DOCTOR OF PHILOSOPHY

Is the 0.018-inch or the 0.022-inch bracket slot system more effective for the levelling and alignment stage of orthodontic treatment?

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Thesis submitted for the degree of Doctor of Philosophy to

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DEDICATION

I would like to dedicate this thesis to my dear father Dr M. Farouk El-Angbawi and to my dear mother Prof Salwa Younis.

DECLARATION

I declare that the work presented in this thesis is all my own work, has not previously been accepted for a higher degree and I have consulted all references cited.

Signed:

Date:

I declare that the conditions of the relevant Ordinance and Regulations have been fulfilled.

Signed:

Date:

ABSTRACT

Aim: To compare the 0.018-inch and 0.022-inch conventional pre-adjusted orthodontic bracket slot systems in terms of the effectiveness of levelling and alignment stage of orthodontic treatment.

Design: Prospective, multi-centre randomised clinical trial.

Setting: This was undertaken in the secondary care hospital environment in Tayside NHS in the United Kingdom.

Subjects and methods: One hundred and five orthodontic patients were randomly allocated to treatment with either the 0.018-inch bracket slot (n= 52) and 0.022-inch bracket slot (n=53) Victory conventional pre-adjusted bracket systems (3M Unitek). The patients were treated in three centres in secondary care hospitals Tayside NHS, United Kingdom. The levelling and alignment stage of treatment was assessed from the start of treatment until the ligation of the working archwire for each bracket slot system (0.016x0.022 stainless steel for the 0.018-inch group and 0.019x0.025 stainless steel for the 0.022-inch group). Periapical radiographs were taken before the start of treatment and after 9 months in treatment for the maxillary central incisors to assess orthodontically-induced inflammatory root resorption (OIIRR). The “Smiles better” questionnaire was completed by the participants at 6 months from the start of treatment.

Primary outcome measures: The duration of the levelling and alignment stage of orthodontic treatment in the maxillary and mandibular arches.

Secondary outcome measures: The number of scheduled appointments for the levelling and alignment stage of orthodontic treatment in the maxillary and mandibular arches, OIIRR at 9 months from the start of treatment using periapical radiographs and patient perception of wearing orthodontic appliances.

Results: The data from 92 patients (mean age 19.55 years) were analysed after the completion of their levelling and alignment stage of orthodontic treatment. An ANOVA test showed no statistically significant difference in the duration or number of scheduled appointments for the levelling and alignment stage in the maxillary and mandibular arches between the two appliance groups. Non-parametric statistical test showed no statistically significant difference in the severity of OIIRR and patient perception of wearing orthodontic appliances between the two study groups except for the soreness of teeth, where more patients in the 0.022-inch group experienced significant teeth soreness than the 0.018-inch group.

Multiple regression analysis determined that 49.6% of the variance in the duration of levelling and alignment duration for the maxillary arch can be explained by five factors: alignment of ectopic tooth, scheduled appointment intervals, gender, bracket slot size system and the number of failed scheduled visits. For the mandibular arch, 50.8% of the variance in the levelling and duration of alignment

can be explained by three factors: scheduled appointment intervals, arch irregularity and the number of debonded brackets.

Conclusions: There is no difference in the effectiveness of the levelling and alignment stage of orthodontic treatment between the 0.018-inch or 0.022-inch conventional bracket slot systems except for the soreness of teeth.

.LIST OF ABBREVIATIONS

3D	Three-Dimensional
ABO (OGS)	American board of orthodontics objective grading system
AC	Aesthetic component
AL	Arch Length
ANOVA	Analysis of Variance
CBCT	Cone beam computed tomography
CLB	Conventional-Ligating brackets
CRF	Case Recorded Form
CONSORT	Consolidated Standards of Reporting Trials
DHC	Dental health component
DI	Discrepancy index
DT	Duration of treatment
FA	Fixed Appliance
ICC	Intraclass Correlation Coefficient
IOTN	Index of orthodontic treatment need
ITA	Index of teeth alignment
LII	Little's Irregularity Index
NiTi	Nickel Titanium
OPT	Orthopantomogram
OIIRR	Orthodontically induced inflammatory root resorption
PAR	Peer assessment rating
RCT	Randomized Clinical Trial
SAI	Scheduled appointment intervals

SEM	Scanning electron microscopy
SLB	Self-ligation brackets
SS	Stainless steel
V	Victory ©

Chapter 1 Introduction

This study is a part of a multi-centre randomised clinical trial designed to compare the effectiveness of orthodontic treatment between the 0.018-inch and 0.022-inch bracket slot systems. In the current presented study comparison between the two systems was done for the effectiveness of the levelling and alignment stage of orthodontic treatment.

The 0.018-inch and 0.022-inch bracket slot systems are widely used by clinicians worldwide with some orthodontist claiming clinical advantages and superiority of one system over the other. However, the scientific evidence supporting this topic is scarce and weak. This leaves the clinician's choice of bracket slot system to mainly clinical preference. There has long been a debate about the reason for the existence of two bracket slot dimension systems; with several orthodontists calling for standardization.

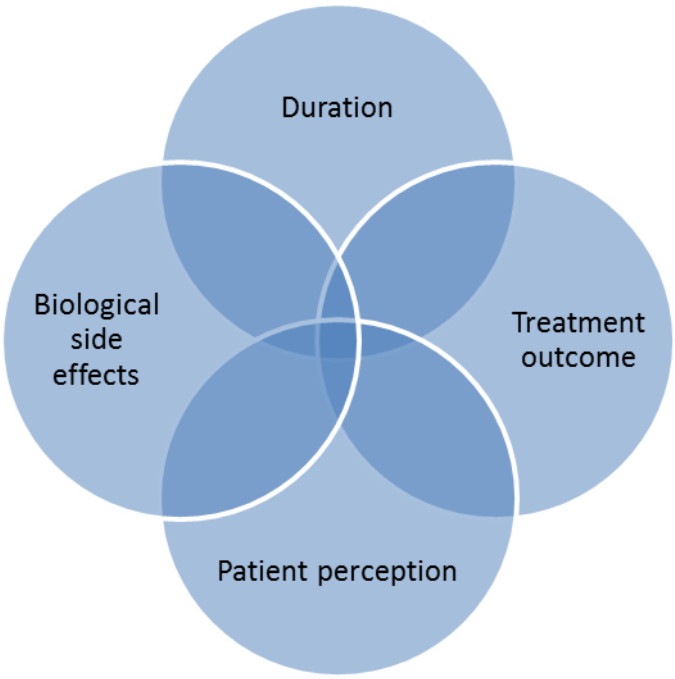

Figure 1 Domains of effective treatment.

The levelling and alignment stage represents one of the main three stages of orthodontic treatment. The effectiveness of this stage involves four domains as shown in Figure 1. The comparison of the effectiveness of levelling and alignment stage between the 0.018-inch and 0.022-inch bracket slot systems using a randomised clinical trial design can provide sufficient evidence to the clinician to make a sound decision about the choice of the most effective system.

In this thesis I will only assess the levelling and alignment stage of treatment where comparison between the 0.018 and 0.022-inch bracket slot systems will be investigated for the following factors:

- Duration and number of visits of the levelling and alignment stage.
- Orthodontically induced inflammatory root resorption (OIIRR) after 9 months from start of treatment.
- Patient perception of wearing fixed orthodontic appliance.

In addition, two validity studies (chapter 5) were undertaken in conjunction with the main randomised clinical trial:

- Film and digital periapical radiographs for the measurement of simulated orthodontically induced apical root shortening.
- Validity of bracket slot size: A scanning electron microscopy study.

Chapter 2 Literature Review

This literature review will give the reader a background on a number of topics related to effectiveness of levelling and alignment stage of fixed orthodontic treatment and the factors that can influence it. Therefore this chapter will focus specifically on these topics which include the following:

- Factors that influence the duration of orthodontic treatment with more focus on the levelling and alignment stage

- Orthodontically induced inflammatory root resorption (OIIRR) as a biological side effect of orthodontic treatment.

