 2007, Feldmann 2007, Shi 2008, Turkoz 2011, Upadhyay 2008).

6.2.4 Selective reporting (reporting bias)

We were able to locate a published protocol for only one study (Chesterfield 2007) study. All intended outcomes were reported in the full trial paper except for 'inflammation of the peri-implant tissues'. Correspondence with the authors confirmed that this was a change from protocol and this outcome was not measured. We assessed this study as low risk of reporting bias.

We assessed five studies at high risk of reporting bias through lack of reporting of the primary outcome of this review (Borsos 2008, Jackson 2008, Ma 2008, Lehnen 2011, Turkoz 2011). In four of these studies, the objective of the trial was not to investigate the effects on anchorage, but to provide alternatives in the way they are used clinically (Borsos 2008, Jackson 2008, Lehnen 2011, Turkoz 2011). Two studies (Basha 2010, Maddalone 2010) assessed at high risk of reporting bias incompletely reported the molar movement outcome (standard deviations omitted). We did not consider incomplete reporting of secondary outcomes as a criterion for an assessment of high risk of reporting bias (Borsos 2008, Feldmann 2007, Lehnen 2011, Upadhyay 2008).

We could not locate published protocols for seven studies (Bechtold 2013, Borsos 2012, Feldmann 2007, Liu 2009, Sharma 2012, Shi 2008, Upadhyay 2008); these were assessed at unclear risk of reporting bias.

6.2.5 Other potential sources of bias

Two studies were assessed at high risk of other potential sources of bias due to the use of restricted randomisation in unblinded studies conducted in single centres. Two single centre studies used fixed-size block randomisation with a relatively small block size of 4 to 6 (Borsos 2008, Feldmann 2007) and unclear methods of allocation concealment. In such instances, it is possible to predict future treatment allocation with relative accuracy.

One study (Lehnen 2011) was assessed at high risk of other potential sources of bias due to differences in the methods of pain relief (injection techniques) given in the same appointment.

In all other studies included in this review no other potential sources of bias were identified.

6.3 Effects of interventions

For the purposes of analysis, the comparisons were as follows:

- Trials comparing surgical anchorage to conventional anchorage
- Trials comparing two types of surgical anchorage (head to head trials)

Table 37 lists the presence or absence of the outcomes reported in the primary studies that are relevant to this review.

6.3.1 Comparison of surgical anchorage to conventional anchorage

Ten studies with 407 randomised and 390 analysed patients compared a type of surgical anchorage to a type of conventional anchorage (Basha 2010, Borsos 2012, Chesterfield 2007, Feldmann 2007, Liu 2009, Ma 2008, Maddalone 2010, Sharma 2012, Shi 2008, Upadhyay 2008). Summary results are presented in the Summary of findings Table 36.

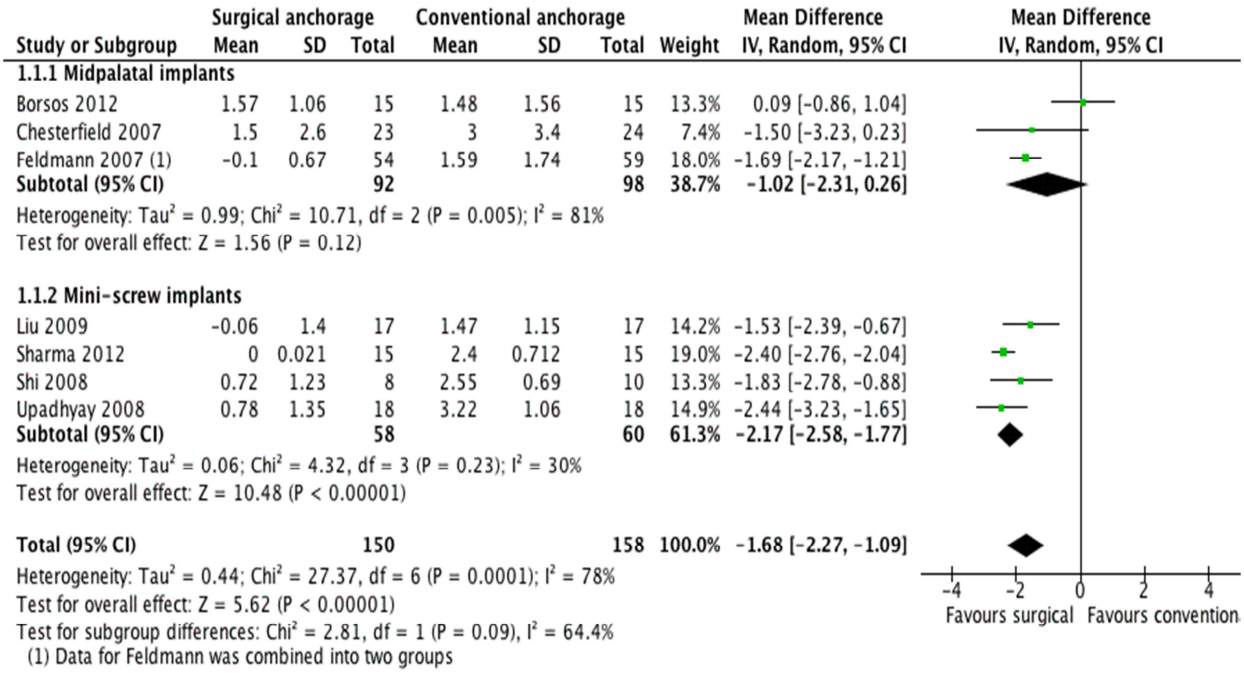
6.3.1.1 Primary outcome:

6.3.1.1.1 Mesiodistal movement of the upper first molar teeth

Seven studies (Borsos 2012, Chesterfield 2007, Feldmann 2007, Liu 2009, Sharma 2012, Shi 2008, Upadhyay 2008) with 308 analysed patients were included in a random effects meta-analysis of surgical anchorage versus conventional anchorage for mesiodistal movement of upper first molar teeth (Figure 24). The conventional anchorage methods

included headgear, transpalatal arches, banding of second molars and application of differential moments. There was strong evidence in favour of surgical anchorage for this outcome, with an overall mean difference of -1.68 (mm) in molar movement (MD -1.68; 95% CI -2.27 to -1.09). There was a substantial amount of heterogeneity (Chi^2 = 27.37, df = 6, P = 0.001; I^2 = 78%). The range of effects within the confidence interval comprised only beneficial effects of surgical anchorage of clinical importance. However these results should be interpreted with caution due to the high level of heterogeneity.

Figure 24: Forest plot of comparison: 1 Surgical anchorage versus conventional anchorage, outcome: 1.1 Mesiodistal movement of the upper first permanent molar



We then analysed according to type of surgical intervention. For midpalatal implants (3 studies, 190 patients analysed) there was an overall mean difference of -1.02 mm in molar movement favouring surgical anchorage (MD -1.02; 95% CI -2.31 to 0.26 mm; Chi^2 = 10.71, df = 2, P = 0.005; I^2 = 81%); for the mini-screw implants (4 studies, 118 patients analysed) there was an overall mean difference of -2.17 mm in molar movement favouring

surgical intervention (MD -2.17; 95% CI -2.58 to -1.77; $Chi^2 = 4.32$, df = 3, P = 0.23; $I^2 = 30\%$).

We were unable to include three studies in the meta-analysis due to Incomplete reporting of this outcome (Ma 2008, Maddalone 2010, Basha 2010). Two of these studies (Basha 2010, Maddalone 2010) did not report standard deviations for the surgical implant arm of the trial. Both studies reported in favour of surgical anchorage for mesiodistal movement of the upper first molar. The mean anchorage loss was 1.73 mm (sd 0.43) in the conventional anchorage group; 0mm in the surgical anchorage (mini-screw) group (Basha 2010). One study (Ma 2008) did not report mesiodistal movement.

6.3.1.2 Secondary outcomes

6.3.1.2.1 Success of anchorage device

Five studies reported on the success of surgical anchorage compared to conventional anchorage (Basha 2010, Chesterfield 2007, Feldmann 2007, Maddalone 2010, Upadhyay 2008). The number of successes, definition of success and the types of anchorage devices used in each of these studies is summarised in Table 38. . Due to the variability in definition of this outcome measure and incomplete outcome reporting we did not pool the results of these studies.

Table 38: Success of surgical appliances

Study	Type of anchorage device	Definition of success/failure	Success rate
Basha 2010	Mini-implants	Loosening of the mini-screw implants and subsequently replaced	71.43% (10/14)
	Transpalatal arch	Success not measured	N/A
Chesterfield 2007	Orthosystem midpalatal implant	Orthodontic failure: failure after orthodontic loading, patients did not end up with implant-assisted anchorage	91.30% (21/23)
	Headgear	Patient did not end up with headgear/headgear did not provide sufficient anchorage	87.50% (21/24)
Feldmann 2007	Nobel-Biocare onplant	Successful anchorage comprises anchorage loss of less than 1 mm, no failures of osseointegration or failures during anchorage system placement, and no dropouts after the treatment started	82.76% (24/29)
	Orthosystem midpalatal implant		93.33% (28/30)
	Headgear		46.67% (14/30)
	Palatal arch		27.59% (8/29)
Maddalone 2010	Mini-screw implant	Loosening of the mini-implant	84.21% (16/19)
	Elastomeric chains or Niti springs	Success not measured	N/A
Upadhyay 2008	Mini-screw implant	Success: Complete stability throughout the retraction phase Failure: loose and subsequently replaced	93.05% (67/72)
	Conventional anchorage	Success not measured	N/A

Two studies provided complete data to compare the success of surgical anchorage to that of conventional anchorage (Chesterfield 2007, Feldmann 2007). The results of these studies were not pooled due to substantial clinical differences in definitions of success of the anchorage devices but are reported as a narrative (Table 38). In the first study (47

patients analysed), success of anchorage device was high in both study arms, with a 91% success rate for surgical anchorage and 88% success rate for conventional anchorage (Chesterfield 2007). With surgical anchorage (Orthosystem midpalatal) reasons for failures were failure after orthodontic loading, patients did not end up with implant-assisted anchorage. With conventional anchorage (headgear) reasons for failures were patients did not end up with headgear or headgear did not provide sufficient anchorage. In the second study (118 patients analysed) the proportion of successful outcomes was greater in the combined surgical anchorage groups than the combined conventional anchorage groups (Feldmann 2007). Reasons for failure with surgical anchorage (Nobel Biocare onplants and Orthosystem implants) were failure of osseointegration, technical problems with the implants, discontinuation of treatment due to poor oral hygiene and anchorage loss more than 1mm. Reasons for failure with conventional anchorage (headgear and palatal arches) were anchorage loss of more than 1 mm, patients discontinued headgear or headgear did not provide sufficient anchorage.

Three studies reported the success of the surgical anchorage arm of the study only (Basha 2010, Maddalone 2010, Upadhyay 2008) again with variability in definitions of success/ failure.

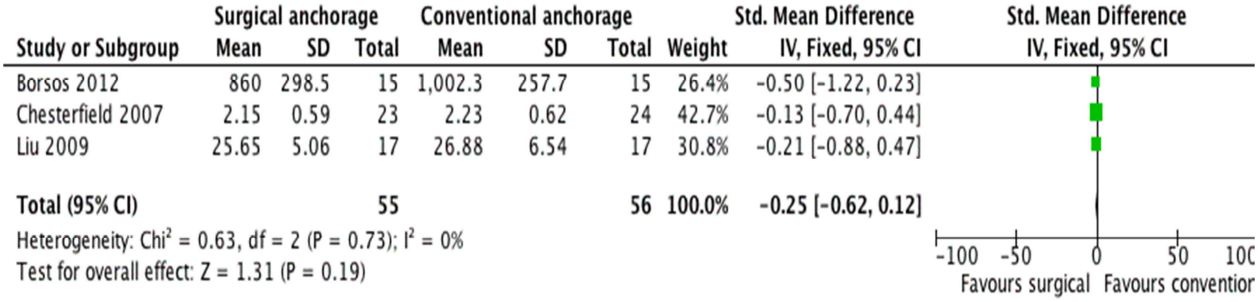
Five studies did not report this outcome (Borsos 2011, Liu 2009, Ma 2008, Sharma 2012, Shi 2008).

6.3.1.2.2 Duration of active treatment

The duration of the complete course of orthodontic treatment was reported in three studies (Borsos 2012, Chesterfield 2007, Liu 2009) with 111 analysed patients. The mean duration of active treatment was reported differently in the three studies; in days (Borsos 2012), months (Liu 2009) and years (Chesterfield 2007). Results of a fixed effect meta-

analysis of overall treatment time (Figure 25) indicated that treatment time was 0.25 standard units shorter on average with surgical anchorage than conventional anchorage (SMD -0.25; 95% CI -0.62 to 0.12). Heterogeneity was negligible for this comparison (Chi^2 = 0.63, df = 2; P = 0.73; I^2 = 0%). We re-expressed the mean difference in years using the summary standard deviations of the Chesterfield study for interpretation; overall treatment time was 0.15 years shorter with surgical anchorage than conventional anchorage (-0.15 years; 95% CI = -0.37 years to 0.07 years). The range of effects contained within the confidence interval include both no effect of the intervention and some effect. There was not strong evidence that surgical anchorage reduced treatment time compared with conventional anchorage.

Figure 25: Forest plot of comparison: 1 Surgical anchorage versus conventional anchorage, outcome: 1.3 Duration of overall treatment.

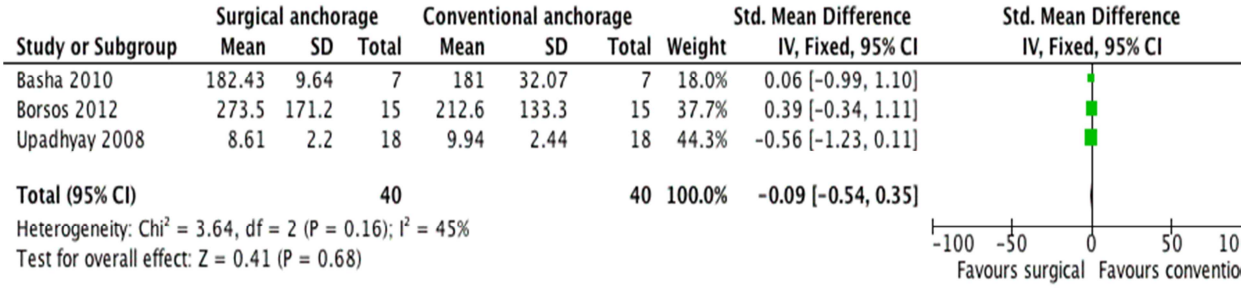


6.3.1.2.3 Duration of space closure

The duration of space closure was reported in three studies (Basha 2010; Borsos 2012; Upadhyay 2008) with 80 analysed participants. The mean duration of space closure was reported differently in the three studies; in days (Basha 2010, Borsos 2012) and months (Upadhyay 2008). Results of a fixed effect meta-analysis (Figure 26) indicated that duration of space closure was 0.09 standard units shorter with surgical anchorage than conventional anchorage (SMD -0.09; 95% CI -0.54 to 0.35). There was a moderate amount of heterogeneity for this outcome (Chi^2 = 3.64, df = 2; P = 0.16; I^2 = 45%). We re-

expressed the standardised mean difference in days using the summary standard deviations of the Borsos 2012 study for interpretation; time to space closure was 12 days shorter with surgical anchorage than conventional anchorage (-12 days; 95% CI = -72 days to 47 days). The range of effects contained within the confidence interval include both no effect of the intervention and some effect. There was not strong evidence that surgical anchorage reduced time to space closure compared with conventional anchorage.

Figure 26: Forest plot of comparison: 1 Surgical anchorage versus conventional anchorage, outcome: 1.4 Duration of space closure



6.3.1.2.4 Number of visits

One study (Chesterfield 2007) with 47 analysed patients reported the number of visits taken to complete the course of orthodontic treatment. This did not include the time taken for surgical placement and osseointegration of the midpalatal implants. The mean number of visits required to complete orthodontic treatment was 26.21 (sd 7.41) for surgical anchorage and 19.2 (sd 4.58) for conventional anchorage. On average 7 visits less were needed to complete orthodontic treatment with conventional anchorage than with surgical anchorage (MD 7.01, 95% CI 10.70 to 3.31).

6.3.1.2.5 Patient perception

Pain

Patient reported pain during anaesthetic injection, following surgery or extraction, in the evening after surgery/ extraction and one week following surgery or extraction in relation to the anchorage device was reported by one study (Feldmann 2007). The results of the VAS for pain are summarised in Table 39. 'The first evening after the intervention, groups A [surgical anchorage] (P .002) and [conventional anchorage] (P .007) had significantly more pain intensity compared to group [surgical anchorage]. The difference in pain intensity between onplant installation and premolar extraction was nonsignificant. One week after the interventions, pain intensity was still significantly higher in group C [conventional anchorage] compared to group [surgical anchorage], which had undergone installation of an Orthosystem implant (P .001). Differences between groups A [surgical anchorage] and [surgical anchorage] were nonsignificant.'

Table 39: Pain perception reported by the Feldmann 2007 study*

	Pain during anaesthetic injection Median(range)	Pain during surgery/extraction Median(range)	Pain on the evening after surgery/extraction Median(range)	Pain 1 week after surgery/extraction Median(range)
Nobel-Biocare Onplant	15 (0-72)	3 (0-14)	38 (0-100)	3 (0-13)
Orthosystem implant	16 (0-84)	3 (0-16)	5 (0-90)	0 (0-5)
Extraction group (headgear and palatal arch)	10 (0-55)	4 (0-28)	28 (0-100)	5 (0-50)

*Pain was self reported on a VAS from 0 to 100 with 'no pain' and 'worst imaginable pain' at the end points of the scale

Self-reported questionnaires assessing patient reported pain on VAS from 0 to 100 were also administered throughout orthodontic treatment (from start of treatment until the first visit after retention). Pain in the three anchorage groups peaked on day 2 after the start of treatment. Values for medians and interquartile ranges were as follows: 46.0 (16.0-76.5) for the surgical anchorage group, 43.8 (14.3-62.3) for headgear and 57.0 (34.5-72) for palatal arches.

Discomfort

Discomfort in relation to the anchorage device was reported in two studies (Feldmann 2007, Chesterfield 2007) with 113 and 47 patients analysed.

When discomfort was assessed in relation to placement of the anchorage device (Feldmann 2007), the results followed a similar pattern to the pain assessed in the same study. The most severe discomfort was experienced on the evening after surgery with the Nobel-Biocare onplants (median 33, range 0 to 96) and the evening after extractions (median 21, range 0 to 88). There was still a degree of discomfort with the Orthosystem midpalatal implants the evening after surgery (median 14, range 0 to 98), however the most severe discomfort experienced with this type of anchorage was during the anaesthetic injection (median 22, range 0-96). The results of the VAS for discomfort are summarised in Table 40.

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Table 40: Discomfort reported by the Feldmann 2007 study*

	Discomfort during anaesthetic injection Median(range)	Discomfort during surgery/extraction Median(range)	Discomfort on the evening after surgery/extraction Median(range)	Discomfort 1 week after surgery/extraction Median(range)
Nobel-Biocare Onplant	17 (0-93)	7 (0-60)	33 (0-96)	5 (0-49)
Orthosystem implant	22 (0-96)	13 (0-84)	14 (0-98)	0 (0-7)
Extraction group (headgear and palatal arch)	13 (0-59)	7 (0-50)	21 (0-88)	3 (0-26)

* Discomfort was self reported on a VAS from 0 to 100 with 'no discomfort' and 'worst imaginable discomfort' at the end points of the scale, data was extracted from graphs

Discomfort was also assessed throughout orthodontic treatment on self-reported questionnaires assessing discomfort on VAS from 0 to 100. Discomfort, expressed as tension from jaws and teeth and soreness from the appliance in the three anchorage groups peaked on day 2 (no data reported).

In the Chesterfield 2007 study, patients randomised to receive implants were asked to indicate through self-reporting questionnaire the grade they would assign to the surgery from 1 (totally comfortable) to 6 (very uncomfortable), immediately after implant placement and on removal of the implant. '75% of the respondents scored between 4 and 6—i.e. at the comfortable end of the scale for implant placement—and no patient scored 1, indicating that the placement of implants was generally acceptable.' These results were repeated over the first three days. On implant removal '40% scored 5, 40% scored 3, and

20% scored 1, indicating that implant removal was slightly less comfortable than implant placement.

6.3.1.2.6 Patient acceptability

One study (Feldmann 2007) reported on patient acceptability in terms of limitations to activities of daily life. The study narratively reported that 'Limitations in daily life and jaw function were throughout the trial low to moderate and with no differences between anchorage groups.' In terms of the impact of orthodontic treatment on the patient's mood and appearance the study further reported 'Assessment of how much orthodontic treatment affected the patient’s mood and appearance peaked at the first rescheduled visit after 6 weeks (overall median = 14.0; median = 99.0) and with no differences between groups.'

6.3.1.2.7 Other secondary outcomes

Residual overjet, adverse effects and economic factors were not reported by any of the included studies.

6.3.2 Comparison of two types of surgical anchorage

6.3.2.1 Primary outcomes:

The primary outcome of mesiodistal movement of molars was reported in only one study (Bechtold 2013) with 25 patients analysed, which reported a mean difference of 1.62 mm (MD 1.62 mm; 95% CI = 0.98 to 2.26) in favour of dual mini-screw implants over single mini-screw imlants.

6.3.2.2 Secondary outcomes:

6.3.2.2.1 Success of early versus delayed loading

Two studies with thirty six patients analysed compared successful between early and delayed loading of mini-screw implant anchorage (Borsos 2008, Jackson 2008). Rates of success were high; all 16 implants (in 16 patients) were successful whether they were early or delayed loaded (Borsos 2008); loading was successful for 9 out of 10 patients in

the early loaded group, and 9 out of 10 patients in the delayed loaded group (Jackson 2008).

6.3.2.2.2 Success of pre-drilled versus self-drilling implants

One study with 62 patients (112 implants) compared success of pre-drilled versus self-drilling implants (Turkoz 2011). Results were reported at the implant level with similar proportion of successes in the two groups (26/34 successes with the self-drilling implants and 67/78 successes with the pre-drilled implants; RR 1.12; 95% CI 0.91 to 1.38). This CI result should be interpreted with caution as results are reported on an implant level rather than a patient level and therefore subject to unit of analysis error.

6.3.2.2.3 Success of single versus dual mini-screw implants

One study with 25 patients (76 implants) compared success of single versus dual mini-screw implants (Bechtold 2013). Results were reported at the implant level with similar proportion of successes in the two groups (21/42 successes with the single mini-screw implants and 45/52 successes with the dual mini-screw implants; RR 1.01; 95% CI 0.84 to 1.22). This CI result should be interpreted with caution as results are reported on an implant level rather than a patient level and therefore subject to unit of analysis error

6.3.2.2.4 Duration of space closure

A single study (Bechtold 2013) compared duration of space closure with single versus dual mini-screw implants. Space closure (months) was quicker on average by just over two months in the single mini-screw implant group than the dual mini-implant group (MD -2.19 months; 95% CI -6.35 to 1.97), though this was not statistically significant.

6.3.2.2.5 Patient perception

Pain

A single study (Lehnen 2011) with 30 analysed patients compared patient pain perception between pre-drilling and self-drilling mini-screw implants. Patients were asked: 'How

would you describe the pain on insertion', and a response was collected on a scale from 0-4, where 0 indicates no pain and 4 indicates a high level of pain. On average, self-reported pain was lower for patients in the pre-drilling group (n = 15, mean 0.73, sd 1.1, median 0.00 (range 0 to 3) compared to patients in the self-drilling group (n = 15, mean value 1.87, sd 1.13, median 2.0, range 0 to 4).

6.3.2.2.6 Other outcomes

The outcomes of residual overjet, duration of space closure, number of visits, adverse effects and economic factors were not reported by these studies.

7 Discussion

7.1 Summary of main results

This is a substantial update with an additional fourteen studies added to the single study of the initial review published in 2008.

7.1.1 Comparison of surgical anchorage to conventional anchorage

Mesiodistal movement of upper molar teeth

The last published version of this review included only one study and the results were inconclusive. The small amount of information available to compare surgical anchorage (midpalatal implant) with conventional anchorage did not indicate that the mesiodistal movement of the upper first permanent molar differed in the two groups.

The results from this updated review indicate that there is some evidence that surgical methods of reinforcing orthodontic anchorage are more effective than conventional methods, such as headgear and other intra oral devices in reinforcing anchorage during orthodontic brace treatment. The pooled mean difference in mesiodistal movement was 1.68 mm and whilst this difference may seem small, it is clinically significant. This is also important when we consider that there are published reports of risk with the use of extra

oral devices. As a result, the use of surgical anchorage has clear advantages over other methods of reinforcing anchorage.

Since the development of the protocol for this review current practice has moved towards the adoption of specific types of surgical anchorage, the most common of which is the mini-screw implants. Hence a post hoc subgroup analysis was undertaken to further investigate the effects of different individual types of surgical anchorage; midpalatal implants and mini-screw implants. Whilst the overall effects favoured surgical anchorage for both subgroups the mean difference in mesiodistal movement was smaller, and thus more favourable, for mini-screw implants than conventional anchorage (headgear and palatal arches).

Secondary outcomes

The effects on secondary outcomes of the review were less certain due to limited reporting of these outcomes and variability in clinical definitions of outcomes, which precluded synthesis. Both methods of anchorage were successful. There was very little evidence of patient reported outcomes such as pain discomfort and acceptability. Importantly, no studies reported on residual overjet at the end of treatment, adverse effects and economic factors.

7.1.2 Comparison of two types of surgical anchorage

The direct comparisons of surgical interventions were two small studies of early and delayed loading of the same mini-screw implants and a single small study comparing pre-drilling and self-drilling mini-screw implants and a single study comparing single and dual mini-screw implants. Results from these studies did not indicate that proportion of successes of the implant between early and delayed loading, or single and dual implants

was different. In the single study comparing pre-drilling and self-drilling mini-screw implants, the only outcome relevant to this review was patient perception.

Only one study reported on the primary outcome of movement of the upper first molar in a mesial or distal direction, and one study reported on the duration of space closure. no studies reported on the residual overjet at the end of treatment. Duration of active treatment, residual overjet, number of visits, acceptability, economic factors and adverse effects were not reported in any of the studies.

7.2 Overall completeness and applicability of evidence

The primary objective of the review was to assess the effects of surgical anchorage techniques compared to conventional anchorage in the prevention of unwanted tooth movement in orthodontic patients, by evaluating the mesiodistal movement of upper first molar teeth. Ten studies, conducted principally in a dental hospital setting, in locations across Europe, Asia and the USA contributed information to the evaluation of this outcome. Participants were adolescents, younger and older adults. The overall risk of bias for the included studies was high or unclear, with only one study assessed as low risk of bias. The pooled estimate of effect showed a mean difference in favour of surgical anchorage, of clinical importance. However this result should be interpreted with caution due to the associated high level of heterogeneity of the pooled studies, and the inclusion of only mini-screw and midpalatal implants as surgical interventions.

A secondary objective was to compare the effects of one type of surgical anchorage with another, and this was assessed in five studies where applicability of the evidence to the review question was good. The overall risk of bias for the included studies this objective was high or unclear. The surgical interventions were diverse and this precluded the calculation of a pooled estimate of effect.

Whilst the updated review comprised fifteen included studies the amount of information contributing to the primary and secondary outcomes varied substantially, and hence only the effects of the primary outcome mesiodistal movement for surgical anchorage techniques compared to conventional anchorage techniques can be estimated with any degree of certainty. The implications of this finding are discussed further in the sections ‘Impications for practice’ and ‘Implications for research’.

7.3 Quality of evidence

See Figure 22, Figure 23, Summary of findings Table 36.

We assessed the studies in this review at varying risks of bias. The evidence for the main outcomes of mesiodistal movement, duration of treatment and adverse events were from included studies at overall high and unclear risk of bias. Only one small study was assessed at overall low risk of bias. The quality of the evidence was moderate for the main primary outcome, due to limitations in the design and conduct of the studies. We assessed the quality of evidence for the additional primary outcome of duration of treatment as low, due to limitations in design and conduct of the studies and to imprecision of results from the two small studies providing data for this outcome. No information on the remaining primary outcome, adverse events, was reported.

Selective reporting was evident for many of the included studies; expected cephalometric and clinical outcomes were not reported or were reported incompletely. Where possible we contacted the authors for additional information on aspects of study design or outcome data. Any additional information obtained was included in the review.

Orthodontic treatment is a long and sometimes painful process. The number of studies reporting patient reported outcomes of relevance to the review such as pain and acceptability was small and the quality of the reported outcomes was poor. This is a definite limitation to the review.

7.4 Potential biases in the review process

We found it difficult to agree a single appropriate end point to measure anchorage loss a-priori (see 'Implications for research' section). In addition, the subgroup analysis which looked at the effects of different types of surgical anchorage compared to conventional anchorage was not pre-determined, but driven by the type of studies found. The results of this post-hoc should be interpreted with caution.

We decided not to pool the results of outcomes with different clinical definitions e.g. success of anchorage, but to present the results of the individual studies narratively.

7.5 Agreements and disagreements with other studies or reviews

The results of this review are in agreement with other systematic reviews on the topic with less rigorous methodology. The inclusion criteria for these reviews has often included a large variation in study design including retrospective studies. These reviews either assessed a variety of surgical anchorage devices or were specifically interested in mini-screw implants. The most common outcome investigated in these reviews was the success or failure of the anchorage device, followed by anchorage loss (molar movement). Mini-screw implants were found to have success rates of 83.3% [167], 87.7% [168], 86.5% [169] and 61-100% [170]. Mini-plates and palatal implants had success rates of 91.4-100% and 74-93.3% respectively. In addition the Li 2011 review reported more distal movement with the midpalatal implants, onplants and mini-screw implants [171]. Reported anchorage loss was also in agreement with this review. The mean difference in

distal molar movement favoured mini-screw implants over conventional anchorage in the Papadopoulos 2011 review (MD -2.4 mm; 95% CI -2.9 to -1.8) [168].

8 Authors' conclusions

8.1 Implications for practice

The last published version of this review included a single study and concluded that the objectives of the review were not met because little evidence was identified for assessment. It was also suggested that midpalatal implants may be an acceptable alternative to headgear reinforced anchorage in orthodontic anchorage.

From this update there is some evidence of moderate quality to suggest that surgical anchorage is more effective than conventional anchorage in the reinforcement of anchorage during orthodontic brace treatment, and that results from mini-screw implants are particularly promising. Importantly, surgical anchorage is not associated with the inherent risks and compliance issues related to headgear.

8.2 Implications for research

Current evidence on the effectiveness of surgical anchorage is based on randomised trials with varying level of bias. In particular methods to reduce the potential for selection bias should be undertaken and reported. Only two of the included studies (Chesterfield 2007; Feldmann 2007) reported calculating the sample size. Future research should ensure that an adequate sample size is achieved.

A wide age range of patients could possibly benefit from surgical anchorage. However including a wide age range in a single study is discouraged because it is known that growing patients respond differently to orthodontic treatment when compared to non-

growing patients. In addition, studies should address both patient and clinician acceptability of the surgical appliances, as important changes to policies can be made as a result of such trials. These could include adding this type of treatment to the syllabus of training orthodontists and/or providing this treatment as part of government or insured healthcare.

Outcomes should consider an appropriate start and end point to measure molar movement as a function of assessing orthodontic anchorage. It was difficult to agree an appropriate end point for measurement of anchorage loss before undertaking the review; a decision was made to use the most common end point(s). Anchorage control is required in all phases of orthodontic treatment and this was reflected in the end points reported in the studies of this review. Points at which anchorage loss was measured included the end of the levelling and alignment phase, end of space closure (including and/or excluding the previous alignment phase), end of anchorage (when the anchorage device was no longer needed) and the end of treatment. A consensus on the most important end point could possibly be achieved by conducting qualitative research; this could be part of an overall design to reach a consensus on outcomes relevant to anchorage devices. Important considerations would be clinical relevance of the end point, an occasion when the biggest difference is likely to occur and/or the objectivity of the end point. For example, choosing 'end of anchorage' as an end point is likely to be the point where maximum movement of the molars is achieved, however it is somewhat a subjective time point. Conversly, the end of treatment is a more objective time point, however the effects of the anchorage devices may be neutralised or further reinforced in an attempt to achieve the ideal occlusion at the end of treatment.

Also studies should focus on relevant outcomes rather than reporting routine cephalometric analysis. Studies included in this review and ongoing studies reported a

variety of relevant outcomes. A single study would need large resources and adequate time to investigate all relevant outcomes and time points, therefore it is recommended that a consensus be agreed on the most important outcomes and how they may be investigated and reported. Areas for research include determining the best size and shape of the implant, as well as the type of material to use. Other areas of comparison are immediate versus delayed and static versus dynamic loading. It is also important to assess patient perception and acceptability. Appropriate outcomes from such research should include anchorage loss, failure rates, financial costs and assessment of discomfort and related quality of life issues. The outcome of success poses a particular challenge when comparing surgical and conventional anchorage. This was previously discussed in a related Cochrane review [157]. It is difficult to find a definition for success that applies to both the surgical and conventional anchorage. The recommendation is to define success according to treatment objectives. For example an appliance would be successful in orthodontic anchorage if it achieves at least no loss of anchorage (0 mm molar movement) or gain of anchorage (distal molar movement).

9 Characteristics of studies

9.1 Characteristics of included studies

Table 41: Characteristics of Basha 2010 study

Basha 2010 [172]	
Methods	• Trial Design: Single Centre RCT (parallel group) • Location: Department of Orthodontics and Dentofacial Orthopedics at JSS Dental College and Hospital, Mysore, Karnataka, India • Recruitment period: not stated • Funding source: not stated • Source of Participants: Patients attending Clinic • Study Duration: not stated • Time points at which follow-up are reported: before retraction of the incisor segment, after retraction of the incisor segment
Participants	• 14 female participants in total, mean age 16 years (SD 1.41) • 7 in mini-implant group • 7 in transpalatal arch group • Inclusion criteria: 1. No systemic disease 2. Minimum age 13 years at the beginning of treatment 3. No congenitally missing teeth except third molars 4. Midlines matching 5. No spacing, mild or no anterior crowding in maxillary arch 6. Maximum anchorage required 7. Extraction of first premolars required 8. Patients with bimaxillary protrusion and ANB of 2-4 degrees
Interventions	• **Comparison 1: Mini-implants (SK Surgical,Pune, India)** 1. Surgical steel, self-drilling mini-implants 2. Length: 8.0 mm, diameter: 1.3 mm 3. Placed between the roots of the first molars and second premolars in the upper arch 4. Immediately loaded with elastomeric chain with a force of 2N. • **Comparison 2: Transpalatal arch** 1. Attached to molars
Outcomes	1- Anchorage loss measured by mesial molar movement • measured in mm on cephalometric radiographs by

	calculating the difference in the distance between pterygoid vertical to maxillary molar • measured from the start of space closure until the end of space closure 2- Success of mini-implants (Loosening of the mini-screw implants and subsequently replaced) 3- Time for space closure (retraction time period) in days
Notes	A pre-adjusted edgewise appliance with a MBT prescription and a 0.022 X 0.028 inch slot was used.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: 'A comparative study consisting of 14 patients (all females) randomised into 2 groups' Comment: Insufficent information about the sequence generation process to permit judgement.
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not addressed.
Blinding of outcome assessment (detection bias)	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias)	Low risk	All randomised patients were accounted for in the analysis
Selective reporting (reporting bias)	High risk	• Selective reporting of outcomes: Insufficient information to permit judgement, • Selective reporting of data: incomplete reporting of the molar movement outcome for the mini-implant group, the mean was present without the standard deviation.
Other bias	Low risk	

Table 42: Characteristics of Bechtold 2013 study

Bechtold 2013 [173]	
Methods	• Trial Design: Single Centre RCT (parallel group) • Location: Orthodontic Department at Yonsei University Dental Hospital, South Korea • Recruitment period: not stated • Funding source: not stated • Source of Participants: Patients attending Clinic • Study Duration: not stated • Time points at which follow-up are reported: T0: before retraction of the anterior segment, T1: after retraction(end of space closure)
Participants	• 25 participants in total • 12 in single mini-screw implant group: mean age 23.58 years (SD 6.92), 1 male, 11 female • 13 in dual mini-screw implant group: Mean age 22.92 (SD7.1), 2 male, 11 female • Inclusion criteria: 1. Adult individuals with normal or mild skeletal 2. Class II skeletal relationship 3. No significant craniofacial defects or asymmetries 4. Intact maxillary permanent dentition including second molars 1. Moderate Class II occlusion Minimal crowding (<3 mm) in the maxilla
Interventions	• **Comparison 1: Mini-screw implants (single)** 1. 7.0 mm in length, 1.8 mm in coronal diameter, and with a tapered body (Orlus 18107, Ortholution, Seoul, Korea) 2. Inserted between the maxillary second premolar and first molar • **Comparison 2: Miniscrew implants (dual)** 1. 7.0 mm in length, 1.8 mm in coronal diameter, and with a tapered body (Orlus 18107, Ortholution, Seoul, Korea) 2. Inserted between the maxillary second premolars and first molars 1. Additional miniscrews were placed between the maxillary first and second premolars
Outcomes	• Distal movement in mm was measured on lateral cephalometric radiographs: perpendicular from the VR (a line perpendicular to the occlusal plane) to the distal cusp tip of the

	upper first molar; differences between T0 (before canine retraction) and T1 (after canine retraction) were calculated • Duration of treatment in months from start of canine retraction to the end of canine retraction
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: 'Subjects were randomly allocated to either group A …. or group B' Comment: Insufficient information about the sequence generation process to permit judgement.
Allocation concealment (selection bias)	Unclear risk	Not addressed
Blinding of outcome assessment (detection bias)	Unclear risk	Not addressed
Incomplete outcome data (attrition bias)	Low risk	All randomised patients were accounted for.
Selective reporting (reporting bias)	Unclear risk	• Selective reporting of outcomes: Insufficient information to permit judgement, (no protocol) • Selective reporting of data: no suggestion of incomplete reporting of data
Other bias	Low risk	Study appears to be free of other sources of bias

Table 43: Characteristics of Borsos 2008 study

Borsos 2008 [174]	
Methods	• Trial Design: Single Centre RCT (parallel group) • Location: Semmelweis University, Budapest, Hungary • Recruitment period: not stated • Funding source: not stated • Source of Participants: Patients attending Clinic • Study Duration: not stated • Time points at which follow-up are reported: at the end of orthodontic treatment
Participants	• 16 participants in total, mean age 14.22 +/- 1.37 years • 8 in the immediate loading group: mean age 14.15 +/- 1.2 years, 5 males and 3 females • 8 in the conventional loading group: Mean age 14.3 +/- 1.6 years, 3 males and 5 females • Inclusion criteria: 2. Dentoalveolar malocclusion requiring premolar extraction 3. Maximum anchorage 4. Ongoing skeletal growth 5. Adequate bone in the implant bed 6. No relevant underlying disease
Interventions	• **Comparison 1: Immediately loaded midpalatal implant (Orthosystem, Straumann, Basle, Switzerland)** 1. Internal diameter of 3.8mm, external diameter of 4.1mm, length 4mm. 2. Inserted by an oral and maxillofacial surgeon 3. Loaded within 72 hours with a custom made, 1.2 X 1.2 mm transpalatal arch, attached to molar bands. • **Comparison 2: Conventional loaded midpalatal implant (Orthosystem, Straumann, Basle, Switzerland)** 2. Internal diameter of 3.8mm, external diameter of 4.1mm, length 4mm. 3. Inserted by an oral and maxillofacial surgeon 4. A non-loaded spacer was applied after implantation 5. Loaded after 12 weeks with a custom made, 1.2 X 1.2 mm transpalatal arch, attached to molar bands.
Outcomes	• Success of anchorage device (all implants remained stable

	throughout treatment)
Notes	The main outcome of this study was the histologic evaluation of the bone-implant contact after treatment.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: 'The patients were randomly assigned to treatment groups in groups of four at a 1:1 ratio' Comment: Insufficient information about the sequence generation process to permit judgement.
Allocation concealment (selection bias)	Unclear risk	Not addressed.
Blinding of outcome assessment (detection bias)	Unclear risk	Not addressed
Incomplete outcome data (attrition bias)	Low risk	All randomised patients were accounted for
Selective reporting (reporting bias)	High risk	• Selective reporting of outcomes: anchorage loss was not an objective of this study; however it would have been an expected outcome in this type of study • Selective reporting of data: no data on the pain and discomfort, the results were reported narratively and for the sample as a whole.
Other bias	High risk	Fixed size blocks were used in a small single centre unblinded trial. This may make it possible to predict future assignments

Table 44: Characteristics of Borsos 2012 study

Borsos 2012 [175, 176]	
Methods	• Trial Design: Single centre RCT (parallel group) • Location: Orthodontic department of the Heim Pal Children's Hospital/Budapest • Recruitment period: Not stated • Funding source: Not stated • Source of Participants: Patients attending Clinic • Study Duration: Time taken from start of canine retraction to end of canine retraction (about 6 months) • Time points at which follow-up are reported: end of canine retraction
Participants	• 18 participants in total, mean age 14 years, range 12y 6m to 17y 5m • 9 in midpalatal implant group: 7 males, mean age 13.9y (12.75 to 15.08y), 2 females, mean age 13.25y (12.58 to 13.92) • 9 in the transpalatal arch group: 3 males, mean age 13.3y (12.5 to14.0y), 6 females, mean age 14.8 (12.92 to 17.42y) • Inclusion criteria: 1. Two upper first premolar extraction therapy 2. Maximum posterior anchorage requirement in the upper arch 3. Post-pubertal growth spurt and sufficient palatal bone morphology for the implant
Interventions	• **Comparison 1: Midpalatal implants (Orthosystem, Strauman AG, Waldenburg, Switzerland)** 1. The surgical procedure followed the Strauman Institute protocol 2. After three months a transpalatal bar was fixed to the implant and connected to the palatal surface of molar bands by laser welding 3. The transpalatal bar was made of a 1.2 square stainless steel wire • **Comparison 2: Transpalatal Arch (TPA)** 1. Goshgarian type TPA combined with a 0.017 x 0.025 inch heat treated stainless steel utility arch
Outcomes	1. Mesial movement (mm) of the upper first molar on superimposed lateral cephalometric radiographs measured from the start of space closure until the end of space closure.

	2. Duration of canine retraction	
Notes	Both groups were treated with Alexander Brackets with a 0.018 x 0.025 inch slots	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: 'the allocation was carried out by using randomised blocks of six' Comment: Insufficient information about the sequence generation process to permit judgement
Allocation concealment (selection bias)	Unclear risk	The method of allocation concealment was not addressed.
Blinding of outcome assessment (detection bias)	Unclear risk	Insufficient information to permit a judgement
Incomplete outcome data (attrition bias)	Low risk	All randomised patients were accounted for.
Selective reporting (reporting bias)	Unclear risk	• Selective reporting of outcomes: Insufficient information to permit judgement, • Selective reporting of data: no suggestion of incomplete reporting of data
Other bias	High risk	Fixed size blocks were used in a single centre unblinded trial. This may make it possible to predict future assignments.

Table 45: Characterisitics of Chesterfield 2007 study

Chesterfield 2007 [161, 177]	
Methods	• Trial Design: Two centre RCT (parallel group) • Location: Chesterfield and North Derbyshire Royal Hospital NHS trust and Charles Clifford Dental Hospital, UK • Recruitment period: 24 months • Funding source: Not stated • Source of Participants: Patients attending Clinic • Study Duration: 3.75 years • Time points at which follow-up are reported: before treatment, end of anchorage
Participants	• 51 (38 female, 13 male), mean age 15.2 • 25 in midpalatal implant group: mean age 15.7 years; 7 males, 18 females • 26 in the headgear group: mean age 14.8 years; 6 males, 20 females • Inclusion criteria: 1. Absolute anchorage needed 2. Any forward movement of the molars would prevent achievement of an ideal class 1 canine relationship 3. Various class1, Class II div 1, Class div 2 • Exclusion criteria: 1. Poor oral hygiene 2. Unwilling to wear fixed appliances 3. Unwilling to wear headgear or have the implant placed 4. Medical history precluding fixed appliance treatment 5. Patients requiring orthognathic surgery
Interventions	• **Comparison 1: Midpalatal implants (Orthoimplant, Strauman AG, Waldenburg, Switzerland)** 1. 6 mm midpalatal implant surgically placed using a stent. 2. Loaded after 3 months with a lab made transpalatal arch connected to the maxillary first molars. • **Comparison 2: Headgear** 1. Headgear with a Nitom locking facebow fitted to bands on the maxillary molars. 2. Variable pull (according to clinical situation) with a force of 450g on each side and duration of 100-120 hours/week. 3. A headgear chart was used.
Outcomes	1-Anchorage loss measured by mesial molar movement:

	• measured in mm on cephalometric radiographs using the Pancherz analysis between T1 (treatment start) and T2 (end of anchorage reinforcement) • measured at the end of anchorage (when the anchorage device was no longer needed) 2-Success of anchorage device (failure after orthodontic loading, patients did not end up with implant-assisted anchorage) 3-Duration of treatment 4-Number of visits per course of treatment 5-Patient perception by measuring discomfort: • questionnaire in which the patients were asked to indicate the grade they would assign to the surgery on a six point scale where 1 was totally uncomfortable and 6 was comfortable. • questionnaire was administered at three time points; immediately after placement of the palatal implant, three days after placement and upon removal of the palatal implant.
Notes	1-Participants were treated by four orthodontists in two centres. 2-A pre-adjusted edgewise appliance with a MBT prescription was used. 3-Other outcome measures were reported not related to this review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: 'randomisation carried out by using computer-generated random numbers in a block design'
Allocation concealment (selection bias)	Low risk	Quote: ‘randomisation carried out by using computer-generated random numbers in a block design by a researcher unconnected with the recruitment of most patients’. Quote: ‘allocation was concealed in consecutively numbered, sealed opaque envelopes, which were opened after the patient and parent agreed to enter the trial’
Blinding of outcome assessment (detection bias)	Low risk	Quotes: • 'all radiographs were made anonymous by obscuring patient details' • ‘implants were concealed by using an opaque marker on both sides of the

		radiograph’ • 'an opaque marker was also placed in the approximate position of an implant on the radiographs of the headgear group’ • ' the grid and measurement of the radiographs were performed by different researchers'
Incomplete outcome data (attrition bias)	Low risk	• Palatal implant group: 23 out of 25 randomised patients were included in the analysis. 2 patients decided against treatment; one moved away and one's family split up. • Headgear group: 24 out of 26 randomised patients were included in the analysis. One patient moved away before the commencement of treatment, one patient had missing follow up radiographs.
Selective reporting (reporting bias)	Low risk	• Selective reporting of outcomes: 'inflammation of the peri-implant tissues' was an intended outcome. This outcome was not reported because it was not measured. • Selective reporting of data: data on patient perception was incompletely reported
Other bias	Low risk	Study appears to be free of other sources of bias

Table 46: Characteristics of the Feldmann 2007 study

Feldmann 2007 [163-166]	
Methods	• Trial Design: Single centre RCT (4 parallel groups) • Location: Gavleborg County Council, orthodontic clinic, public dental service • Recruitment period: 2 years, 2 months • Funding source: The Centre for Research and Development, Uppsala University, Uppsala, and Gävleborg County Council, Gävle, Sweden; the Swedish Dental Society; and the Faculty of Odontology, Malmö University, Malmö, Sweden • Source of Participants: Patients attending Clinic • Study Duration: not stated • Time points at which follow-up are reported: from start of treatment to the end of levelling and alignment, from the end of levelling and alignment to the end of space closure, from the start of treatment to the end of space closure
Participants	• 120 participants in total, mean age 14.3 years • 30 in Nobel Biocare Onplant group: mean age 14.0 years (SD 1.53); 15 males, 15 females • 30 in Orthosystem implant group: mean age 14.6 years (SD 1.99); 15 males, 15 females • 30 in headgear group: mean age 14.0 years (SD 1.72); 15 males, 15 females • 30 in the transpalatal arch group: mean age 14.4 years (SD 1.65); 15 males, 15 females • Inclusion criteria: 1. Healthy, non-smoking adolescents 2. No previous ortho treatment 3. Permanent dentition, no transverse discrepancies 4. Treatment plan involves extraction of at least 2 upper premolars 5. Upper and lower fixed appliances required 6. Require additional form of anchorage on upper 6's
Interventions	• **Comparison 1: Nobel Biocare Onplant** 1. 7.7mm, placed near the palatal midline. 2. Loaded after 16 weeks with a 1.3 mm transpalatal arch connected to maxillary first molars. • **Comparison 2: Orthosystem implant** 1. 3.3mm X 4mm. 2. Loaded after 16 weeks with a 1-2 mm transpalatal arch connected to maxillary first molars.