- Patient perception of wearing fixed orthodontic appliances

- Background about orthodontic brackets and archwires

- Background about the Randomised clinical trial design

2.1. Effective orthodontic levelling and alignment

Effective orthodontic levelling and alignment stage involves four domains that will be discussed in this chapter:

- Duration of treatment
- OIIRR
- Patient perception of wearing fixed appliances
- Levelling and alignment stage outcome

2.1.1. Duration of treatment

Patients, parents, clinical staff and medical management all agree that no one wants a patient to wear orthodontic appliances any longer than necessary. Shorter treatment durations are preferable because of the patient's shorter exposure to stressful biological and psychological side effects as well as lower treatment cost (Segal et al., 2004, Jarvinen and Widstrom, 2002). Success in orthodontic practice may be influenced by an accurate prediction of treatment duration (Shia, 1986). Some orthodontists believe that timely completion of treatment helps more accurately predict financial costs in addition to improving patient satisfaction (Skidmore et al., 2006).

The average length of orthodontic treatment had been investigated in several studies and found to range from as short as a several months to as long as several years (Mavreas and Athanasiou, 2008). This wide range is probably due to the numerous factors that affect the duration of orthodontic treatment and differences

in study design and inclusion criteria between investigations (Mavreas and Athanasiou, 2008).

Mavreas and Athanasiou (2008) published a systematic review to investigate the literature for studies referring primarily to the duration of orthodontic treatment and the factors influencing it. The review included 41 studies that complied with their search criteria that were limited to clinical studies published during the period from 1990 to the beginning of 2005. The authors suggested that accurately designed prospective studies were rare.

In this section the factors that may affect the general full duration of fixed orthodontic treatment will be categorised into patient related and treatment related factors:

Patient related factors	Treatment related factors
- Socio-demographic patient factors	- Extraction vs. non-extraction
- Malocclusion characteristics	- Scheduled appointment intervals
- Patient co-operation	- Type of orthodontic appliance
	- Operator variation & health management

The specific factors related to the duration of levelling and alignment stage of treatment will be discussed in more details in section 2.1.1.3.

2.1.1.1. Patient related factors

2.1.1.1.1. Socio-demographic patient factors

2.1.1.1.1.1. Age

Chronological age

There has always been a general assumption that there is a difference in the rate of tooth movement between adult and young patients. To an extent this may have been explained histologically by identified periodontal structural differences between adults and adolescents, where the latter is in a "state of proliferation" (Reitan, 1954). For many orthodontists this finding may suggest that adult orthodontic treatment is more challenging and would take longer to complete when compared to adolescents and younger patients. However, mature patients are frequently more co-operative and show greater compliance throughout treatment (Popowich et al., 2005). This controversy has led several orthodontists to explore the impact of age on the duration of orthodontic treatment.

Most studies that have investigated patient age as a factor affecting the duration of treatment have assessed the chronological age of the patient at the start of treatment. Three studies (Table 1) have been designed with the primary aim to investigate the effect of the age of the patient at the start of treatment on the duration of orthodontic treatment (Frankmann et al., 1998, Robb et al., 1998, Dyer et al., 1991).

Dyer et al. (1991)and Robb et al. (1998) compared treatment duration between two age groups (adolescents and adults). The mean ages for the groups investigated in both studies were relatively similar. In Dyer et al. (1991) the mean age for the

adolescent group was 12.5 years and 27.6 years for the adult group, while in the study by Robb et al. (1998) the mean age for adolescents was 12.9 years and 31.3 years for the adults. Dyer et al. (1991) included only female patients with Class II malocclusion while Robb et al. (1998) only investigated cases with four premolar extractions that were predominately (94%) Class I. Both studies reported that there was no difference in the duration of treatment between adults and adolescents. In spite of the difference in gender and malocclusion type in the samples between the two studies, they both reported relatively comparable mean duration of treatment (2.5 years).

Moreover, Frankmann et al. (1998) published an abstract reporting a study that was designed primarily to investigate the influence of the age of the patient and type of malocclusion on treatment duration. A relatively larger sample size (705) of Class I and II malocclusions was recruited and divided into 3 age groups (children <12 years, adolescents <12 to <18 years, and adults >18 years). The authors reported a statistically significant reduction in the duration of treatment with increasing age through the 3 groups from children (40.48 months) > adolescents (31.20 months) > adults (25.74 months). However, the results should be considered with caution due to the limited information included in the published abstract about the study design and treatment pattern for the 3 groups.

Table 1: Summary of studies investigating influence of patient age on DT

Study	**Dyer et al 1991**	**Robb et al 1998**	**Frankmann et al 1998**
Study design	**Retrospective**	**Retrospective**	**Retrospective**
Publication	Full article	Full article	Abstract
Sample	56	72	705
Mean age (years)	Adolescents 12.5 Adults 27.6	Adolescent 12.9 Adults 31.3	Children <12 Adolescents <12 to<18 Adults >18
Gender	Females	Males and females	Males and females
Type of malocclusion	Class II	Class I (94%) Class II (6%)	Class I (94%) Class II (6%)
Mean DT (months)	Adolescents 29.52 Adults 30.52	Adolescents 29.4 Adults 30.6	Children 40.48 Adolescent 31.20 Adults 25.74
Outcome	No statistically significant difference	No statistically significant difference	Statistically significant decrease in DT with increase in age.

Vig et al. (1990) and Popowich et al. (2005) investigated the association between different variables and the duration of orthodontic treatment in different private practices. Using the age of the patient at the start of treatment as one of the patient variables, both studies reported that duration of treatment decreased as the age of the patient increased. Although, the study by Popowich et al. (2005) was designed with strict selection criteria, the age range (10-15.99 years) was too narrow to be

fully representative of the effect of age on treatment time. Vig et al. (1990) involved patients with a wider age range of 7-53 years; however the selection criteria were not clear. Thus selection bias may have influenced the results. These results agree with Firestone et al. (1999) who, using young age as a variable in regression analysis, found that younger age was a predictor of increased duration of treatment.

Moreover, Jarvinen et al. (2004) in a retrospective study reported a statistically significant increase in the mean duration of treatment in the younger age group (7-9 years) when compared to their older age group (12-13 years). However, it is important to note that the mean number of appliances used for the younger age group was double that used for the older age group. This may suggest that the treatment duration in the younger age group included removable and fixed appliance phases.

In contrast, Turbill et al. (2001) reported that patients who started treatment under 11years old had statistically significant shorter mean treatment duration (8 months) than patients who were aged 11-16 years (14.7 months). The authors conducted a retrospective study using a large sample size (1506 cases) to investigate the factors that may influence the duration of treatment in general dental practice in England and Wales. The authors suggested that the difference in the mean duration of treatment between the two groups may have been due to the simple nature of interceptive treatment needed for the younger age group when compared to the comprehensive type of treatment offered to the older age group. It is interesting to note that there was no statistically significant difference reported between the 11-

16 years group and the over 16 years group. This may confirm the suggestion from the authors that the difference in the duration of treatment in relation to age was mainly due to the pattern of treatment offered to the patients according to their stage of dental development. It is important to note that patients in the over 16 years group represented a minority in the sample (6.2%); this may have been a significant contributor to bias.

Dental development

von Bremen and Pancherz (2002) were unique in considering the stages of dental development rather than the chronological age of patients to study the effect of early and late treatment for Class II malocclusion on the duration of orthodontic treatment. It is important to note that their patient selection criteria included fixed and functional appliances. The mean treatment duration was 37 months and the duration decreased with dental development: patients in early mixed dentition were treated for an average of 57 months, whilst those in the late mixed dentition required treatment for 33 months, and required treatment in the permanent dentition for 21 months. The authors explained the findings of the relative longer duration of early treatment as a result of the eruption of all permanent teeth being required (excluding third molars) before treatment could be considered to be complete. This unique study provides more information about the most appropriate dental development stage for starting treatment in childhood, but it is not a full presentation of the effect of age on the duration of orthodontic treatment. Moreover, the duration of treatment for some of the patients included in the sample is likely to have comprised both functional appliances and fixed appliances, which may explain the extended duration of treatment.

In summary, it has been reported that there are periodontal structural differences between adults and adolescents (Reitan, 1954), which was thought to have a clinical impact on the duration of treatment. According to the relatively weak evidence available in the literature, this seems not to have been proven at the clinical level. However, some studies have suggested that young patients may require longer orthodontic treatment. This might have been influenced more by the pattern and phases of treatment rather than the rate of tooth movement. The available evidence suggests that patient age at the start of treatment does not seem to be an important factor that influences the duration of orthodontic treatment. This agrees with the conclusion from the systematic review by Mavreas and Athanasiou (2008). However, more adequately designed prospective clinical trials in this area are needed to provide stronger evidence.

2.1.1.1.1.2. Gender:

No study had been conducted solely to investigate the effect of gender on the duration of orthodontic treatment. However, gender has been considered as one of many variables that may affect the duration of orthodontic treatment in several studies, but with no significant difference being found in the majority of these investigations.

Two retrospective studies have reported that gender significantly affects the duration of orthodontic treatment (Table 2); both studies suggested that males take longer to finish treatment than females. Al Yami et al. (1998) using a large sample size of 1870 patients to evaluate the quality of orthodontic treatment in a university clinic found that males took a mean of 0.25 years (4 months) longer to finish

orthodontic treatment than females. Skidmore et al. (2006) used a smaller (but still considerable) sample size of 366 patients to identity factors influencing treatment time in orthodontic patients and found that 38% of the variation in orthodontic treatment time depended on 9 variables of which gender was one. The authors reported that treatment time for males was statistically significantly longer than females with average of 1.2 months. It is important to acknowledge that the sample studied in this study involved an age range between 10.4 and 19.9 years and although this represents a sizeable proportion of orthodontic patients, the results cannot be generalised for all orthodontic patients.

Nonetheless, both studies agreed that males take longer to complete treatment; Al Yami et al. (1998) reported almost a three times greater difference for mean treatment duration between males and females when compared to that reported by Skidmore et al. (2006) (4 and 1.2 months respectively). This difference may be due to variation in inclusion criteria and clinical seating. The later study had strict inclusion criteria aiming to identify the factors that might influence orthodontic treatment duration in private practice, while the former study had a larger sample size in a teaching hospital but with no clearly defined inclusion criteria.

Table 2 Studies investigating gender influence on the duration of treatment

	Skidmore et al 2006	**Al Yami et al 1998**
Design	Retrospective	Retrospective
Primary objective	Identify factors influencing treatment time in orthodontic private practice	Evaluate factors affecting treatment outcome in teaching hospital
Sample size	336 (220 females and 146 males)	1870 (1071 females and 799 males)
Operator	Single operator	Multiple operators
Age group in years	10-20 years	13.4 +/- 4.1
Average treatment duration	Total 23.5 +/-4.7 months Male 24.3 months Female 23.1 months	Total 3.0 +/-1.4 years Male 3.2 +/-1.5 years Female 2.9 +/-1.3 years
Gender influence on duration of treatment	Statistical significant difference. Males take mean 1.2 months longer to finish treatment.	Statistical significant difference. Males take mean 4 months longer to finish treatment.

It is interesting to note that these two studies did not agree with six other retrospective studies which were aimed primarily (Fink and Smith, 1992, Beckwith et al., 1999, Popowich et al., 2005) or secondarily (Vig et al., 1990, Robb et al., 1998, Obrien et al., 1995) to evaluate the factors that might influence the duration of orthodontic treatment. If aggregated, there is an overall sample size of 1400

participants where no effect of gender has been found as a significant influence on orthodontic treatment duration.

The only systematic review that has investigated the factors influencing the duration of orthodontic treatment did not report gender as one of the influencing factors (Mavreas and Athanasiou, 2008). It is not clear from the clinical trials whether the results reported were due to differences in gender or differences in attitude and compliance towards orthodontic treatment. Several studies have compared the co-operation of orthodontic patients as an influencing factor on the duration of orthodontic treatment; this will be discussed later in another section in this (2.1.2.1.3. Patient co-operation).

2.1.1.1.1.3. Ethnicity

No studies investigating the factors affecting orthodontic treatment duration have reported the influence of race or ethnicity on the duration of treatment except Parrish et al. (2011) who reported using multiple variable regression analysis that difference in race significantly influenced the duration of treatment. The sample studied was 732 subjects which included 84 % white, 8% African American, 2% Asian and 4% others. Their results may not be reliable considering that the majority of the sample was of White origin. Despite this single study, there is no substantial evidence on the influence of ethnicity on the duration of orthodontic treatment.

2.1.1.1.1.4. Socioeconomic status

Socioeconomic status of the patient influences general health, dental disease, and dental health related behaviour (Eddie and Davies, 1985). It can be defined in several ways, and different methods have been used and published to either

measure or classify this variable. Turbill et al. (2003) reported that occupation-based social classification and the Carstairs Index may be more sensitive to orthodontic applications than other indicators of socioeconomic status. However, no study has used these two indices to study the effect of the socioeconomic status of the patients on the duration of orthodontic treatment. Fisher et al. (2010) designed a study to identify the pre-treatment characteristics influencing the duration of treatment using data for 400 patients. The authors investigated the socio-demographic status in the form of data related to parental occupation, marital status and insurance status. These socio-demographic variables were found to have no significant influence on the duration of treatment.

Another retrospective study with a larger sample size of 1527 patients evaluated the effect of socioeconomic status on the duration of treatment (Turbill et al., 2001). In this study the social class data for each patient was obtained from the patient's home postcode using the SASPAC software. The authors reported that there was no significant effect for the social class of the patient on treatment duration. However, the same authors reported in a different study (Turbill et al., 2003) that lower social class may be a risk factor for discontinuation of orthodontic treatment, but was not a predictor.

According to the scarce available evidence there seems to be no influence of socioeconomic status on the duration of orthodontic treatment.

2.1.1.1.1.5. Individual variation

It is important to mention that individual factors related to variation in individual metabolic respond may be a hidden influence on the duration of treatment (Evans

et al 1998; Cobb et al 1998). This can be explained by the wide range of the mean of treatment duration reported between studies (15 -36 months). In addition, to the large standard deviation reported for the duration of treatment in most of the studies (Table 1 & 2).

2.1.1.1.2. Malocclusion characteristics

Malocclusion characteristics in association with the duration of treatment have been studied in the literature with several different approaches. This has mainly depended on the method of malocclusion description in different studies. Some have used classifications for the type of malocclusion e.g. Angle classification (Amditis and Smith, 2000, Popowich et al., 2005, Robb et al., 1998, Skidmore et al., 2006, Vig et al., 1990). Others have used indices to quantify the severity of malocclusion such as the PAR index; (Turbill et al., 2001, O'Brien et al., 1995) and Salzman index (Fink and Smith, 1992) or the need for treatment such as the Index of orthodontic treatment need (IOTN) (Turbill et al., 2001) or complexity of cases as Discrepancy index (DI) (Vu et al., 2008). Others have used a customised technique to measure, rank or define different aspects of malocclusion including overjet, overbite, crowding and spacing (Skidmore et al., 2006, Beckwith et al., 1999). Moreover, several studies have used lateral cephalometric radiographic measures to quantify malocclusion and study its correlation with duration of treatment (Popowich et al., 2005, Kim et al., 2000, Fink and Smith, 1992).

2.1.1.1.2.1. Malocclusion classification:

Several studies have used Angle's classification and molar relationships to study the effect of type of malocclusion on the duration of treatment. In this section, Angle and molar classifications are considered together as they are broadly similar.

Popowich et al. (2005) reported in a retrospective study with strict inclusion criteria that Class I non extraction cases finished treatment 5 months (4 appointments) earlier than Class II extraction and non-extraction cases. However, in this study Class II division 2 cases were not included. These results agree with two investigations published as abstracts in 1994 in the Journal of Dental Research using the same sample from the University of Pittsburgh (Colela C, 1994, Vig et al., 1994). Both published abstracts reported that Class II malocclusions required longer treatment duration when compared to Class I; 5 and 4 months respectively. Moreover, Vig et al. (1990) in a retrospective study and using multiple regression analysis to test nine variables in relation to treatment duration suggested that 4.5 months would be added in Class II div 2 cases.

In addition, Vu et al. (2008) designed a retrospective study with a sample of 455 cases to identify factors that affect orthodontic treatment time in a graduate orthodontic clinic. They reported that class II malocclusion was significantly associated with an increase in treatment duration when compared with Class I malocclusion; average treatment time that was longer by 7.4 months. A well-designed retrospective study was undertaken by Skidmore et al (2006) using 366 consecutive patients treated by one orthodontist to identify factors that influence orthodontic treatment duration. In this study, they reported that the mean treatment duration for class I and class II were 21.9 months and 24.9 months respectively.