	• **Comparison 3: Headgear** 1. Attached to maxillary first molars 2. Medium pull with a duration of 10-12 hours/day and 400gm force level 3. Checked every 6 weeks • **Comparison 4: Transpalatal arch** 1. 2.0X1.0 mm 2. Attached to maxillary first molars
Outcomes	1-Anchorage loss measured by mesial molar movement: • measured in mm on cephalometric radiographs using Bjork and Pancherz analyses • measured at the end of levelling and alignment (start of space closure) and at the end of space closure (including and excluding the levelling and alignment phase) • data included in this review was from the end of space closure excluding the levelling and alignment phase 2-Success of anchorage device (Successful anchorage comprises anchorage loss of less than 1 mm, no failures of osseointegration or failures during anchorage system placement, and no dropouts after the treatment started). 3- Pain and discomfort associated with insertion of anchorage device: • comparisons were made between Nobel Biocare onplants, Orthosystem midpalatal implants and conventional anchorage (headgear and palatal arches combined) • self-reported on a visual analogue scale (VAS) from 0 to 100 where 'no pain/discomfort' and 'worst imaginable pain/discomfort' were the end points of the scale • assessed at four time points, during the anaesthetic injection, during surgery/extractions, the evening after surgery/extractions and one week after surgery • Pain in the first two groups was related to mid-palatal implant placement and in the third group related to premolar extractions. 4- Pain, discomfort and effects on daily activities assessed throughout orthodontic treatment: • daily activities included leisure time, speech, ability to take a big bite, ability to chew hard and soft food, the ability to chew against resistance, schoolwork, drinking, laughing, yawning, kissing, in addition to how the orthodontic treatment affected mood and appearance • comparisons were made between the surgical anchorage group (Nobel Biocare onplants and Orthosystem implants combined), headgear and palatal arches

	• self-reported on a VAS from 0 to 100, or a four-point scale • There were multiple time points; at the start of treatment, each day for a week after the start of treatment, 6 weeks into treatment, after levelling and alignment, after space closure, and 6 weeks into retention
Notes	1-Particpants were treated by two orthodontists in a county council setting in Sweden. 2-A straight-wire appliance with a MBT prescription and a 0.022 slot was used 3-Other cephalometric variables were reported that are not related to this review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: 'The allocation sequence was computer generated by a statistician at...' Quote: 'the patients were randomised in blocks of 4 and stratified by sex into 1 of 4 groups'
Allocation concealment (selection bias)	Unclear risk	Quote: The allocation sequence was ..., and concealed in envelopes until randomization' Comment: not stated whether envelopes were opaque and sequentially numbered
Blinding of outcome assessment (detection bias)	High risk	Outcome assessment was not blinded because the appliances were visible on the radiographs
Incomplete outcome data (attrition bias)	Low risk	At the end of space closure the following drop-outs were reported: • Nobel Biocare onplant group: 25 out of 30 randomised patients were included in the analysis because one patient moved away before the commencement of treatment, one implant failed to osseointegrate, two implants were incorrectly positioned and one patient had poor oral hygiene • Orthosystem implant group: 29 out of 30 randomised patients were analysed because one implant failed to osseointegrate. • Headgear group: all randomised patients were included in the analysis • Transpalatal bar group: 29 out of 30 randomised patients were included in the

		analysis because one patient had severe illness and dropped out before commencement of treatment
Selective reporting (reporting bias)	Unclear risk	• Selective reporting of outcomes: There is no suggestion for selective outcome reporting. • Selective reporting of data: data on the duration of treatment (secondary outcome) was incompletely reported.
Other bias	High risk	Fixed size blocks were used in a single centre unblinded trial. This may make it possible to predict future assignments

Table 47: Characteristics of the Jackson 2008 study

Jackson 2008 [178]	
Methods	• Trial Design: Single centre RCT (parallel groups) • Location: University clinic, San Antonio Texas • Recruitment period: not stated • Funding source: A source of support was provided by both the American Academy of Esthetic Dentistry, in the form of a grant, and Straumann, in the form of equipment • Source of Participants: Patients attending Clinic • Study Duration: 8 weeks • Time points at which follow-up are reported: from the time of implant placement until 8 weeks post-placement
Participants	• 20 patients 13 -48 years old, 12 females, 8 males (1 dropout not accounted for) • 10 in the immediately loading group • 10 in the delayed loading group • Inclusion criteria: 1. Dental patients seeking orthodontic treatment 2. Orthodontic implants were deemed necessary for treatment by their orthodontist 3. Both maxillary first molars erupted and present 4. Sufficient bone quantity to completely encase a palatal implant
Interventions	• **Comparison 1: Strauman palatal implants, immediately loaded** 1. 3.3 mm diameter, 4 or 6 mm length 2. Placed by a surgeon 3. Implants were immediately loaded on the day of surgery by an activated 5mm coil spring attached to a palatal arch • **Comparison 2: Strauman palatal implants, delayed loading** 1. 3.3 mm diameter, 4 or 6 mm length 2. Placed by a surgeon 3. Implants were not loaded on the day of surgery as they were attached to the palatal arch with an annealed coil spring, thus not producing any forces
Outcomes	Clinical success of the palatal implant defined as the ability to use the implant in the course of orthodontic treatment.
Notes	The main study outcome was implant stability, not success of anchorage device. The duration of this study was 8 weeks, and the definition for clinical success of the mini-screw implants was the ability to use the implant in the course of orthodontic treatment. An endpoint of eight weeks after mini screw implant placement does not represent a course of orthodontic treatment.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: 'All patients in the study were randomised to either immediately loaded or non loaded treatments using the method of randomly permuted blocks' Quote: 'The randomization scheme was generated by using the web site Randomization.com'
Allocation concealment (selection bias)	Low risk	Quote: 'Third party volunteer sealed the treatment assignment for each participant in a brown envelope, which was open immediately prior to placement of the midpalatal implant' Quote: 'Group designation obtained by randomization was revealed to the primary investigator on the day of the surgery.'
Blinding of outcome assessment (detection bias)	Unclear risk	Not addressed
Incomplete outcome data (attrition bias)	Low risk	1 patient dropped out from the immediate loading group due to failure of the implant.
Selective reporting (reporting bias)	High risk	• Selective reporting of outcomes: does not report anchorage loss • Selective reporting of data: no suggestion of selective reporting
Other bias	Low risk	

Table 48: Characterisitics of the Lehnen 2011 study

Lehnen 2011 [179]	
Methods	• Trial Design: Single Centre RCT (parallel group), each group was further randomised according to the type of anaesthesia given first (split mouth cross-over design) • Location: specialist orthodontic practice in Germany • Recruitment period: 4 months (January to April 2009) • Funding source: Not stated • Source of Participants: Patients attending Clinic • Study Duration: Questionnaires were administered before implant insertion, right after insertion and one day after insertion • Time points at which follow-up are reported: before implant insertion, right after insertion and one day after insertion
Participants	• 30 participants in total, mean age 15.03 years (+/- 0.83) • 15 in pre-drilled group: 8 males and 7 females • 15 in self-drilling group: 8 males and 7 females • Inclusion criteria: 1. Patients having a permanent dentition· 2. Under the age of 18 3. In need of orthodontic treatment involving both extraction of the maxillary premolars and en-masse retraction to reduce an excessive overjet
Interventions	• Comparison 1: Pre-drilled Tomas pins (Dentaurum, Ispringen, Germany) 1. Length: 8.0mm, diameter: 1.6mm. • Comparison 2: Self-drilling Tomas pins (Dentaurum, Ispringen, Germany 1. Length: 8.0mm, diameter: 1.6mm
Outcomes	1. Patient perception (discomfort), questionnaire administered by interviewer
Notes	The questionnaire was administered by an interviewer and had a total of 11 questions: • 1 question about discomfort during placement was included in the data extraction • 5 questions were related to the anaesthesia technique and didn't have data • 2 questions were only applicable to group A (the pre-drilling group) and therefore is not comparable • 1 question was about describing the sensation to try and

	differentiate between pain and pressure, this is applicable to both groups, but had no data • 2 questions on expectations before treatment and if they were met, these two questions are related, but the scale in the second one is not meaningful because it asks if expectations were met on a scale of 1-4, while the first question asks if discomfort was expected; therefore they were excluded

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: 'the patients were divided at random into two groups of the same size while aiming for equal gender distribution. Quote: 'the first injection quadrant was chosen at random' Comment: Insufficient information about the sequence generation process to permit judgement.
Allocation concealment (selection bias)	Unclear risk	Not addressed
Blinding of outcome assessment (detection bias)	Low risk	Quote: 'the interviewer was neither involved in the clinical procedure nor informed about it'
Incomplete outcome data (attrition bias)	Low risk	All 30 participants answered the questionnaires completely
Selective reporting (reporting bias)	High risk	• Selective reporting of outcomes: does not report anchorage loss • Selective reporting of data: data on the questionnaires is incompletely reported
Other bias	High risk	• There was no wash out period in the second randomisation, both injection techniques were given in the same appointment. • There is suggestion that restricted randomisation may have been used because there were a total of 30 participants, and there was equal distribution of participants in each group

Table 49: Characteristics of the Liu 2009 study

Liu 2009 [151]		
Methods	• Trial Design: Single Centre RCT (parallel group) • Location: department of Orthodontics, School of Stomatology, Tongii University, Shanghai, China • Recruitment period: Not stated • Funding source: Not stated • Source of Participants: Patients attending Clinic • Study Duration: not stated • Time points at which follow-up are reported: before and after active orthodontic treatment	
Participants	• 34 participants in total (28 female, 6 male), mean age 20.68 years • 17 in mini-screw implant group: mean age 21.65 years +/- 4.49; 3 males, 14 females • 17 in the transpalatal arch group: mean age 19.71 years +/- 3.06; 3 males, 14 females • Inclusion criteria: 1. Bi-alveolar dental protrusion presenting as Class I or Class II division I malocclusion 2. No patients less than 18 years old 3. No previous orthodontic treatment 4. All four first premolars extracted 5. Maximum anchorage required 6. Agree to have mini-screw implant and TPA placed 7. No congenitally missing teeth except for the third molars	
Interventions	• **Comparison 1: mini-screw implants (Cibei, Ningbo, China)** 1. Self-tapping titanium mini-screw implants 2. 1.2 mm diameter, 8mm length 3. Placed between roots of the maxillary second premolar and first molar • **Comparison 2: Transpalatal arch**	
Outcomes	1- Mesial movement of maxillary first molar on superimposed radiographs measured from the start of space closure until the end of space closure. 2-Total duration of treatment	
Notes		
Risk of bias		
Bias	**Authors'**	**Support for judgement**

	judgement	
Random sequence generation (selection bias)	Low risk	Quote: 'they were randomly assigned to two groups with the aid of a table of random numbers'
Allocation concealment (selection bias)	Unclear risk	The method of allocation concealment was not mentioned
Blinding of outcome assessment (detection bias)	Unclear risk	Not addressed
Incomplete outcome data (attrition bias)	Low risk	All randomised patients were included in the analysis.
Selective reporting (reporting bias)	Unclear risk	• Selective reporting of outcomes: Insufficient information to permit judgement • Selective reporting of data: no suggestion of selective reporting
Other bias	Low risk	

Table 50: Characteristics of the Ma 2008 study

Ma 2008 [180]	
Methods	• Trial Design: Single Centre RCT (parallel group) • Location: Orthodontic Department at the School of Stomatology, Nanjing Medical University, China • Recruitment period: Not stated • Funding source: The Science and Technology Department, Education Department of Jiangsu Province; and the National Natural Science Foundation of China • Source of Participants: Patients attending Clinic • Study Duration: not stated • Time points at which follow-up are reported: From start of treatment until the end of treatment
Participants	• 30 participants in total: age range between 18-22 years, (14 males and 16 females). • 15 in the mini-screw implant group • 15 in the headgear group • Inclusion criteria: 1. The need to distalize upper and/or lower canines into an extraction space, for a distance between 2 and 6 mm, in order to complete the correction of the overjet or the resolution of incisal crowding
Interventions	• **Comparison 1: mini-screw implants (AbsoAnchor, Dentos Inc., Daugu, Korea)** 1. 1.2 mm diameter; maxilla 6 mm length, mandible 5 mm length 2. Placed between the maxillary second premolars and first molars, and between the mandibular first molars and second molars 3. Loaded immediately with 100 g of force using activated nickel titanium coil springs (Grikin Co., Beijing, China) to retract the anterior teeth. 4. One-step retraction of the anterior arch segment was carried out • **Comparison 2: headgear (Shinye Odontological Materials Co. Ltd, Hangzhou, China)** 1. Applied during the same period as for the micro-implant group 2. Outer face bows were bent upwards at an angle of 20 degrees 3. A force of 350 g applied until all premolar spaces were closed 4. One-step retraction of the anterior arch segment was carried out

Outcomes	No outcomes concerned with this review were reported	
Notes	Pre-adjusted straight wire appliances were used with an MBT prescription.	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: 'The subjects were randomly divided (RandA1.0 Software, Planta Medical Technology and Development Co. Ltd, Beijing, China) into two equal groups'
Allocation concealment (selection bias)	Unclear risk	Not addressed
Blinding of outcome assessment (detection bias)	Low risk	Quote: 'Tracing, superimposition, and measurement were undertaken manually by two examiners who did not participate in the study design' Comment: Blinding of outcome assessment probably achieved because the radiographs were taken before and immediately after treatment; at these points of treatment, the appliances are not fixed inside the mouth, and hence do not show on the radiographs.
Incomplete outcome data (attrition bias)	Low risk	All randomised patients accounted for
Selective reporting (reporting bias)	High risk	• Selective reporting of outcomes: movement of molars was not reported • Selective reporting of data: not relevant because no outcomes concerned with this review were reported.
Other bias	Low risk	

Table 51: Characteristics of the Maddalone 2010 study

Maddalone 2010 [181]	
Methods	• Trial Design: Single Centre RCT (parallel group) • Location: Italy, exact setting not specified • Recruitment period: not stated • Funding source: Institutional funding • Source of Participants: Patients attending Clinic • Study Duration: 4 months • Time points at which follow-up are reported: From start of canine retraction for four months
Participants	• 38: age range between 12 and 54 years, gender distribution not mentioned. • 19 in the mini-screw implant group • 19 in the conventional anchorage group • Inclusion criteria: 1. The need to distalize upper and/or lower canines into an extraction space, for a distance between 2 and 6 mm, in order to complete the correction of the overjet or the resolution of incisal crowding
Interventions	• **Comparison 1: mini-screw implants (Imtec Ortho Implant, 3M Unitek)** 1. Placed between 2nd premolar and molar, at an angle of 45º to 90º 2. Chlorohexidene mouthwash 2% was prescribed 2 times/ day 1 day before insertion and 15 days after insertion • **Comparison 2: Conventional anchorage** 1. This consisted of elastomeric chains or Niti springs 2. Attached to 2nd premolar and first molars which were tied together by steel ligatures 3. The force applied ranged from 75 to 150 g 4. Replaced every 15 days to maintain force level 5. force was measured by using a ‘dynamometer’5-mini-implants were placed between molars 6. Mini-implants were placed between molars to act as markers for measurement of molar movement
Outcomes	1- Mesial movement (mm) of maxillary first molar measured clinically using the head of the implant as a reference, measure four months after commencement of space closure 2- Success/failure of mini-implant (loosening of mini-implant) 3-Duration of space closure phase
Notes	Information for this study was obtained from a Google translation of the manuscript reporting the study.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Translated Quote: 'The items were assigned randomly to two groups of study: 19 were treated with distalisation…' Comment: Insufficient information about the sequence generation process to permit judgement
Allocation concealment (selection bias)	Unclear risk	The method of allocation concealment was not mentioned
Blinding of outcome assessment (detection bias)	Unclear risk	Not addressed
Incomplete outcome data (attrition bias)	Low risk	All randomised patients were analysed
Selective reporting (reporting bias)	High risk	• Selective reporting of outcomes: Insufficient information to permit judgement • Selective reporting of data: mesial movement of molars was incompletely reported as the means were reported without standard deviations.
Other bias	Unclear risk	• The method of measurement of molar movement used the head of the mini-screw implants and the canines as a reference, it is unknown if the implant is a stable reference point.

Table 52: Characteristics of Sharma 2012 study

Sharma 2012 [182]	
Methods	• Trial Design: Single Centre RCT (parallel group) • Location: Orthodontic Department at Yonsei University Dental Hospital, South Korea • Recruitment period: not stated • Funding source: not stated • Source of Participants: Patients attending Clinic • Study Duration: not stated • Time points at which follow-up are reported: T0: before retraction of the anterior segment, T1: after retraction(end of space closure)
Participants	• 25 participants in total • 12 in single mini-screw implant group: mean age 23.58 years (SD 6.92), 1 male, 11 female • 13 in dual mini-screw implant group: Mean age 22.92 (SD7.1), 2 male, 11 female • Inclusion criteria: 1. Adult individuals with normal or mild skeletal 2. Class II skeletal relationship 3. No significant craniofacial defects or asymmetries 4. Intact maxillary permanent dentition including second molars 5. Moderate Class II occlusion 6. Minimal crowding (<3 mm) in the maxilla
Interventions	• **Comparison 1: Mini-screw implants (single)** 1. 7.0 mm in length, 1.8 mm in coronal diameter, and with a tapered body (Orlus 18107, Ortholution, Seoul, Korea) 2. Inserted between the maxillary second premolar and first molar • **Comparison 2: Miniscrew implants (dual)** 1. 7.0 mm in length, 1.8 mm in coronal diameter, and with a tapered body (Orlus 18107, Ortholution, Seoul, Korea) 2. Inserted between the maxillary second premolars and first molars 6. Additional miniscrews were placed between the maxillary first and second premolars
Outcomes	• Distal movement in mm was measured on lateral cephalometric radiographs: perpendicular from the VR (a line perpendicular to the occlusal plane) to the distal cusp tip of the upper first molar; differences between T0 (before canine

	retraction) and T1 (after canine retraction) were calculated • Duration of treatment in months from start of canine retraction to the end of canine retraction
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: 'Subjects were randomly allocated to either group A …. or group B' Comment: Insufficient information about the sequence generation process to permit judgement.
Allocation concealment (selection bias)	Unclear risk	Not addressed
Blinding of outcome assessment (detection bias)	Unclear risk	Not addressed
Incomplete outcome data (attrition bias)	Low risk	All randomised patients were accounted for.
Selective reporting (reporting bias)	Unclear risk	• Selective reporting of outcomes: Insufficient information to permit judgement, (no protocol) • Selective reporting of data: no suggestion of incomplete reporting of data
Other bias	Low risk	Study appears to be free of other sources of bias

Table 53: Characteristics of Shi 2008 study

Shi 2008 [183]	
Methods	• Trial Design: Single Centre RCT (parallel group) • Location: Outpatient Department of Orthodontics and Dentofacial Orthopedics, Armed Forces Medical College, Pune, India • Recruitment period: 12 months • Funding source: Not stated • Source of Participants: Patients attending Clinic • Study Duration: Not stated • Time points at which follow-up are reported: From start of treatment to end of canine retraction
Participants	• 30 participants in total, 10 males, 20 females, mean age 17.4 years • 15 in the mini-screw implant group • 15 in the transpalatal arch (TPA) group • Inclusion criteria: 1. Minimum age at the beginning of treatment of 14 years 2. In the permanent dentition 3. Absence of gross caries in any of the maxillary dental units 4. ANB angle < 4º 5. Need for extraction of the maxillary first premolars to be carried out as confirmed by a diagnostic workup 6. Bimaxillary proclination with class I molars and 7. Crowding of < 5 mm in the maxillary arch (assessed using Little's irregularity index) 8. Absence of any systemic illness. • Exclusion criteria: 1. History of previous orthodontic treatment 2. Angle's class III malocclusion 3. Congenital absence of permanent teeth
Interventions	• **Comparison 1: mini-screw implants** 1. Titanium mini-screw implants 2. 1.2 mm diameter and 8 mm length, with a self-tapping design (Denticon OMI) 3. Inserted between the maxillary second premolar and maxillary first molar 4. All patients were recalled 3 days after insertion for loading; the mini-screw implant was checked for mobility, swelling, acute inflammation with discharge or subjective symptoms

	• **Comparison 2: Transpalatal arch** 1. Made with 0.9 mm SS wire soldered to the palatal surface of the first molar bands.
Outcomes	1. mesial movement (mm) of the maxillary first molars on lateral cephalometric radiographs: • The distance between the pterygoid vertical plane (PTV) and the centroid point on the upper first molar was used to determine the position of the upper first molar • The difference between the pre-treatment and post-canine retraction position was used to determine mesial molar movement
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: 'Each subject was assigned a computer-generated random number. When a total of 30 had been recruited they were arranged in ascending order according to their assigned random number. The first patient of the arranged number list was assigned to group A, the next to group B. This was carried out alternatively until all the...'
Allocation concealment (selection bias)	Low risk	Quote: 'the random numbers were generated using EPI Info 6 software (Centers for Disease Control and Prevention [CDC] Atlanta, GA, USA) by a faculty member independent from the study.'
Blinding of outcome assessment (detection bias)	Low risk	Quote: 'the mini-screw implant or TPA was removed to avoid observer bias and a post-canine retraction cephalometric radiograph was taken.' Quote: 'All pre- and post-treatment cephalometric radiographs were hand traced by one investigator (DC) who was masked as to the details of the study.'
Incomplete outcome data (attrition bias)	Low risk	All randomised patients were accounted for in the analysis
Selective reporting (reporting bias)	Unclear risk	• Selective reporting of outcomes: Insufficient information to permit judgement,(no protocol) • Selective reporting of data: no suggestion

		of selective reporting
Other bias	Low risk	Study appears to be free of other sources of bias

Table 54: Characteristics of Turkoz 2011 study

Turkoz 2011 [162]	
Methods	• Trial Design: Single Centre RCT (parallel group) • Location: Turkey • Recruitment period: Not stated • Funding source: Not stated • Source of Participants: Seyying not stated • Study Duration: Not stated • Time points at which follow-up are reported: before loading, after one month of loading the mini-implants, and overall
Participants	• 69 participants in total, 24 males and 32 females • 22 in mini-implant group (Pilot hole diameter 1.1mm): mean age of 15.2 years, 10 males and 12 females • 20 in mini-implant group (Pilot hole diameter 0.9mm): mean age 16.1 years, 7 males and 13 femael • 20 in mini-implant group (self-drilling): mean age 15.4 years, 7 males and 13 female • Inclusion criteria: 1. · Angle Class II malocclusion 2. No history of trauma 3. No significant medical history 4. No congenital anomalies 5. No previous orthodontic treatment
Interventions	• **Comparison 1: Mini-screw implants (Absoanchor; Dentos, Daegu, Korea) (Pilot hole diameter 1.1 mm)** 1. Diameter 1.4 mm and body length of 7 mm 2. Had a pilot hole drilled with a drill of diameter 1.1 mm 3. Loaded after 2 weeks • **Comparison 2: Mini-screw implants (Absoanchor; Dentos, Daegu, Korea) (Pilot hole diameter 0.9 mm)** 1. Diameter 1.4 mm and body length of 7 mm 2. Had a pilot hole drilled with a drill of diameter 0.9 mm 3. Loaded after 2 weeks • **Comparison 3: Mini-screw implants (Absoanchor; Dentos, Daegu, Korea) (Self-drilling)** 1. Diameter 1.4 mm and body length of 7 mm 2. Self-drilling (drill-free) insertion was performed using a manual screwdriver 3. Loaded after 2 weeks

Outcomes	1. Success/failure of the anchorage device: • Failure was recorded when there was significant mobility that could not sustain the orthodontic force • This was assessed before loading, one month after loading and overall	
Notes	Success and failure reported by implant and not by participant	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: 'Sixty-two adolescent patients were randomly assigned to three groups' Comment: Insufficent information about the sequence generation process to permit judgement.
Allocation concealment (selection bias)	Unclear risk	Not addressed
Blinding of outcome assessment (detection bias)	Unclear risk	Not addressed
Incomplete outcome data (attrition bias)	Low risk	All randomised patients were analysed.
Selective reporting (reporting bias)	High risk	• Selective reporting of outcomes: anchorage loss was not an objective of this study; however it would have been an expected outcome in this type of study • Selective reporting of data: no suggestion of selective reporting
Other bias	Low risk	Study appears to be free of other sources of bias

Table 55: Characteristics of the Upadhyay 2008 study

Upadhyay 2008 [184]	
Methods	• Trial Design: Single Centre RCT (parallel group) • Location: Department of Orthodontics of KLES Academy of Higher Education and Research in Belgaum, India • Recruitment period: 18 months • Funding source: Not stated • Source of Participants: Patients attending Clinic • Study Duration: Not stated • Time points at which follow-up are reported: before retraction and after space closure
Participants	• 40 participants in total (all females), mean age 17.5 years • 20 in mini-implant group: mean age of 17.61 years (SD 3.56) • 20 in the conventional anchorage group: mean age 17.38 (SD 2.89) • Inclusion criteria: 1. Cl I bi alveolar protrusion 2. Permanent dentition 3. Minimum age 14 4. No congenitally missing teeth except 8's 5. No history of mouth breathing, tongue thrusting, thumb sucking, orthodontic treatment 6. Class I molars +/- 1mm, 7. inter incisal angle of 116 or less, overbite of 0% to 50%, overjet not exceeding 5mm 8. Well aligned maxillary and mandibular incisors, crowding less than 3.5mm 9. Extraction of all 4's indicated 10. Maximum anchorage indicated
Interventions	• Comparison 1: mini-screw implants 1. Titanium mini-implants, 2. 1.3 mm diameter, 8mm length, 3. Placed between second premolar and first molar in all four quadrants 4. Immediately loaded • Comparison 2: Conventional anchorage 1. Including headgear, transpalatal arches, banding of second molars and application of differential moments.
Outcomes	1- Mesial movement of maxillary first molar on superimposed radiographs measured from the start of space closure until the end of space closure.

	2- Success/failure of mini-implant (Success: Complete stability throughout the retraction phase, Failure: loose and subsequently replaced) 3-Duration of space closure phase	
Notes	Straight wire appliance was used with Roth prescription	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: 'the subjects were randomly divided into 2 groups' Quote: 'the allocation sequence, which was generated by the statistician on this project using computer-generated random numbers' Quote: A restricted randomization method was used in blocks of 10 to ensure that equal numbers of patients were allocated to each treatment group'
Allocation concealment (selection bias)	Unclear risk	Quote: 'The principal investigator (M.U.) was blinded to the allocation sequence' Comment: • the actual method of blinding was not mentioned. • blinding of other investigators was not addressed.
Blinding of outcome assessment (detection bias)	Unclear risk	Quote: 'measurement analysis of the cephalogram was performed blindly' Quote: 'One faculty member (K.N.) examined all 72 cephalograms. The same faculty member conducted the measurement analysis of the cephalograms and was unaware of the objectives of the study. Quote: 'All data were entered into computer databases by research assistants, who were also blinded to the treatment group.' Comment: the faculty member examining the radiographs could have seen the intervention on the radiograph if there was no attempt to mask it, even if they were unaware of the study objectives.
Incomplete outcome data	Low risk	• 40 randomised, 36 analysed • Mini-screw implant group: 18 out of 20

(attrition bias)		randomised patients were included in the analysis, 2 dropped out before commencement of treatment. This was because one moved away and one became too ill for treatment. • Conventional anchorage group: 18 out of 20 randomised patients were included in the analysis, 1 dropped out before commencement of treatment because they refused intervention, and one had poor quality cephalometric radiographs.
Selective reporting (reporting bias)	Unclear risk	• Selective reporting of outcomes: Insufficient information to permit judgement • Selective reporting of data: no suggestion of selective reporting
Other bias	Low risk	There was en-masse retraction in the mini-implant group and sequential retraction in the conventional group; however this would bias the results towards underestimating the effects of the mini-implants.

9.2 Characteristics of excluded studies

Table 56: Excluded studies with reasons

Study	Reason for exclusion
Altug-Atac 2008 **[185]**	Interventions did not include a type of surgical anchorage.
Baxmann 2010 **[186]**	Randomisation doesn't occur between two types of anchorage reinforcement.
Bondemark 2005 **[124]**	Interventions did not include a type of surgical anchorage.
Chen 2008 [187]	This study is not a randomised controlled trial as confirmed after translation of this article.
Cheng 2004 **[188]**	Randomisation doesn't occur between two different types of anchorage reinforcement.
Deguchi 2008 **[189]**	This study is not a randomised controlled trial.
Garfinkle 2008 **[190]**	This is a split mouth study
Gelgor 2007 **[135]**	This study is not a randomised controlled trial, as confirmed by author correspondence.
Gollner 2009 **[191]**	This study is not a randomised trial.
Kadioglu 2008 **[192]**	This study is not a randomised trial.
Lee 2011 **[193]**	This study is not a randomised controlled trial, as confirmed by author correspondence.
Melsen 2007 **[194]**	Interventions don't include a type of surgical anchorage.
Moon 2008 **[195]**	Interventions don't include a type of surgical anchorage.
Motoyoshi 2007 **[196]**	This study is not a randomised controlled trial.
Palagi 2010 **[197]**	Interventions did not include a type of surgical anchorage.
Papadopoulos 2010 **[126]**	Interventions did not include a type of surgical anchorage.
Polat-Ozsoy 2011 **[198]**	Interventions did not include a type of surgical anchorage.
Schatzle 2009 **[199]**	This study did not include patients undergoing orthodontic treatment with fixed appliances.
Thiruvenkatachari 2008 **[200]**	This study is not a randomised controlled trial.
Upadhyay 2008-2 **[201]**	This study is not a randomised controlled trial, as confirmed by author correspondence.
Upadhyay 2012 **[202]**	This study is not a randomised controlled trial, as confirmed by author correspondence.
Wiechmann 2007 **[203]**	This study is not a randomised controlled trial.

Wilmes 2009 **[204]**	This study is not a randomised controlled trial.
Zhou 2009 **[205]**	This study is a prospective controlled trial. However there is no indication that randomisation was carried out. Correspondence address for the authors could not be found to confirm.

9.3 Characteristics of ongoing studies

Table 57: Characterisitics of the Bearn 2008 study

Bearn 2008	
Study name	What is the most effective method for providing orthodontic anchorage? A randomised clinical trial of Headgear, AbsoAnchor mini-screws, palatal arch
Methods	• Trial Design: Multi-centre RCT (parallel group) • Location: Secondary care/ dental hospitals • Recruitment period: Not known • Funding source: British Orthodontic Society foundation • Source of Participants: Patients attending Clinic • Study Duration: start date 16 July 2008, proposed end date 31 July 2015 • Time points at which follow-up are reported: 5 time points for follow-up
Participants	• Males and females accepted, age range not known, total sample number 45 • Inclusion criteria: 1. In the permanent dentition 2. Having a malocclusion requiring fixed appliance therapy with premolar extractions in the upper arch 3. Assessed as requiring an additional form of anchorage (i.e. treatment requires mid-arch extraction plus an additional form of anchorage) • Exclusion criteria: 1. Craniofacial syndrome or cleft lip and/or palate 2. Medical contraindication to use of mini-implants (systemic steroid tablets, insulin dependent diabetes mellitus, haematological disorders, require antibiotic cover for invasive dental procedures, allergy to local anaesthetic)
Interventions	• **Comparison 1: Mini-screw implants** • **Comparison 2: Headgear**

	• **Comparison 3: Transpalatal arch**
Outcomes	• Primary Outcome Measures: 1. Effectiveness of anchorage reinforcement defined as molar movement determined by superimposed 3D scans of study models • Secondary Outcome Measures: 1. PAR Index / ABO scores from start and end of treatment study models 2. Soft tissue response to anchorage device from records and intra-oral photographs 3. Treatment process (duration of treatment, duration of each visit, number of visits, patient cooperation, smoking status) from data collection sheets 4. Anchorage device failure from data collection sheets 5. Patient experience from questionnaires
Starting date	16 July 2008
Contact information	Dr Roberta Littleford University of Dundee, Tayside Clinical Trials Unit, Ninewells Hospital & Medical School, Research & Development Office, Level 2 Residency Block, Dundee, Scotland, DD1 9SY, UNITED KINGDOM Tel: 01382 740376 r.littleford@dundee.ac.uk
Notes	

Table 58: Characterisitics of the Biavati/ Migliorati 2011 study

Biavati/ Migliorati 2011	
Study name	Three Dimensional Movement Analysis of Maxillary Impacted Canine Using TADs: a Randomized Clinical Trial
Methods	• Trial Design: Single-centre RCT (parallel group) • Location: Orthodontic Department, Genoa University, Italy • Recruitment period: not known • Funding source: University of Genova, University of Michigan • Source of Participants: Patients attending Clinic • Study Duration: not known • Time points at which follow-up are reported: beginning of traction and after 3 months after traction
Participants	• Males and females accepted, age range from 10-60 years, total sample number not stated • Inclusion criteria: 1. Presence of one or two impacted maxillary canine requiring surgical exposure and orthodontic treatment • Exclusion criteria: 1. Permanent teeth extraction-based treatment 2. Current or previous orthodontic treatment in the last 12 months 3. Current systemic disease 4. Current antibiotic or anti-inflammatory therapy that can may compromise the result
Interventions	• **Comparison 1: Temporary anchorage devices (TADs)** 1. Alloy type IV titanium screw 2. 1.5mm diameter and 8-10 mm long 3. Placed under local anaesthesia in an area between the first premolar and first molar, on the buccal or labial side according to the canine position and teeth position. • **Comparison 2: Canti-levers with a TMA sectional**
Outcomes	• Primary Outcome Measures: 1. Canine and first molar movement by superimposition of two consecutive TC cone beam using at least 5 landmarks point. • Secondary Outcome Measures: 1. Side effect of traction 2. Evaluation of soft tissue health with clinical evaluation (bleeding on probing, gingival index, plaque index). 3. Root cervical resorption of other teeth due to canine movement

	4. Bone quality after three month of traction
Starting date	September 2011
Contact information	Orthodontics Department, Dental School, Genoa University, Genoa, Italy, 16100 Contact: Doctor Marco Migliorati, 00393383825781, marco.migliorati@gmail.com
Notes	

Table 59: Characterisitics of the Jung 2006 study

Jung 2006 [206-208]	
Study name	Early loading of palatal implants (ortho-type II) a prospective multicenter randomised controlled clinical trial
Methods	• Trial Design: Multi-centre RCT (parallel group) • Location: Four University centres: Mainz, Dresden, Greifswald and Aachen (Germany) • Recruitment period: 3 years • Funding source: Not known • Source of Participants: Patients attending Clinic • Study Duration: 5 years total study duration • Time points at which follow-up are reported: Start of treatment, 6 months after loading, 12 months after loading, end of treatment
Participants	• 124 participants in total • Inclusion criteria: Orthodontic indication for skeletal anchorage, adequate bone for palatal implant, good oral hygiene and normal wound healing capacity, written informed consent • Exclusion criteria: cleft lip and palate, syndrome associated craniofacial anomalies, reduced immune defence, diseases requiring continuous steroid treatment, radiotherapy, chemotherapy, bone metabolism disease, drug or alcohol abuse, pregnancy
Interventions	• **Comparison 1: Ortho-implant type II anchor system** 1. Standard loading after 12 weeks • **Comparison 2: Ortho-implant type II anchor system** 1. Immediate loading within one week
Outcomes	1- Anchorage loss measured by mesial molar movement in mm on casts and cephalometric radiographs using the Pancherz analysis, measured at the end of treatment 2- Success of anchorage device measured by Implant survival and no abnormal mobility using the percussion test, measured 6 months and 12 months after loading. 3- Patients acceptance rate of palatal implants measured at the end of treatment by a questionnaire.
Starting date	December 2006
Contact information	BA Jung, Department of Orthodontics, University medical center Mainz, Augustusplatz 2, 55131 Mainz, Germany, email: brjung@uni-mainz.de
Notes	The results reported at this point in time are an interim analysis involving 41 participants and reporting the outcome success of anchorage device. The trial is still ongoing.

Table 60: Characterisitics of the Miller 2009 study

Miller 2009	
Study name	Study of the efficacy of skeletal anchorage (mini-screw) compared to dental anchorage during orthodontic treatment
Methods	• Trial Design: Single-centre RCT (parallel group) • Location: Bretonneau Hospital, Paris, France • Recruitment period: Not known • Funding source: Assistance Publique - Hôpitaux de Paris, DENTOS • Source of Participants: Patients attending Clinic • Study Duration: 4 years, 4months estimated total study duration • Time points at which follow-up are reported: before and after space closure
Participants	• 100 participants in total, males and females accepted, age range from 12-50 years • Inclusion criteria: 1. Aged from 12 to 50 years old 2. Patient needs orthodontic treatment with extraction of 2 maxillary bicuspids 3. Patient has signed informed consent • Exclusion criteria: 1. Patient younger than 12 and older than 50 years old 2. Patient without social security affiliation 3. Patient with a medical condition that indicates against orthodontic treatment
Interventions	• **Comparison 1: Mini-screw implant** • **Comparison 2: Dental Anchorage**
Outcomes	1. Amount of extraction space closure after 8 months of treatment 2. Angle classification of the canines 3. Parallelism of the dental axis on 3D CT scans 4. Treatment efficacy 5. Patient satisfaction
Starting date	February 2009
Contact information	Bretonneau Hospital, Paris, France, 75018
Notes	

Table 61: Characterisitics of the Sandler 2008 study

Sandler 2008	
Study name	Efficiency and Effectiveness of Three Methods of Anchorage Reinforcement in Orthodontics
Methods	• Trial Design: Single-centre RCT (parallel group) • Location: District General Hospital orthodontic department, Chesterfield, UK • Recruitment period: Not known • Funding source: British Orthodontic Society Foundation • Source of Participants: Patients attending Clinic • Study Duration: 4 years estimated total study duration • Time points at which follow-up are reported: not stated
Participants	75 participants, both male and female eligible, age range from 12-17
Interventions	• **Comparison 1: Mini-screw implants** • **Comparison 2: headgear (12-14 hours per day)** • **Comparison 3: Nance palatal arch**
Outcomes	1. Anchorage loss measured from lateral Cephalometric radiographs and 3-D model scanning, records will be taken at three points 2. Patient perception of the different treatment methods, including surgical experience
Starting date	July 2008
Contact information	Not known
Notes	This study is now complete and will be reported when this review is updated.

10 Data and analyses

Table 62: Data and analysis: Surgical anchorage versus conventional anchorage

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Mesiodistal movement of the upper first permanent molar	7	308	Mean Difference (IV, Random, 95% CI)	-1.68 [-2.27, -1.09]
1.1.1 Midpalatal implants	3	190	Mean Difference (IV, Random, 95% CI)	-1.02 [-2.31, 0.26]
1.1.2 Mini-screw implants	4	118	Mean Difference (IV, Random, 95% CI)	-2.17 [-2.58, -1.77]
1.3 Duration of overall treatment	3	111	Std Mean Difference (IV, Fixed, 95% CI)	-0.25 [-0.62, 0.12]
1.4 Duration of space closure	3	80	Std Mean Difference (IV, Fixed, 95% CI)	-0.09 [-0.54, 0.35]
1.5 Number of visits	1	47	Mean Difference (IV, Fixed, 95% CI)	7.01 [3.47, 10.55]

Table 63: Data and analysis: two types of surgical anchorage

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
2.1 Mesiodistal movement of the upper first permanent molar	1	25	Mean Difference (IV, Random, 95% CI)	1.62 [0.98, 2.26]
2.2 Success of anchorage device	4	224	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.94, 1.19]
2.2.1 Early versus delayed loading	2	36	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.83, 1.20]
2.2.2 Single versus dual mini-screw implants	1	76	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.84, 1.22]
2.2.3 Pre-drilling versus self-drilling	1	112	Risk Ratio (M-H, Fixed, 95% CI)	1.12 [0.91, 1.38]
2.3 Duration of space dlosure	1	25	Mean Difference (IV, Random, 95% CI)	-2.19 [-6.35, 1.97]

11 Search strategies

Figure 27: Medline via OVID search strategy

1. exp Orthodontics/
2. orthodontic$.mp.
3. or/1-2
4. exp Dental Implants/
5. exp Dental Implantation/
6. ((dental adj4 implant$) or (oral adj4 implant$) or (titanium adj4 implant$) or (palatal adj4 implant$) or (endosseous adj4 implant$)).mp.
7. osseointegration.mp.
8. "titanium plate$".mp.
9. "zygoma$ wire$".mp.
10. (mini-screw$ or "mini screw$" or mini-screw$ or microscrew$ or "micro screw$" or micro-screw$ or spiderscrew$ or "spider screw$" or spider-screw$).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
11. (surgical$ or surgery).mp.
12. onplant$.mp.
13. "temporary anchorage device".mp.
14. TAD.ti,ab.
15. or/4-14
16. Orthodontic Anchorage Procedures/
17. anchor$.mp.
18. or/16-17
19. 3 and 15 and 18

Cochrane Search filter for MEDLINE via OVID*Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomized trials in MEDLINE: sensitivity maximising version (2009 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of The Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.2 [updated September 2009]*.

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

Figure 28: OHG Trials Register Search Strategy

(orthodontic* and anchor*)

Figure 29: CENTRAL search strategy

#1 MeSH descriptor Orthodontics explode all trees

#2 orthodontic* in All Text

#3 (#1 or #2)

#4 MeSH descriptor Dental implants explode all trees

#5 MeSH descriptor Dental Implantation explode all trees

#6 ((dental in All Text near/4 implant* in All Text) or (oral in All Text near/4implant* in All Text) or (titanium in All Text near/4 implant* in All Text) or (palatal in All Text near/4 implant* in All Text) or (endosseous in All Text near/4 implant* in All Text))

#7 osseointegration in All Text

#8 "titanium plate*" in All Text

#9 "zygoma* wire*" in All Text

#10 (mini-screw* in All Text or "mini screw*" in All Text or mini-screw* in All

Text or microscrew* in All Text or "micro screw*" in All Text or micro-screw* in All Text or spiderscrew* in All Text or "spider screw*" in All Text or spider-screw* in All Text)

#11 (surgical* in All Text or surgery in All Text)

#12 onplant* in All Text

#13 "temporary anchorage device*" in All Text

#14 TAD in Title, Abstract or Keywords

#15 (#4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14)

#16 MeSH descriptor Orthodontic Anchorage Procedures this term only

#17 anchor* in All Text

#18 (#16 or #17)

#19 (#3 and #15 and #18)

Figure 30: Embase via Ovid Search strategy

1. exp Orthodontics/
2. orthodontic$.mp.
3. or/1-2
4. exp Dental Implants/
5. exp Dental Implantation/
6. ((dental adj4 implant$) or (oral adj4 implant$) or (titanium adj4 implant$) or (palatal adj4 implant$) or (endosseous adj4 implant$)).mp.
7. osseointegration.mp.
8. "titanium plate$".mp.
9. "zygoma$ wire$".mp.
10. (mini-screw$ or "mini screw$" or mini-screw$ or microscrew$ or "micro screw$" or micro-screw$ or spiderscrew$ or "spider screw$" or spider-screw$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
11. (surgical$ or surgery).mp.
12. onplant$.mp.
13. "temporary anchorage device".mp.
14. TAD.ti,ab.
15. or/4-14
16. Orthodontic Anchorage Procedures/
17. anchor$.mp.
18. or/16-17
19. 3 and 15 and 18

Filter for EMBASE via OVID

1. random$.ti,ab.
2. factorial$.ti,ab.
3. (crossover$ or cross over$ or cross-over$).ti,ab.
4. placebo$.ti,ab.
5. (doubl$ adj blind$).ti,ab.
6. (singl$ adj blind$).ti,ab.
7. assign$.ti,ab.
8. allocat$.ti,ab.
9. volunteer$.ti,ab.
10. CROSSOVER PROCEDURE.sh.
11. DOUBLE-BLIND PROCEDURE.sh.
12. RANDOMIZED CONTROLLED TRIAL.sh.
13. SINGLE BLIND PROCEDURE.sh.
14. or/1-13
15. ANIMAL/ or NONHUMAN/ or ANIMAL EXPERIMENT/
16. HUMAN/
17. 16 and 15
18. 15 not 17
19. 14 not 18

Figure 31: Clinicaltrials.gov search strategy

An advanced search using the following 'search terms' and 'interventions':

Orthodontic AND anchorage OR Temporary AND anchorage OR Surgical AND anchorage | mini-screws OR mini-screws OR micro-screws OR microscrews OR spiderscrews OR spider AND screws OR titanium AND plates OR miniplates OR zygoma AND wire

12 Acknowledgements

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13 Contributions of authors

- Amendment of methodology: Safa Jambi (SJ), supervised by Kevin O'Brien (KOB)
- Searching other resources: SJ
- Examination of titles and Abstracts: SJ, Jonathan Sandler (JPS), KOB
- Retrieval and examination of full text reports: SJ, JPS
- Final decisions on study inclusion: SJ, JPS, KOB, Tanya Walsh (TW)
- Development of data collection forms: SJ
- Piloting of data collection forms, data extraction and management: SJ, JPS
- Risk of bias assessment: SJ, JPS, KOB, TW
- Data Synthesis: SJ, TW
- Writing the review: SJ, KOB, TW
- The original version of this review was jointly conceived and designed by Richard Skeggs and Philip Benson.