Although a 3 months difference in mean treatment duration between the two types of malocclusion reported in this study was less than that reported by the previous studies, it was still statistically significant. This agrees with the results from (Haralabakis N B, 2004) who reported using a multiple regression analysis that Angle Class II malocclusion was one of the variables related to significant increase in treatment duration.

The noted difference reported in the previously mentioned studies (summarised in Table 3) in the difference in mean treatment duration between Class I and II malocclusions might be due to the different clinic seating in each study (private practice and teaching hospital).

It is interesting to note that even different levels of Class II malocclusion (molar relationship) had been found to affect treatment duration. A unique study by Janson et al. (2009) et al (2009) evaluated the treatment success rate of a non-extraction approach to class II malocclusions according to initial anteroposterior discrepancy reported that treatment time was significantly greater in patients with complete class II malocclusion (31.20 months) when compared with patients with half class II malocclusion (25.06 months).

Several studies suggested that correcting the anteroposterior relationship of the posterior segment explains the extended duration of treatment in Class II malocclusion (Robb et al., 1998, Turbill et al., 2001). In agreement, Vu et al. (2008) mentioned that any deviation from a class I molar relationship lengthens treatment duration. However, this was not always true for patients with Class III malocclusions. Only one study had reported that Class III malocclusions take

statistically significantly longer duration to treat in comparison to Class I malocclusion (Vig et al., 1994). In contrast, several studies found no statistically significant difference in the mean treatment time between class I and class III malocclusions (Vig et al., 1990, Skidmore et al., 2006, Vu et al., 2008). However, in most of these studies the sample sizes for Class III cases were not large enough in comparison to the Class I and Class II cases. For example, Class III sample in the study by Skidmore et al. (2006) represented only 1.4% of the total sample size.

Vig et al. (1990) highlighted the interaction between types of malocclusion and other variables and their effect on orthodontic treatment duration. They mentioned that good patient co-operation reduced treatment times for patients with class II malocclusion but not for class I malocclusion. Moreover, Amditis and Smith (2000) found that Class I cases finished treatment 2.5 months earlier than Class II cases if treated with 0.018 inch slot brackets. This difference in treatment duration was found to be statistically significant and is of clinical importance although it should be noted that there are a number of confounding variables that were not controlled in this study, all of which could have influenced this result.

Most studies that have explored the effect of type of malocclusion on the duration of treatment are retrospective in design; whilst others are not peer-reviewed journal articles or only published as abstracts (Table 3). Popowich et al. (2005) was the only published investigation designed with a primary aim to investigate the treatment outcome between Class I and II malocclusions. They concluded that the evidence available regarding the influence of the type of malocclusion on the duration of treatment is not robust. However, all the studies discussed above have agreed that patients with Class II malocclusion take longer to treat than Class I

malocclusion; whilst there is minimal evidence to support the effect of class III malocclusion on treatment duration.

2.1.1.1.2.2. Severity of malocclusion:

Several indices were developed to quantify the severity of malocclusion in different ways to allow for relatively objective assessment of the severity or complexity of malocclusion. Many studies have relied on these indices to quantify the severity of malocclusions to facilitate statistical analysis to demonstrate the impact of the severity of malocclusion on the effectiveness of orthodontic treatment (Fink and Smith, 1992, Turbill et al., 2001, Obrien et al., 1995, Teh et al., 2000).

Table 3: Studies comparing duration of treatment in Class I and II malocclusions.

	Study design	**Sample**	**Primary aim**	**Difference in DT**	**Phases of treatment**
Popowich et al (2005)	retrospective	237	Factors that predict duration of treatment in Class II	Class II is 5 months longer. Statistically significant difference	Single phase
Vu et al (2008)	retrospective	455	Factors affecting duration of treatment	Class II is longer 7.4 months. Statistically significant difference	Single phase
Vig et al (1994)	retrospective (abstract)	311	Factors affecting duration of treatment in Class II	Class II is 5 months longer. Statistically significant difference	Not mentioned
Skidmore, et al (2006)	retrospective	366	Factors affecting duration of treatment	Class II is 3 months longer. Statistically significant diff	Single phase

Salzmann index

Fink and Smith (1992) used the Salzmann index (Salzmann, 1967) to determine the severity of malocclusion for pre-treatment models in a study designed to identify factors that influence the duration of orthodontic treatment. The authors reported through a multiple regression analysis that the pre-treatment Salzmann index correlated with treatment duration. This is the only study that has evaluated the factors influencing duration of orthodontic treatment using the Salzmann index, which was developed in 1967 as a measure of orthodontic treatment need. The authors suggested that the Salzmann index was not sensitive enough to detect detailed finishing of the cases. It has been reported later that this type of index lacks validity (Grewe and Hagan, 1972) and is of low reliability (Albino et al., 1978) which makes its use in research work questionable.

Peer assessment rating PAR index

The PAR index is an occlusal index designed and validated as a tool to measure how much a case deviates from normal alignment and occlusion (Deguzman et al., 1995, Richmond et al., 1992a). This index was designed as an orthodontic treatment outcome measure assessing the difference in scores between pre-treatment and post-treatment study models (Richmond et al., 1992b). In a recent review, it has been recently reported that the PAR index is the most widely used index in orthodontic longitudinal studies (Bellot-Arcis et al., 2012).

Several retrospective studies have investigated the effect of severity of the pre-treatment malocclusion on the duration of orthodontic treatment using the PAR

index. Obrien et al. (1995) undertook a study which included only Class II division 1 malocclusion cases aged 11-14 years, Turbill et al. (2001) included all types of Angle's classification cases of malocclusion with no age restrictions from National Health Service practices in England and Wales. Turbill et al. (2001) used the British PAR weightings with a large sample size (1527), about six times the sample size included byObrien et al. (1995) who used the American PAR weighting. However, both studies agreed that the increased pre-treatment PAR score had an association with longer treatment duration. Another study was undertaken in the National Health Service but with a smaller sample size (128) in Scotland reported the same positive influence of pre-treatment PAR score on the duration of treatment (Teh et al., 2000). This agrees with three more studies undertaken in Europe using British weighted PAR in university teaching hospitals (Firestone et al., 1999, Taylor et al., 1996) and private practice (Haralabakis N B, 2004) .

Moreover, Robb et al. (1998) designed a study using patients' records from private practices in Chicago, USA mainly to use the PAR index as a method to compare the effectiveness of treatment in adults and adolescents. The authors reported that the pre-treatment PAR score explained 14% of the variability in treatment duration. However, no statistical support for this finding was shown. Several multiple regression analyses were conducted in this study, which were unfortunately not clearly reported.

Cassinelli et al. (2003) conducted an interesting study to investigate the factors associated with the orthodontist's assessment of difficulty. One of the methods used to assess difficulty and severity of malocclusion was the scoring the pre-

treatment models using PAR index (British weightings). The authors divided the sample into easy and difficult cases. Easy cases had a relatively low mean PAR score of 19.6 (SD 8.6) and a mean duration of treatment of 24.8 (17.4) months while difficult cases had a higher mean PAR score of 27.5 (SD 9.3) and longer duration of treatment of 33.8 (12.8) months. The differences between the two groups were found to be statistically significant. It is worth mentioning that the standard deviations reported for the PAR scores and duration of treatment were relatively wide which may had affected the statistical analysis. It can be argued that the PAR score is not designed to assess difficulty of treatment; however, the results from this study still suggest the positive correlation between the increased pre-treatment PAR score and increased duration of treatment.

In contrast, Popowich et al. (2006) used the American PAR weighting to investigate the effect of malocclusion on the duration of treatment as a secondary outcome. They found that pre-treatment PAR was not associated with treatment duration. A total of 237 patient records were collected from three orthodontic private practices located in Alberta, Canada chosen according there single phase philosophy of treating Class II malocclusion. The authors applied clear and strict inclusion criteria, although the patients' records selected were not consecutive, which may have led to selection bias. Moreover, the statistics and data used to conclude that there was no correlation between the severity of malocclusion and duration of treatment were not demonstrated in the published article.

Table 4 Studies assessing the correlation between the severity of malocclusion using the PAR index and duration of treatment.

Study	Correlation between PAR and duration of treatment	R^2	Location	Sample size
Teh et al 2000	Yes	The whole model represent 29%	Practice (Scotland) UK	128
O'Brien et al 1995	Yes	R^2= 49%	Teaching hospital USA	250
Turbill et al 2001	Yes Specifically high scores for buccal occlusion	Small effect on the duration of treatment	NHS practice (England and Wales)	1056
Firestone et al 1999	Yes	38%	Teaching hospital Switzerland	232
Robb et al 1998	Yes	14%	Private practices Chicago, USA.	72
Taylor et al 1994	Yes	77%	Teaching hospital (Glasgow) UK	81
Cassinelli et al 2003	Yes	not mentioned	Practice (Ohio) USA	100
Popowich et al 2006	No	No	Practice (Alberta) Canada	237
Haralabakis & Tsiliagkou 2004	Yes	46.33%	Private practice Greece	360

The PAR index has been used widely in the field of orthodontics in the last two decades. Table 4 demonstrates a list of studies that investigated the effect of the severity of malocclusion using the PAR index on the duration of treatment. Some of these studies used the American weighting (O'Brien et al., 1995, Robb et al., 1998, Popowich et al., 2006) whilst others used the British weighting (Turbill et al., 2001, Cassinelli et al., 2003). All studies reported in Table 4 agree that pre-treatment PAR score is correlated with treatment duration except for one which did not (Popowich et al., 2006). It is important to note that all the studies investigating this subject were retrospective designs; however the agreement between these studies is clinically useful.

Discrepancy index (DI)

The DI has become an accepted and reliable index for quantifying the complexity and severity of cases based on pre-treatment orthodontic record analysis and measurements from dental casts and radiographs (Cangialosi et al., 2004).

A unique recent study was conducted with a primary aim to investigate the relationship between the ABO discrepancy index (DI) and treatment duration (Parrish et al., 2011). Seven hundred and thirty two patient records were collected for this study from a university teaching hospital in Indianapolis, USA. It was reported that there was a significant association between the ABO DI index and the duration of treatment where the total DI score explained 9% of the variation in treatment duration. This is in agreement with Vu et al. (2008) who found that DI was correlated with increased treatment duration in a study undertaken in similar teaching hospital seating in Indiana University, USA.

Parrish et al. (2011) suggested that for every unit increase in the DI there is an estimated 11 days increase in the duration of treatment and that different components of the DI can differentially increase the duration of treatment. Paradoxically, it is interesting to note that Teh et al. (2000) reported using a regression model that for every single point increase in the pre-treatment PAR score the treatment duration would increase by 0.05 months (1.5 days).

2.1.1.1.2.3. Impacted teeth (canine)

Maxillary canines are second to the 3rd molars in their prevalence of impaction with a reported incidence of 0.8% to 2.8% (Ericson and Kurol, 1986). However, this prevalence might be higher among patients seeking treatment in orthodontic clinics (Ferguson, 1990). Most studies that have investigated the impact of alignment of an impacted tooth on the duration of orthodontic treatment have mainly included maxillary canines in their samples (Table 5).

Several studies have reported that the duration of orthodontic treatment involving the alignment of an impacted maxillary canine ranges from 18 to 30 months (Stewart et al., 2001, Fleming et al., 2009b). This seems to be within the wide range of duration of treatment reported in many studies for orthodontic cases (Table 5). Most of the studies that investigated the duration of treatment for malocclusions involving impacted canines agreed that the severity of the impaction (location) can influence the duration of treatment (Fleming et al., 2009b, Becker and Chaushu, 2003, Zuccati et al., 2006).

Orthodontic treatment for patients with an impacted canine is perceived to be more difficult and time-consuming than routine orthodontic cases (Stewart et al., 2001).

However, only one study exists that has investigated the difference in the duration of treatment between routine orthodontic treatment and treatment of malocclusion involving alignment of impacted maxillary canines (Stewart et al., 2001). The sample included 47 patients with impacted maxillary canines (29 unilateral and 18 bilateral) and a matched group with no impacted teeth (47 patients). The authors reported a statistically significant increase in the duration of treatment in the impacted maxillary canine group when compared to the control group (28.3+/-8.2 and 22.4+/-6.9 months respectively). Moreover, there was a statistically significant increase in the duration of treatment in the bilaterally impacted maxillary canine subgroup compared to the unilateral subgroup (32.3+/-8.5 and 25.8+/-7.0 months respectively). However, the authors mentioned that the difference between the subgroups should be interpreted with caution as there might be a risk of sample bias due to the small number recruited and difference in the severity of impaction between the two subgroups.

In summary there is a general perception among clinicians that orthodontic treatment involving alignment of impacted canines increases the duration of treatment. This is supported by only a single retrospective study which included a control group for comparison with the impacted canine group (Stewart et al., 2001). However,Vu et al. (2008) study failed to detect a significant increase in treatment duration among patients with impacted maxillary canines when compared to a large sample of orthodontic patients. This may be explained by the small sample recruited with impacted canines and the wide variety of patients included in the study, which included orthognathic patients.

In addition, there seems to be an agreement among most studies that the severity of impacted canine is correlated with an increase in the duration of treatment. However, comparisons between studies can be difficult due to the use of different angles and measurements to quantify the severity of impaction (Fleming et al., 2009b, Becker and Chaushu, 2003, Zuccati et al., 2006).

Table 5 Studies that investigated the influence of orthodontically aligning impacted maxillary canines on treatment duration

Study	Sample	Duration of treatment	Significant difference between control
Iramaneerat et al 1998	50	28.8 months	No control
Becker and Chaushu 2001	46	21.5 months	No control
Stewart et al 2001	47	Impacted canine 28.3+/-8.2 months (unilateral 25.8+/-7, bilateral 32.3+/-8.5)	Yes Control 22.4+/-6.9 months
Zuccati et al 2006	87	16 months traction period	No control
Schubert et al 2009	57	18.1 months	No control
Vu et al 2008	455 (24 impacted canines)	31.21+/-7.9 months	Yes Control 28.93+/-11.5 months

2.1.1.1.2.4. Skeletal discrepancy

Most of the indices discussed earlier in this section are primarily concerned with occlusal traits. This does not represent the whole discrepancy requiring orthodontic

treatment, and in particular skeletal discrepancies. Skeletal measures of morphological variation are generally derived from cephalometric analysis (Kim et al., 2000). Several investigators have incorporated cephalometric variables in addition to different occlusal indices as representative of the severity of malocclusion and its effect on treatment duration (Table 6).

Table 6 Studies which investigated the effect of skeletal antroposterior and vertical discrepancy on the duration of orthodontic treatment.

Study	Type of malocclusion	ANB	Vertical face height
Kim et al 2000	Class II	Yes	Yes
Fink and Smith (1992)	All types	Yes	Yes
Fisher et al., 2010	All types	No	Yes
Popowich et al 2005	Class II	Yes	Yes

Kim et al. (2000) undertook a study to assess the predictive value of 41 commonly used cephalometric parameters with regard to treatment outcome in Class II division 1 malocclusion which, among others, included treatment duration. Seventeen out of the 41 cephalometric variables that were investigated were correlated with an increased duration of treatment. The authors reported that 20% of the variance in treatment duration can be explained by these 17 variables. The variables included were skeletal, dental and soft tissue variables. The antero-posterior skeletal variables were ANB angle, facial angle and Wits discrepancy while the vertical skeletal variables were mandibular plane angle, Sn-GoGn angle

and ANS-Gn length. However, the authors mentioned that not all the 17 variables reached the $P < 0.05$ level of significance.

Popowich et al. (2005) in an attempt to identify factors that influence treatment duration in Class II division 1 malocclusion agreed with the findings reported by Kim et al. (2000) regarding the significant correlation between ANB angle and the duration of treatment. However, Popowich et al. (2005) failed to find any significant correlation between the vertical face height and the duration of treatment in Class II division 1 malocclusion.