14 Declarations of interest

Two of the authors of this review, Philip Benson and Jonathan Sandler, were involved as authors in one of the included studies (Chesterfield 2007); and Jonathan Sandler was involved in one of the ongoing studies (Sandler 2008). Decisions on study inclusion, data extraction and risk of bias assessments for these studies were performed independently of these authors.

15 Differences between protocol and review

- The inclusion criteria were changed:
    - Quasi-random studies were no longer eligible for the review
    - To coincide with recent advancements in measurement techniques, studies in which measurements were made on superimposed digital models were also considered eligible for the review.
- The electronic search strategy was amended by the Trials Search Coordinator to include additional terms (endosseous, temporary anchorage device, TAD, Orthodontic Anchorage Procedures).
- The handsearch was expanded to include relevant journals on oral implants.
- The search for unpublished studies was expanded to include trial registries.
- Subgroup analysis was carried out to further investigate the effects of different types of surgical anchorage. This was a post-hoc analysis as we did not expect to find multiple trials investigating surgical anchorage.

16 Sources of support

16.1 Internal sources

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16.2 External sources

The Ministry of Higher Education/ Taiba University, Saudi Arabia

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INVESTIGATIONS INTO ORTHODONTIC ANCHORAGE

A thesis submitted to The University of Manchester for the degree of

Doctor of Philosophy

In the Faculty of Medical and Human Sciences

2014

SAFA JAMBI

SCHOOL OF DENTISTRY

Volume II of II

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SECTION IV: The Evaluation of the Effect of Functional Appliances on Orthodontic Anchorage

1 Chapter 1: Introduction

Functional appliances have been traditionally used for the treatment of Class II malocclusion with the aim of modifying a patient's growth. However, the results of randomized clinical trials have revealed that the growth modifying effects of functional appliances are minimal [209-212] and clinically insignificant. Nevertheless, this research has also shown that they are very effective at correcting some of the features of malocclusion by dental movement.

The type of tooth movement that occurs from the use of functional appliances includes distalising upper molars, molar correction and overjet reduction [24-27, 29, 30]. Furthermore, some clinicians suggest that because of these tooth movements, the Twin Block can be used for 'anchorage preparation'. For example, in a case report using a Twin Block to treat a Class II division II case [32] it was suggested that a Twin Block can be used instead of headgear. It has also been suggested that a Herbst appliance can be used for distal movement [213].

If this concept is expanded it would not be unreasonable to state that the use of the Twin Block prior to fixed appliance treatment (phase I) for Class II malocclusion simply prepares "anchorage" for the final phase of treatment (Phase II). Consequently, there may be an influence on the need for extractions as part of phase II treatment.

This study was carried out in three main stages:

The first stage was to investigate various methods of measuring tooth position, tooth movement and the use of measures of crowding on digital models.

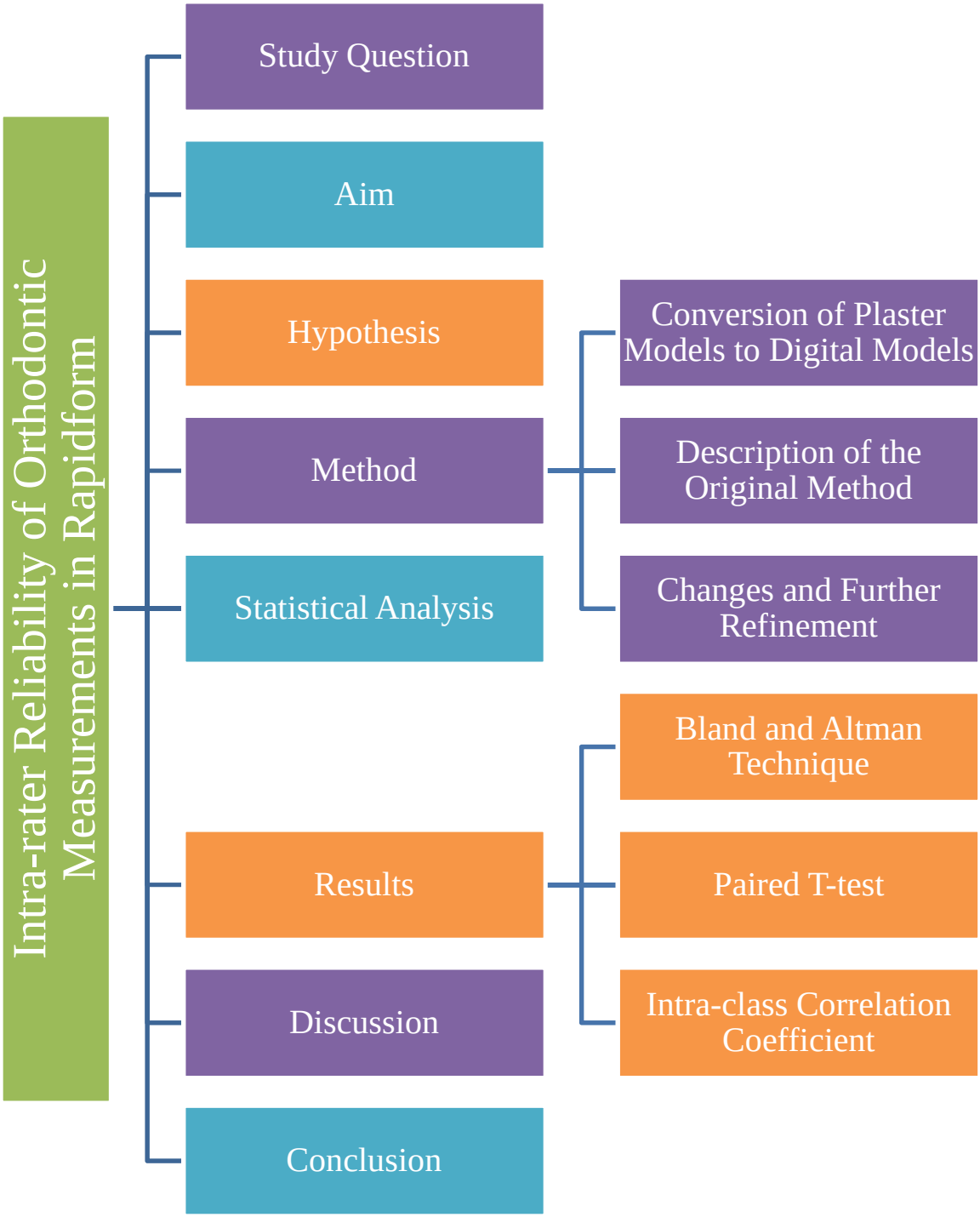
I will describe how I used these measurements as part of the methodology for assessment of the anchorage potential of functional appliances by evaluating their influence on tooth movement and intra-arch relationship. The results of this part of the study will be discussed.

Finally I will present the methodology and discuss the results obtained when assessing these tooth movements and other orthodontic characteristics on the decision of orthodontists to extract teeth as part of the second phase of treatment.

2 Chapter 2: Intra-rater reliability of orthodontic measurements on digital models

Figure 32 shows the order in which in which the topics are presented in this chapter.

Figure 32: A flow chart summarising the main topics discussed in Chapter 2



2.1 Study question

Are repeated measurements made by a single examiner consistent on digital models?

2.2 Aim

To assess the intra-rater reliability of 3 dimensional measurements used in this investigation.

2.3 Objective

To show that there is no difference between repeated measurements when assessing intra-rater reliability for 3 dimensional measurements

2.4 Method

The following section describes the formation of the digital models and the 3 dimensional measurements.

2.4.1 Conversion of Plaster study models to digital models:

The plaster models used in a previously completed Class II study [28] were scanned and converted into digital models by staff at 'Bioprecision Diagnostics'. This is a professional firm specialised in digitising, storing and analysing study models and radiographs. The models were delivered and collected by myself personally from door to door to minimise any damage or loss.

After receiving the models in their digitised form, I visually checked that the scans were accurate by comparing them to the plaster models.

2.4.2 Description of the original method

Inspection and 3D analysis of the digital model was performed using Rapidform™2006 software produced by INUS Technology (Seoul, South Korea). The following measurements were made; overjet, molar relationship, distal movement of the upper first molar, change in angulation (mesio-distal) of the upper first molar, change in inclination (labio-lingual) of the lower incisors. A detailed step-by-step guide to the technique is in Appendix 1.

The original methodology for superimposition of models and measurement of the change in teeth movement in Rapidform™2006 has been developed and validated by previous researchers [97, 99]. It is important to note that the methods developed by these investigators are complimentary. AlAbdallah developed the method for superimposing and measuring tooth movement on maxillary models, and Thiruvenkatachari developed the method for measuring tooth movement on superimposed mandibular models.

I will give an overview of the technique here to give a better understanding of the basic principles. The following is a brief outline of the main principles of the procedure.

- The models for all stages of treatment were scanned and imported into the software.
- The digital models were color-coded to represent the stage of treatment.
- The pre-treatment digital models were oriented to create occlusal, sagittal and transverse planes; thus forming a common coordinate system. All future measurements on pre-treatment and follow-up models were made in relation to these planes and coordinate system.
- Each tooth that we wished to assess was shaded and disassembled from the main model, this is termed the tooth shell. The shading of the tooth is the only subjective

procedure in this technique. Copies of the tooth shell were made according to the number of stages of treatment.

- The centre of mass of one of the tooth shells was created automatically by the software, and transferred to the remaining copies of the tooth shell.
- The long axis of one of the tooth shells was then calculated by the software:
    - To create the long axis of a posterior tooth, the tooth shell is created, and the software calculates the long axis of the crown. Again the only step in this technique subject to human error is the initial shading of the tooth to form the tooth shell.
    - To create the long axis of the anterior tooth, the tooth shell and centre of mass are created. The middle of the incisal edge is then defined manually. The software then forms long axis connecting the centre of mass and the middle of the incisal edge.
- Simple linear measurements were made with the software by measuring the distance between two user-defined reference landmarks.
- For measurement of tooth movement, the baseline and follow-up model(s) were superimposed using the following methods:
    - The maxillary models were superimposed on the palatal rugae area, and the mandibular models were superimposed on the labial plate of bone 3 mm below the gingival margin. This is obtained by shading the area of interest (palatal rugae or labial plate of bone) and/or defining at least three reference points in the area of interest. The software automatically finds areas of similar morphology on the follow up model and performs the superimposition. A third technique for superimposition which may be helpful is a ‘best fit’ method in which the software superimposes the models according to the best fit of the whole 3D model.

- There is a tool in the software which checks the accuracy of the superimposition. This is displayed both visually and numerically. Visually a dark blue colour indicates perfect superimposition, and green yellow and red are moving further away from good superimposition. In addition a numerical value is given to indicate the amount of deviation of the superimposed models. A value of 0 indicates no deviation (perfect superimposition); higher numbers indicate higher degrees of deviation.
- Superimposing the models can be repeated until an acceptable superimposition is achieved.

- To ensure that each tooth shell representing a certain stage of treatment occupies the correct place in space, each tooth shell copy was matched with the models representing the same phase of treatment. This was accomplished by superimposing the tooth shell on the respective model using one of the three superimposition methods used above. It can be thought of as reassembling the tooth to the model after its place in space has been determined.
- Finally the measurements were made:
  - movement (distal movement) was determined by measuring the distance between the centres of mass of the teeth on the superimposed models.
  - Change in angular measurements (inclination, angulation, rotation) was measured by projecting the long axes of the teeth on an appropriate plane (occlusal, sagittal, or transverse), and measuring the angle between them.

2.4.3 Changes and further refinement of the method:

2.4.3.1 Measurement of overjet:

Previous research validated linear measurements in Rapidform software; however it did not describe reference landmarks for measurement of overjet. This was performed at one phase of treatment without the need for superimposition. After creating a common

coordinate system and defining a reference frontal plane, the overjet was measured by calculating the horizontal distance between the centres of the incisor edges of the upper and lower right central incisors Figure 33.

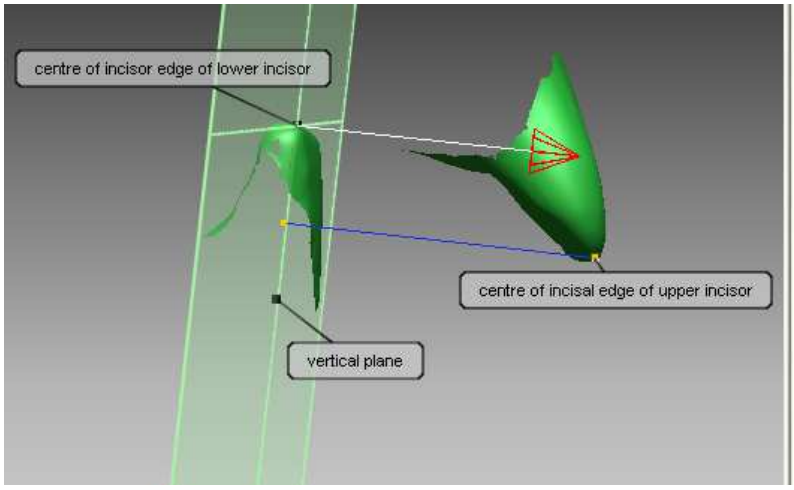


Figure 33: Overjet Measurement in Rapidform

2.4.3.2 Canine and molar relationship:

For the assessment of the canine and molar relationship I decided to use visual inspection and classification on the 3D model and quantitative assessment. The quantitative measurement would give a more objective measurement on the amount of anchorage required to correct the relationship.

For the visual inspection of the models, the models were placed in the 'left' and 'right' default positions, and the canine and molar relationship judged. The more severe form of the relationship was recorded, for example a full unit 2 etc.

For the quantitative measurement of canine, the following was done:

1- The long axis of the upper canine was constructed, using the centre of mass as a reference point.
2- The long axis of the lower canine was constructed in the same way.
3- The distance between the two long axes was calculated
4- This was given a negative value if the relationship was towards class II and a positive value if it was class I to III.

The molar relationship was measured in the same way (Figure 34).

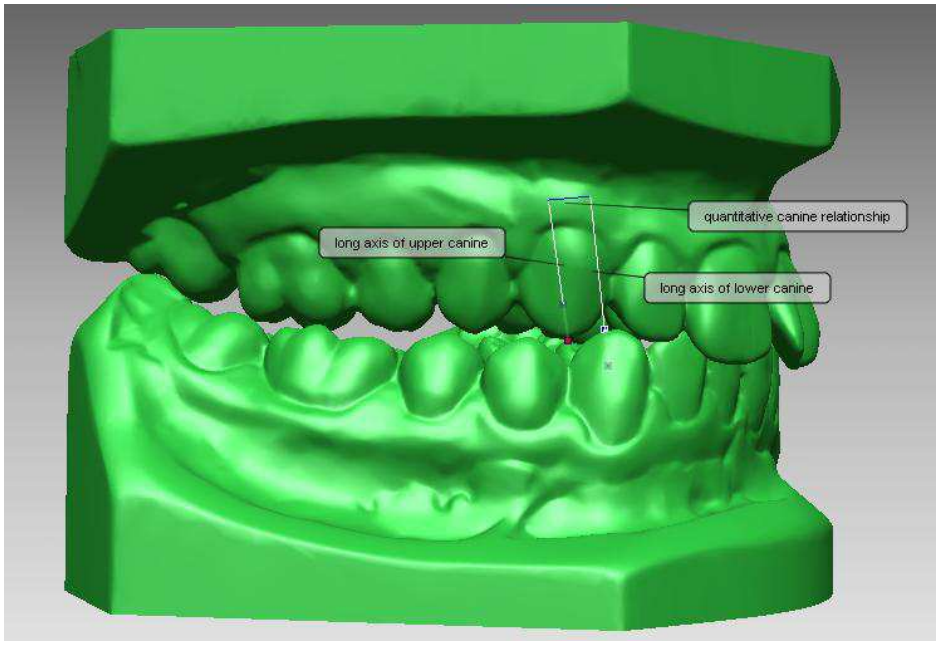


Figure 34: Quantitative canine relationship in Rapidform

2.5 Statistical analysis

Intra-rater reliability of the measurement was calculated by assessing agreement between repeated 3D measurements of the centre of mass. The following variables were assessed: the X, Y and Z coordinates for the centres of mass of the teeth. The centre of mass was chosen for the following reasons:

1. The centre of mass is a key measurement in the 3D analysis of the digital models

2. The creation of the centre of mass of a particular tooth depends directly on shading of the tooth's anatomical crown to form the baseline and follow-up shells. The shading of the tooth is completely objective, in that there was no input from the computer software.
3. The formation of baseline and follow-up shells as detailed in the previous research had a significant effect in decreasing the error of the method [99].
4. The centre of mass is created early in the method of measurement; the software creates further steps automatically.

A sample size calculation suggested that in order to carry out a reliability study of the 3D measurements, based on the results of a previous study, it was necessary to measure 48 cases twice [97]. Forty-eight cases were chosen at random from the scanned Class II models, and in each case, the centre of mass was measured on the upper first molars (right and left). The measurements were repeated two weeks later.

To assess repeatability the following processes were done:

1. A scatterplot to give a visual representation of the agreement

2. The Bland and Altman plot to assess the 95% limits of agreement between the two measurements [214]. The 95% limits of agreement depend on the following assumptions about the data; that the mean and SD of the differences are constant throughout the range of measurements, and that these differences are from an approximately normal distribution. In order to check these assumptions, I performed two plots, a scatter diagram of the difference in measurements against the mean of the two measurements, and a histogram of the differences between the

two measurements. A decision of the acceptable limits of agreement was made before the analysis. Since this is an evaluation of the same method by the same examiner it was decided that the mean of the difference between measurements should be 0mm and the limit of agreement should not exceed 0.5mm on each side of the mean.

3. A paired t-test was used to compare the mean of the initial measurements to the mean of the repeated measurements. A difference between means greater than 0.5 mm was considered clinically significant.

4. The intra-class correlation coefficients were calculated to assess correlation between initial and repeat measurements [215].

2.6 Results

The agreement of the repeated measurements of the centre of mass for the mean X, Y and Z coordinates of upper molars is shown in Figure 35 to Figure 46 for the Bland and Altman technique. Table 64 contains data on the t test and Table 65 illustrates the data for the intra-class correlation coefficient.

2.6.1 Bland and Altman technique

2.6.1.1 Agreements at the X coordinate:

A simple plot of the repeated measurements shows high agreement between the first and second measurements at the X coordinate, (Figure 35). The difference between the measurements follows a normal distribution as shown by Figure 36 and Figure 37. The Bland and Altman plot shows that the mean measurement difference is 0.01 (95% limits of agreement: -0.13, 0.11), (Figure 38).

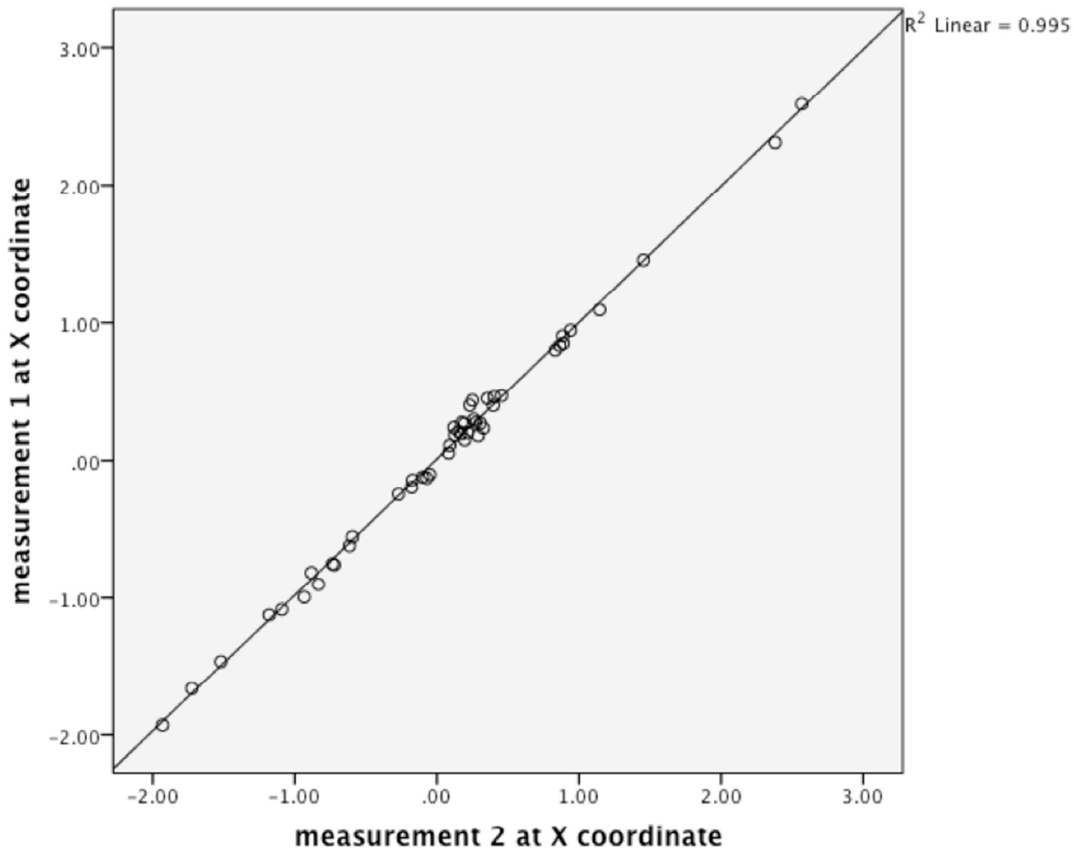


Figure 35: Scatter plot of repeated measurements at the X coordinate

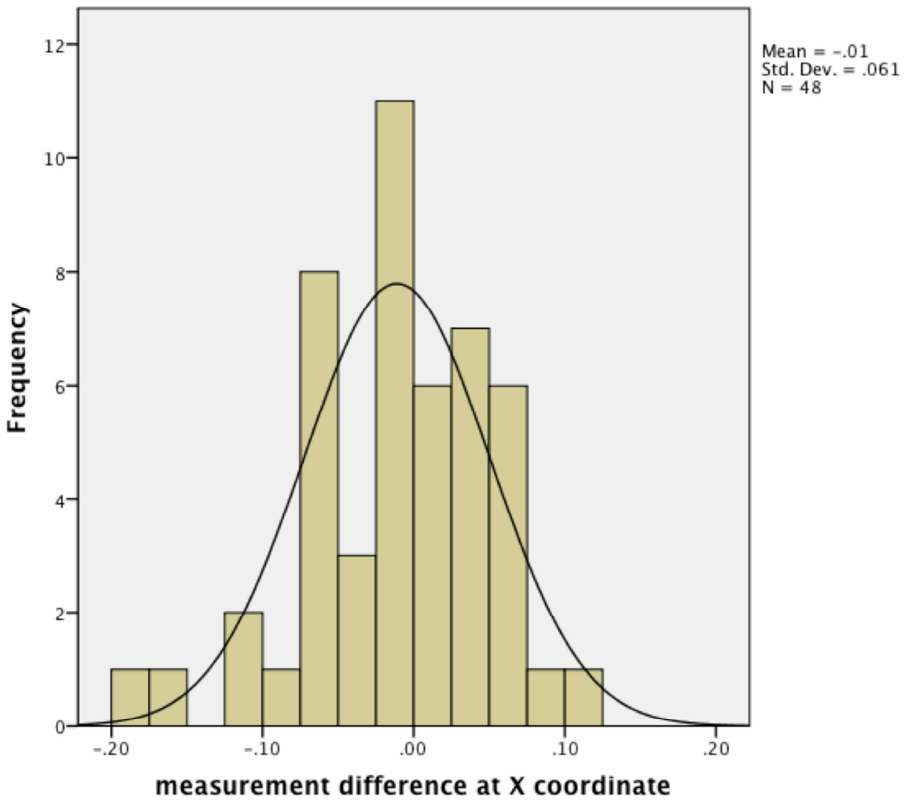


Figure 36: Histogram of the difference between measurements at the x coordinate, showing a normal distribution of the measurement difference

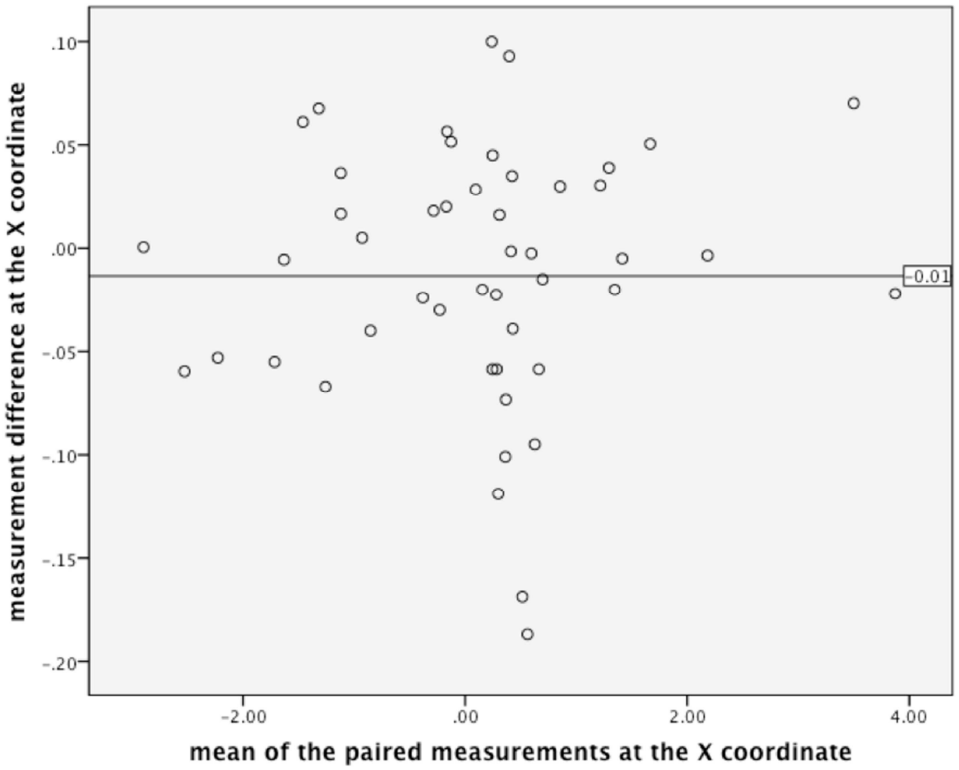


Figure 37: Plot of difference against mean at X coordinate, showing a normal distribution of the measurement difference

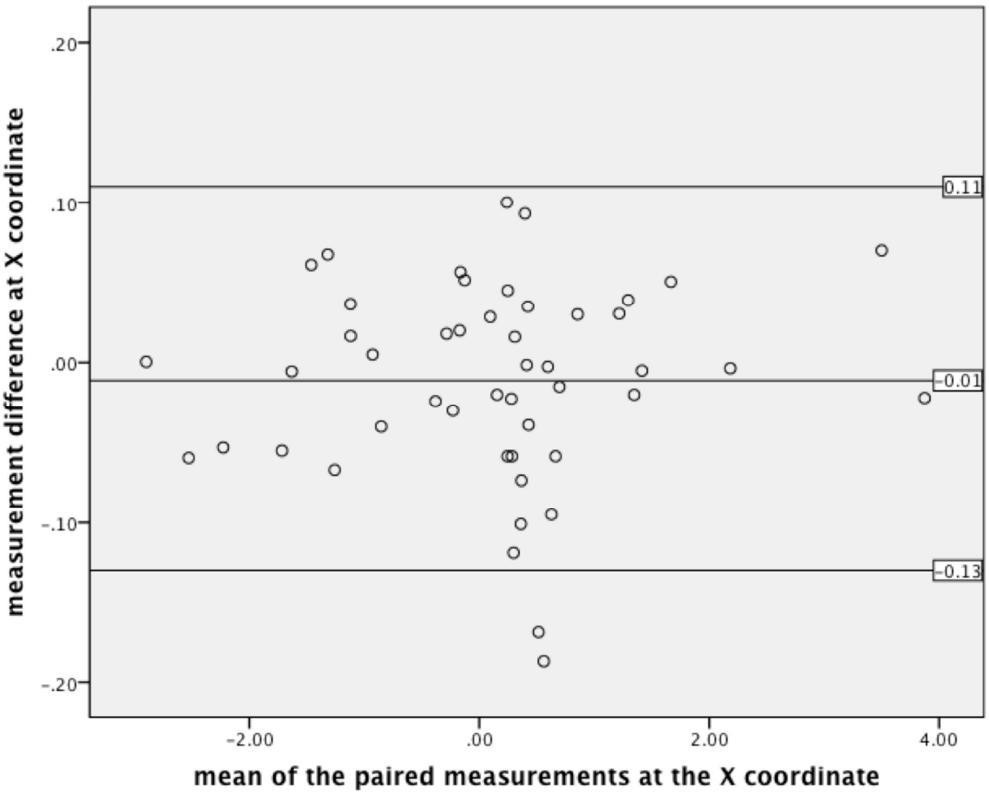


Figure 38: Bland and Altman plot showing agreement at the X axis and 95% confidence limits of agreement

2.6.1.2 Agreement at the Y coordinate

A simple plot of the repeated measurements shows good agreement between the first and second measurements at the Y coordinate, (Figure 39). The difference between the measurements follows a normal distribution as shown by Figure 40 and Figure 41. The Bland and Altman plot shows that the mean measurement difference is -0.07 (95% limits of agreement: -0.41, 0.27), (Figure 42).

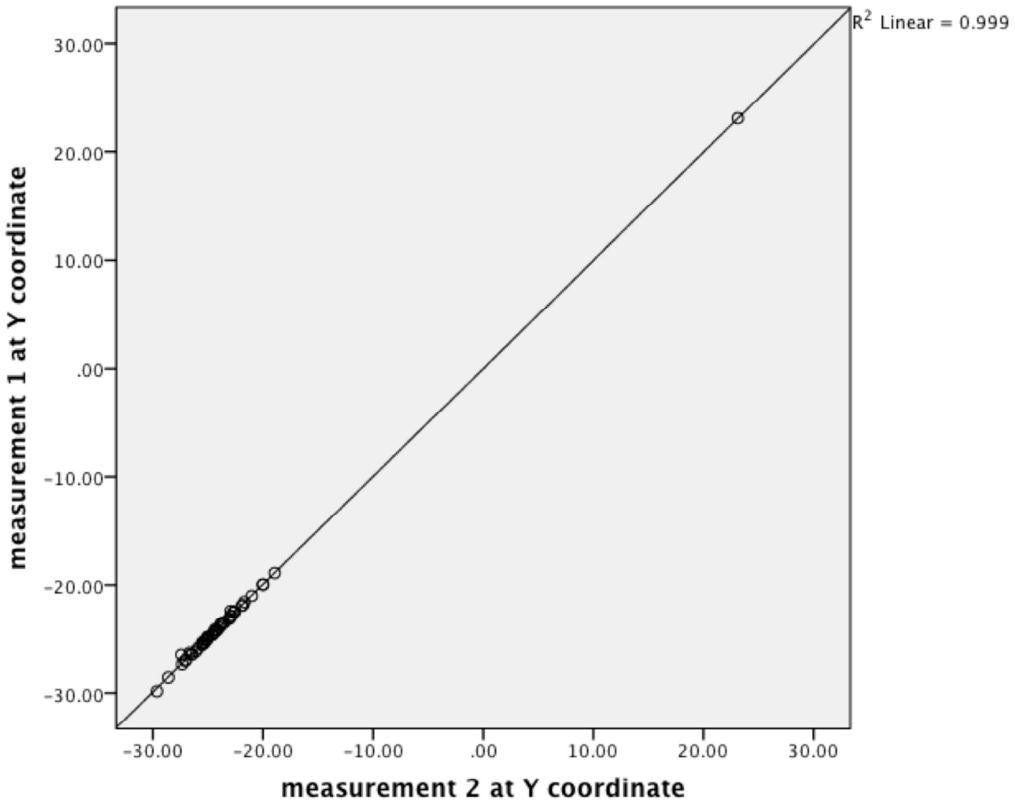


Figure 39: Scatter plot of repeated measurements at the Y coordinate

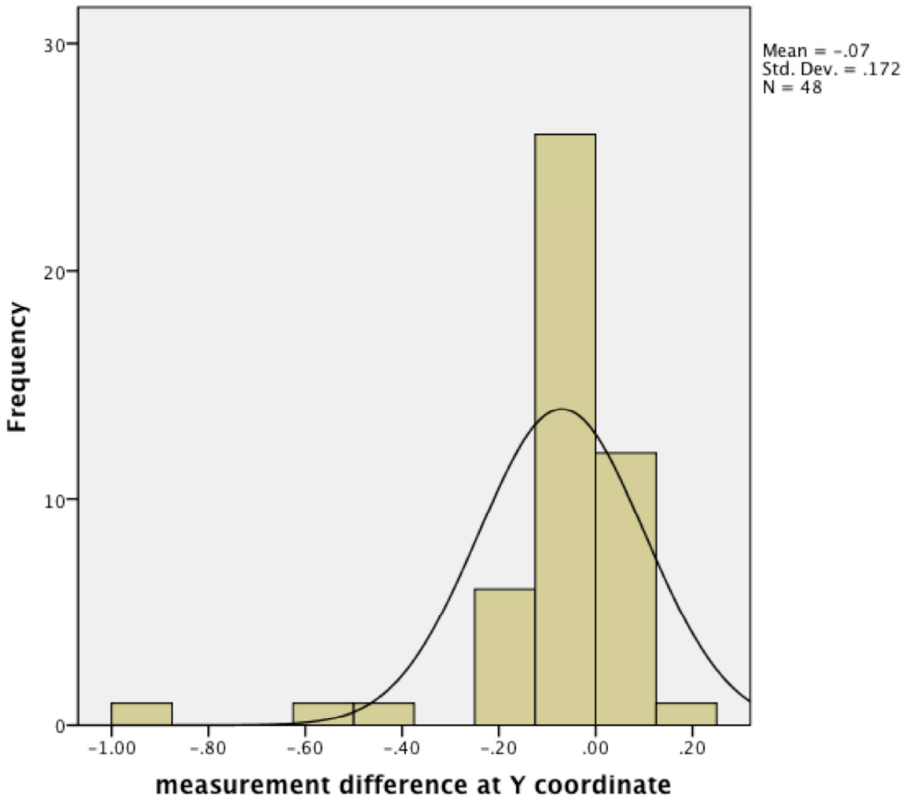


Figure 40: Histogram of the difference between measurements at the Y coordinate, showing a normal distribution of the measurement difference

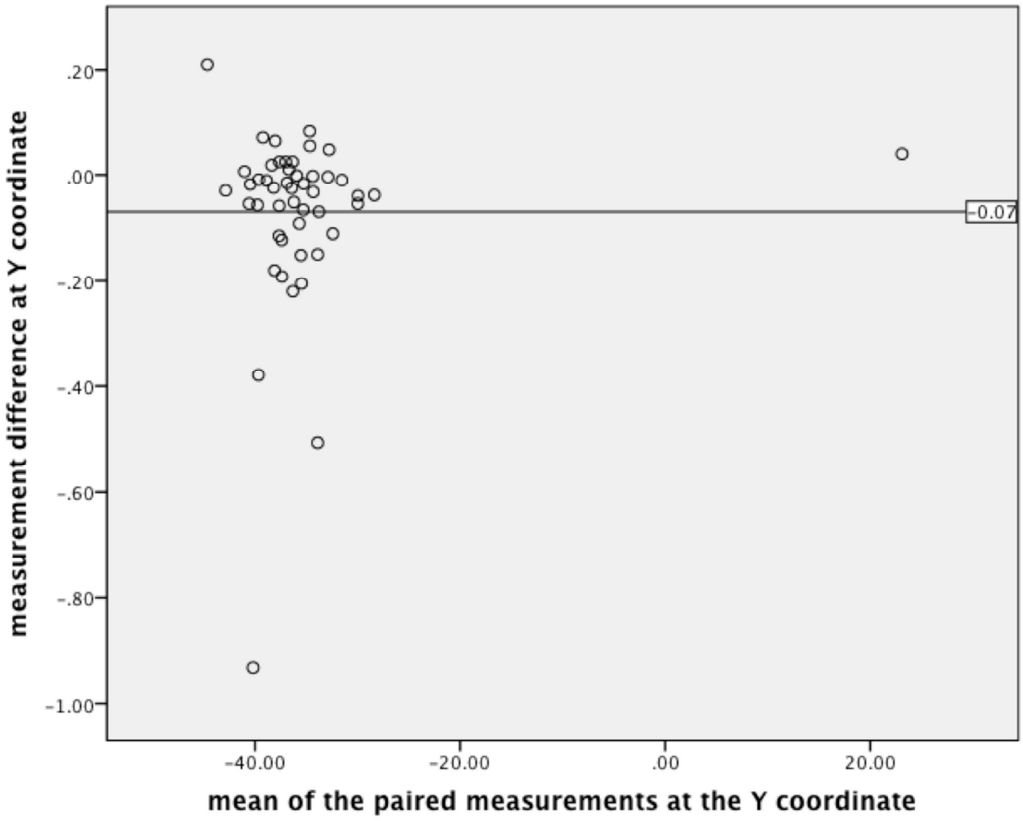


Figure 41: Plot of difference against mean at Y coordinate, showing a normal distribution of the measurement difference

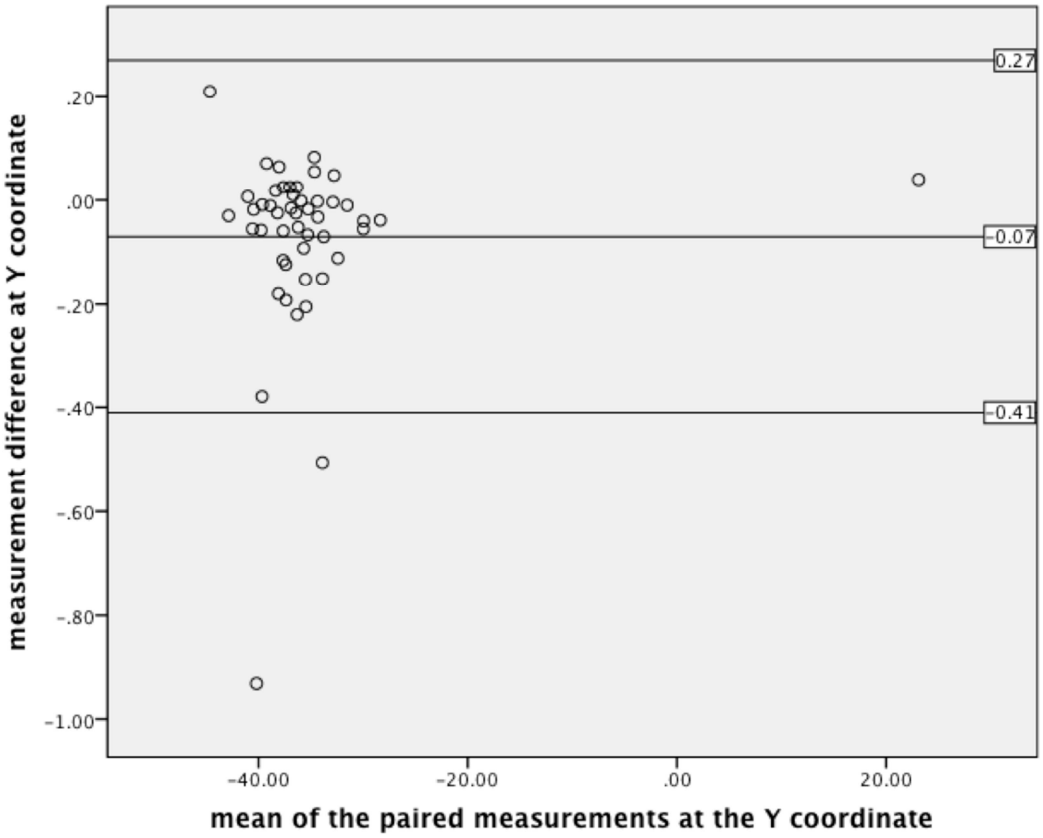


Figure 42: Bland and Altman plot showing agreement at the Y coordinate and 95% limits of agreement

2.6.1.3 Agreement at the Z coordinate

A simple plot of the repeated measurements shows good agreement between the first and second measurements at the Z coordinate, (Figure 43). The difference between the measurements follows a normal distribution as shown by Figure 44 and Figure 45. The Bland and Altman plot shows that the mean measurement difference is 0.07 (95% limits of agreement: -0.37, 0.23), (Figure 46).

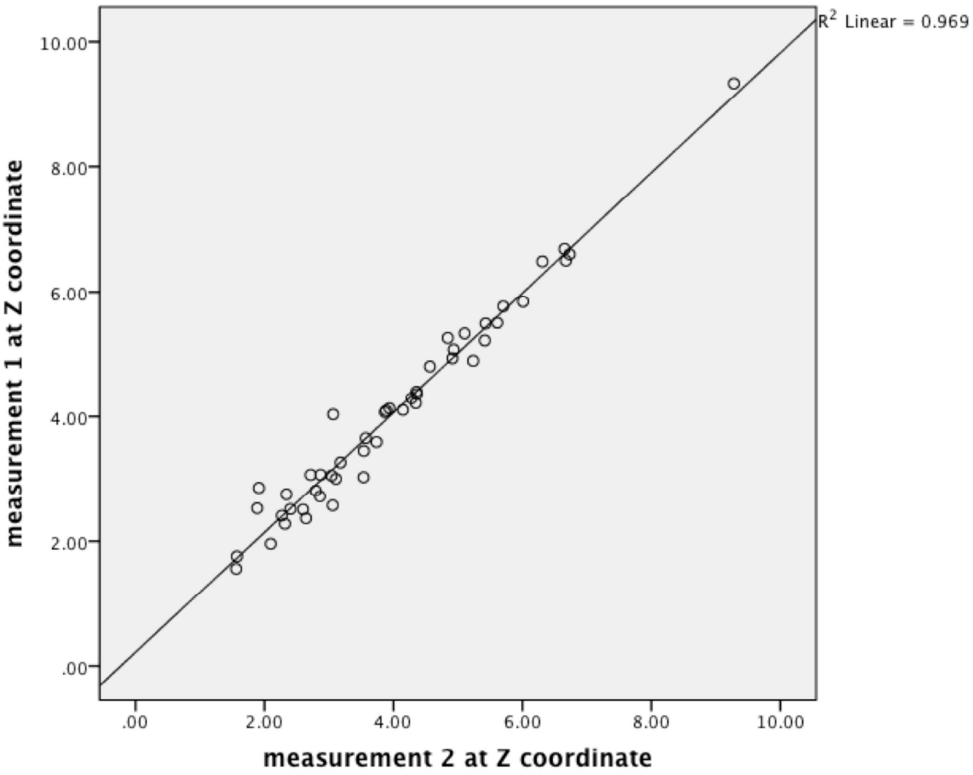


Figure 43: Scatter plot of repeated measurements at the Z coordinate

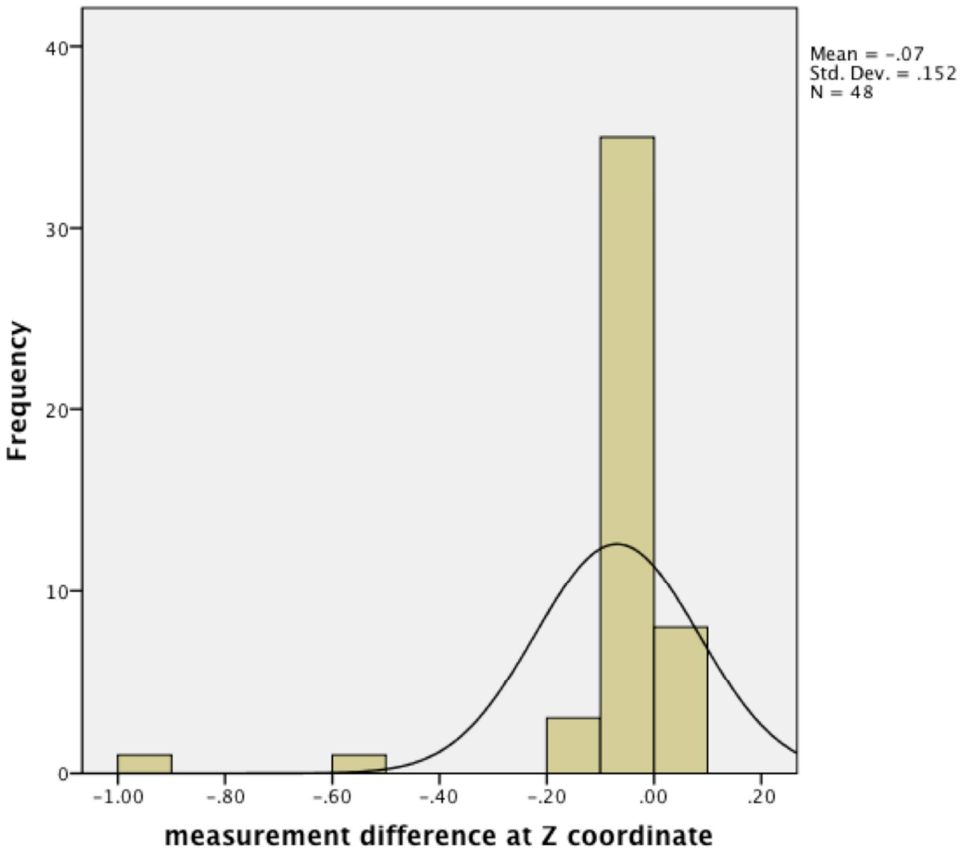


Figure 44: Histogram of the difference between measurements at the Z axis, showing a normal distribution of the measurement difference

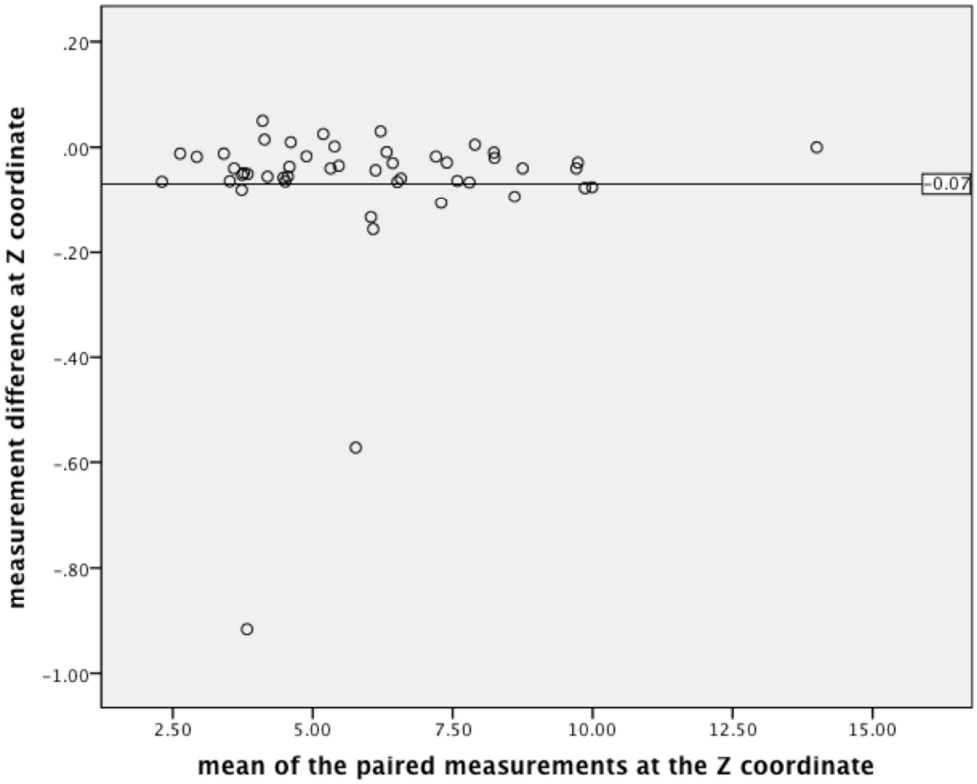


Figure 45: Plot of difference against mean at Z coordinate, showing a normal distribution of the measurement difference.