The results by Fink and Smith (1992) agreed with the findings from Kim et al. (2000) for the antero-posterior dimension reporting an increased duration of treatment for patients with an increased ANB angle. Interestingly, when examining the vertical angles, decreased treatment duration correlated with an increased mandibular plane angle. Moreover, in a recent case-controlled study, the influence of pre-treatment characteristics on the duration of treatment was investigated using two groups representing long and short duration of treatment (Fisher et al., 2010). In agreement with Fink and Smith (1992), but in contrast to Popowich et al. (2005), Fisher et al. (2010) found that decreased lower facial height was correlated with longer duration of treatment.

Cephalometric radiographs contain a potentially infinite number of variables and there is no uniformly accepted analysis throughout the orthodontic speciality (Kim et al., 2000). Five studies have investigated the skeletal cephalometric variables as factors affecting the duration of orthodontic treatment (Table 6). Each study

investigated selected angles and measurements, which makes comparison of their results difficult. It is important to note that Kim et al. (2000) only recruited Class II division 1 patients while Fink and Smith (1992) and Fisher Fisher et al. (2010) included patients with all types of malocclusion; in spite of this the ANB angle was shown to be correlated with treatment duration in the three studies. This may be reflected clinically in the form of an increased overjet; which concurs with its increased weight in the PAR index. This suggests the influence of pre-treatment PAR score on the duration of treatment as outlined in the previous section.

The lower facial height and the mandibular angle representing the vertical facial dimension and its influence on the duration of treatment had also been reported. Fink and Smith (1992) and Fisher et al. (2010) both reported that the mandibular plane angle was correlated with treatment duration.

The clinical impact of the information extracted from lateral cephalometric radiographs had been debated (Han et al., 1991, Devereux et al., 2011), with a tendency towards building clinical diagnosis on clinical findings and 3D imaging (if available). However, the influence of skeletal variables on the duration of treatment has so far only been reported through lateral cephalomteric measurements.

2.1.1.1.2.5. Treatment need (IOTN index)

The index of orthodontic need (IOTN) was developed in 1990s by a team in the United Kingdom (Richmond et al., 1994); however it was based on an original index that was used in the Swedish Public Dental Health System. Although, the

IOTN dental health component (DHC) is not based on strong scientific evidence it is a reliable and popular index for prioritising treatment in several countries in Europe (Bellot-Arcis et al., 2012).

There is no study available in the literature that has aimed to investigate the effect of orthodontic treatment need on the duration of treatment. However, studies designed to investigate the influence of various factors on the duration of treatment have included the influence of IOTN (Cassinelli et al., 2003, Firestone et al., 1999, Taylor et al., 1996, Turbill et al., 2001).

Turbill et al. (2001) undertook a study with a large sample size (1506) to investigate factors that influence the duration of treatment in National Health Service practices. The authors decided to use the IOTN dental health component DHC and aesthetic component AC to investigate the influence of treatment need on the duration of treatment. Only DHC grade 5 “high need” was reported to be among the factors that were found to be correlated with increased treatment duration. It is important to note that the patients were not normally distributed in the different categories for the DHC; where more than 80% of the patients were in the “clear need” and “high need” of treatment while 19% were ranked as of “borderline need” of treatment leaving less than 1% of the patients in the little need treatment. This can be explained by the policy of the National Health Service in England and Wales in prioritising patients according to treatment need. This may have introduced a degree of selection bias that could have influenced the results. However, such a bias can be difficult to overcome when trying to prioritise treatment in a clinical environment.

Taylor et al. (1996) designed a similar study with smaller sample size (81 patients) to investigate the factors that can influence duration of treatment in Scotland. Despite the fact that both studies were undertaken under almost similar National Health Service environment, Taylor and Jones (1995) did not agree with the finding from Turbill et al. (2001) as the former reported that IOTN score was not considered a factor that can significantly influence duration of treatment. It is important to mention that Taylor et al. (1996) reported a high intra-examiner agreement for the IOTN scores while Turbill et al. (2001) et al. (2001) did not report any data about the reliability of the investigators.

Moreover, Firestone et al. (1999) reported that the IOTN (DHC and AC) did not significantly influence the duration of treatment. The study was designed with a primary aim to compare treatment outcomes in two different decades in a teaching hospital in Switzerland using data from 232 patient notes.

Cassinelli et al. (2003) undertook an interesting study which was designed to investigate factors that contributed to the orthodontist assessment of difficulty. The authors reported that the cases that the orthodontists identified as “difficult” had statistically higher IOTN (AC and DHC) grades when compared to the cases that were identified as “easy”. Interestingly, the difficult cases had statistically significantly longer duration of treatment than the easy group; 33.8 and 24.8 months, respectively

Among the multiple studies that have investigated factors that can influence the duration of treatment only very few had considered treatment need in the form of IOTN. Not all of these studies are in agreement, especially as none were designed primarily to assess the correlation between treatment need and treatment duration. Therefore, the evidence regarding IOTN as an influential factor on treatment duration is not conclusive. It may be argued that the severity of malocclusion may dictate complex treatment and longer duration as demonstrated by Cassinelli et al. (2003). However, the treatment of high need malocclusion does not necessitate complex treatment that requires increased duration of treatment. Moreover, it is important to acknowledge that IOTN was designed as an index for treatment need and not complexity of malocclusion.

2.1.1.1.3. Patient co-operation and compliance

Nanda and Kierl (1992) suggested that successful orthodontic treatment may depend on several factors that include patient and parent co-operation during treatment. It has been suggested that several factors may influence the patient's response to treatment that may include age, gender, socioeconomic status, patient personality, parental influence on the child and patient perception of their malocclusion (Graber, 1975, Mehra et al., 1998).

Several studies have investigated the co-operation of orthodontic patients during treatment and the influence of this on the duration of treatment (Table 7). Surprisingly, the systematic review conducted by Mavreas and Athanasiou (2008) did not include the influence of patient co-operation and compliance on the duration of treatment.

In the mid-eighties, Shia (1986) retrospectively investigated the records of 500 patients from his practice to evaluate the factors that might influence the duration of treatment. He reported 18 factors that had an influence on the duration of treatment with the patient cooperation factors on the top of his list. Interestingly, the author never presented any of the data analysis. In the late nineties, Beckwith et al. (1999) investigated the records of 140 patients from five orthodontic practices to identify factors affecting the duration of treatment. Beckwith et al. (1999) reported that patient co-operation was the main factor affecting duration of treatment. Skidmore et al. (2006) conducted a similar study using records for 366 patients from a sole orthodontic practice. They reported that three of the top four factors influencing the duration of treatment were related to patient co-operation. It is interesting to note from these three studies that through the last four decades, the patient co-operation factor has been consistent in playing a significant role in influencing the duration of treatment.

On the contrary,Grewe and Hermanso.Pc (1973) reported no relationship between duration of treatment and subjective assessment of patient cooperation. Cassinelli et al. (2003) conducted a study to identify factors that are related to difficulty of treatment. Patient co-operation was evaluated by assessing missed appointments, broken appliances and oral hygiene. They found that difficult cases require significantly longer treatment in comparison to less difficult cases. Interestingly, the level of patient co-operation between the groups was similar.

Few studies have not included patient co-operation among those factors that could influence duration of treatment. (Haralabakis N B, 2004) excluded patients who had more than two missed appointments and more than 5 broken, loose or lost appliances. This exclusion may have been based on the assumption that the patient co-operation factors would be a confounding factor that could significantly influence the results.

Patient co-operation has been mainly investigated by evaluating several factors including:

- Missing scheduled appointments
- Breakage of appliance or debond
- Adequate oral hygiene through treatment.
- Co-operation in using elastics

Table 7: Studies that investigated the influence of patient co-operation on treatment duration

	Failure to attend appointments	**Debonded brackets**	**Elastics wear compliance**	**Oral hygiene**
Taylor et al 1996	Negative (fixed & removable)	Negative	Not investigated	Negative
Popowich et al 2005	Negative	Positive (second most important factor)	Not investigated	Positive
Beckwith et al 1999	Positive (first most important factor) every missed appointment= 1 month 17.6%	Positive (second most important factor)	Negative	Positive
Shia 1986	Positive	Positive	Not investigated	Not investigated
Fink & Smith 1992	Positive (second most important) every 1 missed appointment = 0.8 months 5.2%	Not investigated	Not investigated	Not investigated
Skidmore et al 2006	Positive (one failed appointment can increase DT by 1.4 months ; 2 or missed appointments increase DT by 3 months)	Positive (every debond = 0.3 months; 3 or more debonds can increase DT by 1.5 months)	Positive (one poor elastic wear increase DT by 1.4 months)	Positive (>3 poor OH increase DT by 2.2 months)
O'Brien et al 1995	Positive (represented greatest effect in regression model)	Positive (represent greatest effect in regression model)	Not investigated	Not investigated

2.1.1.1.3.1. Failure to attend appointments

Seven studies evaluated the influence of failure to attend appointments by patients or the percentage of appointments that have been attended and the influence on the duration of treatment (Table 7). Five studies reported that failed appointments could result in a statistically significant increase in the duration of treatment. Beckwith et al. (1999) ranked the failed appointments as the first major factor influencing the duration of treatment from a regression analysis model (17.6% of the variance in treatment duration), while Fink and Smith (1992) ranked it as the second most important factor (5.2% of the variance in treatment duration). In agreement, Obrien et al. (1995) reported that patients failing to attend appointments was one of two factors that exerted the greatest effect on the duration of treatment.

It has been estimated from regression models undertaken by several studies that a single failed appointment can increase the duration of treatment by 0.8 to 1.4 months (Table 7).

However, two studies reported that failed appointments did not statistically significantly influence the duration of treatment (Taylor et al., 1996, Popowich et al., 2005). It is important to note that the sample size (81patients) used by Taylor et al. (1996) was too small to be used for regression analysis involving a large number of independent variables. This may have introduced a potential for error in the data analysis. Popowich et al. (2005) overcame the sample size limitation associated with the study by Taylor et al. (1996), however, still agreed with their results. It is important to consider that Popowich et al. (2005) only included Class II patients in the statistical analysis.

2.1.1.1.3.2. Elastic wear compliance

Elastic wear depends mainly on patient co-operation. Fortunately, not all types of malocclusions necessitate the use of elastic wear. Inter-arch elastics are generally used in Class II and III malocclusions to correct incisor, molar and canine relationships. Compliance of patients in using elastics can be a potential influential factor on the duration of treatment (Table 7).

Beckwith et al. (1999), Skidmore et al. (2006) investigated various factors that can be related to patient co-operation and their influence on the duration of treatment. Although, the two studies had similar sample distribution in the types of malocclusion with more than half the sample having a Class II malocclusion they did not agree on the influence of patient compliance in elastic wear on the duration of treatment. Skidmore et al. (2006) used a regression model and suggested that every reported “poor elastic wear” appointment increased mean treatment time by 1.4 months, and 3 or more reported “poor elastic wear” appointments increased it by 4.5 months. On the contrast, Beckwith et al. (1999) failed to find a significant correlation between elastic wear compliance and duration of treatment.

2.1.1.1.3.3. Oral hygiene

There is a general consensus that patients with good oral hygiene are more likely to co-operate with other aspects of treatment (Nanda and Kierl, 1992, Egolf et al., 1990). However, Elmangoury (1981) explained that orthodontic patient co-operation is not composed of a simple general dimension.

Most studies that have highlighted the effect of patient co-operation on the duration of treatment reported a significant correlation between the maintenance of good oral hygiene and the duration of treatment (Beckwith et al., 1999, Popowich et al., 2005). As it has been suggested that good oral hygiene could be a sign of a cooperative patient. Using a regression model Skidmore et al. (2006) suggested that poor oral hygiene can increase treatment duration by up to 1.2 months.

2.1.1.1.3.4. Broken (debonded) appliances

Repairing broken or debonded orthodontic appliances by rebonding brackets or recementing bands is inconvenient for the clinician as this may interfere with the procedures planned for each visit. Multiple repairs can be associated with poor patient co-operation; which can be explained patients not following instruction of avoiding certain activities or foods during treatment. However, this can also be related to the characteristics of bonding material used and technique. This explains why Skidmore et al. (2006) suggested that appliance breakage can be considered as an indirect factor reflecting patient co-operation.

Obrien et al. (1995), Popowich et al. (2005) agreed that orthodontic appliance breakages or debonds are one of most important factors influencing the duration of treatment for Class II patients. Beckwith et al. (1999) confirmed this finding using regression analysis and reported that appliance breakage was ranked as the second most important factor influencing duration of treatment in a sample that included the four Angle's classes of malocclusion.

Moreover, Skidmore et al. (2006) reported a statistically significant increase in treatment duration with appliance breakage. Using a regression model, the authors suggested that every appliance debond (bracket/ band) can increase treatment duration by 0.3 months and 3 or more debonds can increase duration of treatment up to 1.5 months. It is important to note that Skidmore et al. (2006) is the only study in the literature to differentiate rebonding due to breakage and repositioning which is the clinician's decision. This study therefore provides a realistic indication of the relationship between bracket rebonding due to patient co-operation and treatment duration.

To summarise this section, there is an agreement among the above mentioned studies that factors related directly or indirectly to patient co-operation can influence the duration of orthodontic treatment. In the absence of high quality prospective randomised controlled clinical trials, the available weak evidence suggests that patient co-operation is one of the factors that has a significant impact on the duration of treatment.

2.1.1.2. Treatment related factors

Formal treatment planning for each orthodontic case following accurate diagnosis allows the orthodontist to evaluate different treatment options and mechanics. In this section of the literature review I will explore the literature to evaluate the influence of treatment related factors on the duration of treatment.

2.1.1.2.1. Extraction vs. non-extraction

Extraction patterns for orthodontic treatment have changed over time since the beginning of the last century, when Tweed broke his teacher's guidelines (Angle) by presenting cases that were treated with extractions as a part of the orthodontic treatment plan claiming that this will minimise relapse. That was not well received by the majority of the orthodontic society members at that time. However, this changed through the years with a "roller coaster effect"; there were ages where extractions were popular and others where extractions were considered anathema. At present, the decision of extraction is totally built on the individualised malocclusion characteristics for each patient according to different diagnostic criteria (Lim et al., 2008).

Several studies have investigated the influence of extractions on the duration of orthodontic treatment. Seven studies were found with primary aim to investigate the effect of extraction on treatment outcome including the duration of treatment (Vig et al., 1990, Popowich et al., 2005, Janson et al., 2007, Lim et al., 2008, Germec and Taner, 2008, Xu et al., 2006, Janson et al., 2012, O'Brien et al., 2003). Vig et al. (1990), Popowich et al. (2005) and Janson et al. (2012) retrospectively investigated the effect of extraction on different types of malocclusion; while Xu

et al. (2006), Lim et al. (2008) and Germec and Taner (2008) retrospectively investigated the influence of extraction on boarder line extraction cases.

Vig et al. (1990) studied the duration of orthodontic treatment with and without extraction in a pilot study. Five orthodontic practices were selected in Michigan, USA according to their rate of extractions. The planned inclusion criteria by the authors indicated offices with extreme rate of extraction which reached as low as 15% and as high as 70%. However, the inclusion criteria were not followed with one of the selected practices having an extraction rate of 55.4%. Records of 438 non-consecutive patients from these practices were examined. When all the patients' records from the five practices in the study were added the mean duration of treatment reported for the non-extraction and the extraction cases were almost similar (31.2 and 31.3 months respectively). However, there was an increase in the mean duration of treatment in the extraction group when compared with the non-extraction group in each practice (mean difference range 2.1 to 7.4 months). This difference was found to be not statistically significant except in one practice. A stepwise regression analysis was constructed to test the association between the duration of treatment and nine variables. It was reported that extraction was correlated with treatment duration, and 2.9 months are to be added to an extraction case. These findings should be interpreted with caution due to the high risk of bias resulting from the study design and influence of confounding factors which the authors appropriately highlighted in their article.

Popowich et al. (2005) , Janson et al. (2006), Janson et al. (2007), and Janson et al. (2012) investigated the influence of extraction on the treatment duration in Class II

malocclusion.Popowich et al. (2005) sought to identify variables that might predict treatment duration in class II division 1 extraction and non-extraction cases. They applied strict inclusion criteria and all cases (237 patients) were treated in a single phase. Treatment duration for both class II division 1 extraction and non-extraction were almost similar at 24.97 and 25.7 months respectively.