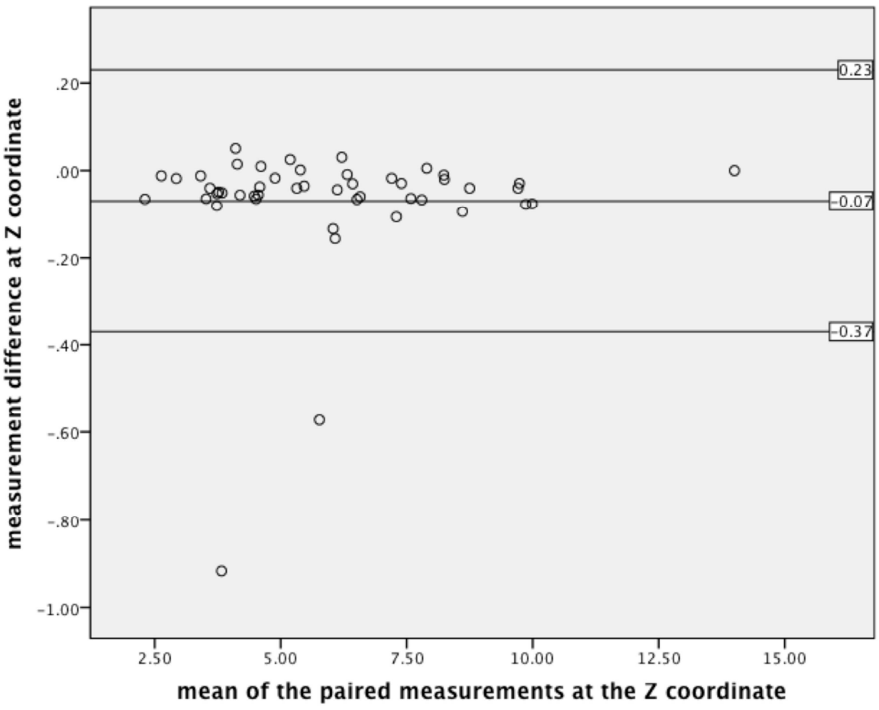


Figure 46: Bland and Altman plot to test agreement at the Z coordinate and 95% limits of agreement

2.6.2 Paired t-test

The paired t-test shows statistically significant differences of means at the Y and Z coordinates, but not at the X coordinate, (Table 64). However these differences are less than 0.1mm and are not considered clinically significant.

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Repeated measurements at X coordinate	.01	.06	.009	-.007	.029	1.224	47	.227
Pair 2	Repeated measurements at Y coordinate	.07	.17	.025	.020	.120	2.835	47	.007
Pair 3	Repeated measurements at Z coordinate	.07	.15	.022	.025	.113	3.157	47	.003

Table 64: Paired t-test assessing agreement between paired measurements at X, Y and Z coordinates

2.6.3 Intra-class correlation coefficient

The Intra-class correlation shows good correlation between repeated measurements at the X, Y and Z coordinates, (Table 65).

	Intraclass Correlation	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Repeated measurements at the X coordinate	.998	.996	.999	810.1	47	47	.000
Repeated measurements at the Y coordinate	1.000	.999	1.000	6983.540	47	47	.000
Repeated measurements at the Z coordinate	.995	.992	.997	440.065	47	47	.000

Table 65: Intraclass correlation coefficient showing good correlation between repeated measurements at X, Y and Z coordinates

2.7 Discussion:

Several methods were used to assess the intra-rater reliability of centre of mass measurements, and all these methods showed very high reliability. This is an expected finding as the software greatly decreases human error and the steps involved in the creation of the centre of mass are not technique sensitive. This agrees with the previous research assessing the reliability of these methods [97, 99].

After extensive use in this and other projects, it is worth discussing the use of Rapid Form software in the analysis of orthodontic models. It is clear that this is a sophisticated program that gives measurements accurate to fractions of a millimetre. Importantly, it allows several types of superimposition, and the most accurate is the 'fine'

superimposition, that is done solely by the software. However, this is only successful when the two structures to be superimposed are close together in three planes of space. Other types of superimposition involve the researcher manually selecting corresponding points or areas on the two models for superimposition, and then carrying out computer superimposition on these landmarks. I found that performing the manual superimposition followed by the fine superimposition usually gave the best and quickest results.

While the superimposition is accurate, there is a significant drawback in that it is rather difficult to learn the methodology. This is further compounded because measuring the scans is labour intensive and time consuming. For example, it took an average of 5-6 hours to measure 43 variables on each case, sometimes longer. The use of the software is also subject to purchasing an expensive license. These drawbacks currently limit the use of these methods to research studies rather than clinical care.

It was more difficult to superimpose on the lower arch because the area for superimposition was a continuous smooth surface, and it was, therefore, more difficult to identify landmarks for superimposition. In addition, there were a few cases in which the lower arch was expanded at the end of treatment that made the superimposition difficult. The superimposition of the lower incisors was relatively problematic mainly because of poor impressions in the lower arch, reshaping of the lower incisors at the end of treatment, and the presence of broken or chipped lower incisors in the models. In spite of these factors the superimpositions were still at an acceptable level of accuracy.

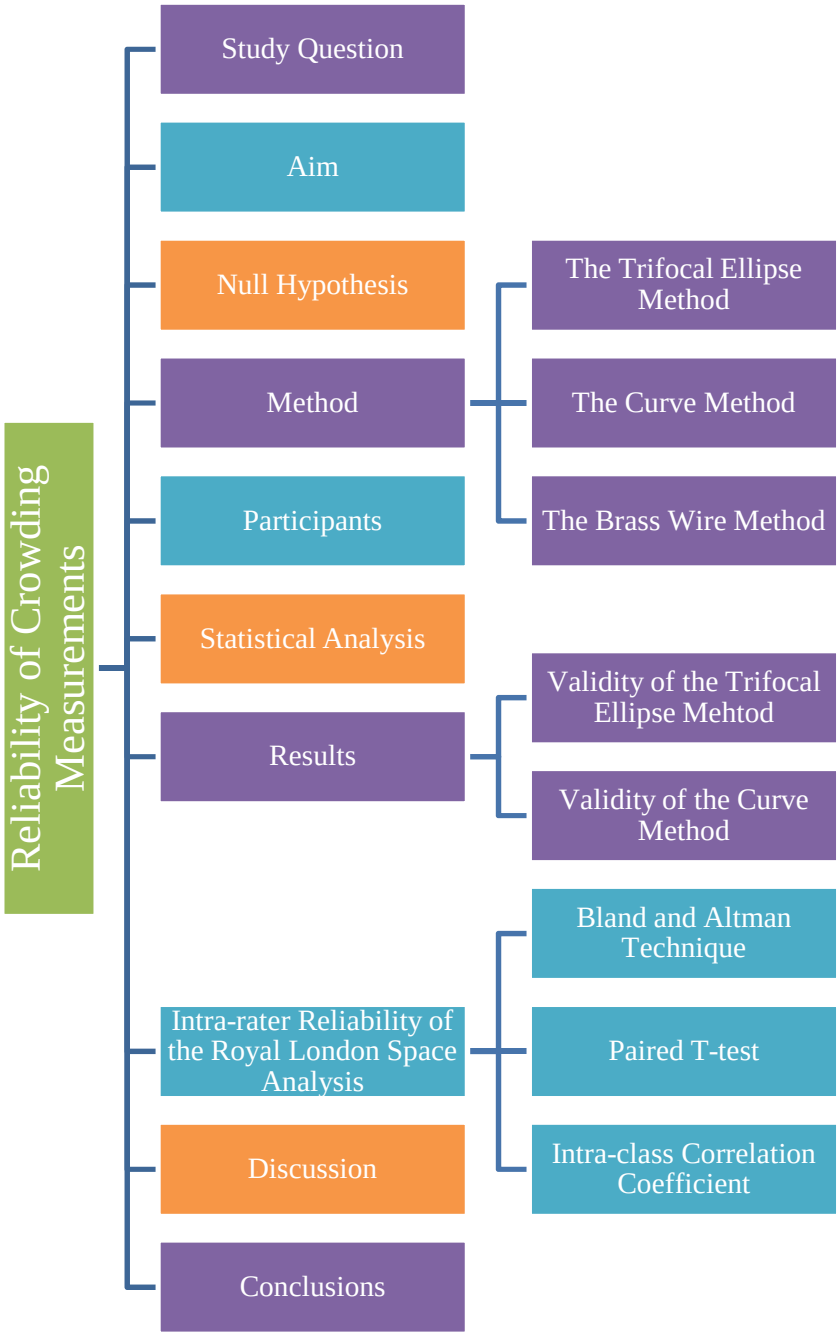
2.8 Conclusion

The 3 dimensional measurement technique used showed high reproducibility which is acceptable for use in this research.

3 Chapter 3: Reliability of crowding measurements

Figure 47 shows the order in which in which the topics are presented in this chapter.

Figure 47: A flow chart summarising the main topics discussed in Chapter 3



3.1 Study question

Are crowding measurements made on digital 3-dimensional models comparable to those made using a conventional method of crowding measurement?

3.2 Aim

To develop a method for measurement of crowding on digital 3-dimensional models and assess its validity

3.3 Objectives

To show that there is no difference between paired measurements when assessing the validity of the crowding method on digital 3-dimensional models.

3.4 Method

Previous research has not involved a method of measurement of crowding on 3 dimensional models using Rapidform software. I carried out several methods to attempt to measure crowding, these were:

1- Arch length discrepancy using the tri-focal ellipse method

2- Arch length discrepancy using the curve method

As there is no “gold standard” for the measurement of crowding, these two methods were compared to traditional and widely accepted method of measuring crowding; the brass wire method.

I will explain each method in the following text.

3.4.1 Trifocal ellipse method:

The basic concept of this method was derived from the Brader arch form or trifocal ellipse [216]. I constructed a reproducible arch form using the software to measure the arch

length. The arch form was formed of three circles with different centres and radii (trifocal). The three circles were as follows: The first circle is formed by defining the projected centres of mass of the six anterior teeth and was called the anterior circle. The second circle is formed by defining the projected centres of mass of the canine, 2nd premolar and 1st molar on the right side, and was called the right circle. The third circle is formed by defining the projected centres of mass of the canine, the 2nd premolar and the 1st molar on the left side and was called the left circle. The right and left circles intersect the anterior circle at the projected centre of mass of the canines, and their superimposition forms a trifocal ellipse. Thus, the ellipse was formed from an anterior arc, a right arc and a left arc, (Figure 48).

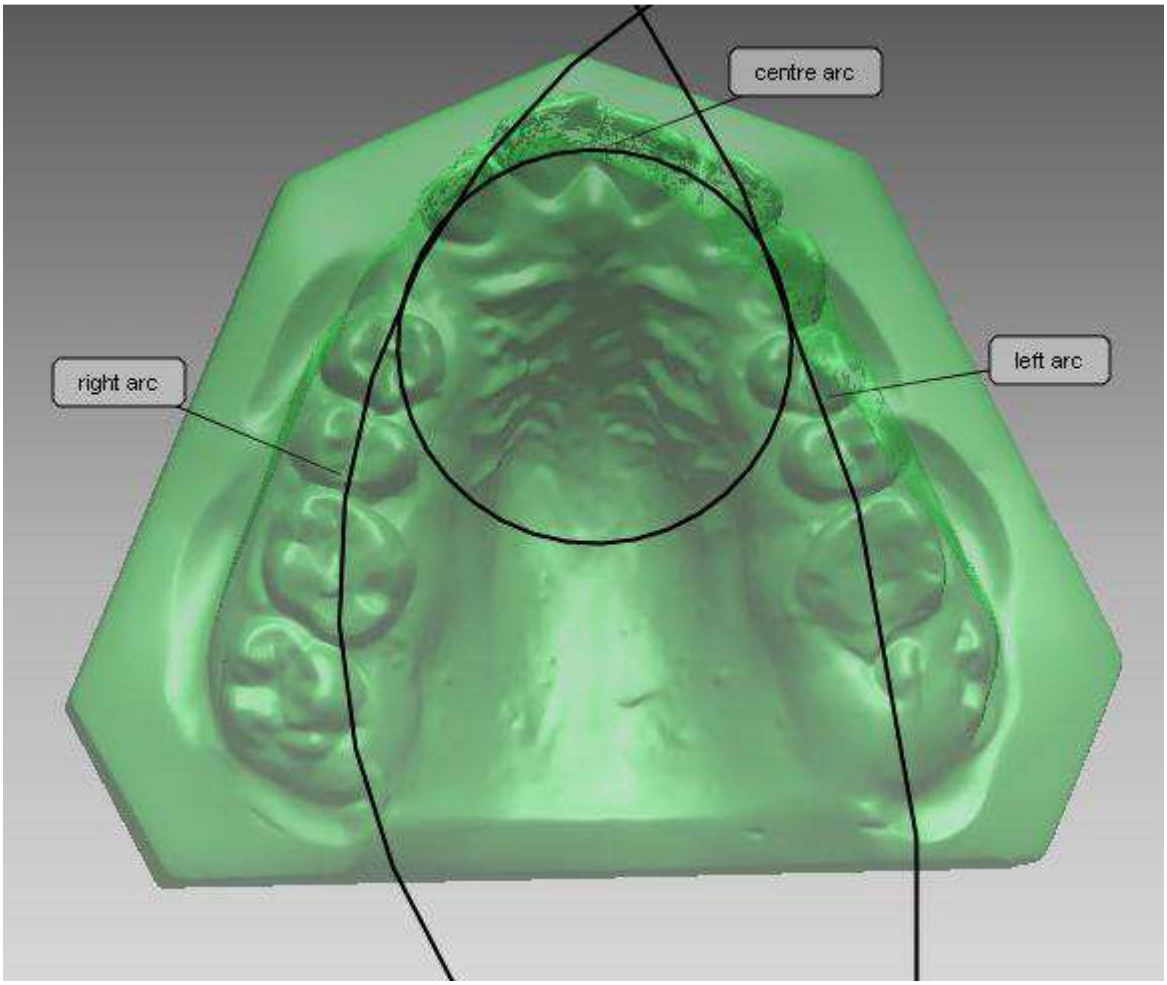


Figure 48: Formation of tri-focal ellipse to measure crowding in Rapidform™2006

The following reference points were used:

- Reference points on the mesial contact point of first molars:

These points represent the lateral boundaries of the arch in the posterior region, as well as the distal boundary of the arch.

- Reference points the centre of mass of the canines:

These represent the lateral boundaries of the arch in the anterior region. These two points also represent the intercanine width which is an important clinical parameter and should remain constant throughout treatment.

- Reference points the centre of mass if the incisors:

These two points represents the front (mesial) boundary of the arch.

The mesiodistal widths of teeth were taken as a linear measurement. Where teeth were unerupted or partially erupted, the mesiodistal measurements were estimated by measuring the contralateral tooth on the same model or the erupted tooth on the follow-up models.

3.4.2 The curve method:

I developed an "electronic' version of the brass wire technique using the software. This was done by defining reproducible landmarks based on the centre of mass of the molars, canines and central incisors to form the arch perimeter, (Figure 49). The anterior, lateral and posterior boundaries of the curve were the same as in the tri-focal ellipse method. The mesiodistal tooth measurements were taken from the previously collected data measurements made for the evaluation of the when assessing the tri-focal ellipse method.

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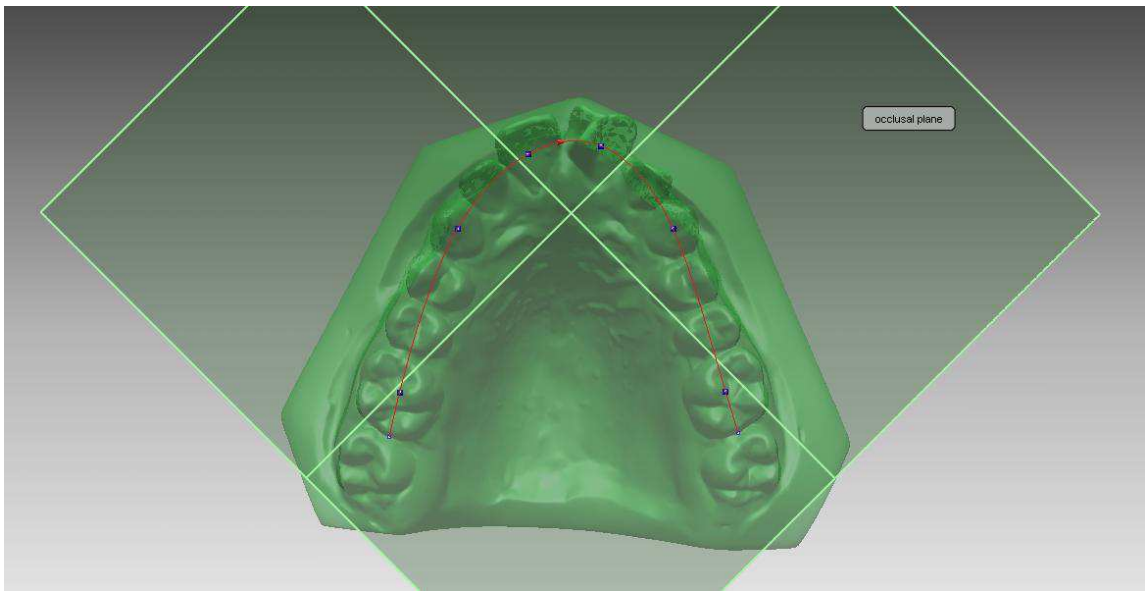


Figure 49: Curve method for crowding measurement in Rapidform^{TM}2006

3.4.3 The brass wire method

The space requirement calculation for this technique was done using traditional methods by calculating arch perimeter using a brass wire and directly measuring the widths of the teeth. The first stage involved measuring the mesiodistal widths of all teeth anterior to the second molars on a set of study models (Figure 50). In order to measure the arch perimeter, I adapted a brass wire to the arch going through the contact points of the teeth in a smooth curve. The arch wire extended from the mesial of the second molar on one side extending around the arch to the mesial of the second molar on the opposite side. If the teeth were severely crowded, rotated or proclined, then the curve was adapted to where my judgement of an ideal arch is, (Figure 51). The brass wire was then straightened and measured with the digital calliper to give the arch perimeter measurement.

Figure 50: Measurement of tooth width in the brass wire technique

Figure 51: Measurement of arch perimeter in the brass wire technique

3.5 Participants

The maxillary study casts of 20 subjects were randomly selected from the archived models of patients enrolled in previously completed randomised study that evaluated the effects of Herbst and Twin Block appliances in Class II patients [28]. Measurements of individual tooth widths and the arch perimeters (space available) were recorded. I then calculated the total tooth width (space needed), and arch length discrepancy (space available – space needed) for each model.

The same study models were used for the software measurements and the conventional measurements. Measurements from the trifocal ellipse method were made first; two weeks later measurements were made using the conventional method without referring to the previous values. When the trifocal ellipse method was found unsatisfactory, the curve method was developed and compared to both previous methods. The whole sample was measured by each of the three methods; no exclusions were made due to tooth morphology or shape of the arch.

3.6 Statistical analysis

Validity for both 3 dimensional scan methods was assessed against the traditional brass wire technique; the following techniques were used:

1. Scatter plots,
2. Bland and Altman technique [214],
3. Paired t-test
4. Intraclass correlation coefficient [215]

3.7 Results

3.7.1 Validity of the trifocal ellipse method:

There was low agreement in arch length discrepancy measurements between the trifocal ellipse method and the brass wire method as evidenced by a scatter plot, the Bland and Altman technique, paired t-test and intraclass correlation coefficient, (Figure 52, Figure 53, Figure 54, Table 66 and Table 67).

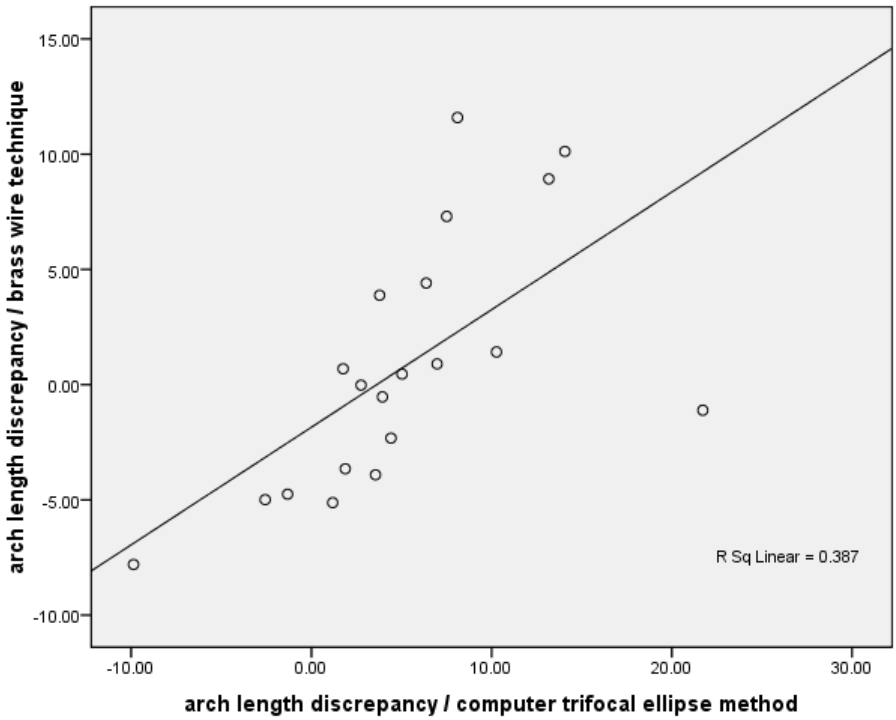


Figure 52: Scatter plot showing poor agreement between brass wire technique and trifocal ellipse computer method

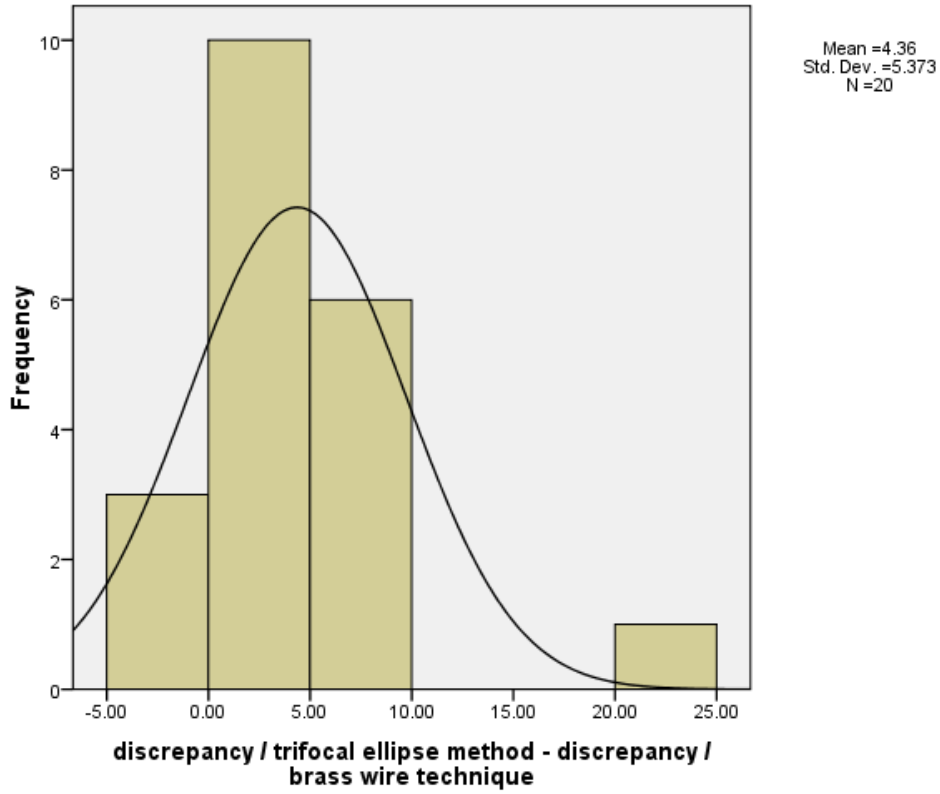


Figure 53: Histogram showing normal distribution of the measurement difference between the trifocal ellipse computer method and brass wire method

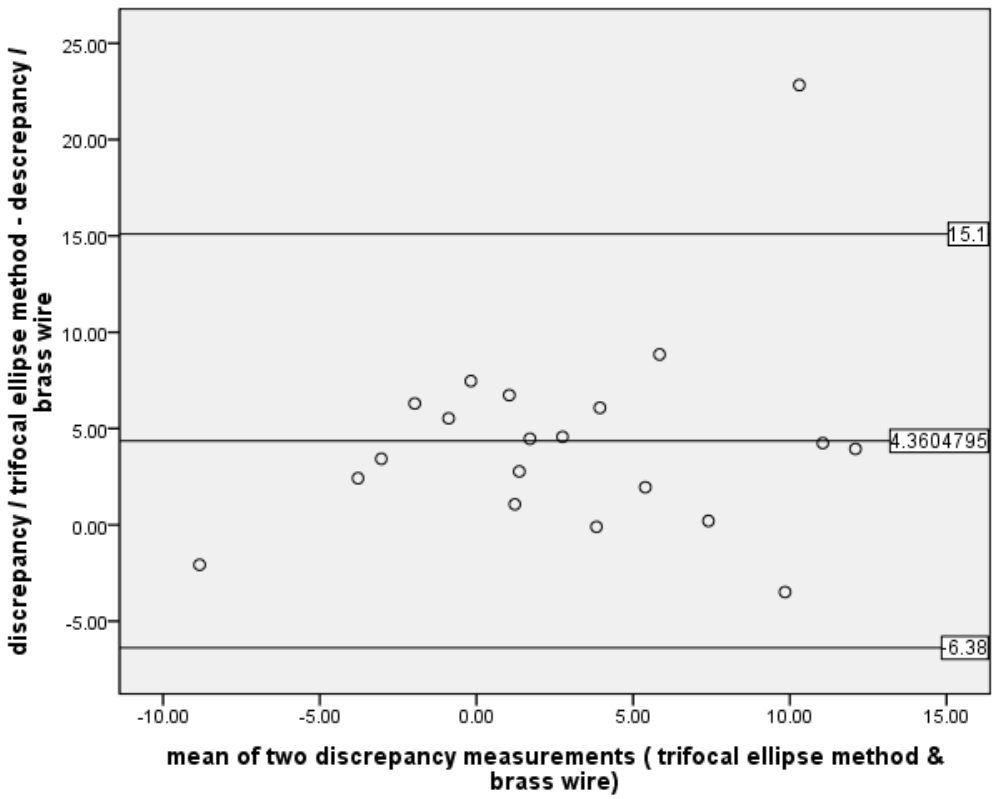


Figure 54: Bland and Altman plot showing a very wide 95% limits of agreement for the difference between discrepancy measurements made by the trifocal ellipse computer method and the brass wire method

		Paired Differences					t	df	Sig. (2-tailed)
					95% Confidence Interval of the Difference				
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper			
Pair 1	**brass wire technique calculated arch length discrepancy – trifocal ellipse computer calculated arch length discrepancy**	-4.360	5.373	1.202	-6.875	-1.846	-3.629	19	.002

Table 66: Paired t-test showing a statistically significant difference between the mean arch length discrepancy of the brass wire method and the trifocal ellipse method

	Intraclass Correlation	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Arch length discrepancy measured by the trifocal ellipse and brass wire methods	.493	.016	.776	4.128	19	19	.002

Table 67: Intraclass correlation coefficient showing fair agreement in arch length discrepancy measurements between the trifocal ellipse method and the brass wire method

3.7.2 Validity of the curve method:

There was moderate agreement, but wide 95% limits of agreement, in arch length discrepancy measurements between the curve method and the brass wire method. This was shown by a scatter plot, the Bland and Altman technique, paired t-test and intraclass correlation coefficient, (Figure 55, Figure 56, Figure 57, Table 68 and Table 69).

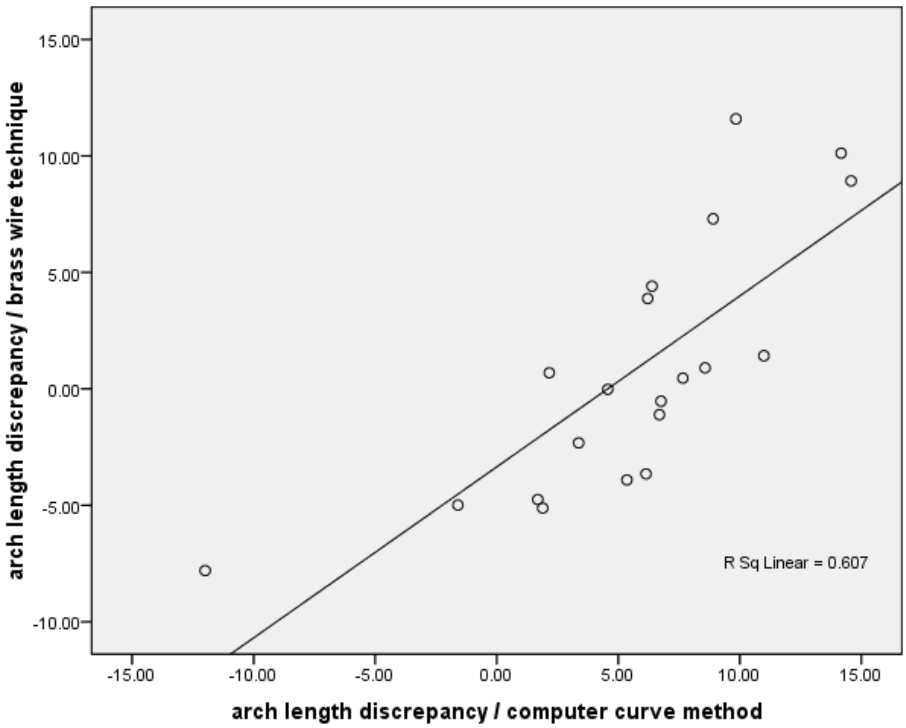


Figure 55: Scatter plot showing agreement in arch length discrepancy measurements between the curve computer method and the brass wire method

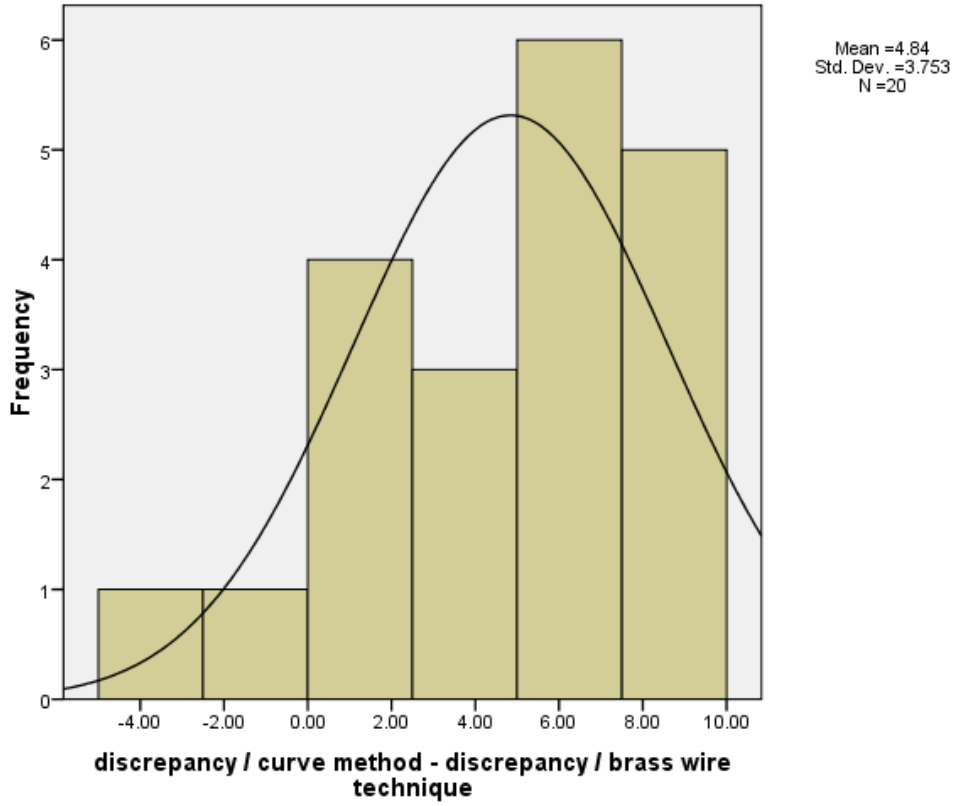


Figure 56: Histogram showing that the difference in measurements between the curve computer method and the brass wire method follows a normal distribution

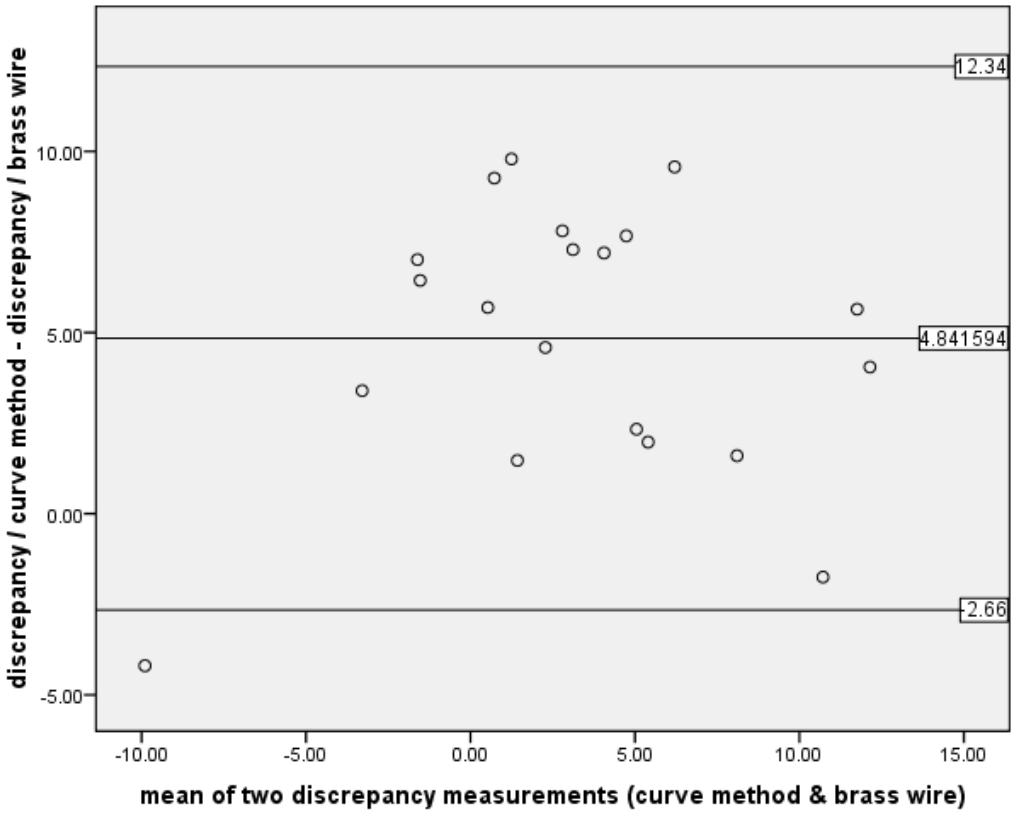


Figure 57: Bland and Altman plot showing very wide limits of agreement for the difference in measurements between the curve method and the brass wire method

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	**brass wire technique calculated arch length discrepancy - arch length discrepancy using curve method**	-4.842	3.753	.839	-6.598	-3.085	-5.769	19	.000

Table 68: Paired t-test showing a statistically significant difference between the mean arch length discrepancy of the brass wire method and the curve method

	Intraclass Correlation	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Arch length discrepancy measured by the curve and brass wire methods	.572	-.081	.851	7.989	19	19	.000

Table 69: Intraclass correlation coefficient showing moderate agreement in arch length discrepancy measurements between the curve method and the brass wire method

These results reveal that the difference between both computer methods and the copper wire method was statistically and clinically significant.

Further visual inspection of the data revealed that the discrepancy between measurements was mainly due to arch measurements. As a result, we decided to use a conventional method to measure the space requirements on the models; the Royal London Space analysis.

It was necessary to assess intra-rater reliability; the following section explains the methods undertaken to assess intra-rater reliability for the Royal London Space Analysis.

3.8 Intra-rater reliability of the Royal London space analysis

Intra-rater reliability was assessed by calculating the repeatability of measuring upper and lower space requirements using the Royal London space analysis on 36 plaster models. There was no real advantage in making the measurements on digital models because all of the components of the Royal London space analysis were taken for each treatment stage separately; there was no need for superimposition of the models. The extra time and

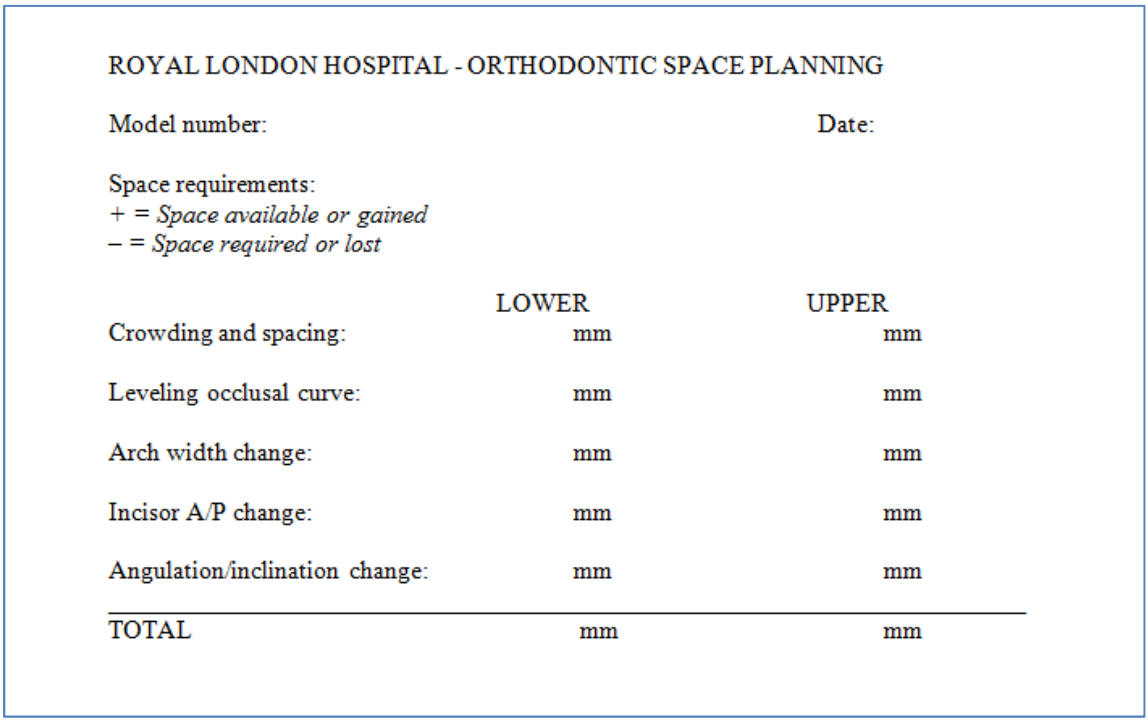
labour involved would not have been justified. In addition, the software has limitations in that the measurement of angulation/inclination was not developed.

The sample size was derived from a previous study assessing the reliability of the Royal London space analysis [86]. The study models were chosen randomly from archived pre-treatment models of patients enrolled in a previously completed randomized controlled trial comparing the effects of Twin Block and Herbst functional appliances [28]. There was at least a period of two weeks between the first measurement and the repeat measurement.

The space requirements were assessed as described in the literature [84, 85], using the form in Figure 58. The measurements and scores were recorded to the nearest half millimetre. Crowding and spacing was assessed anterior to the mesial surface of the first molars using a clear ruler. The sizes of any permanent unerupted teeth were determined by measuring these teeth on follow-up models. Guidance for space requirements for levelling the occlusal curve, arch width change, incisor A/P change, angulation change and angulation change was performed as described in the literature [84].

To assess repeatability the following statistical techniques were undertaken a scatter plot, Bland and Altman 95% limits of agreement, a paired t-test and the intra-class correlation coefficient.

Figure 58: Assessment of space requirements using the Royal London space analysis



ROYAL LONDON HOSPITAL - ORTHODONTIC SPACE PLANNING

Model number: Date:

Space requirements:
+ = *Space available or gained*
– = *Space required or lost*

	LOWER	UPPER
Crowding and spacing:	mm	mm
Leveling occlusal curve:	mm	mm
Arch width change:	mm	mm
Incisor A/P change:	mm	mm
Angulation/inclination change:	mm	mm
TOTAL	mm	mm

3.8.1 Bland and Altman technique

3.8.1.1 Royal London score / upper arch

A simple plot of the repeated measurements shows good agreement between the first and second measurements of the Royal London score in the upper arch, (Figure 59). The difference between the measurements follows a normal distribution as shown by Figure 60 and Figure 61. The Bland and Altman plot shows that the mean difference between repeated measurements is 0.4 mm (95% limits of agreement: -0.28, 3.7), (Figure 62).

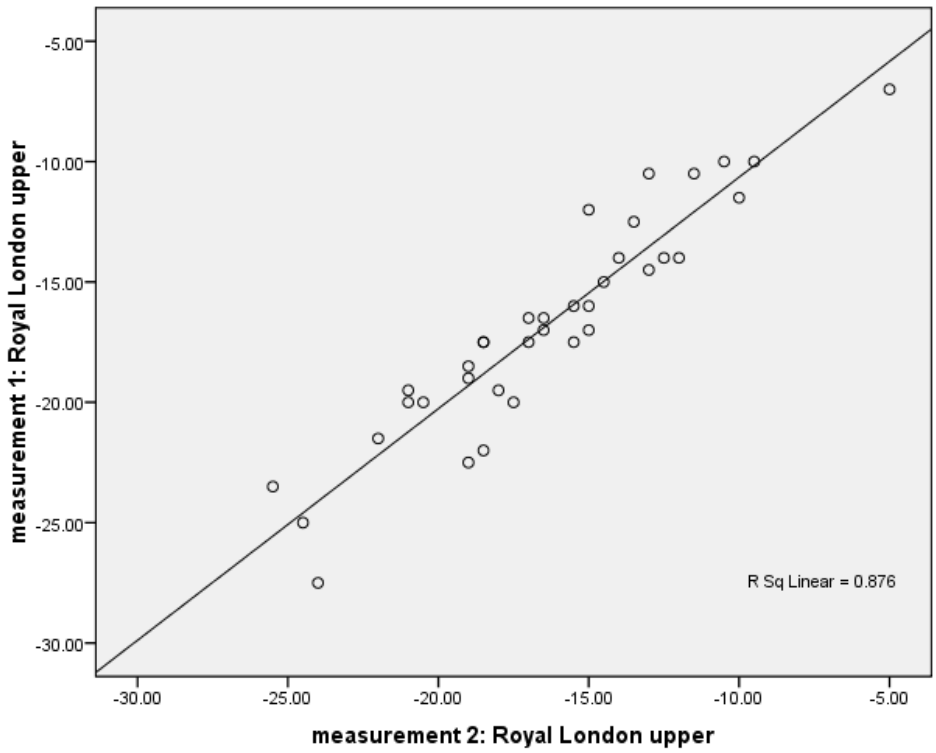


Figure 59: Scatter plot of repeated measurements of the Royal London space analysis in the upper arch

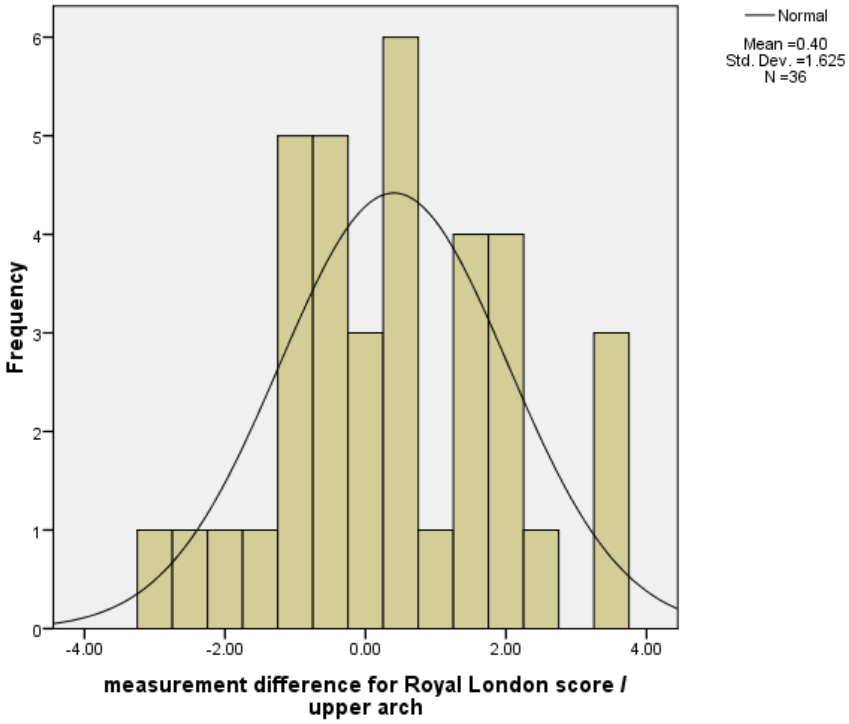


Figure 60: Histogram of the difference between repeated measurements of the Royal London space analysis in the upper arch, showing a normal distribution of the measurement difference

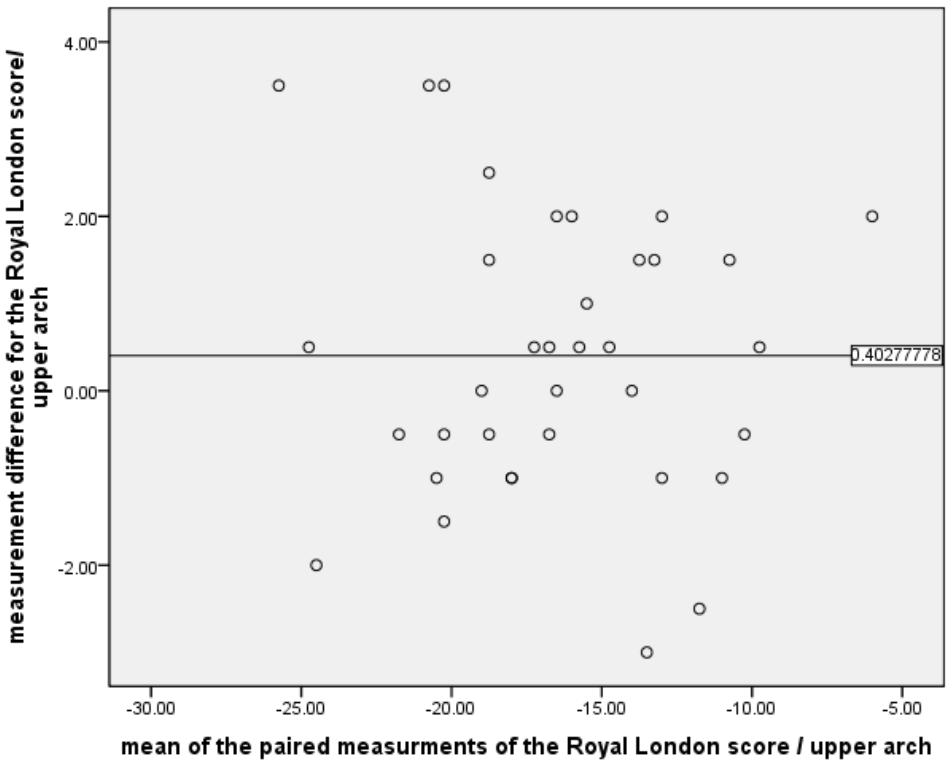


Figure 61: Plot of difference against mean of the Royal London score in the upper arch, showing a normal distribution of the measurement difference.

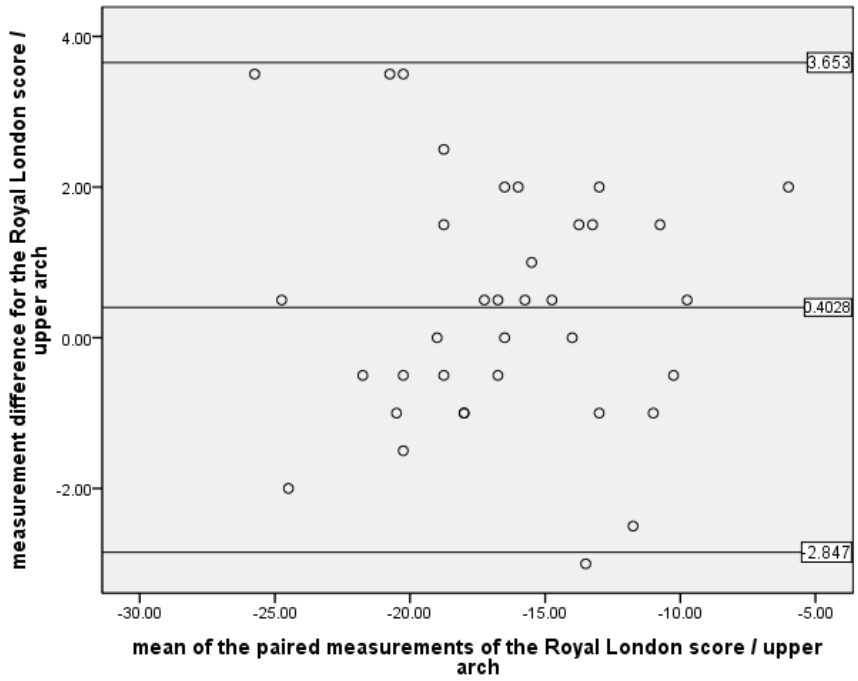


Figure 62: Bland and Altman plot showing agreement of the Royal London score in the upper arch and 95% limits of agreement

3.8.1.2 Royal London score / lower arch

A simple plot of the repeated measurements shows good agreement between the first and second measurements of the Royal London score in the lower arch, (Figure 63). The difference between the measurements follows a normal distribution as shown by Figure 64 and Figure 65. The Bland and Altman plot shows that the mean difference between repeated measurements is 0.11 mm (95% limits of agreement: -1.90, 2.13), (Figure 66).

Figure 63: Scatter plot of repeated measurements of the Royal London space analysis in the lower arch

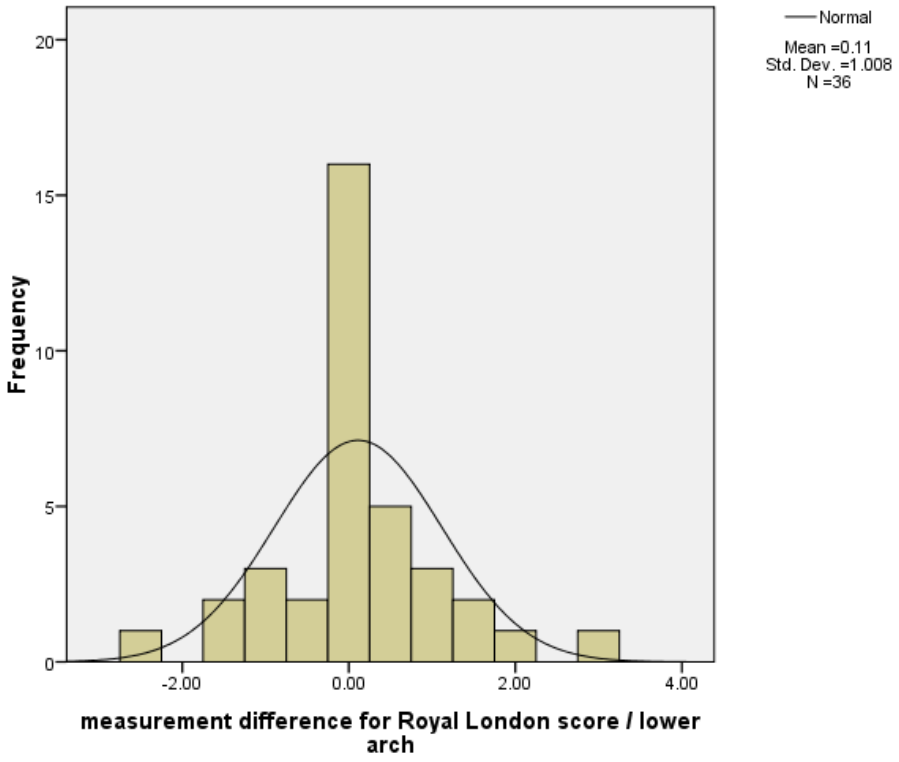


Figure 64: Histogram of the difference between repeated measurements of the Royal London space analysis in the lower arch, showing a normal distribution of the measurement difference

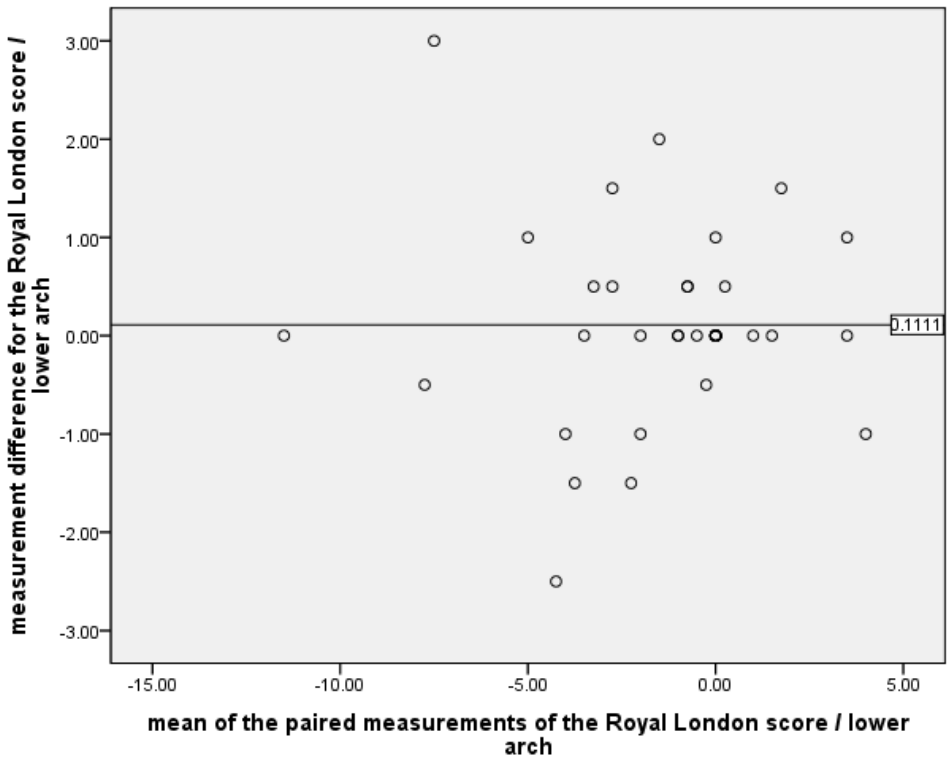


Figure 65: Plot of difference against mean of the Royal London score in the lower arch, showing a normal distribution of the measurement difference

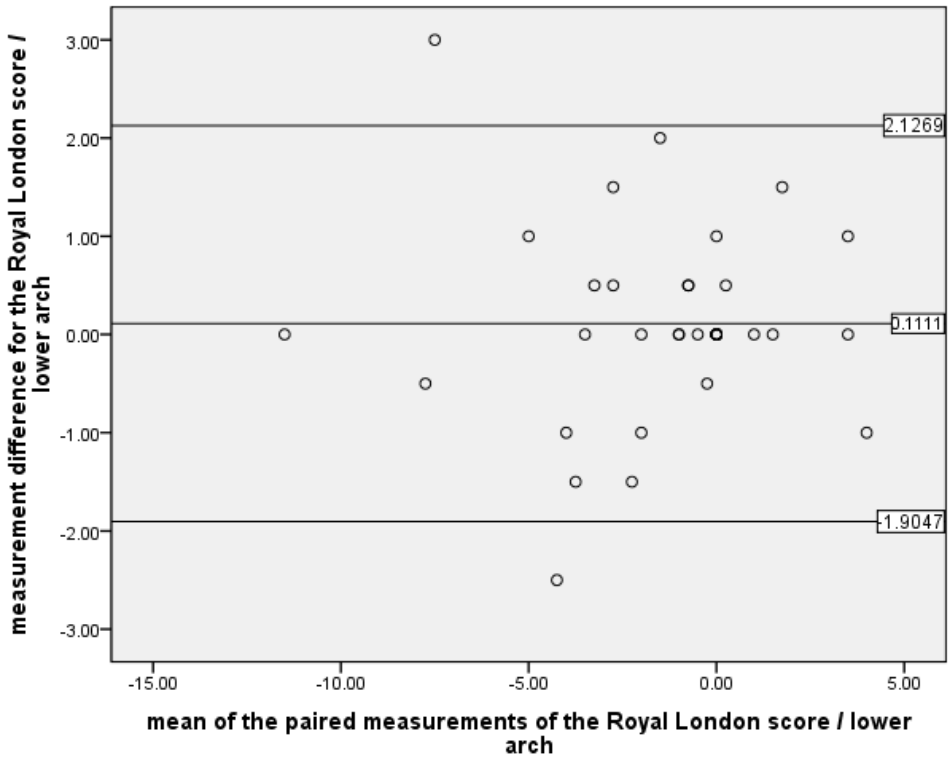


Figure 66: Bland and Altman plot showing agreement of the Royal London score in the lower arch and 95% limits of agreement

3.8.2 Paired t-test

There are no statistically significant differences in the paired measurements for the Royal London score in the upper and lower arches, (Table 70).

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	**Measurement 1 RoyLon_Upp – Measurement 2 RoyLon_Upp**	-0.403	1.625	0.271	-0.953	0.147	-1.487	35	0.146
Pair 2	**Measurement 1 RoyLon_Low – Measurement 2 RoyLon_Low**	-0.111	1.008	0.168	-0.452	0.230	-0.661	35	0.513

Table 70: Paired t-test assessing agreement between paired measurements of the upper and lower arch Royal London score

3.8.3 Intra-class correlation coefficient

The Intra-class correlation shows good correlation between repeated measurements of the Royal London score in the upper and lower arches, all of which are statistically significant, (Table 71).

	Intraclass Correlation	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Repeated measurements of the Royal London score / upper arch	.933	.873	.965	29.931	35	35	.000
Repeated measurements of the Royal London score / lower arch	.951	.907	.975	39.227	35	35	.000

Table 71: Intraclass correlation coefficient showing good correlation between repeated measurements of the upper and lower arch Royal London score

In summary, the Royal London space analysis had acceptable reproducibility for use in this study.

3.9 Discussion

The overall finding was that the 3D software methods developed were not acceptable for measurement of crowding on digital models. However, these can be used as a basis for further development of crowding methods in the software.

Two methods for measuring arch-length discrepancies were attempted for this investigation. Both methods utilised absolute linear measurements to measure mesiodistal tooth-widths, and then measurement of curve(s) to assess the arch perimeter. The ‘curve workbench’ in Rapidform was used to develop the method. This took considerable time and trial and error to learn to construct and measure the curve using predetermined reliable landmarks.

For each of these methods, crowding measurements were compared to the established brass-wire technique. Statistically and clinically significant differences were found

between each of the two methods and the brass wire technique. Although the brass-wire technique is not an absolute “gold standard”, it is a currently accepted method of measuring crowding in orthodontics. Errors in the data were checked by visually examining the data and manually calculating automatic sums. The measurements of tooth widths and arch lengths in the data set were checked against the original measurements. No errors in the data could be detected. Therefore, as a final measure, visual inspection of the models was assessed; it was obvious that the Rapidform measurements gave results that were clearly not sensible. As a result these methods could not be used in the digital assessment of crowding in Rapidform. In many ways this was an expected finding because the measurement of mesiodistal tooth widths is a linear measurement with known high reliability. It was not possible to determine the exact source of error in curve measurement and it may be assumed that this is related to the way the curve is projected to the occlusal plane.

When the results of previous studies attempting to measure arch length using digital models are considered it is clear that these reveal contrasting and perhaps inaccurate results. For example, Hui Chen et al developed a method to measure arch length discrepancy on 3D digital models using generic software, and reported that digital measurement was more accurate than traditional measurements [67]. However, they did not report any data to support this claim. OrthoCad uses a curve measurement to calculate arch length discrepancy. A study comparing OrthoCad to the brass wire technique found no statistically significant difference between the two methods. However, this study did not have a sample size calculation, and may have lacked power. Another study comparing OrthoCad to using straight segments of the arch presented conflicting results. In the upper arch the significant error was related to the tooth width measurement, but in the lower arch the significant error was related to the arch perimeter measurement. The latter finding would be considered an expected finding since a curve measurement of the arch perimeter

was being compared to a linear measurement; this finding tends to agree with this present study.

Crowding was considered an important factor in this study, therefore the Royal London space analysis was chosen as an alternative to software measurements. The advantage of this analysis is that it takes into consideration other factors which may have an impact on space requirements. Intra-rater reliability was high and comparable to previous research [86]. As a result, it was decided that this should be used to assess orthodontic space requirements in the last part of this research.

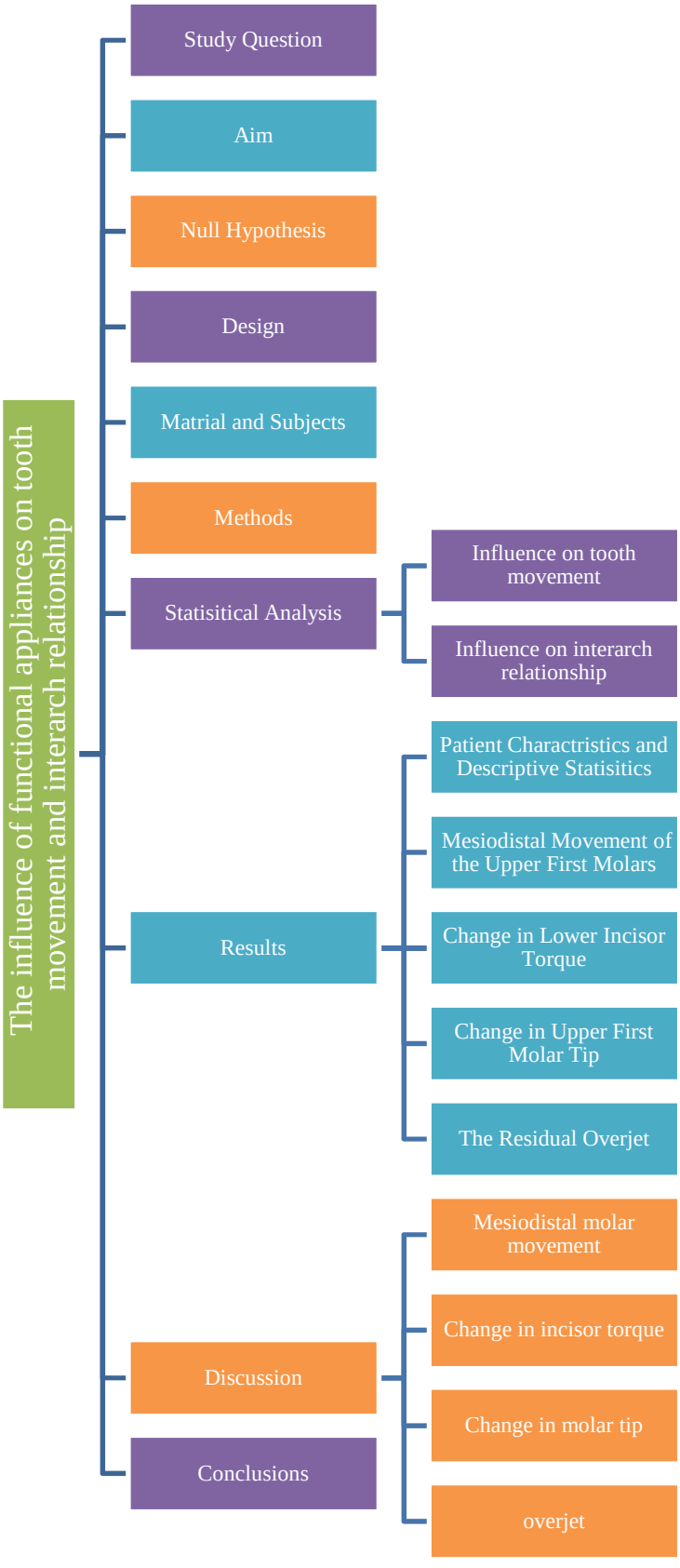
3.10 Conclusions

- Methods of measuring crowding from scans of study models were not comparable to conventional methods.
- The Royal London analysis shows good intra-rater reliability.

4 Chapter 4: The influence of functional appliances on tooth movement and inter-arch relationship

Figure 67 shows the order in which in which the topics are presented chapter 4.

Figure 67: A flow chart summarising the main topics discussed in Chapter 4



4.1 Study question:

Does the type of functional appliance (fixed or removable) influence tooth movement and interarch relationship?

4.2 Aim

To evaluate the effect of different types of functional appliances on three-dimensional tooth movements and interarch relationship in patients with Class II Division I malocclusion.

4.3 Objectives

To show that the type of functional appliance does not have an influence on tooth movement and inter-arch relationship

4.4 Design:

A retrospective comparative study with two parallel groups.

4.5 Materials and subjects:

Maxillary and mandibular study casts of 83 subjects were selected from archived models of patients enrolled in a previously completed randomized controlled trial comparing the effects of Twin Block and Herbst functional appliances [28]. The inclusion criteria for the trial were overjet ≥ 7 mm, second premolars erupted and no craniofacial syndrome. The patients were randomly allocated to two groups; a Twin Block group and a Herbst group, (Figure 68 and Figure 69). The treatment process included an initial functional phase of treatment with either a Twin Block or Herbst appliance (Phase I), followed by a fixed appliance phase of treatment (Phase II), (Figure 70). Data was collected at the following stages of treatment:

- DC1 pre-treatment

- DC2 at the end of the functional appliance phase of treatment
- DC3 at the end of the fixed appliance phase of treatment.

We only included participants who had records in all three stages of treatment. Figure 71 shows the flow and selection of patients for this study.

Figure 68: The Twin Block appliance

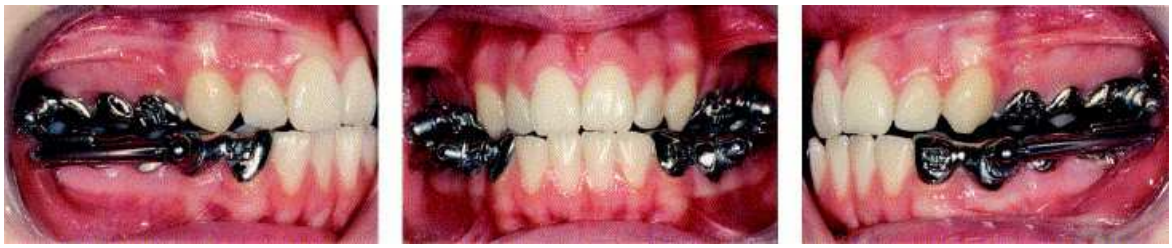


Figure 69: The Herbst appliance

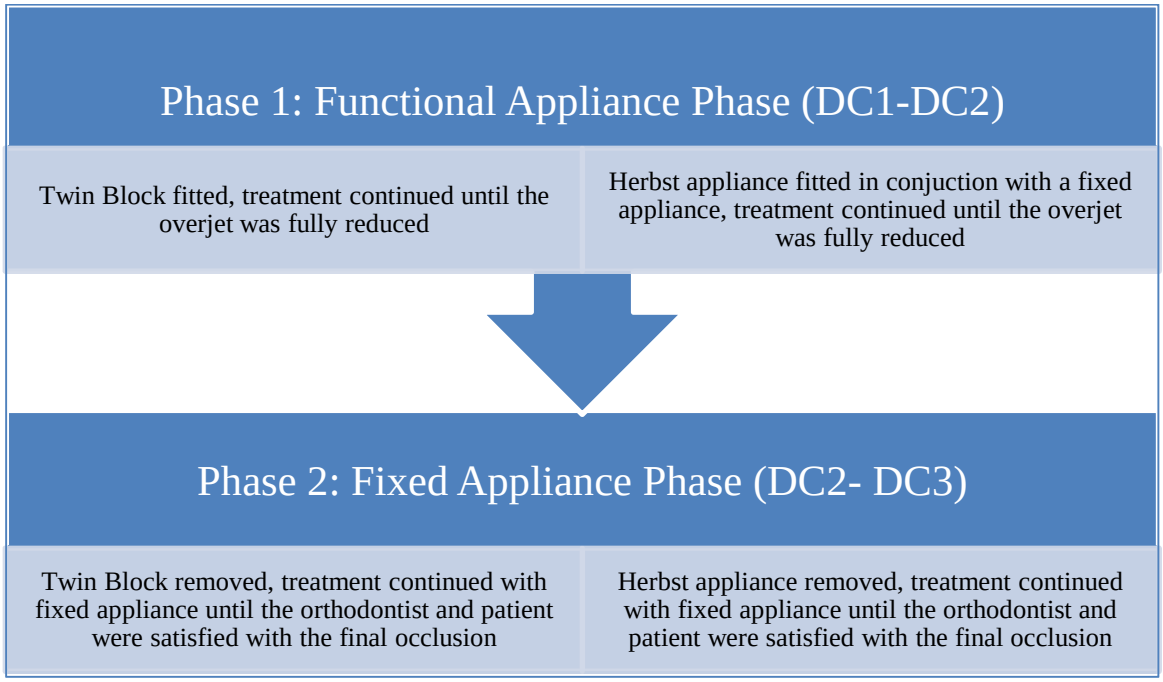


Figure 70: The process of phase 1 and phase 2 treatment.

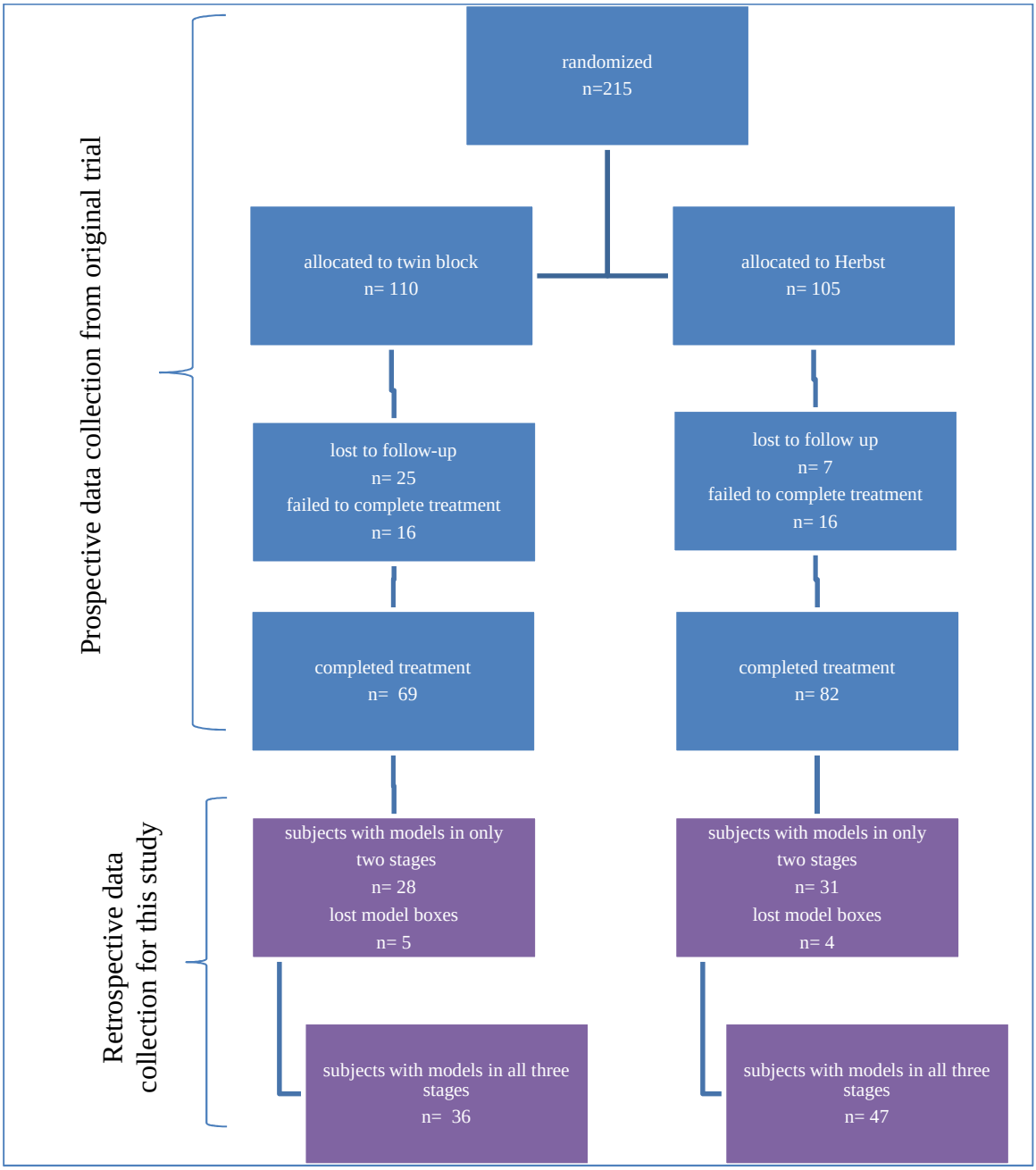


Figure 71: Selection of subjects for this investigation

4.6 Methods:

This part of the study was involved with measuring “key anchorage preparation” tooth movement as a result of functional appliance use.

The primary outcome was the anchorage potential measured by the change in the position of the upper first molar in a mesial or distal direction, using superimposed 3D digital

models. This was measured at the end of the functional appliance phase of treatment (DC2) and at the end of active treatment (DC3).

The secondary outcomes were:

a. The change in torque of the lower incisors (DC2 and DC3)
b. The change in tip of the upper first molars (DC2 and DC3)
c. The residual overjet at the end of functional appliance treatment (DC2).

A formal sample size calculation performed for the primary outcome (distal molar movement) showed that a sample size of 32 in each group had 85% power to detect a difference in means of 2 mm assuming that the common standard deviation is 2.6 using a two group t-test with a 0.05 two sided significance level. To reduce selection bias, all participants satisfying the inclusion criterion for this study were included. Therefore, the sample for this study consists of 36 patients in the Twin Block group and 47 patients in the Herbst group.

4.7 Statistical analysis

4.7.1 Influence on tooth movement:

A regression analysis was used for assessing the influence of the functional appliances on

- distal movement of the upper first molars,
- change in lower incisor torque and
- change in upper molar tip.

The dependent variable was the amount of tooth movement, and the independent variable was the type of functional appliance. Initially a univariate analysis was used to assess the effect of the functional appliances. This analysis was further adjusted by carrying out a multiple regression with the covariates; age at the end of functional, length of treatment in functional appliance, treatment centre (13 centres were involved), the number of missed appointments and the number of casualty appointments.

Data relating to age, gender, number of appointments, length of time in treatment and treatment centres were obtained from previous research documentation. Data related to all types of tooth movement (distal movement, tip, torque) and inter-arch relations (overjet and molar relationship) were measured on digital models as described previously. Table 72 shows the variables that were measured on the digital models.

Type of measurement	**Assessed at DC2**	**Assessed at DC3**
Distal movement of the upper first molars	yes	yes
Change in tip of the upper first molars	yes	yes
Change in torque of the lower incisors	yes	yes
Overjet	yes	no

Table 72: The type of 3D measurements made and the time points at which they were taken

The amount of tooth movement was measured on both right and left sides of the digital models at two time points (DC2, DC3). Molar tooth movements were analysed as a cluster using the robust error method. For the lower incisor torque, the measurements of the two incisors in each lower quadrant were averaged, then the right and left sides were analysed as a cluster. A separate regression analysis was used at each time point.

4.7.2 Influence on inter-arch relationship (overjet)

Overjet was measured at the end of functional appliance treatment (DC2). A simple linear regression was used to analyse the effect of the type of functional appliance on the value of overjet at DC2. This analysis was further adjusted for with the following covariates; age at the end of functional, length of treatment in functional appliance, treatment centre (13 centres were involved), the number of missed appointments and the number of casualty appointments.

4.8 Results

4.8.1 Patient characteristics and descriptive statistics

The gender and age at the beginning of treatment of the sample used in this study is shown in Table 73. Descriptive statistics for the primary and secondary outcomes and for the covariates used in the regression analyses are shown in Table 74 and Table 75.

	Patients randomised and included in this study		**Patients randomised and not included in this study**	
	Twin Block n=36	**Herbst n=47**	**Twin Block n=73**	**Herbst n=57**
Age in months at entry into the trial (standard deviation)	148.67 (11.34)	153.79 (14.12)	148.66 (15.75)	151.12 (16.69)
Age in months at start of functional (standard deviation)	151.56 (10.97)	156.96 (14.51)	149.93 (16.18)	154.07 (16.91)
Gender male	9	24	39	25
female	27	23	34	32

Table 73: Gender and age distribution between Twin Block and Herbst groups

Outcomes	Twin Block n= 36		Herbst n= 47	
	Mean	Std. deviation	Mean	Std. Deviation
End of functional (DC2-DC1)				
Distal movement of upper right first molar (mm)	0.162	1.732	-.804	1.667
Distal movement of upper left first molar (mm)	0.826	1.833	-.558	2.030
Residual overjet (mm, at DC2 only)	4.779	2.234	4.069	2.784
Change in torque of lower right incisors	10.428	13.749	9.836	25.021
Change in torque of lower left incisors	15.246	21.275	16.489	19.000
Change in tip of upper right first molar	8.084	19.275	-2.881	23.968
Change in tip of upper left first molar	7.538	18.311	1.950	26.065
End of active treatment (DC3- DC1)				
Distal movement of upper right first molar (mm)	2.838	2.918	1.985	2.995
Distal movement of upper left first molar (mm)	3.348	2.108	2.391	2.687
Change in torque of lower right incisors	10.279	22.795	14.000	25.977
Change in torque of lower left incisors	8.469	23.624	11.353	24.124
Change in tip of upper right first molar	19.945	25.759	20.437	27.401
Change in tip of upper left first molar	21.415	22.447	16.134	24.520

*(-) sign for distal mesiodistal movement indicates movement in the distal direction, (-) sign for incisor inclination indicates retroclination, (-) sign for tip indicates distal tip

Table 74: Descriptive statistics for primary and secondary outcomes at DC2 and DC3

Variable	Twin Block Mean (standard deviation)	Herbst Mean (standard deviation)
Age at the end of functional (months)	162.559 (11.950)	163.5319 (14.30240)
Length of treatment in functional (months)	11.470 (6.593)	6.149 (3.375)
Number of missed appointments	.278 (.566)	.213 (.549)
Number of casualty appointments	1.306 (1.508)	4.277 (3.275)
Treatment Centre	Count	Count
Treatment centre 1	4	6
Treatment centre 2	3	5
Treatment centre 3	4	2
Treatment centre 4	0	2
Treatment centre 5	4	5
Treatment centre 6	5	6
Treatment centre 7	2	4
Treatment centre 8	3	4
Treatment centre 9	7	5
Treatment centre 10	1	1
Treatment centre 11	1	1
Treatment centre 12	0	2
Treatment centre 13	2	4

Table 75: Descriptive statistics for factors considered as covariates

4.8.2 Movement of the upper first molars

4.8.2.1 Regression analysis at DC2

When the types of functional appliance were the only variables entered in the regression, the amount of distal molar movement at DC2 was not influenced by the use of a Twin Block or Herbst appliance, (Table 76). When relevant covariates were fitted to the model, statistically significant influence of the following factors were found; age of the patient at the end of functional appliance phase, number of casualty appointments, (Table 77). The overall effect of centre was also statistically significant.

Distal movement at DC2	***Coef.***	***Std. Err.***	***T***	***P>|t|***	***[95% Conf. Interval]***	
Twin Block appliance	-.0948772	.1906693	-0.50	0.620	-.4741792	.2844247
_cons	1.669595	.1248292	13.38	0.000	1.42127	1.91792

Table 76: Results of regression analysis to investigate the influence of the type of functional appliance on the amount of distal molar movement of the upper first molars at the end of functional appliance treatment (DC2)

Distal movement at DC2	*Coef.*	*Std. Err.*	*T*	*P>|t|*	*[95% Conf. Interval]*	
Twin Block appliance	-.2646638	.2572943	-1.03	0.307	-.7766956	.2473681
Age at DC2	-.0162614	.0061039	-2.66	0.009	-.0284086	-.0041143
Time in functional	-.0182517	.0204418	-0.89	0.375	-.0589322	.0224288
Treatment centre 2	.9147983	.2259606	4.05	0.000	.4651224	1.364474
Treatment centre 3	.9485704	.3490769	2.72	0.008	.2538851	1.643256
Treatment centre 4	-.2032319	.2890133	-0.70	0.484	-.7783866	.3719229
Treatment centre 5	1.217698	.4202503	2.90	0.005	.3813732	2.054023
Treatment centre 6	.6072798	.3674313	1.65	0.102	-.1239318	1.338491
Treatment centre 7	.6971513	.3116927	2.24	0.028	.0768631	1.317439
Treatment centre 8	.706347	.5571143	1.27	0.209	-.4023458	1.81504
Treatment centre 9	.7845121	.3406073	2.30	0.024	.106682	1.462342
Treatment centre 10	-.4762793	.2980462	-1.60	0.114	-1.06941	.1168517
Treatment centre 11	.4534143	.4643857	0.98	0.332	-.4707428	1.377571
Treatment centre 12	.2869202	.3025096	0.95	0.346	-.3150932	.8889335
Treatment centre 13	.4712632	.2960523	1.59	0.115	-.1178998	1.060426
Number of missed appointments	.1562783	.1637725	0.95	0.343	-.1696394	.482196
Number of casualty appointments	-.0730972	.0326977	-2.24	0.028	-.1381676	-.0080267
_cons	4.129606	.91475	4.51	0.000	2.309195	5.950016

Table 77: Results of the adjusted regression analysis investigating the influence of type of functional appliance and important covariates on the amount of distal movement of the upper molars at DC2

4.8.2.2 Regression analysis at DC3

When the types of functional appliance were the only variables entered in the regression, the amount of distal molar movement at DC3 was not influenced by the use of a Twin Block or Herbst appliance, (Table 78). When the covariates were fitted to the model, no significant predictorsof distal molar movement was present, (Table 79).

Distal movement at DC3	***Coef.***	***Std. Err.***	***T***	***P>|t|***	***[95% Conf. Interval]***	
Twin Block	.4421887	.4493189	0.98	0.328	-.4516497	1.336027
_cons	2.876541	.2852043	10.09	0.000	2.309179	3.443903

Table 78: Results of regression analysis to investigate the influence of the type of functional appliance on the amount of distal molar movement of the upper first molars at DC3

Distal movement at DC3	*Coef.*	*Std. Err.*	*T*	*P>|t|*	*[95% Conf. Interval]*	
Twin Block appliance	.302665	.5694351	0.53	0.597	-.830547	1.435877
Age at DC2	-.0154921	.0192271	-0.81	0.423	-.0537553	.022771
Time in functional	.0319216	.0513217	0.62	0.536	-.0702117	.134055
Treatment centre 2	-1.289456	.7617304	-1.69	0.094	-2.805348	.2264357
Treatment centre 3	-.4417006	1.07317	-0.41	0.682	-2.577378	1.693976
Treatment centre 4	1.941371	2.598619	0.75	0.457	-3.230046	7.112788
Treatment centre 5	-.0237122	1.115567	-0.02	0.983	-2.243762	2.196338
Treatment centre 6	1.197321	1.029588	1.16	0.248	-.8516238	3.246266
Treatment centre 7	-.6605626	.882641	-0.75	0.456	-2.417074	1.095949
Treatment centre 8	-1.373695	.9505047	-1.45	0.152	-3.265259	.51787
Treatment centre 9	-.1802245	.980393	-0.18	0.855	-2.131269	1.77082
Treatment centre 10	-2.091284	.8621568	-2.43	0.018	-3.807031	-.3755371
Treatment centre 11	-2.690251	1.494204	-1.80	0.076	-5.663812	.2833099
Treatment centre 12	-1.040943	.7745796	-1.34	0.183	-2.582406	.5005191
Treatment centre 13	-.088276	.8926327	-0.10	0.921	-1.864672	1.68812
Number of missed appointments	-.3510802	.3448416	-1.02	0.312	-1.037337	.3351765
Number of casualty appointments	-.0251981	.0706017	-0.36	0.722	-.1657	.1153038
_cons	5.665052	2.988531	1.90	0.062	-.2823141	11.61242

Table 79: Results of the adjusted regression analysis investigating the influence of type of functional appliance and important covariates on the amount of distal movement of the upper molars at DC3

4.8.3 The change in lower incisor torque

4.8.3.1 Regression analysis at DC2

When the types of functional appliance were the only variables entered in the regression, change in lower incisor torque at DC2 was not influenced by the use of a Twin Block or Herbst appliance, (Table 80). When important covariates were fitted to the model, the only statistically significant influences were found with the type of functional appliance and the age at the end of functional, (Table 81).

Lower incisor torque at DC2	*Coef.*	*Std. Err.*	*T*	*P>|t|*	*[95% Conf. Interval]*	
Twin Block	-3.134539	2.179321	-1.44	0.154	-7.469903	1.200826
_cons	22.80052	1.654282	13.78	0.000	19.50963	26.09142

Table 80: Results of regression analysis to investigate the influence of the type of functional appliance on the change in lower incisor torque at DC2

Lower incisor torque at DC2	*Coef.*	*Std. Err.*	*T*	*P>|t|*	*[95% Conf.*	*Interval]*
Twin Block appliance	-5.761013	2.747715	-2.10	0.039	-11.22914	-.2928863
Age at DC2	-.2230249	.0815413	-2.74	0.008	-.3852973	-.0607525
Time in functional	.0575912	.2128443	0.27	0.787	-.3659823	.4811648
Treatment centre 2	.004427	3.953935	0.00	0.999	-7.864154	7.873008
Treatment centre 3	8.448466	6.499701	1.30	0.197	-4.486351	21.38328
Treatment centre 4	-2.901358	3.467483	-0.84	0.405	-9.801868	3.999152
Treatment centre 5	-.299801	5.269012	-0.06	0.955	-10.78547	10.18587
Treatment centre 6	-3.441115	4.161751	-0.83	0.411	-11.72326	4.841033
Treatment centre 7	-1.937372	3.506518	-0.55	0.582	-8.915564	5.040821
Treatment centre 8	-5.656152	5.633055	-1.00	0.318	-16.86629	5.553984
Treatment centre 9	-.0994871	4.714892	-0.02	0.983	-9.482421	9.283447
Treatment centre 10	-5.649229	5.221389	-1.08	0.283	-16.04012	4.741667
Treatment centre 11	-2.888033	4.605639	-0.63	0.532	-12.05355	6.27748
Treatment centre 12	-6.732572	5.607811	-1.20	0.233	-17.89247	4.427327
Treatment centre 13	1.098182	4.194434	0.26	0.794	-7.249008	9.445372
Number of missed appointments	2.444129	2.418788	1.01	0.315	-2.369412	7.25767
Number of casualty appointments	-.3371779	.4668752	-0.72	0.472	-1.266289	.5919333
_cons	61.10621	13.42408	4.55	0.000	34.39145	87.82098

Table 81: Results of the adjusted regression analysis investigating the influence of type of functional appliance and important covariates on the change in lower incisor torque at DC2

4.8.3.2 Regression analysis at DC3

When the types of functional appliance were the only variables entered in the regression, change in lower incisor torque at DC3 was not influenced by the use of a Twin-block or Herbst appliance, (Table 82). When important covariates were fitted to the model, statistically significant influences were found with the following factors; type of functional appliance, the age at the end of functional, the length of time in functional appliance, treatment centre (Table 83).

Lower incisor torque at DC3	***Coef.***	***Std. Err.***	***T***	***P>|t|***	***[95% Conf. Interval]***	
Twin Block	-1.41364	2.535627	-0.56	0.579	-6.45781	3.630529
_cons	24.144	1.880068	12.84	0.000	20.40394	27.88405

Table 82: Results of regression analysis to investigate the influence of the type of functional appliance on the change in lower incisor torque at DC3

Lower incisor torque at DC3	*Coef.*	*Std. Err.*	*T*	*P>|t|*	*[95% Conf. Interval]*	
Twin Block appliance	-7.01842	3.009074	-2.33	0.022	-13.00667	-1.030171
Age at DC2	-.2266815	.0824687	-2.75	0.007	-.3907994	-.0625635
Time in functional	.8527954	.2182187	3.91	0.000	.4185263	1.287064
Treatment centre 2	-6.929473	2.504426	-2.77	0.007	-11.91344	-1.945505
Treatment centre 3	2.362794	4.575255	0.52	0.607	-6.742253	11.46784
Treatment centre 4	-10.62326	3.832643	-2.77	0.007	-18.25047	-2.996061
Treatment centre 5	-2.742175	5.627473	-0.49	0.627	-13.9412	8.456854
Treatment centre 6	-4.099581	4.124952	-0.99	0.323	-12.3085	4.109335
Treatment centre 7	-4.861838	4.986165	-0.98	0.332	-14.78462	5.060947
Treatment centre 8	-.3812497	3.618226	-0.11	0.916	-7.581749	6.81925
Treatment centre 9	.3290717	4.910821	0.07	0.947	-9.443774	10.10192
Treatment centre 10	-.4961684	7.357092	-0.07	0.946	-15.13725	14.14491
Treatment centre 11	-25.12655	8.035331	-3.13	0.002	-41.11737	-9.135736
Treatment centre 12	2.063883	14.17414	0.15	0.885	-26.14355	30.27131
Treatment centre 13	-2.191121	3.084491	-0.71	0.480	-8.329455	3.947212
Number of missed appointments	-4.614047	2.682486	-1.72	0.089	-9.952364	.7242693
Number of casualty appointments	-.1114521	.415978	-0.27	0.789	-.9392747	.7163705
_cons	60.38701	12.61518	4.79	0.000	35.282	85.49201

Table 83: Results of the adjusted regression analysis investigating the influence of type of functional appliance and important covariates on the change in lower incisor torque at DC3

4.8.4 The change in upper first molar tip

4.8.4.1 Regression analysis at DC2

When the types of functional appliance were the only variables entered in the regression, change in upper first molar tip at DC2 was not influenced by the use of a Twin-block or Herbst appliance, (Table 84). When important covariates were fitted to the model, the only statistically significant influences were found with treatment centre, (Table 85).

Change in molar tip at DC2	***Coef.***	***Std. Err.***	***T***	***P>|t|***	***[95% Conf. Interval]***	
Twin-block	-3.494031	2.700903	-1.29	0.199	-8.866989	1.878926
_cons	17.87397	2.034406	8.79	0.000	13.82689	21.92106

Table 84: Results of regression analysis to investigate the influence of the type of functional appliance on the change in upper first molar tip at DC2

Change in molar tip at DC2	*Coef.*	*Std. Err.*	*T*	*P>|t|*	*[95% Conf. Interval]*	
Twin-block appliance	-2.611253	3.41618	-0.76	0.447	-9.409667	4.187162
Age at DC2	-.0700699	.100402	-0.70	0.487	-.2698763	.1297364
Time in functional	-.235508	.2747553	-0.86	0.394	-.7822886	.3112725
Treatment centre 2	7.908655	5.799088	1.36	0.176	-3.631897	19.44921
Treatment centre 3	9.289619	3.732651	2.49	0.015	1.861407	16.71783
Treatment centre 4	12.80941	6.942428	1.85	0.069	-1.006461	26.62528
Treatment centre 5	.7186416	5.263145	0.14	0.892	-9.75535	11.19263
Treatment centre 6	10.24714	5.225313	1.96	0.053	-.151563	20.64585
Treatment centre 7	1.56276	4.87019	0.32	0.749	-8.129227	11.25475
Treatment centre 8	-4.926614	4.062589	-1.21	0.229	-13.01142	3.158195
Treatment centre 9	9.296138	6.178077	1.50	0.136	-2.998627	21.5909
Treatment centre 10	7.17612	8.959093	0.80	0.426	-10.65304	25.00528
Treatment centre 11	15.68065	9.537816	1.64	0.104	-3.300212	34.66151
Treatment centre 12	-10.36103	4.8571	-2.13	0.036	-20.02697	-.6950948
Treatment centre 13	8.573283	6.576732	1.30	0.196	-4.514831	21.6614
Number of missed appointments	1.586618	2.52209	0.63	0.531	-3.432502	6.605738
Number of casualty appointments	.2534244	.5057123	0.50	0.618	-.7529752	1.259824
_cons	24.71534	15.79539	1.56	0.122	-6.718489	56.14918

Table 85: Results of the adjusted regression analysis investigating the influence of type of functional appliance and important covariates on the change in upper first molar tip at DC2

4.8.4.2 Regression analysis at DC3

When the types of functional appliance were the only variables entered in the regression, change in upper molar tip at DC3 was not influenced by the use of a Twin-block or Herbst appliance, (Table 86). When important covariates were fitted to the model, the only statistically significant influences were found with treatment centre, (Table 87).

Change in molar tip at DC3	***Coef.***	***Std. Err.***	***T***	***P>|t|***	***[95% Conf. Interval]***	
Twin-block	-1.473662	3.844941	-0.38	0.703	-9.122474	6.175151
_cons	24.11976	2.273429	10.61	0.000	19.59719	28.64234

Table 86: Results of regression analysis to investigate the influence of the type of functional appliance on the change in upper first molar tip at DC3

Change in molar tip at DC3	*Coef.*	*Std. Err.*	*T*	*P>|t|*	*[95% Conf. Interval]*	
Twin-block appliance	-1.135599	5.571865	-0.20	0.839	-12.22396	9.952766
Age at DC2	-.1133969	.1583044	-0.72	0.476	-.4284326	.2016388
Time in functional	-.1451905	.3954941	-0.37	0.715	-.9322488	.6418678
Treatment centre 2	-8.569078	6.952713	-1.23	0.221	-22.40542	5.267262
Treatment centre 3	-11.62693	5.88909	-1.97	0.052	-23.34659	.0927306
Treatment centre 4	-6.718025	7.40778	-0.91	0.367	-21.45998	8.023927
Treatment centre 5	-10.26329	9.126731	-1.12	0.264	-28.42607	7.89948
Treatment centre 6	1.005622	7.142326	0.14	0.888	-13.20806	15.2193
Treatment centre 7	2.273598	6.729585	0.34	0.736	-11.1187	15.6659
Treatment centre 8	-2.511219	10.01761	-0.25	0.803	-22.44689	17.42445
Treatment centre 9	-2.058308	7.899245	-0.26	0.795	-17.77831	13.66169
Treatment centre 10	-25.54389	6.053775	-4.22	0.000	-37.59129	-13.4965
Treatment centre 11	-15.09927	6.709624	-2.25	0.027	-28.45184	-1.746691
Treatment centre 12	-2.687154	10.91131	-0.25	0.806	-24.40135	19.02705
Treatment centre 13	-6.308787	6.872406	-0.92	0.361	-19.98531	7.367736
Number of missed appointments	-3.605464	2.828482	-1.27	0.206	-9.234323	2.023395
Number of casualty appointments	-.74	.723	-1.03	0.307	-2.183	.695
_cons	51.916	23.754	2.19	0.032	4.645	99.187

Table 87: Results of the adjusted regression analysis investigating the influence of type of functional appliance and important covariates on the change in upper first molar tip at DC3

4.8.5 The residual overjet at DC2

When the types of functional appliance were the only variables entered in the regression, the amount of residual overjet at DC2 was not influenced by the use of a Twin-block or Herbst appliance, (Table 88). When important covariates were fitted to the model, the only statistically significant influence was that of treatment centre, (Table 89).

Residual overjet at DC2	**Coef**	**Std Err**	**t**	**P>|t|**	**95% confidence interval**
Twin-block	-0.709	0.567	-1.25	0.215	-1.838, 0.419
cons	4.779	0.427	11.19	0.000	3.929, 5.628

Table 88: Results of the regression analysis to investigate the influence of the type of functional appliance on the amount of residual overjet at DC2

Residual overjet at DC2	Coef	Std Err	t	P>|t|	95% confidence interval
Twin-block appliance	-0.155	0.732	0.21	0.833	-1.618, 1.308
Age at DC2	0.030	0.021	1.42	0.161	-0.012, 0.073
Time in functional	0.106	0.064	1.67	0.100	-0.021, 0.234
Number of missed appointments	-0.500	0.577	-0.87	0.389	-1.653, 0.653
Number of casualty appointments	-0.010	0.112	-0.09	0.927	-0.235, 0.214
Treatment centre 2	-2.759	1.142	-2.42	0.019	-5.041, -0.477
Treatment centre 3	-0.370	1.276	-0.29	0.772	-2.920, 2.179
Treatment centre 4	1.290	1.888	0.68	0.497	-2.482, 5.062
Treatment centre 5	-1.965	1.168	-1.68	0.098	-4.300, 0.370
Treatment centre 6	2.095	1.101	1.90	0.062	-0.106, 4.296
Treatment centre 7	-1.571	1.273	-1.23	0.222	-4.115, 0.974
Treatment centre 8	-1.286	1.318	-0.98	0.333	-3.921, 1.348
Treatment centre 9	-0.741	1.050	-0.71	0.483	-2.840, 1.358
Treatment centre 10	-0.596	1.851	-0.32	0.748	-4.294, 3.102
Treatment centre 11	-0.928	2.045	-0.45	0.651	-5.016, 3.159
Treatment centre 12	0.613	1.888	0.32	0.746	-3.159, 4.386
Treatment centre 13	0.668	1.259	0.53	0.597	-1.846, 3.183
cons	-0.759	3.413	-0.22	0.825	-7.579, 6.061

Table 89: Results of the adjusted regression analysis investigating the influence of type of functional appliance and important covariates on the amount of residual overjet at DC2

4.9 Discussion:

A summary of the significant predictors of tooth movement following treatment with Herbst and Twin Block appliances is presented in Table 90.

Table 90: Summary of factors significantly influencing tooth movement after treatment with Herbst and Twin Block appliances

Outcome	Significant predictors	Coef	P value	95% confidence intervals
Distal movement of upper first molars (DC 2)	Age at the end of functional	-0.16	0.009	-0.028, -0.004
	Number of casualty appointments	-0.07	0.028	-0.138, -0.008
Distal movement of upper first molars (DC 3)	No significant predictors			
Change in lower incisor torque (DC 2)	Type of functional appliance (Twin Block)	-5.76	0.039	-11.229, -0.293
	Age at end of functional	-0.22	0.008	-0.385, 0.061
Change in lower incisor torque (DC 3)	Type of functional appliance (Twin Block)	-7.02	0.022	-13.007, -1.030
	Age at end of functional	-0.23	0.007	-0.391, -0.063
	Length of time in functional	0.853	0.000	0.419, 1.287
Change in molar tip (DC 2)	No significant predictors			
Change in molar tip (DC 2)	No significant predictors			
Residual overjet (DC 2)	No significant predictors			

4.9.1 Mesiodistal movement of the upper first molars

The overall finding in this study was that there was no influence of the type of functional appliance on the amount of mesiodistal movement of the molars at any stage of the treatment. Furthermore, the amount of molar movement was less than 1 mm distally for the Herbst and less than 1 mm mesial movement for the Twin Block at the end of functional. At the end of treatment there was an overall mesial movement for both appliances. This could have been due to controlled mesial movement at the end of treatment.

Maxillary mesiodistal movement has been reported in other studies of the effects of functional appliances. Therefore, it was expected that both appliances would have had a greater distalising effect and that this would be more pronounced with the Herbst appliance, because it is a fixed appliance and associated with better compliance. However, this study did not confirm this expectation.

Nevertheless, the distal movement that we report is similar to other studies evaluating this treatment. For example, in a trial comparing Twin Block and Herbst appliances, the overall movement of the maxillary molars at the end of fixed appliance, was 0.40 and 0.48 mm in a mesial direction [52]. Similarly, in another trial comparing early treatment with Twin block to an untreated control it was reported that the upper molars moved distally by 0.77 mm [51]. Finally, in an investigation of the Bionator appliance the amount of upper molar was also found to be a net mesial movement of 0.25mm per year [55].

The only functional appliance that had an obvious distalising effect was the Bass appliance which produced 2.54 mm of distal maxillary molar movement [59]. In this trial

the Bass appliance was combined with a high-pull headgear, and the distal movement of the maxillary molars may be due to the effect of the headgear.

Another significant finding is that the older patients at DC2 and patients with more casualty appointments in the functional phase of therapy were associated with less mesial movement of the upper molars. This may be a factor of cooperation. That is to say, in this study, older patients are more compliant, and therefore there is less mesial movement. In addition, patients with more casualty appointments were associated with less mesial movement; this effect was small and not clinically significant. The effect of age and number of casualty appointments in the functional phase was not present at DC3. This may be due to the reduced amount of compliance and cooperation needed with fixed appliances. This could also be caused by controlled loss of anchorage in the final stages of treatment.

Although centre was statistically significant, the low numbers treated in each centre make a meaningful calculation of a ‘centre effect’ impossible.

4.9.2 Change in lower incisor torque

Lower incisor proclination is generally considered to be an unstable and unwanted tooth movement. In this study the lower incisors had proclined at the end of DC2 following the functional appliance phase of treatment. By the end of DC3 the incisors had recovered their original position to a degree by uprighting, however they were still proclined in relation to the pre-treatment position. There is no doubt that this effect has been reported in other studies [51, 52, 180, 181] and is caused by the forces applied to the lingual of the lower incisors.

It was interesting that the Herbst appliance proclined the lower incisors more than the Twin Block. This may be due to two main factors, firstly the Herbst is worn full time and there is potentially a greater force of longer duration than with the Twin Block. Secondly, this may also be due to the proclining effect of any fixed appliance that was placed on the lower labial segment during the initial Herbst appliance phase of treatment.

When torque was evaluated it was evident that this was influenced by the age of the patient. The older the patient at DC2, the less incisor proclination was present at DC2 and DC3. This might be because the older patients were treated after the peak growth of the mandible, and therefore there were less dentoalveolar changes with this group, but this can only be conjecture. Although it seems that the size of the effect was minimal, it may be clinically significant.

The time spent in the functional phase was also an explanatory factor for the change in lower incisor torque, but only in DC3. This could be a reflection of the difficulty of uprighting lower incisors following the functional phase of treatment. For each extra month spent in the functional phase, the change in torque increases by 0.85 degrees.

4.9.3 Upper molar tip

The trend with upper molar tip in both twin-block and Herbst appliances is a slight change in tip in the mesial or distal direction at DC2, followed by a more pronounced mesial tip at the end of DC3. The type of functional appliance did not influence the change in tip of the upper molars at DC2 and DC3. There were no other important factors, which influenced the change in tip at DC2 and DC3.

None of the trials on functional appliances referred to in the literature review section reported changes in the angulation of the upper first molars. However, it is thought that part of the effect of functional appliances is a Class II traction effect, which leads to the distal tipping of the upper first molars. This study did not reinforce this theory.

4.9.4 Overjet

All patients in this study had an over jet ≥ 7mm at the start of treatment. The overjet was reduced to a near normal overjet at the end of the functional appliance phase. This was not influenced by the type of functional appliance. Furthermore, no other explanatory variables influenced the residual overjet at the end of the functional appliance phase.

It was expected that the use of the Herbst appliance may result in a smaller residual overjet because it is a fixed appliance and needs less patient compliance, however this was not the case. Therefore the use of fixed appliances in a clinical setting should be weighed against potential disadvantages such as difficulty of placement, frequent breakages and marked lower incisor proclination.

This is also similar to other investigations of this type of treatment, for example, in the study comparing Twin Block to Herbst appliance, both the Twin Block and Herbst appliances were found equally effective in the reduction of the overjet [52]. This suggests that the overjet reduction at the end of functional is maintained throughout the fixed phase of treatment. In other functional appliance trials, effective overjet reduction was found with the Twin Block, Bass and Bionator appliances [51, 53, 55, 59, 64, 172].

It appears that the true difference in overjet reduction between functional appliances isn't in their ability to reduce the final overjet, but in the efficiency in which the overjet is reduced. In other words, some functional appliances reduce the overjet faster than others.

For example, it has been shown that the Herbst appliance is more efficient than the Twin Block in reducing the overjet [52]. The trade-off for this efficiency is more casualty appointments and the higher cost of the Herbst [52].

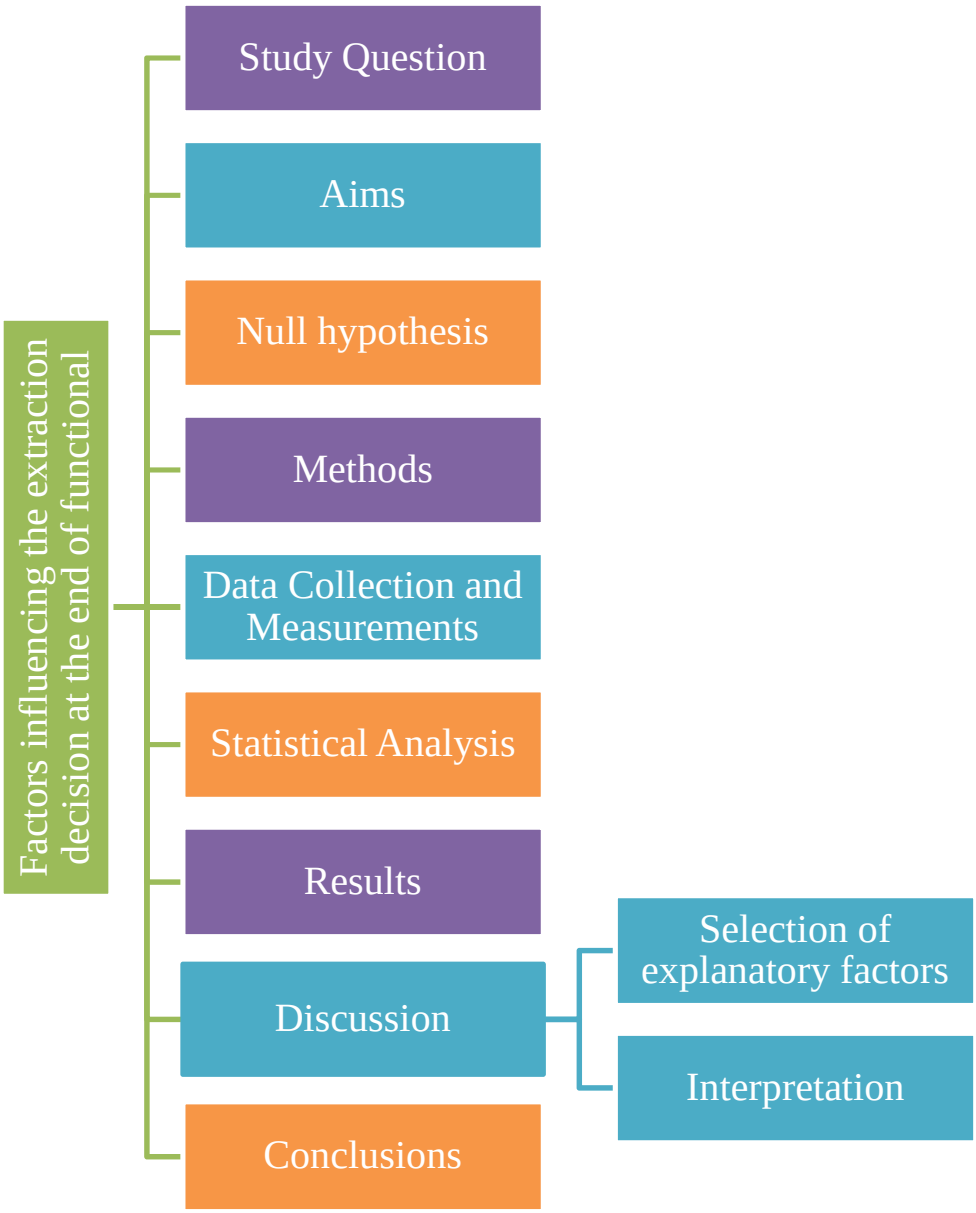
4.10 Conclusions:

- The Herbst appliance proclines the lower incisors more than the Twin-block appliance.
- The time spent on ‘functional’ treatment influenced the final incisor proclination at the end of treatment.
- The amount of residual overjet at the end of functional is not influenced by the type of appliance; however the Herbst appliance is more efficient in overjet reduction than the Twin Block
- Distal molar movement and distal molar tip were not influenced by the type of functional appliance

5 Chapter 5: Factors influencing the extraction decision at the end of functional appliance treatment

Figure 72 shows the order in which in which the topics are presented in this chapter

Figure 72: A flow chart summarising the main topics discussed in Chapter 5



5.1 Study question

Do the type of functional appliances and malocclusion characteristics at the end of a functional appliance phase influence the decision to extract?

5.2 Aims

To evaluate the influence of types of functional appliance and malocclusion factors on the decision to extract teeth following the initial phase of functional appliance treatment in patients with Class II Division I malocclusion.

5.3 Objectives

To show the following:

- The type of functional appliance does not influence the decision to extract at the end of functional appliance treatment.
- Selected malocclusion characteristics (Royal London space analysis pre-treatment, Royal London space analysis post-functional, change in lower incisor torque, molar relationship post-functional) do not influence the decision to extract.

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5.4 Methods

This study was carried out using the same set of data as the previous section of the study. Full details are included on page 363.

5.4.1 Factors that may influence the decision to extract

When we consider the factors that may influence the decision to extract at the end of the functional appliance phase of treatment, the prime influences may be the type of functional appliance. There may also be many other variables that are associated with the morphological features of the malocclusion. These variables can all be fitted into

regression models in the search for those that may have an effect. However, it is good statistical practice to limit the variables included in a regression analysis.

A rule of thumb for the maximum number of explanatory variables to include in a model is that there should be at least 5-10 times as many responses in each of the two categories defining the outcome (extraction, non-extraction) as there are variables.

Therefore I identified the variables to be fitted into the models by selecting them from the following sources:

- A review of the literature concerned with factors that influence the decision to extract teeth. This information is included in Table 91.

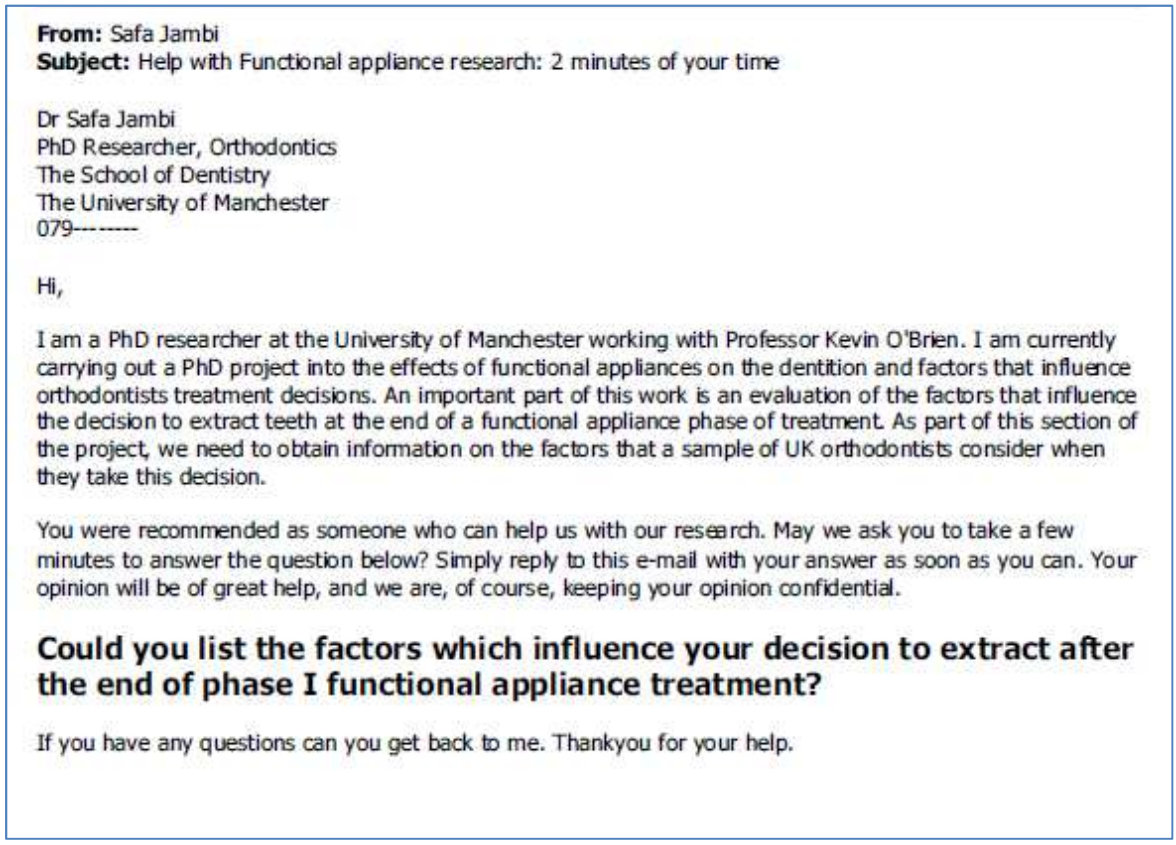
Table 91: Factors influencing the decision to extract reported in each study

Study	Crowding /arch length discrepancy	Incisor protrusion (inclination)	Class II severity	Profile improvement	Incompetent lips	overjet	Curve of spee	Frankfort mandibular plane angle and lower anterior facial
Baumrind et al	yes	yes	yes	yes	no	no		no
Xie et al		yes			yes			
Takada	yes					no		
Li et al	yes	yes				yes	yes	yes
Bishara	yes			yes				

- An exploratory study was conducted to gather the opinion of a group of orthodontists on the factors that influence their decision to extract teeth at the end of a first phase of functional appliance treatment. An email questionnaire was sent to 12 orthodontists in the UK (Figure 73). The e-mail contained a brief summary of the objective of this part of the study, a statement of confidentiality, and an invitation to take part by answering one question:

  ‘Could you list the factors which influence your decision to extract after the end of phase I functional appliance treatment?’

  A period of 4 weeks was allowed for participants to respond to the e-mail. At the end of the 4 weeks, a thank you reply was sent to all respondents.



From: Safa Jambi
Subject: Help with Functional appliance research: 2 minutes of your time

Dr Safa Jambi
PhD Researcher, Orthodontics
The School of Dentistry
The University of Manchester
079--------

Hi,

I am a PhD researcher at the University of Manchester working with Professor Kevin O'Brien. I am currently carrying out a PhD project into the effects of functional appliances on the dentition and factors that influence orthodontists treatment decisions. An important part of this work is an evaluation of the factors that influence the decision to extract teeth at the end of a functional appliance phase of treatment. As part of this section of the project, we need to obtain information on the factors that a sample of UK orthodontists consider when they take this decision.

You were recommended as someone who can help us with our research. May we ask you to take a few minutes to answer the question below? Simply reply to this e-mail with your answer as soon as you can. Your opinion will be of great help, and we are, of course, keeping your opinion confidential.

Could you list the factors which influence your decision to extract after the end of phase I functional appliance treatment?

If you have any questions can you get back to me. Thankyou for your help.

Figure 73: E-mail questionnaire to gather clinicians’ perceptions of factors influencing the extraction decision

Ten out of 12 participants responded to my e-mail. The factors from all the e-mails were collected and further placed in categories to make the data manageable.

These categories were crowding, overjet, upper incisor inclination, lower incisor inclination, centreline deviation, overbite, concerns about health of teeth and periodontium, soft tissue concerns and other, (Table 92).

Table 92: Factors influencing the extraction decision for the 10 respondents, showing how they were further placed in categories

Factor influencing extraction	Frequency	Category, overall frequency
Crowding	7	Crowding at the end of functional, 14
Degree of crowding in upper and lower arches	2	
Arch length discrepancy out	1	
Distribution of crowding eg one incisor blocked	1	
Curve of spee	3	
Residual overjet	2	Overjet at the end of functional, 3
Amount of overjet reduction in functional phase	1	
Degree of incisor proclination, upper	2	Upper incisor inclination at the end of functional, 2
Degree of incisor proclination, lower	2	Lower incisor inclination at the end of functional, 12
Amount of proclination of lower incisors during functional treatment	2	
Incisor inclination post functional	3	
Inclination of lower incisors	1	
Degree of lower incisor proclination	2	
Change in inclination of teeth on ceph	1	
Proclination of labial segments	1	
Centrelines	4	Centreline deviation at the end of functional, 4
Degree of overbite	3	Overbite at the end of functional, 3
Teeth of poor prognosis	3	Concerns about health of teeth and periodontium, 8
Decay/ caries	1	
Caries/pathology	1	
Periodontal factors eg recession	1	
Dental health issues	1	
Previous trauma	1	
Lip competence/ST relationship	1	Soft tissue concerns, 8
Soft tissues, fullness of lips, lip	1	

protrusion		
Lip competence	1	
Nasolabial angle	1	
Profile pre and post functional	1	
Facial aesthetic aims	1	
Facial pattern	1	
Facial pattern	1	
The original malocclusion	2	Other
Underlying skeletal pattern/proposed lower incisor position	1	
Degree of correction of severe skeletal discrepancies	1	
Growth pattern	1	
Patient cooperation	1	
Oral hygiene	1	
Type of fixed appliance to be used	1	
Aiming to maintain class I molars	1	
Retroclination during Twin Block phase	1	
Incisor inclination pre functional	2	
The degree of crowding before treatment	1	
Final post op upper incisor angulation and ‘guessed’ anticipated relapse during alignment	1	
Patient expectation	1	

5.5 Data Collection and measurements:

The final factors that we selected were crowding, overjet, upper incisor inclination change, curve of spee, and arch width change, molar relationship at the end of functional and lower incisor inclination change. The Royal London score was used to assess the first five factors in a single overall score.

5.6 Statistical analysis

A logistic regression was used to predict the probability of extraction versus non-extraction.

The following predictor variables were used:

1. Type of functional appliance
2. Royal London Space analysis: upper space required pretreatment (DC1)
3. Royal London Space analysis: lower space required pretreatment (DC1)
4. Royal London Space analysis: upper space required post-functional (DC2)
5. Royal London Space analysis: Lower space required post-functional (DC2)
6. Molar relationship post-functional (DC2)
7. Lower incisor inclination change

The Royal London score for the upper and lower arches were entered separately in the analysis, as the decision to extract between lower and upper arches may be different. The repeated measures of the Royal London space analysis at the start of treatment and post functional were analyzed taking into account the non-independence of measurements.

5.7 Results

The data for the logistic regression on the decision to extract are shown in table 91. This reveals that the odds of extraction with Twin Block were 2.35 those of extraction with the

Herbst. There is some evidence of statistical significance but the 95% confidence interval is wide, an indication of the uncertainty around the estimate (Table 93).

The addition of covariates had little impact on this estimate. Taking treatment allocation and other covariates into account, there was a statistically significant effect of the Royal London upper and lower measurements (Table 94). The probability of extraction decreases as the Royal London measurements increase (Figure 74 and Figure 75). In other words as the space requirements decreased (positive value), the probability of extractions is less.

Table 93: Results of logistic regression analysis to investigate the influence of the type of functional appliance on the dichotomous decision to extract

	Odds Ratio	**Standard Error**	**z**	**P value**	**95% confidence interval**
Treatment with a Twin Block	2.355	1.170	1.72	0.085	0.889, 6.235
cons	0.270	0.097	-3.65	0.000	0.134, 0.546

Table 94: Results of logistic regression analysis to investigate the influence of independent variables on the dichotomous decision to extract

	Odds Ratio	**Standard Error**	**z**	**P value**	**95% confidence interval**
Twin Block appliance	2.448	1.272	1.72	0.085	0.884, 6.780
Royal London upper	0.959	0.020	-2.02	0.043	0.921, 0.999
Royal London lower	0.738	0.075	-3.00	0.003	0.606, 0.901
Molar relationship	0.971	0.109	-0.27	0.790	0.779, 1.210

Change in lower incisor torque	1.004	0.012	0.30	0.765	0.981, 1.027
cons	0.085	0.080	-2.60	0.009	0.013, 0.544

Figure 74: Predictive margins for extraction as the Royal London analysis score changes in the upper arch

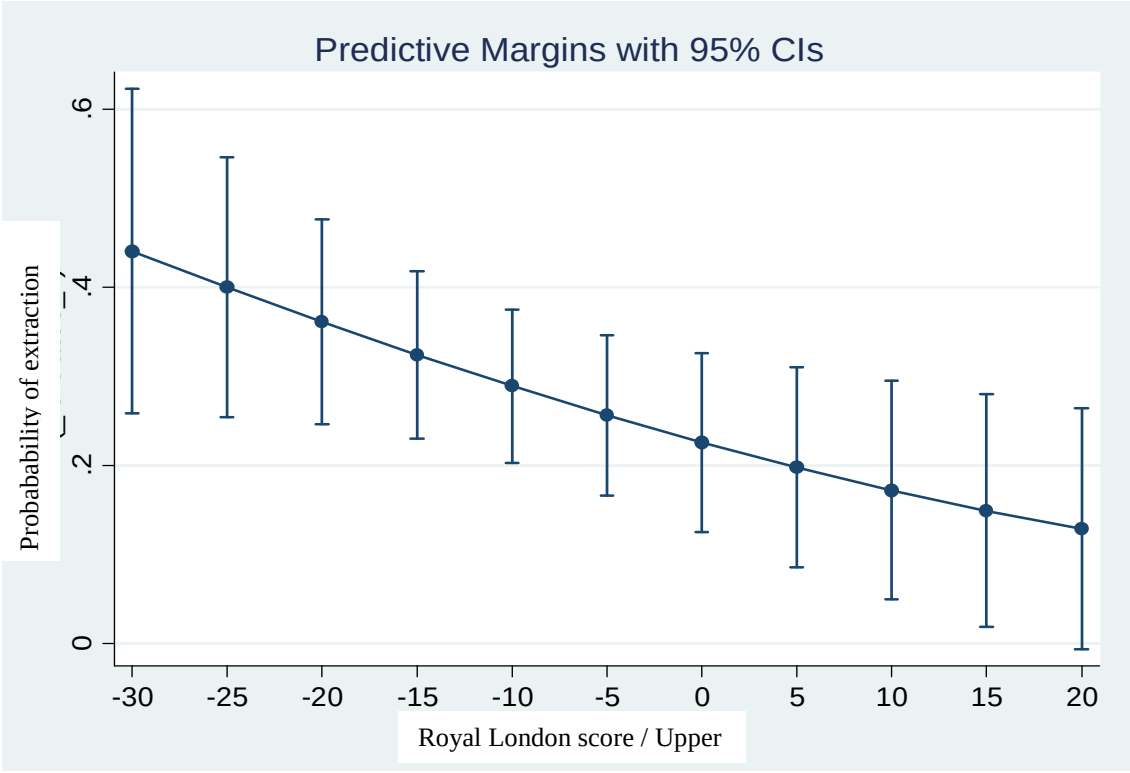
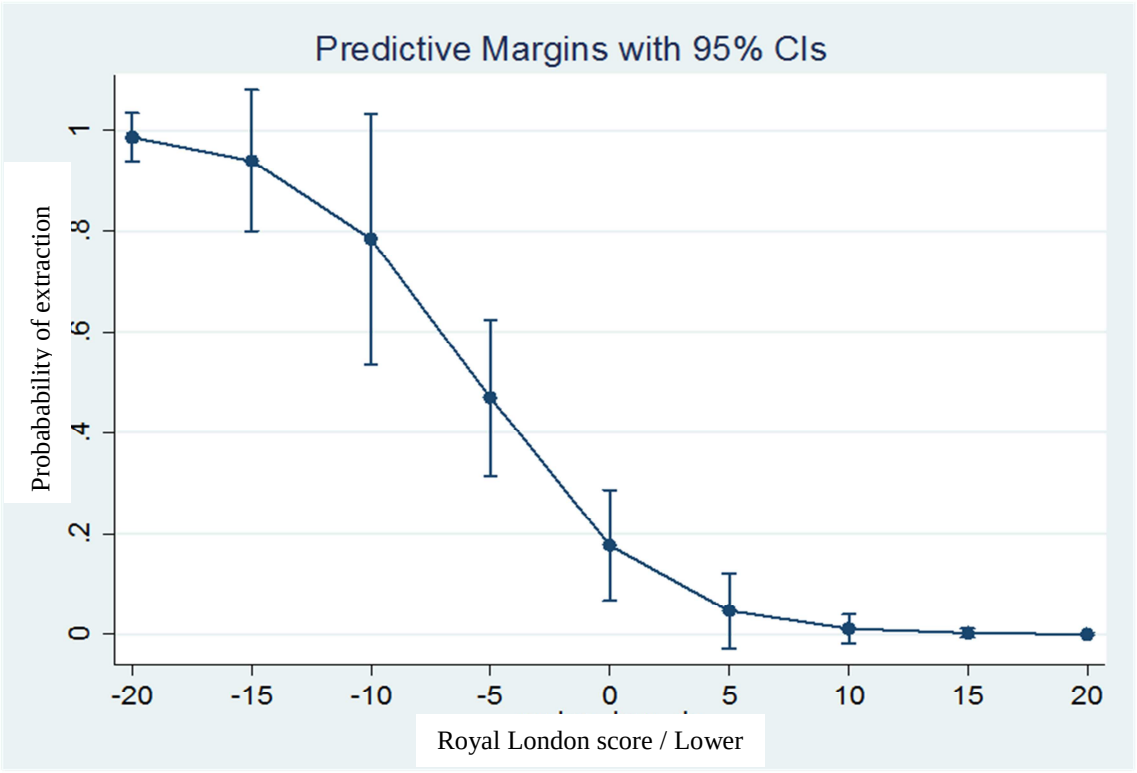


Figure 75: Predictive margins for extraction as the Royal London analysis score changes in the lower arch



5.8 Discussion

5.8.1 Interpretation:

The Royal London analysis clearly influenced the odds of extraction at the end of the functional phase of treatment. The regression analysis suggests that the odds of extraction increase for each millimetre of space required. This effect is more pronounced in the lower arch as compared to the upper arch (Figure 74and Figure 75)

While it was advantageous to use the Royal London analysis to increase the power of the study, there may be a disadvantage in interpretation. We do not know exactly which of the orthodontic variables included in the Royal London analysis most influences the extraction decision. However, in reality the major factors contributing to the Royal London score are the amount of crowding, overjet and arch width change. Therefore, from a clinical point of view the use of the Royal London Analysis is logical.

The logistic regression showed some evidence that the odds of extraction with Twin Block are 2.35 those of extraction with the Herbst. Although this finding was not statistically significant, this finding should be taken into consideration, as it may be clinically relevant. Fewer extractions would be expected with the fixed Herbst appliance than with the removable Twin Block. This is mainly because as the Herbst was placed in conjunction with a fixed appliance, lower incisor crowding would not have been present at the end of the functional appliance phase.

An interesting finding was that there was no influence of molar relationship on the extraction decision at the end of functional phase of treatment, when the remaining variables are taken into account. It may be suggested that the molar relationship are approximating the ideal required relationship at the end of the functional phase of treatment, therefore it does not have any bearing on the decision to extract. In addition, if

the molars weren't completely corrected, less invasive and more appropriate alternative techniques could be used as an alternative to extractions, such as Class II elastics. This may also reflect a natural reticence of clinicians to extract teeth when the treatment is of almost 12 months duration, however, this is only conjecture.

It was surprising to find that the change in lower incisor torque did not have an influence on the decision to extract. . This does not seem to agree with common clinical experience and with previous studies [35, 39, 42].

5.8.1 Selection of explanatory factors:

Two general methods can be used for selecting the independent factors that should be included in the analysis. The first is an automatic selection procedure (backwards, forwards, stepwise, all subsets) in which relevant factors are added or removed sequentially, to investigate the factors which have the most effect on the dependent variable. Unfortunately, these procedures allow the data to drive the theory [217]. Furthermore, there is no guarantee that the Forward and Backward procedures would agree on the same model.

Finally, multiple testing results in an increase in the risk of a type 1 error, leading to significant findings arising by chance. As a result, good statistical practice suggests careful selection of independent variables which are driven by theory.

In this research, the factors chosen to include in the regression was driven by theory using results from previous research.

We supplemented this information by carrying out a small complementary survey of a sample of clinicians in order to obtain a list of factors that they felt would influence their

decision on extractions at the end of the first phase of treatment. This question was kept simple, as we wanted as many open-ended responses as possible. The advantage of this approach was that the replies were not influenced by the researcher's knowledge and experience. In addition, we were looking for independent opinion rather than consensus.

The most common reasons stated for extraction following the functional appliance phase of treatment were crowding and lower incisor inclination; this reinforces the inclusion of these two factors in the analysis. This was followed by concerns about health of teeth and periodontium, soft tissue and profile considerations, centreline deviation, overjet and overbite. Overbite and centreline deviation were dentoalveolar factors mentioned by clinicians as important factors when considering extraction at the end of functional appliance phase, however they were not included in the regression analysis because these factors weren't found in the literature. Therefore, there wasn't a strong theoretical background for their inclusion.

Another important consideration in selecting the factors for the regression analysis is the use of the Royal London Space analysis. From a statistical point of view, the Royal London Space analysis has the advantage of decreasing the number of independent variables as it is an overall score of the space needed which takes into consideration five of the factors we decided to include in the analysis (crowding, overjet, upper incisor inclination change, curve of spee, and arch width change). Thus increasing the power of the analysis.

5.9 Conclusions

- The type of functional appliance does not influence the decision to extract in this sample.
- A higher Royal London space analysis score (positive value) is associated with less odds of extraction.

SECTION V: Overall Discussion and Conclusions

1 Overall discussion

Two systematic reviews and a retrospective study were undertaken to assess the factors influencing orthodontic anchorage.

The results of these studies suggest that headgear, surgical anchorage and functional appliances, namely the Twin Block and Herbst appliance can be used to reinforce anchorage in orthodontic treatment. For each of these methods there are advantages and disadvantages that should be considered when planning anchorage. Functional appliances would mainly be used in adolescent patients with large overjets and who have shown that they are able to comply with treatment. Surgical anchorage may be used in all cases to reduce the compliance and where aesthetics are important as it is hidden inside the mouth. The final choice will depend on the orthodontist expertise and the patient's beliefs and needs.

1.1 Surgical anchorage

Trials comparing surgical anchorage to headgear are generally of good quality, and the findings were promising. The small number of trials we assessed showed that surgical anchorage, in particular mini-screw implants, are comparable to headgear when distalising the upper first molars is considered, without the inherent drawback of compliance.

Although this is a positive finding, it should be emphasised that midpalatal implants are invasive and sometimes require an additional clinical expertise and interdisciplinary treatment. This is not always feasible. In addition to prolonging the overall treatment time, the pain encountered with placement and healing of some types of midpalatal implants is comparable to dental extractions [106]. Therefore, this would probably not be the appliance of choice.

Mini-screw implants, on the other hand, are easy to place and remove, and are placed in the buccal alveolar bone, an area that is more comfortable to work in. They are less visible than headgear and are placed and removed by the orthodontist, so compliance issues are greatly reduced. Their use is promising and it appears that min-screws can be used for other tooth movements such as intrusion. Although this may be the device of choice, it would be important to remain competent in a non-surgical method of anchorage reinforcement to use in patients who are uncomfortable with idea of placing pins in their mouth. I would offer headgear.

1.2 Distalising appliances

When we assessed the literature reporting distal movement appliances, the overall quality of the trials was very different to the trials assessing surgical anchorage. Trial reporting was very poor, and in some instances there seemed to be inconsistencies within the reports. The most common comparison was an intra-oral appliance compared to cervical headgear. It appears that some intra-oral appliances can distalise molars better and faster than headgear; however this also leads to more mesial movement of the anterior teeth. So that any anchorage gained posteriorly is counteracted by that lost anteriorly.

1.3 Functional appliances

Although functional appliances are traditionally used for growth modification, this research has shown that they can also be thought of as an anchorage appliance. Importantly, in comparison to surgical anchorage, the use of functional appliances is non-invasive.

Functional appliances would probably not be the appliances of choice to develop orthodontic anchorage except in cases in which the anchorage is especially challenging due to very large over jets. Importantly, they require considerable patient compliance and are full time appliances. In addition, they are associated with retention issues; retention of the effects of the twin block and retention at the end of treatment which is complicated by proclination of the lower labial segment.

There are considerations to be taken when using a functional appliance for anchorage preparation:

1. Functional appliances are associated with an increase in the lower incisor proclination; this should be taken into consideration when planning retention at the end of fixed appliance therapy.
2. The lower incisor torque at the end of treatment is influenced by three factors; a greatly prolonged time spent in the functional appliance phase, younger adolescent patients and with the fixed functional appliance (Herbst). These factors should be taken in consideration when planning a case. One should make sure that these three factors are not combined in a single patient. In addition attempts should be made to avoid unnecessary prolongation of this phase and consideration should be given to prompt discontinuation of the appliance when follow-up appointments don't show good progress or appointments are not adhered to.
3. The Royal London space requirement is an important factor considered at the end of the functional phase that will increase the odds of extraction. If pre-treatment space requirement indicates extraction, this will probably not change after functional appliance treatment. Therefore, careful consideration on the necessity of the functional appliance should be taken into account. If the overjet was the main component leading to a negative Royal London score, then a Twin Block may be useful. However, if the anchorage

requirements were high enough to warrant extractions and an additional anchorage appliance, an alternative appliance may be chosen which can be used concurrently with the fixed appliance phase in attempt to decrease the time spent in overall treatment and the overall burden of care.

2 Concluding commentary

An accepted definition of anchorage in orthodontics is the resistance to unwanted tooth movement. It is recognised that achieving anchorage is a common difficulty in providing orthodontic treatment. This thesis has explored the anchorage potential of commonly used appliances, namely surgical anchorage, distal movement appliances and functional appliances.

2.1 Overall conclusions

1. Surgical anchorage is comparable to headgear anchorage, without the inherent risks and compliance issues associated with headgear (null hypothesis accepted).
2. Molar distalising appliances are comparable to headgear at distalising molars; however this effect is counteracted by loss of anterior anchorage.
3. Fixed and removable functional appliances are equally effective in reducing the overjet.
4. The Royal London space analysis score has an effect on increasing the odds of extraction.
5. Fixed and removable functional appliance treatment in adolescence does not effectively distalise or change the tip of the upper first molars and cannot be used for molar anchorage preparation.

2.2 Implications on further research

1. The CONSORT statement should be used in the reporting of future orthodontic trials.

2. It is also recommended that the CONSORT guidelines be consulted when planning a trial as it contains information about all issues which can bias a trial.

3. Particular attention should be given to blinding of the allocation sequence in orthodontic trials.

4. Further research is indicated to test the efficiency and efficacy of mini-screw implants and distalising appliances and to define outcomes in orthodontic trials.

5. Qualitative research is indicated to assess the acceptability and compliance issues of appliances.

6. Development of other methods for 3D crowding measurements which are valid and reliable

7. Further research is indicated to validate the factors influencing the decision to extract.

   a. the regression weights from the current analyses can be cross-validated on a different sample.

   b. research in the form of a Delphi study can be conducted to reach consensus among orthodontists on the factors influencing extraction at the end of functional appliance treatment.

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Appendix: Rapidform Instructions

Table of contents:

1. Terminology

Figure 76 shows the view of the screen after opening the Rapidform software.

Basic terminology used:

1. Project window: The window on the left hand side which consists of list of all the models (shells) and reference landmarks created in the software.
2. Perspective window: This is the window where all the models and reference landmarks are viewed. To view an item, click the relevant button in the project window, it will then appear in the perspective window. To remove the item from the perspective window, re-click the relevant button.
3. Workbench: these are the different platforms in Rapidform. The methodology described here only uses the ‘Scan’ and ‘Polygon’ workbenches.
4. Menu bar: The region of the screen where drop down menus are displayed
5. Tool bar: A strip of icons used to perform certain functions.
6. RMB and LMB: The use of computer mouse is required to obtain full functionality of the software. RMB is used as an abbreviation for ‘click right mouse button’, and LMB is an abbreviation for ‘click left mouse button’.

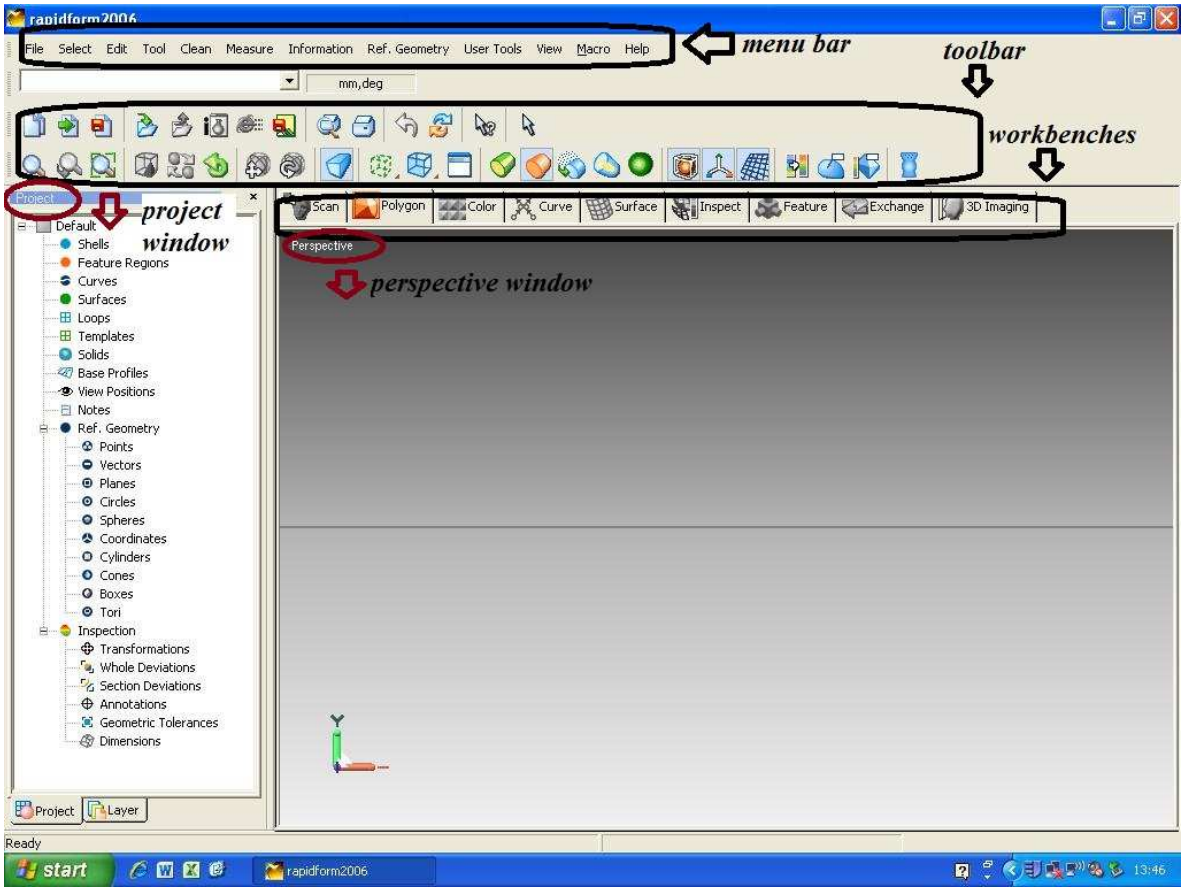

Figure 76: Rapidform screen and common terminology

2. Importing and colour coding the models:

Import models twice :

From the “File” menu choose “Import” then select the file containing the digital model you want to analyse. Make sure either “Scan” or “Polygon” workbenches are selected.

Shading the digital models:

Once imported, the digital models are transparent and you need to shade them. Place the mouse cursor anywhere in the perspective window and press the RMB. Choose from the drop menu “Display Mode” then choose “Shaded” or simply press F4 as a shortcut.

Colour code each stage of the imported models, figure 2:

a. RMB on the name of the model from project window

b. Choose “Change Material” from the drop down window, then change the colour of the model.

c. Repeat for all models.

d. With experience we found that the colours that provide good visualisation of the occlusal features are: yellow, black, red and green

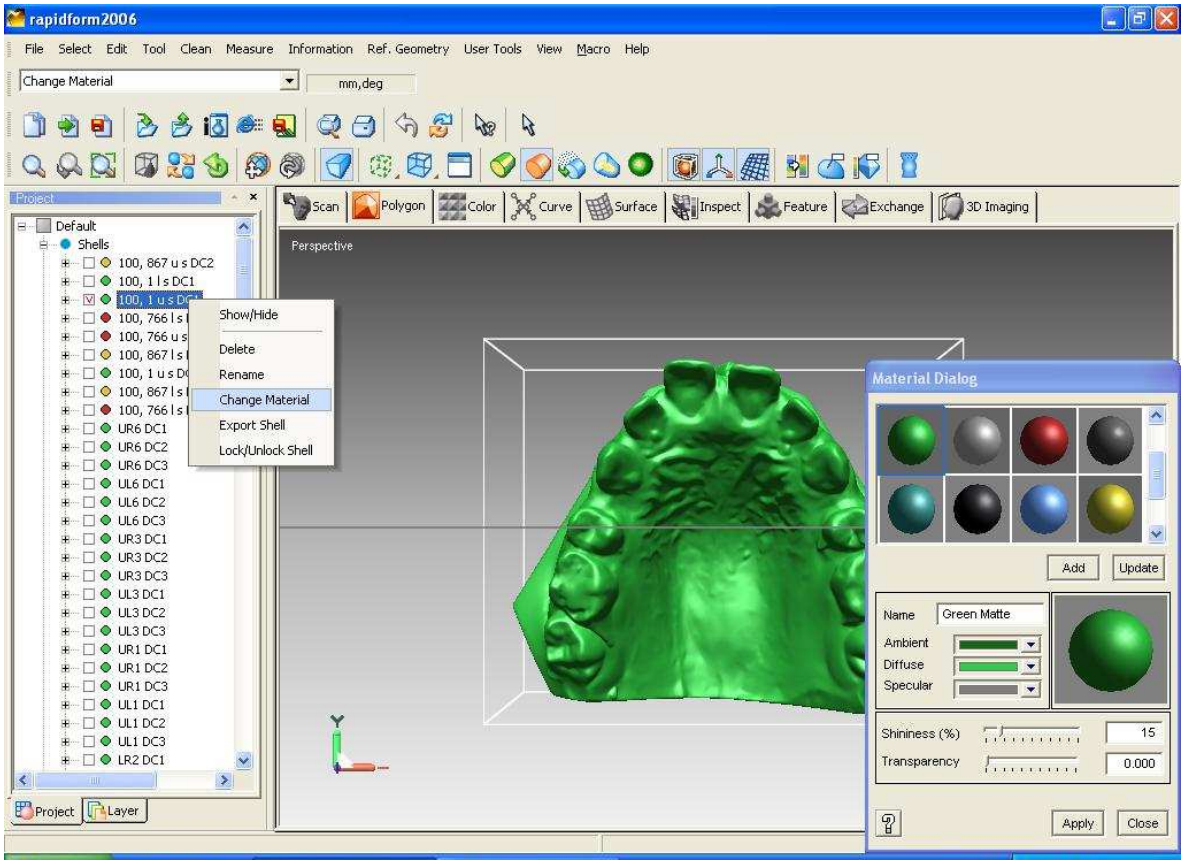

Figure 77: Colour coding the models in Rapidform

3. Standardising the coordination for the maxillary baseline model

See Figure 78-7

1. View the maxillary baseline model only in the perspective window.

2. The maxillary baseline model will now be displayed from different angles (view points). This can be achieved by three ways:
    a. RMB on the model in the perspective window, then choose ‘View Point’ and the required option, Figure 78.
    b. From the “View” menu choose “view Point” then choose the required option.
    c. You can use Alt button on your keyboard with numbers from 1 to 7 to perform the same command
3. Click the Alt + 3 buttons, use the LMB to move the model and orient it so that you are viewing the right side of the model with the incisors towards the top of the screen and the molars towards the bottom of the screen, Figure 79.
4. Place the mouse cursor on the model, press Ctrl + LMB to move the model till the occlusal plane approximate the straight line of the side of the screen, Figure 79.
    a. To aid positioning of the models, the ‘grid’ and ‘bounding box’ can be shown or hidden by clicking the relevant icons on the toolbar.
5. From “Edit” menu choose “Transform” then “Shell Trackball”
6. RMB on the baseline model and select ‘All’
7. Use the red circle on the trackball to orient the model until the occlusal plane is parallel to the straight line of the side of the screen, Figure 80.
8. RMB on the model and choose “Done”.
9. Click the Alt + 4 buttons, and repeat steps (4-8) for the other side, Figure 80.
10. Click Alt +1 to view the model occlusally.
11. Switch on the Grid from the toolbar or “View” menu. This Grid is parallel to the transverse plane and should appear as a line from this view.

12. Select ‘Shell Trackball’ (step 5), then orient the model so that the Grid passes through the buccal groove of both right and left maxillary molars. This can be accomplished by using the ‘green arrow’ and the ‘blue circle’, Figure 81.

13. Click Alt + 5 to view the model from the front. Place the mouse cursor on the model, press Ctrl + LMB to move the model till the occlusal plane approximate the straight line of bottom of the screen. Repeat steps (5-8) to orient the occlusal plane so it is parallel to the bottom of the screen, using the green circle, Figure 82.

14. Click Alt + 6 to view the model from the back. Place the mouse cursor on the model, press Ctrl + LMB to move the model till the occlusal plane approximate the straight line of the top of the screen. Repeat steps (5-8) to orient the occlusal plane so it is parallel to the top of the screen, also using the green circle, Figure 82.

15. To be able to visualise all the reference landmarks in one screen we need to move the axes origin to the base of the incisive papillae

a. From the menu bar choose ‘Ref. Geometry’→ ‘Create’→ ‘Point’→‘Pick Point’ then choose a point at the base of the incisive papillae by LMB on the model in the perspective window.

b. From the project widow on the left hand side of the screen, rename the created point by RMB on the point, then select ‘rename’ and click enter. (If enter is not clicked when renaming a reference landmark, the name will not change)

c. LMB on the reference point in the project window to show its x, y and z components.

d. From the menu bar select ‘Edit’→ ‘transform’→ ‘model’; a dialog box will appear. In the middle column enter the exact but opposite signs of the x, y, and z components of the created point.

e. If this was done correctly then the x, y and z components should now all show zero value.

16. Once you are satisfied with the orientation of the model lock its position by RMB on the name of the model in the project window and select ‘Lock/Unlock Shell’

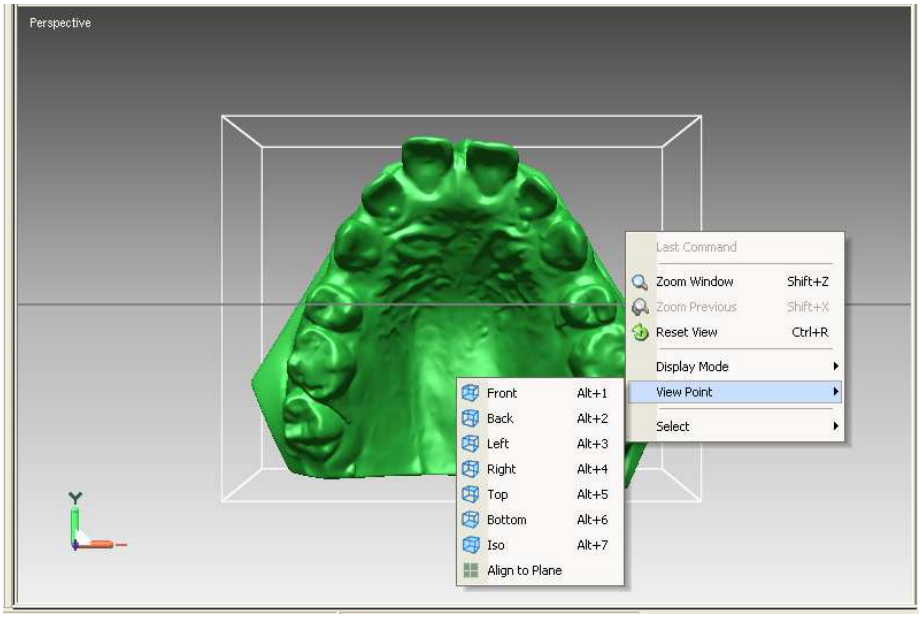

Figure 78: Selecting the viewpoint of the model

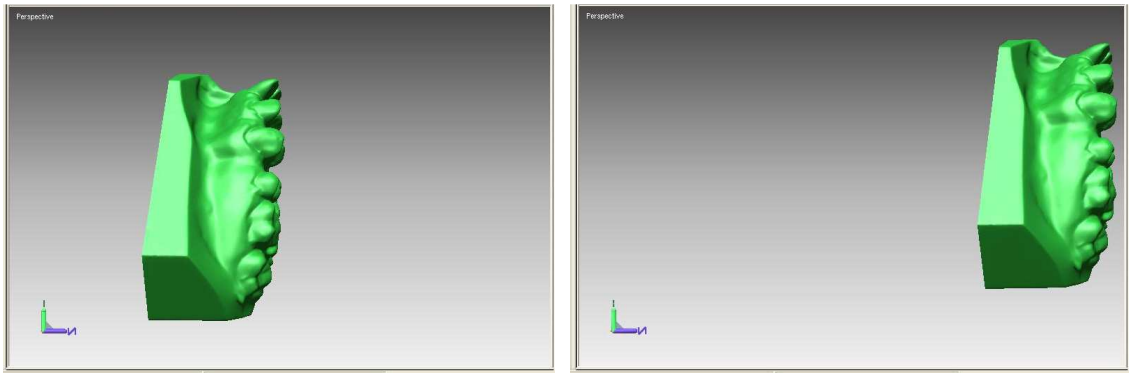

Figure 79: Orientation of the model so that the occlusal plane is parallel to the side of the screen

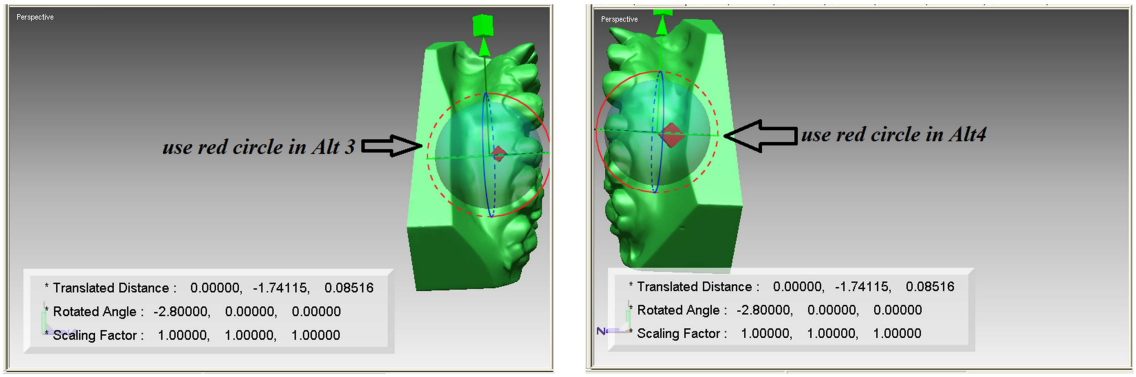

Figure 80: Using shell trackball to orient the model in Alt 3 and Alt 4

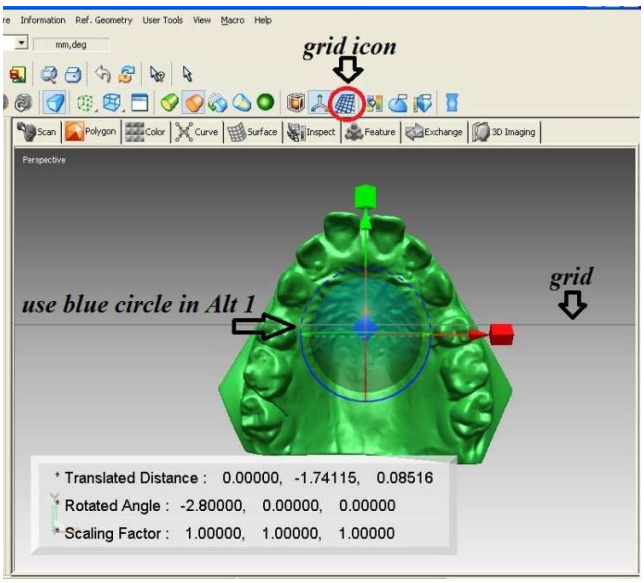

Figure 81: Using shell trackball to orient the model in Alt 1

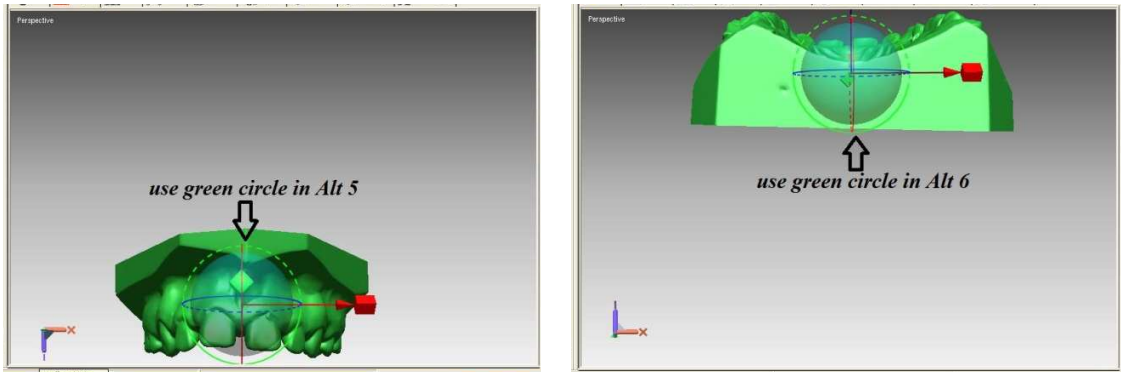

Figure 82: Using shell trackball to orient the model in Alt 5 and Alt 6

4. Superimposing upper follow up models on maxillary baseline models

1. From the project window select the baseline and one follow up maxillary model.
2. Make sure that the maxillary baseline model is locked.
3. Superimpose the models by using the fine superimposition:
    a. Choose ‘Scan’ workbench, on the menu bar select ‘Build’→ ‘Register’→ ‘Fine’
    b. Select both models by highlighting their name in the project menu, then RMB in an empty space in the perspective window and select “Done”. This will bring the models closer together.
4. To superimpose on the Rugae area use one or both of the following methods, Figure 83:
    a. Regional superimposition:
        i. From the menu bar select ‘Build’→ ‘Register’→ ‘2 Shells’→ ‘Regional’, then select the models by highlighting their names in the project window. The last model you choose will show on the screen.
        ii. From the menu bar select ‘Select’→ ‘Mode’→ ‘Paint Brush’, then paint the rugae area on the model in the perspective window. The size of the area you include depends on the quality of the impression and similarities between the models.
        iii. To be able to move the model in the middle of painting, RMB on the model, and select pause, when you have finished moving the model for inspection, RMB again and select pause, then continue painting.
        iv. To control size of the paint brush press shift + LMB
        v. To delete unwanted paint area, press control + LMB

vi. To finish, RMB and click ‘Done’.

vii. RMB, select→ None to erase the shaded area

b. Initial superimposition:

i. From the menu bar select ‘Build’→ ‘Register’→ ‘2 Shells’→ ‘Initial’ then select both models. You will see now three screens, on both small screens you can individually zoom and change the view to select the identical rugae points.

ii. Select a point on the first model, then select the corresponding point on the other model.

iii. At least three corresponding points should be chosen, there is no upper limit for the number of points to be selected.

iv. When the maximum number of corresponding points have been chosen, RMB→ Done.

5. Check the quality of the superimposition by viewing the superimposed models in the perspective window, and using one or more of the following methods, Figure 84:

a. From the menu bar select ‘Measure’→ ‘Shell/Shell Deviation’; then select each of the superimposed models. The quality of the superimposition is shown by the colour coding and by a numerical value. Inspect the rugae area for the quality of the superimposition. A blue area indicates very good superimposition, and numerically 0.8 and below is an accurate superimposition.

b. From menu bar select ‘Measure’→ ‘Cross Section’→ ‘Model’; then set Axis at X and press Alt+4 to examine the sagittal cross section of the models and assess the approximation of the models at the rugae area. Slide the “Position” of the cross section to the left or the right to scan the whole rugae area. You

could also set Axis at Y and press Alt+5 to visualise the rugae area from the frontal view.

6. Lock models

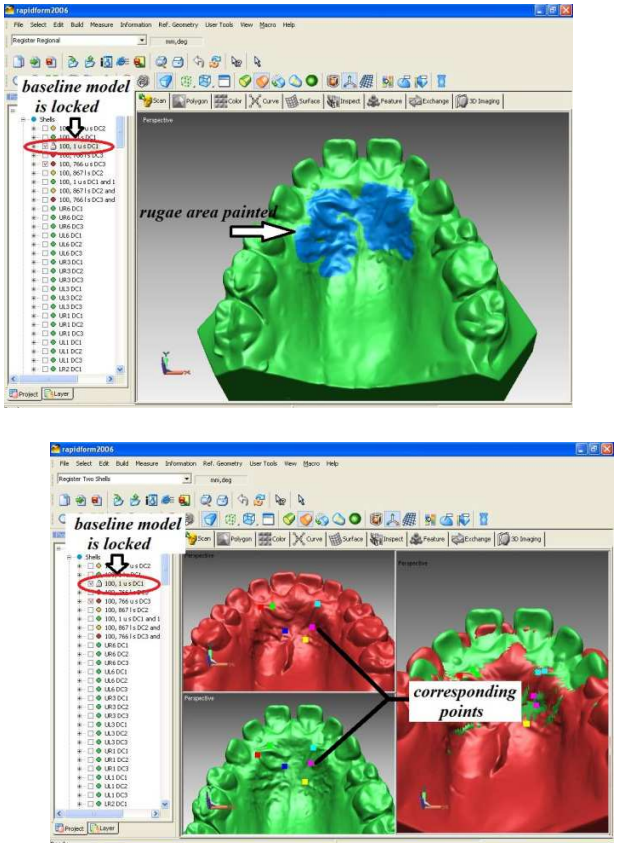

Figure 83: Regional superimposition by painting the rugae area; and initial superimposition by selecting corresponding points on baseline and follow up models

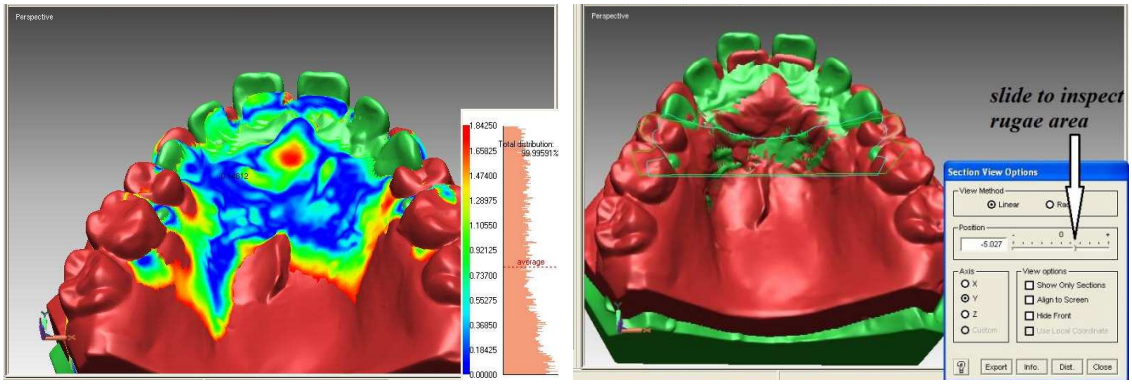

Figure 84: Checking the superimposition by viewing shell/shell deviation and the cross section of the models.

5. Combining maxillary and mandibular models:

1. Using the second set of imported models and view the maxillary and mandibular models of one stage of treatment.
2. From the menu bar select ‘Build’→ Combine Shells; then select the maxillary and mandibular models.
3. RMB→ done
4. Repeat steps (1-3) for all stages of treatment.

6. Superimposing ‘combined models’ in occlusion on maxillary corresponding models

1. View only the baseline models in occlusion and the maxillary baseline model.
2. Superimpose models using the ‘Fine’ registration option (step IV/ 3).
3. If the models are too far apart, first superimpose using the ‘Initial’ option (IV/ 4/ b), followed by the ‘Fine’ option.
4. Check that the superimposition is perfect by using shell/shell deviation (step IV/ 5/ a), ie a solid blue colour should show when checking the superimposition.
5. Repeat for the models at each stage of treatment.

6. Lock models

7. Superimposing mandibular models on ‘combined models’ in occlusion

1. View only the baseline models in occlusion and the mandibular baseline model.

2. Superimpose models using the ‘Fine’ registration option (step IV/3).

3. If the models are too far apart, first superimpose using the ‘Initial’ option (IV/4/b), followed by the ‘Fine’ option.

4. Check that the superimposition is perfect by using shell/shell deviation (step IV/5/a), ie a solid blue colour should show when checking the superimposition.

5. Repeat for the models at each stage of treatment.

6. Lock models

8. Creating and duplicating tooth shells from the baseline models

Create the following tooth shells in all stages of treatment; UR6, UR3, UR1, UL1, UL3, UL6 in the maxillary model, and LR2, LR1, LL1, LL2, LR3, LL3, LR6, LL6 in the mandibular model:

1. View the maxillary baseline model in the perspective window.

2. Place the cursor on the model and RMB→ ‘Select’→ ‘Face’, Figure 85.

3. Use the paint brush to shade the tooth you want to study by moving the mouse while LMB, Figure 86.

4. Pause the shading to view different angles of the model by RMB→ ‘Pause’

5. Zoom in and out by using the mouse scroll wheel.

6. Move the model in the perspective window by RMB→ ‘Pause’, then Ctrl+LMB.

7. Control the size of the paint brush area by pressing Shitf+LMB, and move the mouse slightly until the appropriate size is achieved.

8. Delete unwanted painted area by pressing Ctrl+LMB, and move the mouse to unshade the area.

9. When the whole crown is shaded, from the menu bar select ‘Edit’→ ‘Copy’; then ‘Edit’→ ‘Paste’.

10. Repeat ‘Edit’→ ‘Paste’ to form duplicate shells. The number of duplicates depends on the number of treatment stages to be analysed.

11. Rename the created shells in the project window

12. RMB on the model, → ‘select’→none to erase the shell.

13. Repeat steps (VIII/ 2-12) for each tooth to be studied on the maxillary model.

14. View the mandibular baseline model in the perspective window

15. Repeat steps (VIII/ 2-12) for each tooth to be studied on the mandibular model.

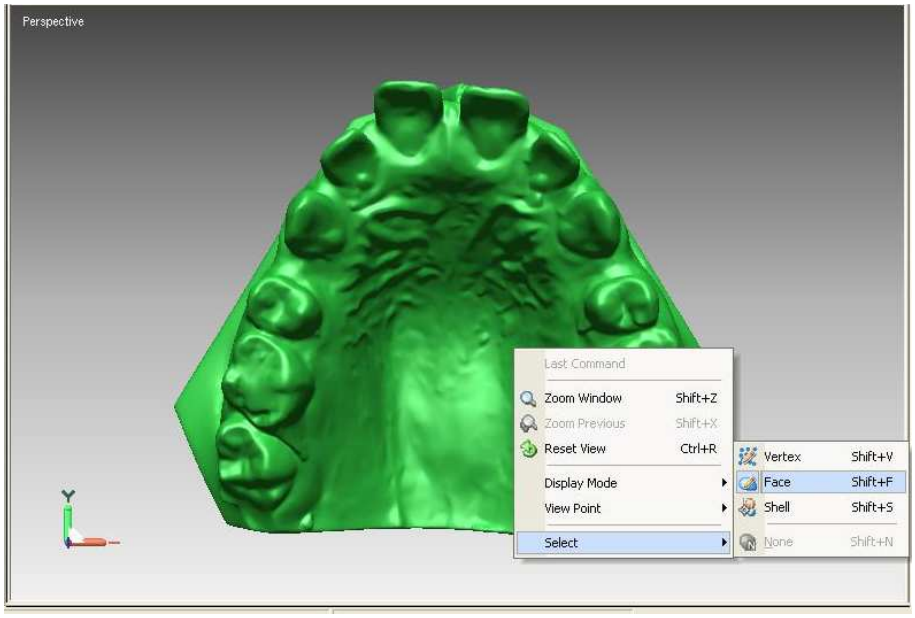

Figure 85: Creating a tooth shell on the maxillary baseline model

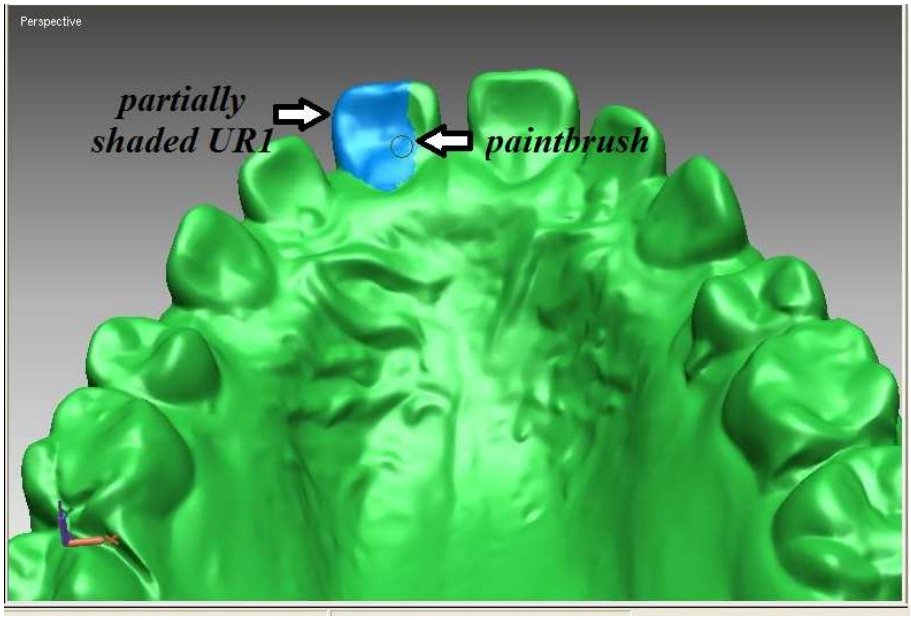

Figure 86: Shading a tooth shell on a baseline maxillary model

9. Creating vectors of rotations for the molars

Create vectors of rotations (VR) for the following tooth shells in all stages of treatment; UR6, UL6 in the maxillary model.

The VR is created on the baseline shell of each molar and copied to the followup shells.

View only one shell at a time. Start by viewing the baseline shell of a molar in the occlusal view (Alt 1), move the shell so that you are viewing the whole occlusal view, Figure 87.

From the menu bar select ‘Ref. Geometry’→ ‘Create’→ ‘Vector’→ ‘Pick Points’

Pick a point on the mesio-palatal cusp tip and a point on the disto-buccal cusp tip by using the LMB, Figure 87.

RMB on the molar shell →’Done’; a vector (line) will be created in the perspective window

Rename the vector in the project window

View only the follow up shell of the tooth and the vector created in the previous step.

From the menu bar select ‘Ref. Geometry’ menu choose ‘Create’→ ‘Vector’→ ‘Pick Points’; then pick the exact points that form the ends of the previously created vector Figure 88 .

RMB on the shell → ‘Done’; a second vector will be created which is a duplicate of the first vector.

Rename the created vector

Repeat steps (IX / 7-10) for each follow up molar shell.

Repeat steps (IX / 2-10) for the remaining molar teeth.

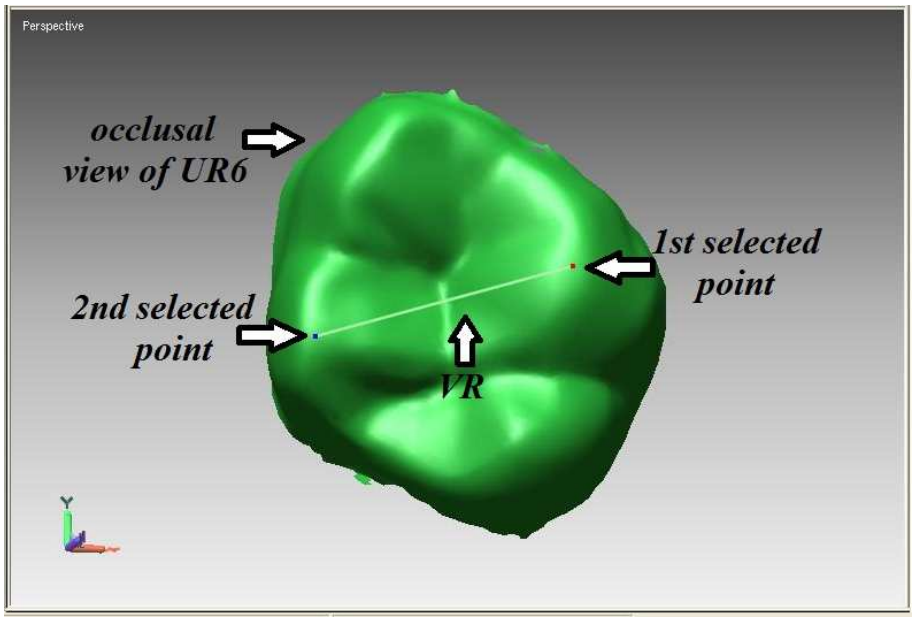

Figure 87: Creating the vector of rotation (VR) on a baseline tooth shell

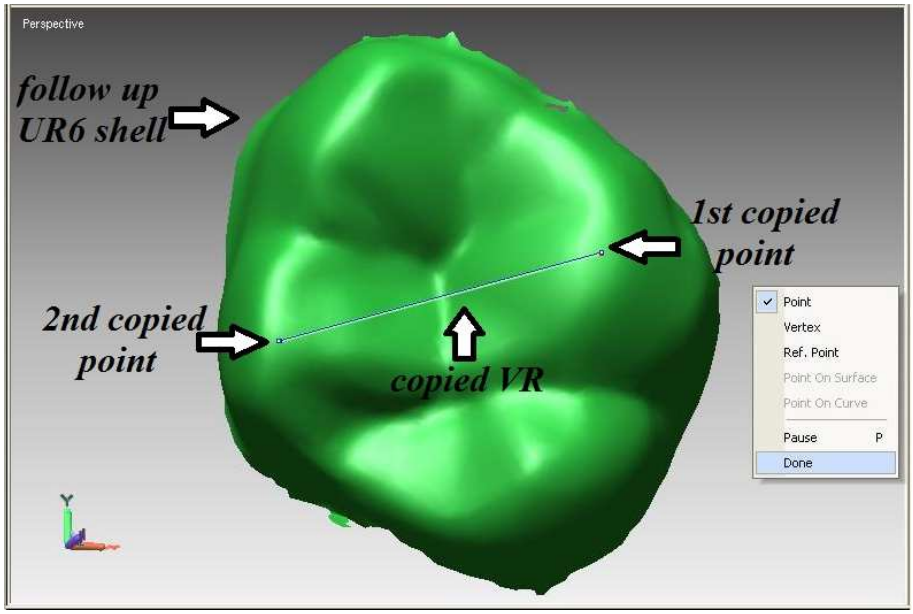

Figure 88: Copying the vector of rotation (VR) on a follow up tooth shell

10.Creating vectors of rotation for the incisors:

Create vectors of rotations (VR) for the following tooth shells in all stages of treatment; LR2, LR1, LL1, LL2 in the mandibular model

1. View only one shell at a time. Start by viewing the baseline shell of an incisor in the occlusal view in the lower arch (Alt 2). Move the shell so that you are viewing the whole occlusal view, Figure 89.

From the menu bar select 'Ref. Geometry'→ 'Create'→ 'Vector'→ 'Pick Points'

Pick two points on the incisor edge of the incisor by using the LMB, start from the mesial to the distal end, Figure 89.

RMB on the incisor shell →'Done'; a vector (line) will be created in the perspective window

View only the follow up shell of the incisor and the vector created in the previous step.

Repeat steps (IX/ 6-10) for the follow up incisor shells.

Repeat steps (X/ 1-5) for the remaining incisor teeth.

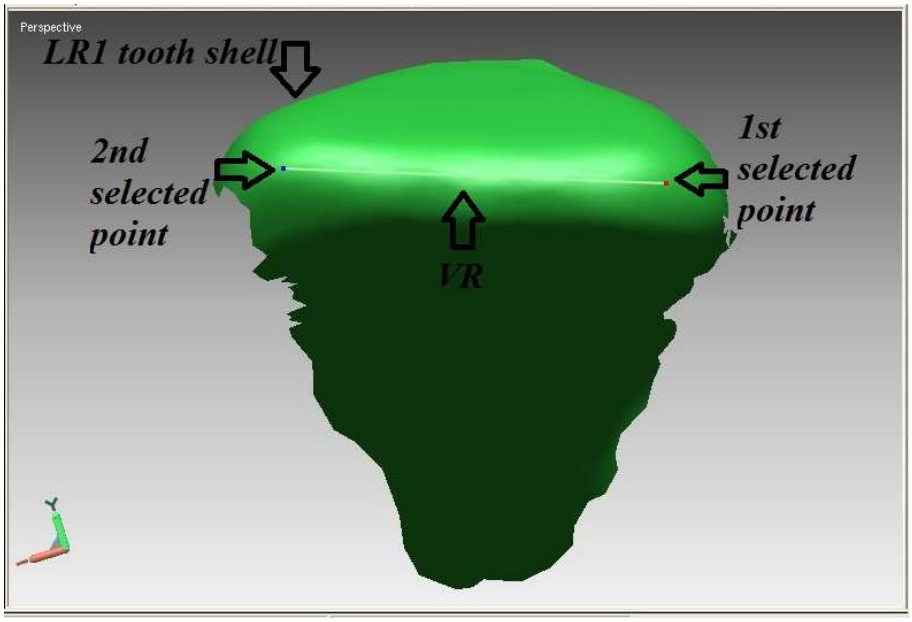

Figure 89: Creating the vector of rotation (VR) of an incisor tooth

11.Creating the middle of the incisal edge for incisors and canines

Create centre of incisal edge (COI) for the following shells; UR1, UL1, UR3, UL3 in the maxillary model and LR2, LR1, LL1, LL2, LR3, LL3 in the mandibular model.

1. This step is similar to creating the VR in that the COI is created on the baseline shell of each incisor and copied to the follow up shells.

View the baseline shell of an incisor tooth in the occlusal view (Alt 1 for the maxillary teeth and Alt 2 for the mandibular teeth). Move the tooth until an optimum view of the incisal edge is achieved, Figure 90.

From the menu bar select ‘Ref. Geometry’→ ‘Create’→ ‘Point’→ ‘Pick Point’

Pick a point in the middle of the incisor edge by using LMB, and rename it in the project window.

View only the follow up incisor shell and the point created in the previous step.

Copy this point on the follow up incisor shell.

Repeat steps (XI / 5-6) for each follow up shell.

Repeat steps (XI / 2-6) for the remaining incisor and canine teeth.

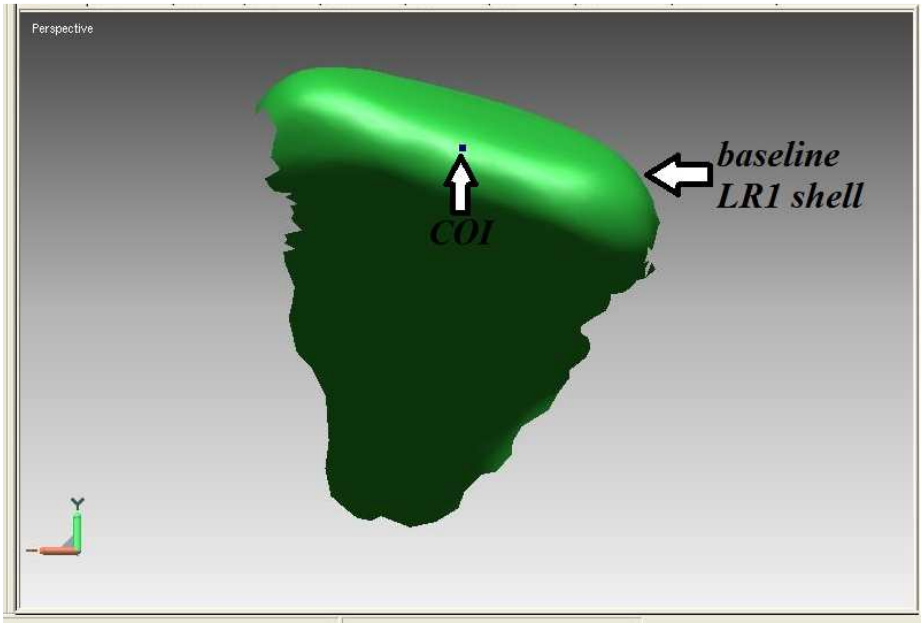

Figure 90: creating the center of the incisal edge (COI) for an incisor

12. Superimposing the tooth shells on the corresponding maxillary and mandibular models

Superimpose the following tooth shells on their corresponding follow up models: UR6, UR3, UR1, UL6, UL3, UL1 on the follow up maxillary models; LR2, LR1, LL1, LL2, LR3, LL3, LR6, LL6 on the follow up mandibular models.

1. View a follow up tooth shell and its follow up maxillary or mandibular model in the perspective window.
2. From the menu bar select ‘Build’→ ‘Register’→ ‘Fine’
3. Then select the follow up tooth shell and the follow up model by clicking their names in the project window, Figure 91.
4. In the perspective window, RMB → ‘Done’
5. Check the quality of the superimposition by using the shell/shell deviation method, Figure 92.

6. If the superimposition is not satisfactory, use the initial superimposition option, and check the quality of the superimposition.
7. Repeat for all the follow up tooth shells

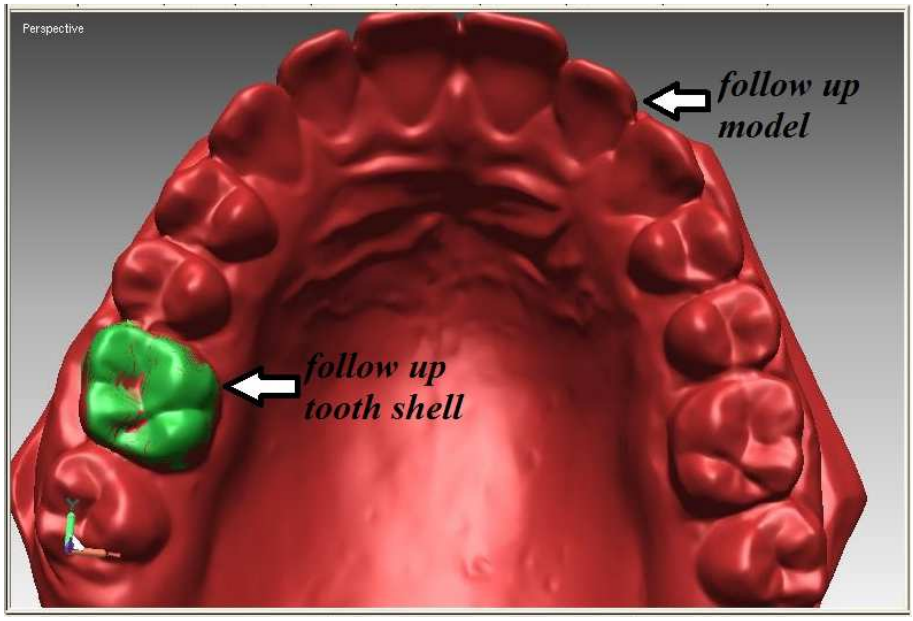

Figure 91: Superimposing the follow up tooth shell on the follow up model by using the 'Fine' option.

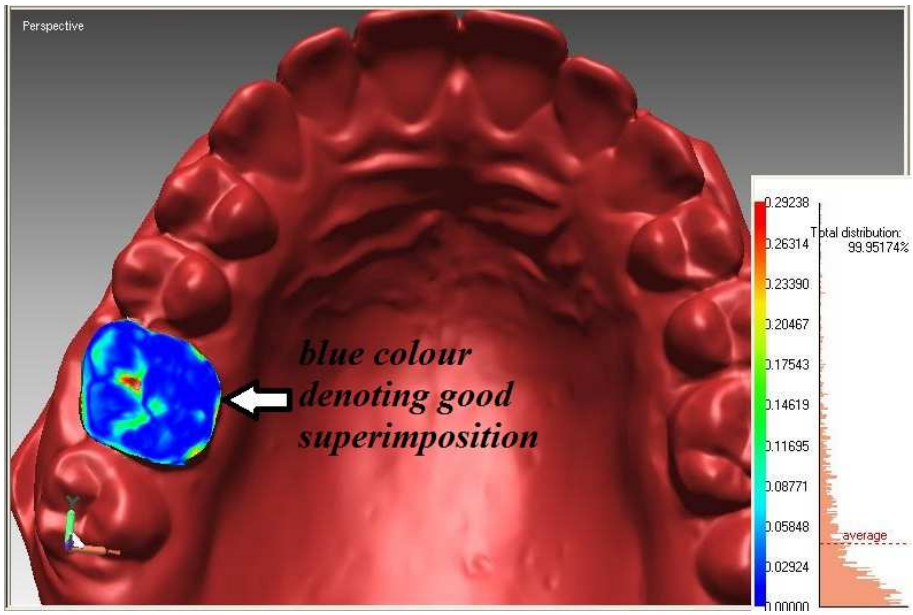

Figure 92: Checking the quality of the superimposition by using shell/shell deviation

13.Creating the centre of mass for tooth shells

Create center of mass for the following tooth shells in all stages of treatment: UR6, UR3, UR1, UL1, UL3, UL6, LR2, LR1, LL1, LL2.

1. View required shell
2. From the menu bar select ‘Information’ → ‘Shell’
3. LMB on the tooth shell to select it.
4. RMB on an empty area in the prospective window → ‘Add Center of Mass as Ref. Point’, Figure 93.
5. Rename the created points (always remember to press enter after renaming a point, otherwise it will not change)
6. Repeat with the remaining tooth shells.

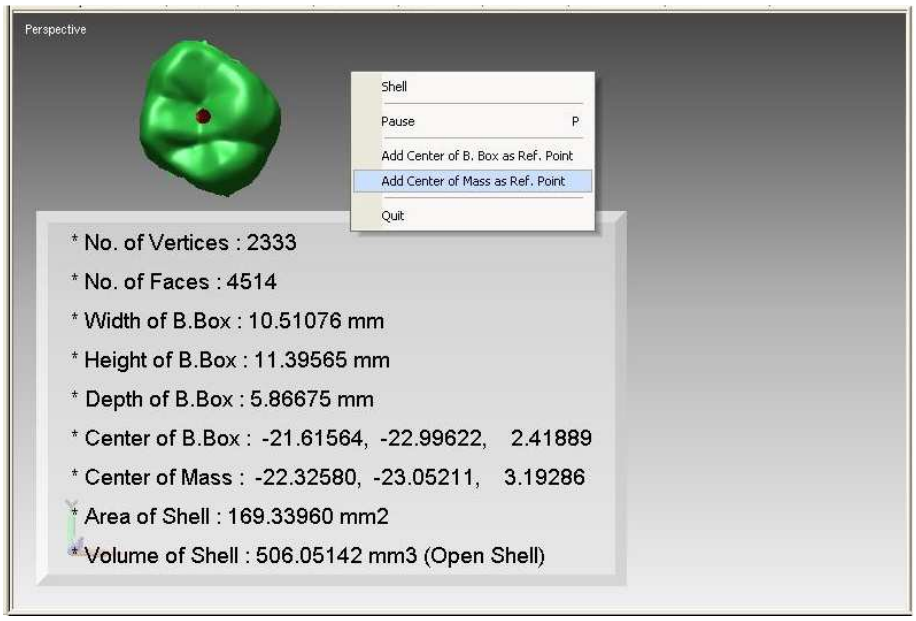

Figure 93: Creating the centre of mass

14.Creating the long axis of molar teeth

Create long axis of the following molar teeth shells in all stages of treatment: UR6, UL6, LR6, LL6

1. View the required shell in the perspective window.

From the menu bar select ‘Select’→ ‘Flood Fill’

LMB on the shell of the molar

From the menu bar select ‘Ref. Geometry’→ ‘Create’→ ‘Circle’→ ‘Fit Region’

Choose Create and a circle will be formed on the occlusal surface of the molar, Figure 94.

Choose Close

From the menu bar select ‘Ref. Geometry’→ ‘Create’→ ‘Vector’→ ‘From Ref. Circle’

LMB on the created circle and the long axis of the molar will be created, Figure 95.

Rename the created vector in the project window, (always remember to press enter after renaming a point, otherwise it will not change)

Repeat for the remaining teeth

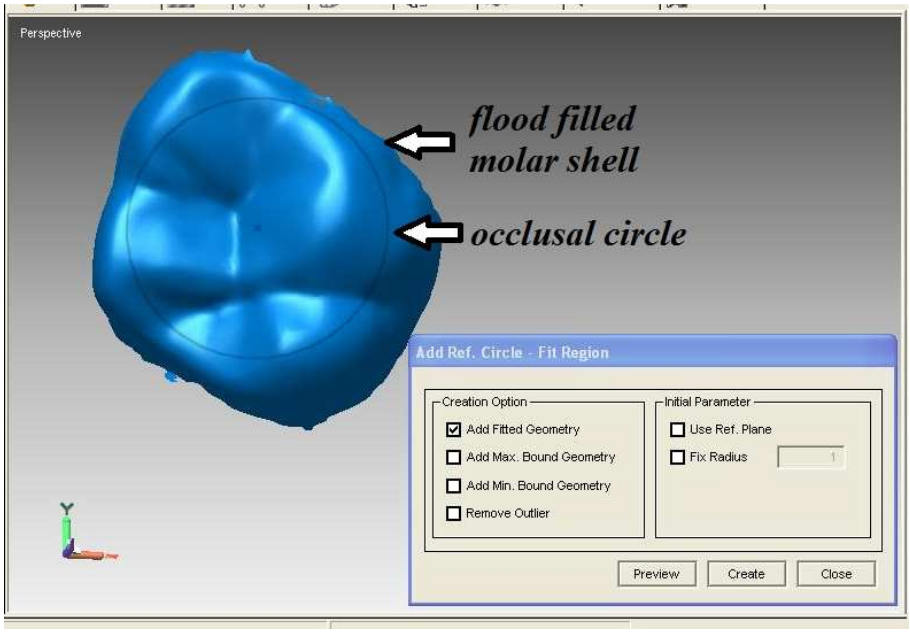

Figure 94: Creating the long axis of molar teeth, step 1

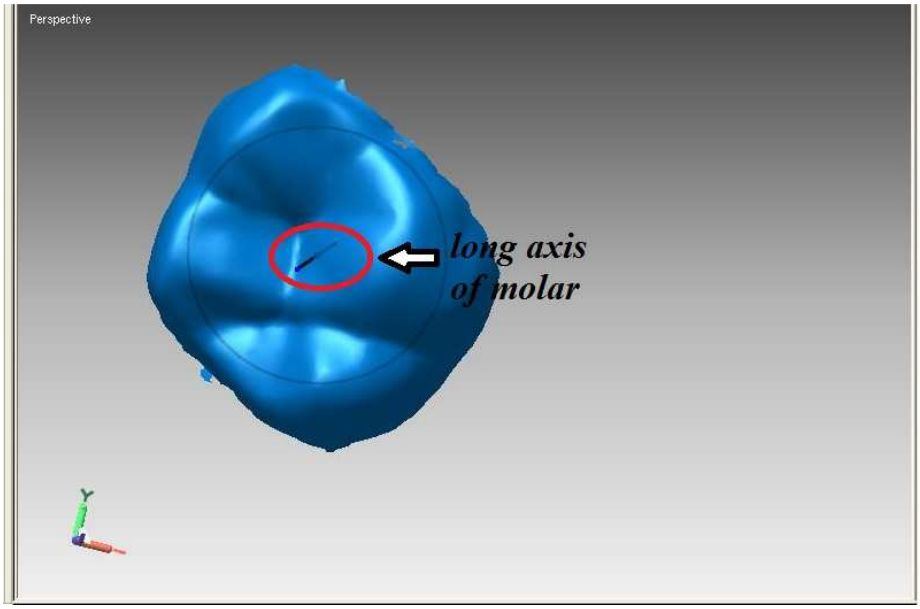

Figure 95: Creating the long axis of the molar

15.Creating the long axis of incisor and canine teeth

Create the long axis of the following teeth in all stages of treatment: UR3, UL3, LR3, LL3, LR2, LR1, LL1, LL2

1. View the required shell, the long axis of the shell, and the centre of incisal edge.

From the menu bar select ‘Ref. Geometry’→ ‘Create’→ ‘Vector’→ ‘Pick Points’

RMB on an empty area in the perspective window and select ‘Ref. Point’

In the project window, LMB on the name of the centre of mass of the required incisor and the centre of the incisal edge .

RMB on an empty area in the perspective window and select ‘Done’, Figure 96.

Rename the created vector (always remember to press enter after renaming a point, otherwise it will not change)

Repeat for the remaining incisor and canine teeth.

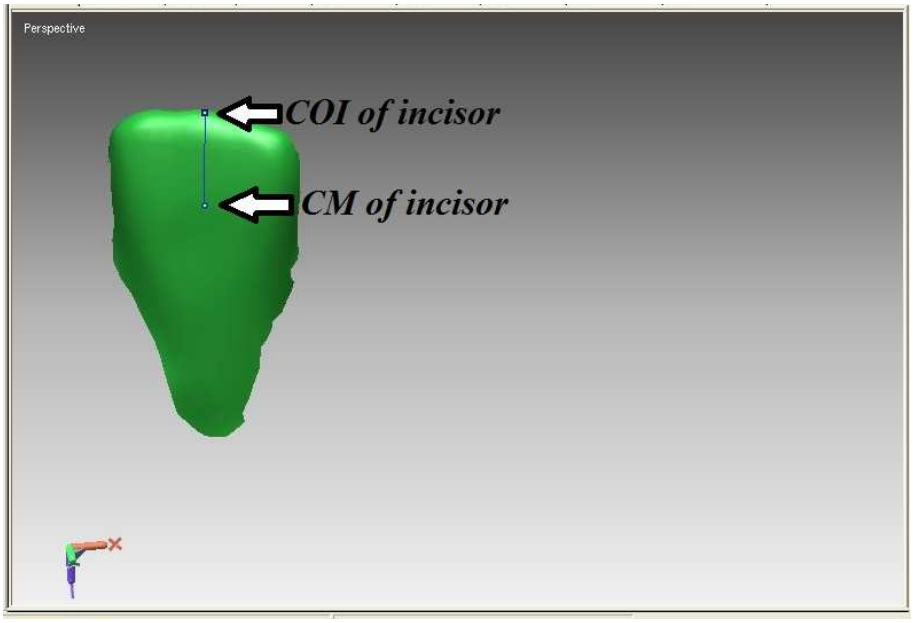

Figure 96: Creating the long axis of an incisor tooth

16.Creating reference planes

Create the following reference planes: occlusal plane, saggital plane, overjet plane and overbite plane.

1. From the menu bar select ‘Ref. Geometry’→ ‘Create’→ ‘Plane’→ ‘Input Normal &Position’

Change the values displaced in the “Normal” box to the following:

X=0, Y=0, Z=1 : to produce the Occlusal plane

X=1, Y=0, Z=0 : to produce the Sagittal plane

X=0, Y=1, Z=0 to produce the Transverse plane

Rename the created planes

To create the overjet plane, view the required lower incisor shell and it’s corresponding COI point.

Make sure you are viewing the incisor from the (Alt 5) view.

From the menu bar select ‘Ref. Geometry’→ ‘Create’→ ‘Plane’→’Pick Point with Viewing Direction’

In the project window, LMB on the name of the COI; a reference plane will be created, Figure 97.

Rename the created plane.

To create the overbite plane, continue viewing the same lower incisor and COI point.

Change the viewing angle to (Alt 2).

From the menu bar select ‘Ref. Geometry’→ ‘Create’→ ‘Plane’→ ‘Pick Point with Viewing Direction’

In the project window, LMB on the name of the COI; a reference plane will be created, Figure 98.

Rename the created plane.

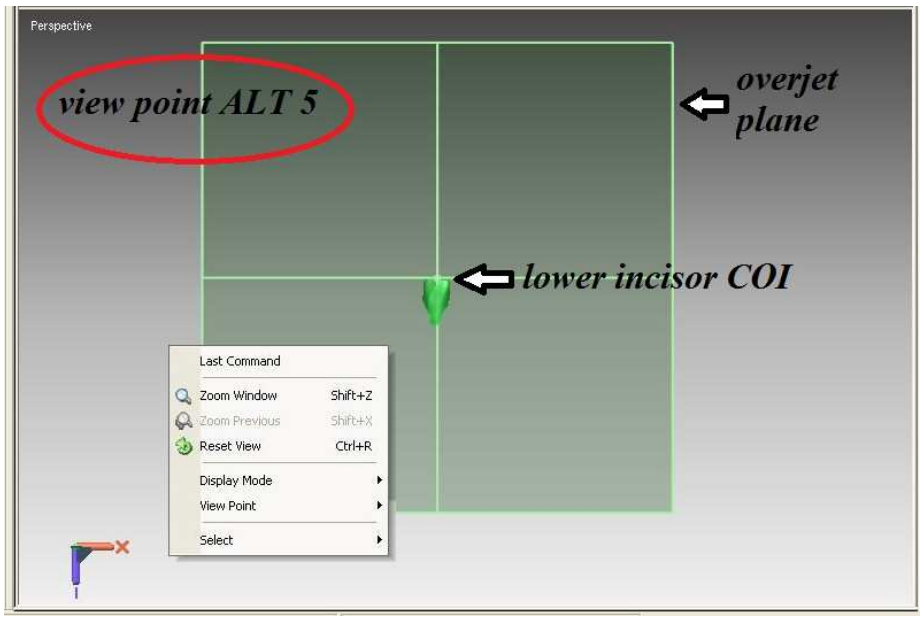

Figure 97: Creating the overjet plane

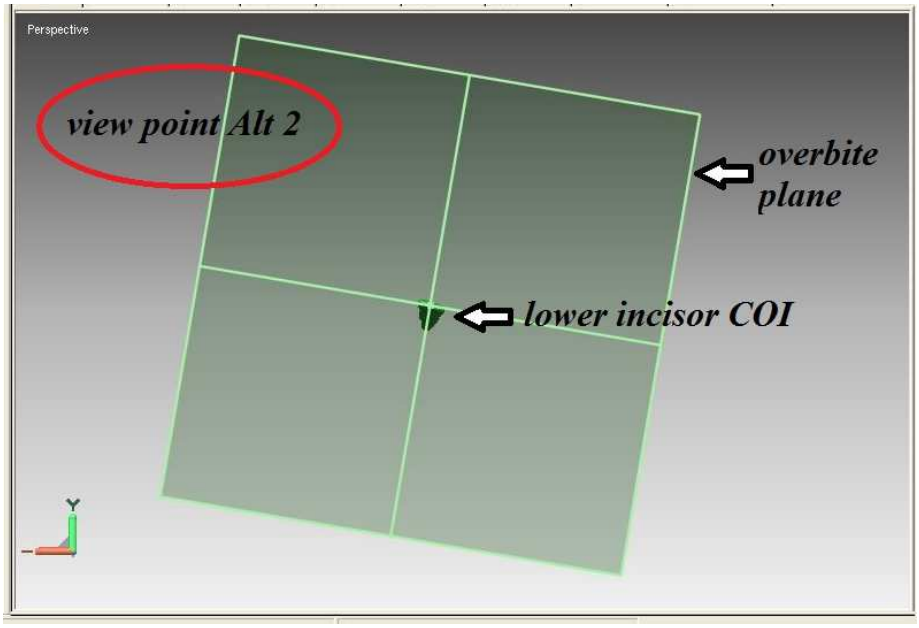

Figure 98: Creating the overbite plane

17.Registering centres of mass (CM) on the occlusal plane

Register CM of the following teeth shells on the occlusal plane in all stages of treatment: UR6, UL6.

1. View the occlusal plane and the centres of mass in the prospective window

From the menu bar select ‘Ref. Geometry’→ ‘Create’→ ‘Points’→ ‘Project on Ref. Plane’

RMB on the occlusal plane the CM’s in the project window

Rename the created points

18.Registering vectors of rotation (VR) on the saggital plane

Register VR on the saggital plane for the following teeth shells in all three stages of treatment. UR6, UL6. Please note that registering the lower incisor shells will be performed at a later stage.

1. View the Saggital plane and the required vector of rotation

From the menu bar select ‘Ref. Geometry’→ ‘Create’→ ‘Points’→ ‘From Ref. Vector’

LMB on the vectors of rotation

Put 1 as the number of divisions then OK, two reference points will be created which are copies of the ends of the vector.

Rename the created points

From the menu bar select ‘Ref. Geometry’→ ‘Create’→ ‘Points’→ ‘Project on Ref. Plane’

LMB on the saggital plane, then LMB on the points that were created from the vectors in step 4; two reference points will be created which are projected on the saggital plane.

Rename the created points

From the menu bar ‘Ref. Geometry’→ ‘Create’→ ‘Vector’→ ‘Pick Points’

RMB on an empty area in the prospective window and select ‘Ref. Point’

In the project window RMB on the projected points created in step 7; a vector will be created which is a projection of the VR on the saggital plane.

Rename the created vector

Repeat with the remaining VRs

19. Create reference landmarks for measurement of the dental midline deviation

1. View the maxillary model of one stage of treatment in the (Alt 5) view

From the menu bar choose ‘Ref. Geometry’→ ‘Create’→ ‘Point→ ‘Pick Point’ then LMB on a point in the middle of the contact area between the central incisors.

Rename ‘MIDUP’

Project this point to occlusal plane:

View the occlusal plane and the ‘MIDUP’ point in the prospective window

From the menu bar select ‘Ref. Geometry’→ ‘Create’→ ‘Points’→ ‘Project on Ref. Plane’

RMB on the occlusal plane the MIDUP point in the project window; a projected point will be created

Rename this point ‘OPP MIDUP’

Create the 1st vector, Figure 99:

From the “Ref. Geometry” menu choose “Create” - “Vector” - “Pick Points”

RMB on empty area in the perspective window and select ‘Ref. Point’

In the project window, select the two created points: ‘MIDUP’ and ‘OPP MIDUP’; a vector will be created.

Project this vector to the transverse plane (repeat steps in stage XVIII using the transverse plane

Rename the created vector.

View the mandibular model of the same stage of treatment in the (Alt 5) view

Repeat steps (2-7) on lower model. This time name the points ‘MIDLO’ and ‘OPP MIDLO’

Create the 2nd vector, Figure 100, in the same manner as the 1st vector (step 7).

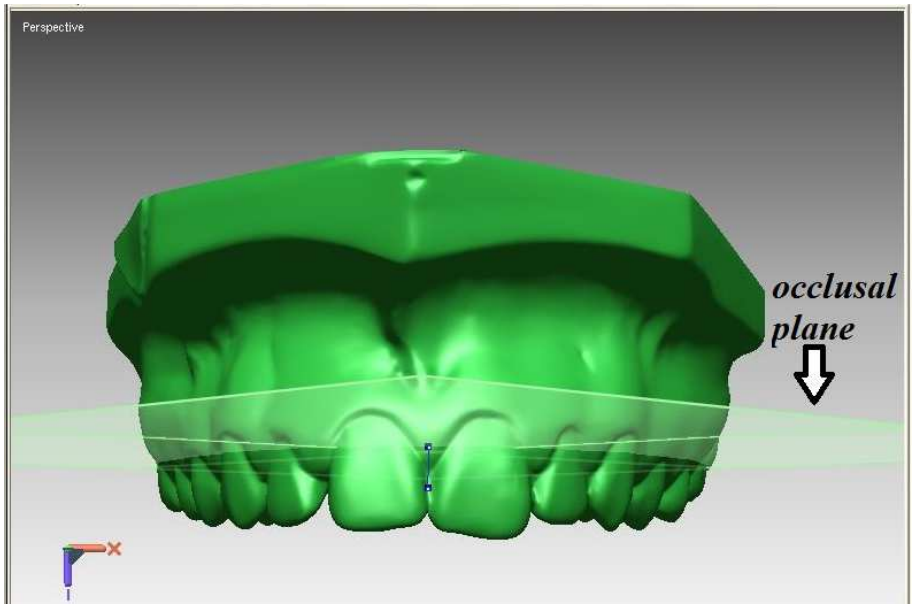

Figure 99: Creating the first reference vector for measurement of midline deviation

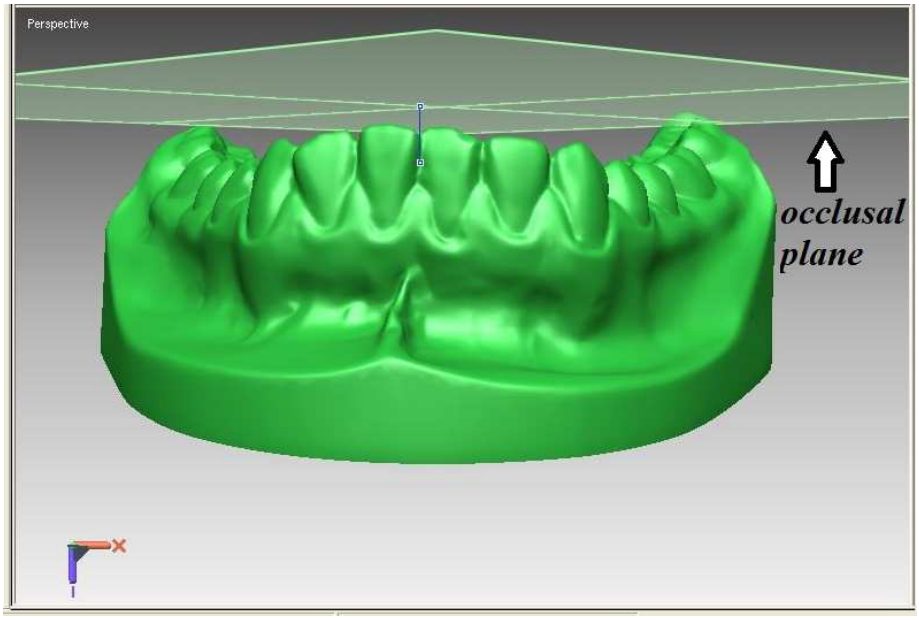

Figure 100: Creating the second reference vector for measurement of midline deviation

20.Measuring linear movement of the molar

Measure the linear movement of UR6, UL6. See Figure 101

1. Activate ‘Polygon’ workbench

2. In the prospective window, view the following reference landmarks;
    a. the centres of mass (CM) of a baseline molar, (created in stage XIII).
    b. CMs of the follow up molars, (created in stage XIII).
3. From the menu bar select ‘Measure’→ ‘Distance’→ ‘Point/Point’→ ‘Along Line’
4. RMB on an empty area of the prospective window and make sure that the ‘Ref. Point’ is selected.
5. In the project window, select the CM of a follow up shell then the CM of the baseline shell.
6. A box will appear at the bottom of the screen. The last line in that box reads: Displacement then three values are displaced. These values are in order the X, Y and Z linear movements of the tooth.
7. Record the linear measurements
8. Repeat steps (5-7) for each follow up shell.

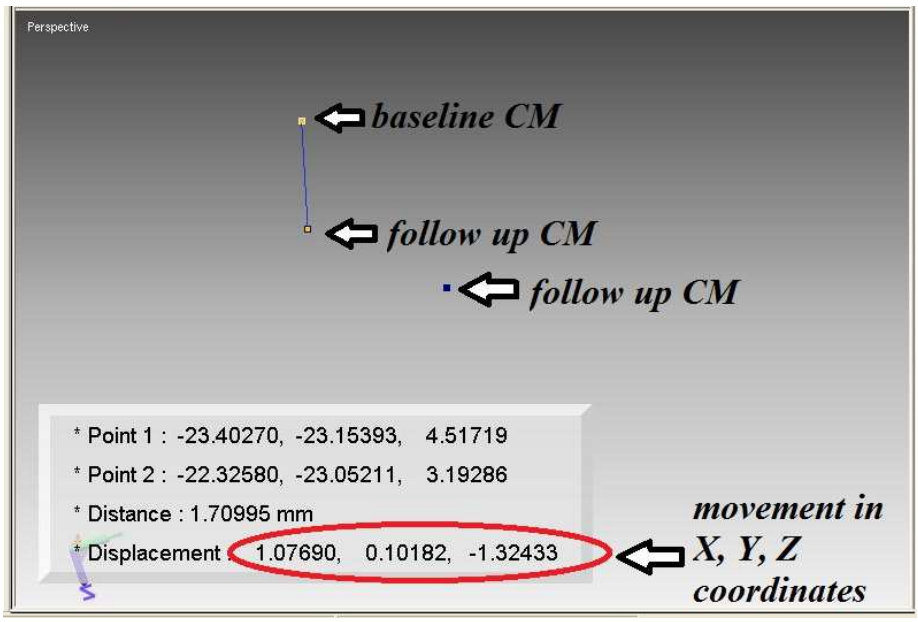

Figure 101: Measuring linear movement of the molars

21.Measuring the distal movement of the upper molars

Measure the distal movement of UR6, UL6. See Figure 102

1. Activate ‘Polygon’ workbench
2. In the prospective window, view the following reference landmarks; the projected centres of mass (CM) of the baseline and follow up molars, (created in stage XVII).
3. From the menu bar select ‘Measure’→ ‘Distance’→ ‘Point/Point’→ ‘Along Line’
4. RMB on an empty area of the prospective window and make sure that the ‘Ref. Point’ is selected.
5. In the project window, select the projected CM of the follow up shell then the projected CM of the baseline shell.
6. A box will appear at the bottom of the screen. The value after ‘Distance’ is the amount of distal movement
7. Determine the direction of movement (mesial or distal) by visual inspection of the CM.
8. Record the linear measurements
9. Repeat steps 2-8 for each follow up shell.

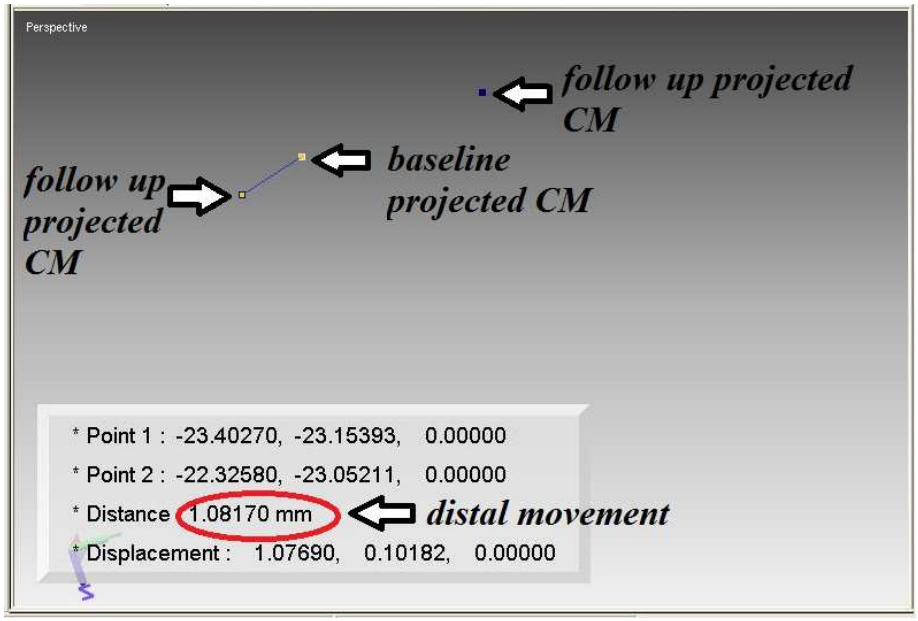

Figure 102: Measuring distal movement of the molars

22.Measuring change in tip of the upper molars

Measure the change in tip of UR6, UL6. See Figure 103

1. Activate “Polygon” workbench
2. In the prospective window, view the following reference landmarks; the projected vectors of rotation (VR) of the baseline and follow up molars, (created in stage XVIII).
3. From the menu bar select ‘Measure’→ ‘Angle’→ ‘2 Vectors’
4. In the project window, select the projected VR of the follow up shell then the projected VR of the baseline shell.
5. A box will appear at the bottom of the screen, the value after ‘Small Angle’ is the change in tip of the molars.

6. To determine the direction of movement (mesial or distal tip) by visual inspection of the long axis of the baseline and follow up molar shells. The long axes of the molars were created in stage (XIV).
7. Record the angular measurements
8. Repeat steps (2-8) for the remaining follow up shells.

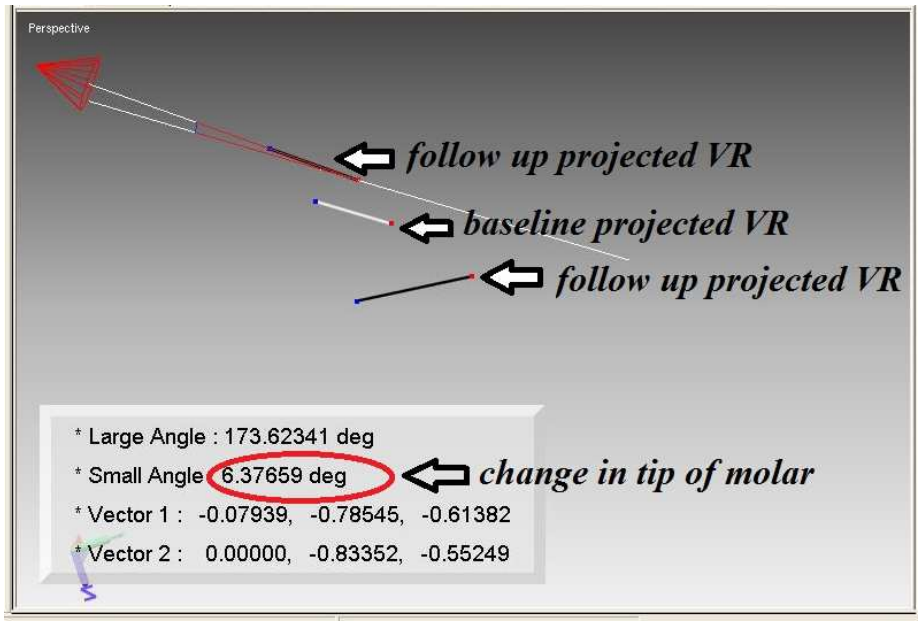

Figure 103: Measuring change in tip of the molars

23.Measuring the overjet

See Figure 104

1. Activate “Polygon” workbench
2. In the prospective window, view the following reference landmarks;
    a. the overjet plane (created in stage XVI) and
    b. the COI of the most prominent upper incisor, (created in stage XI).
    c. Viewing the upper and lower incisor shell is optional.

3. From the menu bar select ‘Measure’→ ‘Distance’→ ‘Point/Ref. Plane

4. LMB on the overjet plane in the prospective window and the COI in the project window.

5. A box will appear, the value after ‘Distance’ is the overjet measurement

6. Record the measurement

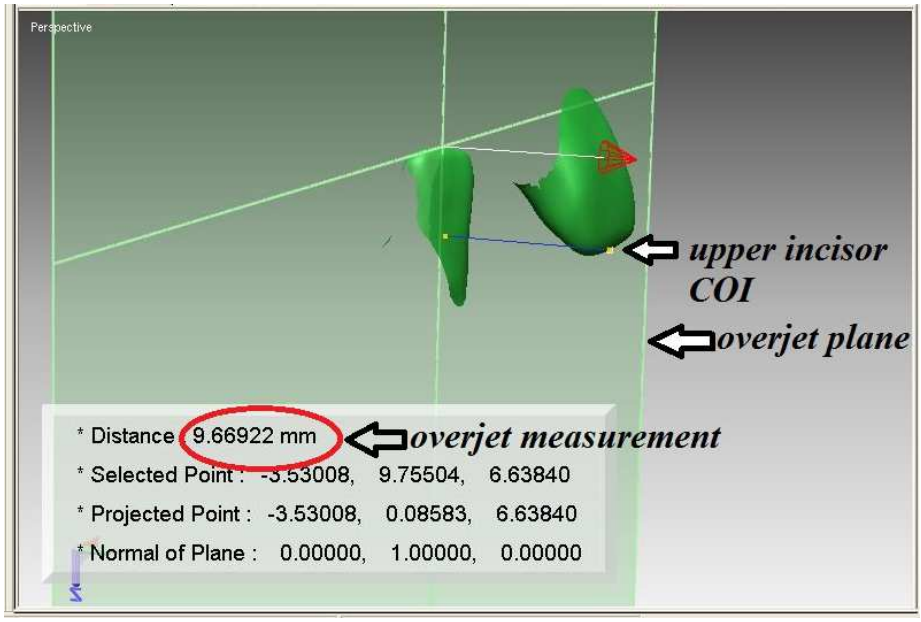

Figure 104: Measuring the overjet

24.Measuring the overbite

See Figure 105

25. Activate “Polygon” workbench

26. In the prospective window, view the following reference landmarks;

- **a.** the overbite plane (created in stage XVI) and
- **b.** the COI of the most prominent upper incisor, (created in stage XI).
- **c.** Viewing the lower and upper incisor shell is optional.

27. From the menu bar select ‘Measure’→ ‘Distance’→ ‘Point/Ref. Plane’

28. LMB on the overbite plane in the prospective window and the COI in the project window.

29. A box will appear, the value after 'Distance' is the overbite measurement

30. Record the measurement

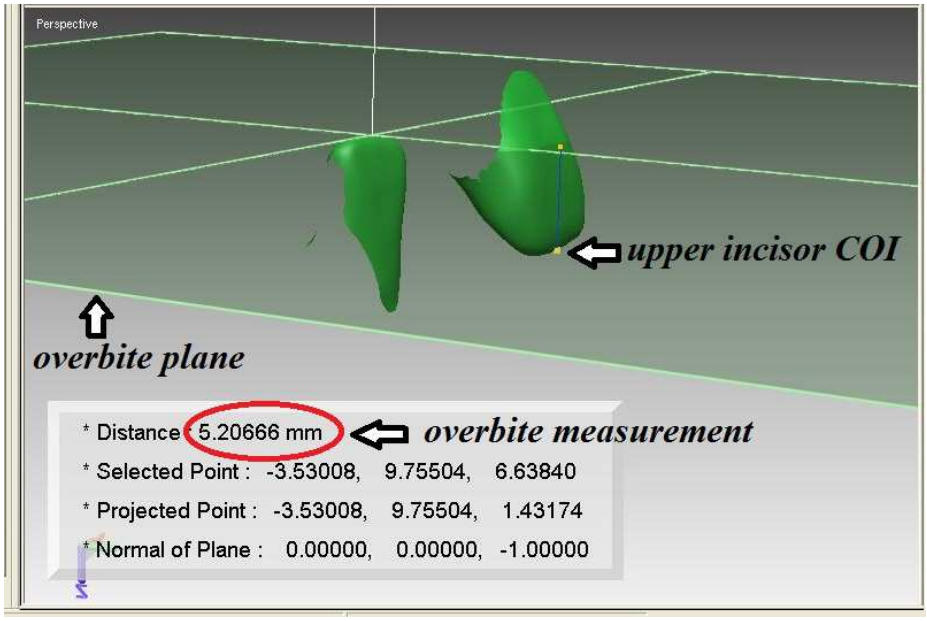

Figure 105: Measuring the overbite

31.Measuring dental midline deviation

See Figure 106

1. Activate "Polygon" workbench

2. In the prospective window, view the following reference landmarks;

- **a.** the 1st and 2nd reference vectors created in stage XIX.
- **b.** Viewing the models in occlusion in Alt 5 is optional.

3. From the menu bar select 'Measure'→ 'Distance'→ 'Ref. Vector/Ref. Vector'

4. LMB on the 1st and 2nd reference vectors

32. A box will appear, the value after ‘Distance’ is the amount of dental midline deviation

33. Record the measurement

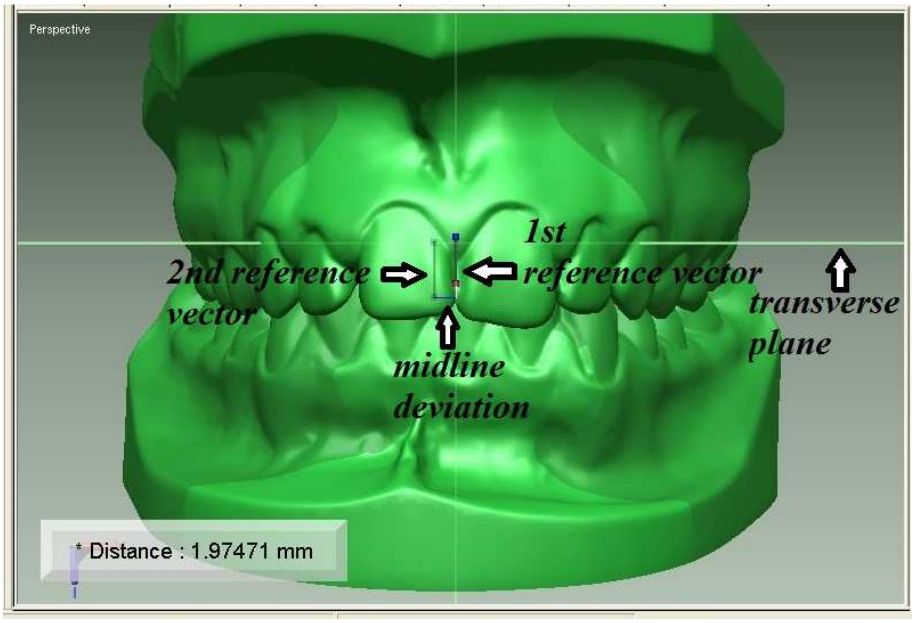

Figure 106: Measuring the dental midline deviation

34.Measuring ‘quantitative’ canine and molar relationship

Measure canine and molar relationship on the right and left sides. See Figure 107

1. Activate “Polygon” workbench

2. In the prospective window, view the following reference landmarks;

- **a.** the long axis of upper and lower right molars (created in stage XIV)
- **b.** viewing the model in occlusion is optional

3. From the menu bar select ‘Measure’→ ‘Distance’→ ‘Ref. Vector/Ref. Vector’

4. LMB on the long axis of the upper molar and the long axis of the lower molar.

5. A box will appear, the value after ‘Distance’ is the quantitative relationship.

6. Record the measurement

7. Repeat steps (2-6) for the molars on the other side and the canines on the right and left.

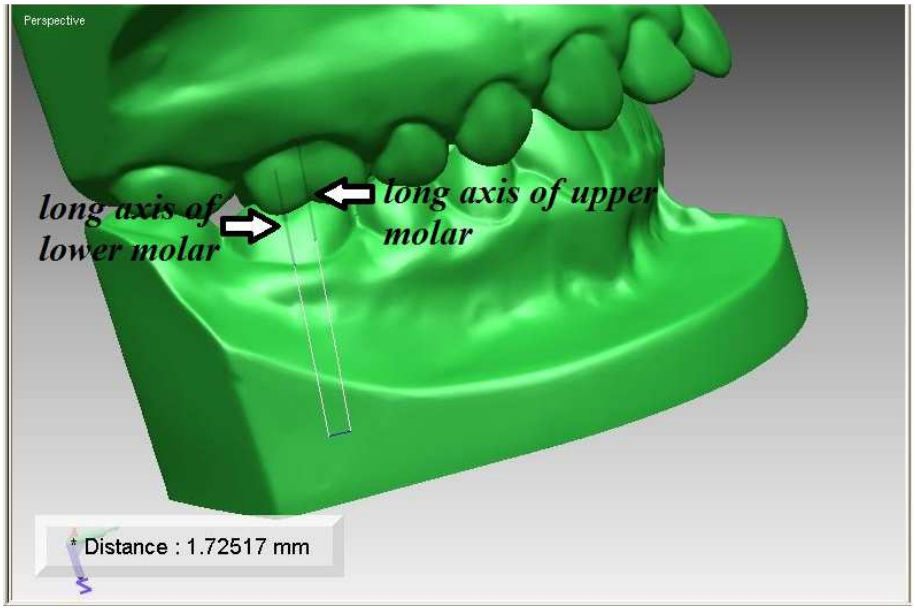

Figure 107: Measuring molar relationship

35.Measuring crowding

1. Activate “Polygon” workbench
2. In the prospective window, view the following;
    a. The mandibular model in(Alt 2)
    b. The occlusal plane
3. Move the mandibular model slightly until both the labial and lingual surfaces of the lower incisor can be seen, Figure 108.
4. Create reference points on the anatomical contact points of the lower incisors and canines. A total of ten points should be created as shown in (Figure 108).

a. From the menu bar select ‘Ref. Geometry’→ ‘create’→ ‘point’→’On Ref. Plane’

b. LMB on the occlusal plane.

c. Select the anatomical contact points on the mandibular model

d. Rename the points

5. From the menu bar select ‘Measure’→ ‘Distance’→ ‘Point/Point’→ ‘Along Line’

6. RMB on an empty area in the perspective window and select ‘Ref Point’

7. LMB on the adjacent contact points starting from the canine on one side to the canine on the other side.

8. For each contact point displacement (two adjacent points), a box will appear; record the value after ‘Distance’, Figure 108.

9. A total of five values should be obtained, the sum of these is the crowding of the lower arch.

10. For upper crowding view the following:

a. The upper maxillary model in (Alt 1)

b. The occlusal plane

11. Repeat steps (3-9)

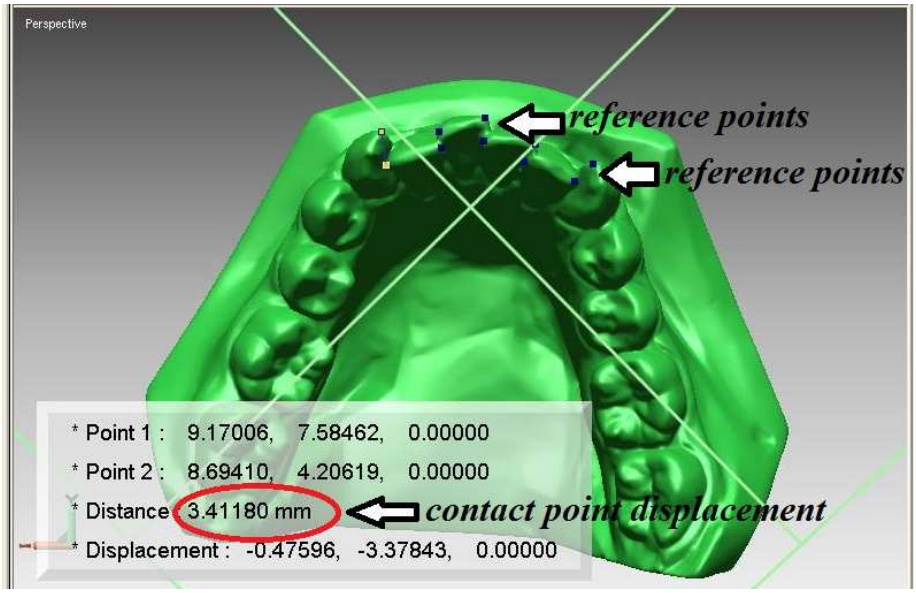

Figure 108: crowding measurement

36. Superimposing mandibular follow up models on mandibular baseline models

1. From the project window select the baseline mandibular model and one follow up mandibular models.
2. Make sure that the mandibular baseline model is locked.
3. Superimpose the models by using regional superimposition:
    - **a.** Activate the ‘Scan’ workbench
    - **b.** From the menu bar select ‘Build’→ ‘Register’→ ‘2 Shells’→ ‘Regional’, then select the models by highlighting their names in the project window. The last model you choose will show on the screen.
    - **c.** From the menu bar select ‘Select’→ ‘Mode’→ ‘Paint Brush’, then paint a horseshoe shaped area on the lingual plate of the mandibular model, Figure 109. This should start 3 mm below the gingival margin and extend as far down into the sulcus as possible.
    - **d.** To be able to move the model in the middle of painting, RMB on the model, and select pause, when you have finished moving the model for inspection, RMB again and select pause, then continue painting.
    - **e.** To control size of the paint brush press shift + LMB
    - **f.** To delete unwanted paint area, press control + LMB
    - **g.** To finish, RMB and click ‘Done’, the two models will be superimposed.
    - **h.** RMB, select→ None to erase the shaded area
    - **i.** Check the quality of the superimposition by inspecting the horseshoe shaped area on both models, using shell/shell deviation as outlined in stage (IV / 5 / a).
4. Repeat step 3 with the remaining follow up model(s).

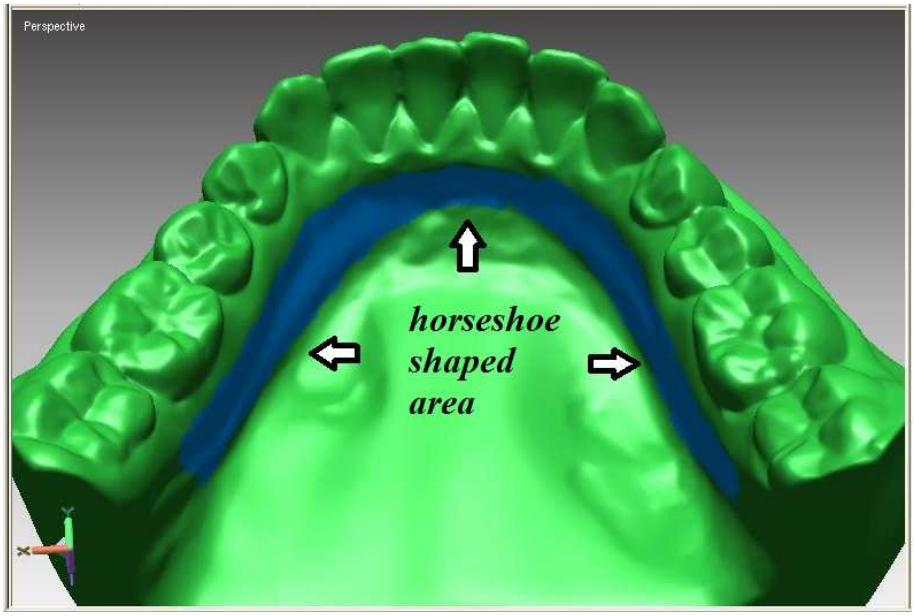

Figure 109: Superimposing mandibular models on a horseshoe shaped area on the lingual plate

37.Superimposing lower incisor shells on lower follow up models

Superimpose the following tooth shells on their corresponding follow up models: LR2, LR1, LL1, LL2,

1. View a follow up tooth shell and its follow up mandibular model in the perspective window.
2. Make sure the mandibular model is locked.
3. From the menu bar select ‘Build’→ ‘Register’→ ‘Fine’
4. Then select the follow up tooth shell and the follow up model by clicking their names in the project window, Figure 91.
5. In the perspective window, RMB → ‘Done’
6. Check the quality of the superimposition by using the shell/shell deviation method, Figure 92.

7. If the superimposition is not satisfactory, use the initial superimposition option, and check the quality of the superimposition.
8. Repeat for all the follow up tooth shells

38.Measure linear movement of the lower incisors

Measure the linear movement of LR2, LR1, LL1, LL2. This is the same method used for the molars (stage XX). See Figure 101

1. Activate ‘Polygon’ workbench
2. In the prospective window, view the following reference landmarks;
    a. the centres of mass (CM) of a baseline incisor and (created in stage XIII).
    b. CMs of follow up incisors, (created in stage XIII).
3. From the menu bar select ‘Measure’→ ‘Distance’→ ‘Point/Point’→ ‘Along Line’
4. RMB on an empty area of the prospective window and make sure that the ‘Ref. Point’ is selected.
5. In the project window, select the CM of a follow up shell then the CM of the baseline shell.
6. A box will appear at the bottom of the screen. The last line in that box reads: Displacement then three values are displaced. These values are in order the X, Y and Z linear movements of the tooth.
7. Record the linear measurements
8. Repeat steps (5-7) for each follow up shell.

39.Measure the change in lower incisor inclination

Measure the change in inclination of LR2, LR1, LL1, LL2. This is the same method used for the change in tip of the molars (stage XXII). See Figure 103

1. Register the VR of each lower incisor shell on the saggital plane as outlined in stage (XIII)
2. Activate “Polygon” workbench
3. In the prospective window, view the following reference landmarks;
    a. the projected vectors of rotation (VR) of a baseline incisor
    b. the projected vectors of rotation of the follow up incisors,
4. From the menu bar select ‘Measure’→ ‘Angle’→ ‘2 Vectors’
5. In the project window, select the projected VR of a follow up shell then the projected VR of the baseline shell.
6. A box will appear at the bottom of the screen, the value after ‘Small Angle’ is the change in torque of the incisors.
7. Determine the direction of movement (proclined or retroclined) by visual inspection of the long axis of the baseline and follow up incisor shells. The long axes of the incisors were created in stage (XIV).
8. Record the angular measurements
9. Repeat steps (3-8) for the remaining follow up shells.