It is interesting to note that the same data was used in another publication (Popowich et al., 2006) to compare class II treatment duration among three different practices. It was reported that the overall Class II non –extraction group averaged 1.7 more appointments than the class II extraction group; and this difference was statistically significant. The authors explained this difference by the noticeable increased use of class II appliances for the non-extraction group which usually need more appointments for adjustments. Conversely, this difference may not be considered clinically significant.

Table 8 Studies (retrospective) that investigated the influence of extraction on the duration of orthodontic treatment

Study	**Sample size**	**Type of Angle's malocclusion**	**Results**
Vig et (1990)	238	All types	No statistically significant difference
Popowich et al 2005	237	Class II	No statistically significant difference
Janson et al 2007	112	Class II	No statistically significant difference
Janson et al 2012	84	Class II	No statistically significant difference

A Brazilian research team designed a series of retrospective studies to compare duration of treatment in Class II non-extraction patients and Class II patients treated with different extraction patterns (Popowich et al., 2005, Janson et al., 2007, Janson et al., 2012, Janson et al., 2006). Janson et al. (2007) demonstrated using the records of 112 patients that there was no statistically significant difference in the duration of treatment between Class II malocclusions treated with 2 maxillary premolar extractions and non-extraction (26.99 and 31.8 months respectively). It is worth mentioning that there was no statistically significant difference between the two groups in the PAR score before treatment. Moreover, Janson et al. (2012) in a recent study demonstrated using a smaller sample (84 patients' records) that there was no statistically significant difference in the duration of treatment between Class II malocclusions treated with four premolar extraction and non-extractions (28.3 and 29.6 months respectively). Both groups had similar severity of malocclusion (measured using treatment priority index) at the start of treatment; however, there was statistically significant more mandibular crowding in the extraction group than the non-extraction group.

It is interesting to note that the results from the studies mentioned above (including only patients with Class II malocclusions) that the duration of treatment in the extraction group was less than the non-extraction groups, yet not statistically significant (Popowich et al., 2005, Janson et al., 2007, Janson et al., 2012).

Severity of malocclusion may affect the treatment planning decision by shifting towards extractions in severe malocclusions. This may have affected the results of the previously mentioned studies (Table 8) in comparing the treatment duration

between extraction and non-extraction groups in retrospectively designed studies. In order to overcome this problem, three studies (Table 9) were designed to compare between extraction and non-extraction orthodontic treatment in border-line cases where both treatment plans could be applicable (Xu et al., 2006, Lim et al., 2008, Germec and Taner, 2008).

Xu et al. (2006) designed a retrospective study to compare treatment outcome in borderline extraction patients in Chinese population. Thirty nine cases were found to meet strict inclusion criteria. Non-extraction group was 16 patients and extraction group was 23 patients. All patients who were included in the extractions group had 4 premolars extracted. It was reported that extraction group had increase treatment duration compared to the non-extraction group (24.7 and 22.1 months respectively). However, no statistical tests were published to identify any significant difference, this may be explained by the small sample size in the non-extraction group (16 patients).

In 2008 Lim et al. designed a similar study using borderline extraction cases from a Korean population. Sample included in the study was relatively larger (100 patients) however; the identification criteria of borderline extraction cases were not clearly mentioned. Lim et al. (2008) reported that extraction group had longer duration of treatment when compared to the non-extraction group (27.2 and 23.0 months, respectively). Similar to Xu et al. (2006), Lim et al. (2008) did not use statistical tests to identify significant difference between the two groups, however the sample size was relatively larger.

Table 9 Studies that investigated the effect of extraction in orthodontic treatment in border-line cases on DT

Study	Design	Aim of study	Sample patients	Identification of Border line cases	Results
Xu et al. (2006)	Retrospective	Compare treatment outcome between extraction & non-extaction in boarder line cases	39	Clear criteria described	Extraction 24.7+/-8.2 and non-extraction 22.1+/-8.3 months
Lim et al. (2008)	Retrospective	Aesthetic impact of premolar extraction & non-extraction in boarder line cases	100	Criteria not clear	Extraction 27.2 and non-extraction 23 months
Germec and Taner (2008)	RCT	Effect of extraction & non-extraction therapy with air-rotor stripping on facial aesthetics in boarder line patients	26	Clear criteria described	Extraction 24.8+/-6.9 and non-extraction with air-rotor stripping 17.0+/-4.6 months

All the above mentioned studies in this section are retrospectively designed; this may explain the difficulty in achieving ethical approval and recruiting patients for prospective clinical studies that can compare the effect of extraction and non-extraction orthodontic treatment. However, Germec and Taner (2008) was the only study group to design a randomised clinical trial to assess the effect of extraction and non-extraction therapy with air rotor stripping. After a recruitment period of 4 years only 26 patients with border line extraction malocclusion agreed to participate in the study. The authors reported that the extraction group had statistically significant increase in the duration of treatment when compared to the non-extraction with air rotor stripping group.

Several studies were designed to identify factors that can influence the duration of orthodontic treatment. These studies were not designed primarily to investigate the effect of extraction on treatment outcome. Some studies reported correlation between extraction and increased duration of treatment while other studies did not (Taylor et al., 1996, Turbill et al., 2001, Beckwith et al., 1999, Skidmore et al., 2006).

Taylor et al. (1996) in a study investigating the factors associated with the standard and duration of orthodontic treatment, where both fixed and removable appliances were included. They used multiple regression analysis of the duration of treatment for the fixed appliance cases (81), where extraction was not included in the equation. The authors concluded that the duration of fixed appliance treatment is impossible to predict. Beckwith et al (1999) in a study to evaluate the factors

affecting the duration of treatment reported through a multiple regression analysis more than half the variance in treatment duration by six variables. Extraction variable was not one of the six. The mean treatment time for extraction cases was 29.2 while for non-extraction cases was 27.8 months and the difference was not statistically significant. This may be accounted for by the number of non-extraction cases being triple that of the extraction cases and the lack of strict inclusion criteria that may had introduced bias.

Conversely, other studies reported the correlation between extraction and treatment duration finding extraction cases take longer to treat (Fink and Smith, 1992, Fisher et al., 2010, Hamilton et al., 2008, Skidmore et al., 2006, Vu et al., 2008). The mean difference between treatment duration for extraction and non–extraction groups varied among the available studies ranging from as low as 2.6 months (Skidmore et al., 2006) to as high as 7 months (Vu et al., 2008). This may reflect the variation in the inclusion criteria among the studies.

Haralabakis N B (2004) investigated the effect of six variables and their interrelation on the duration of orthodontic treatment in a single private practice. Clear selection criteria were followed in this study and almost half the variation of treatment duration was explained by an equation containing 4 variables and the interaction between them. The extraction variable was included in this equation. Turbill et al. (2001) investigated factors that influence the duration of treatments in several National Health Service practices using a large sample size (1506). Using multiple regression analysis it was reported that multiple premolar extraction was the factor most strongly related to treatment duration.

Interestingly, delaying the extraction decision has been found to be one of the most time consuming variables in orthodontic treatment. Skidmore et al (2006) reported that extractions resulted in a further 3.3 months of treatment (24.6 months in total) than non-extraction (21.3 months). In addition, extraction midway through treatment resulted in an additional 5.9 months of treatment in comparison to those finally completed on a non-extraction basis (27.2 months).

Some of the studies that have confirmed extraction treatment to take longer than non-extraction treatment have also investigated the pattern of extractions as well. Turbill et al. (2001) and Alger (1988) reported that cases involving two maxillary premolar extractions were found to take less time in treatment than four premolar extraction, both studies reported almost the same difference 2.5 months. Janson et al. (2006) demonstrated that treatment time is shorter in the two maxillary premolar extractions than in the four premolar extraction cases due to time spent in the correction of the molar relationship. They reported a significant treatment duration difference of 4.6 months. This agrees with the results from (Fink and Smith, 1992) which suggested that each extracted premolar added 0.9 months to treatment duration.

To summarise, the influence of extraction on the duration of treatment is controversial. Studies that were mainly designed to investigate the impact of extraction on treatment outcome were divided. The first group of studies which evaluated the impact of extraction retrospectively on routine cases suggested that there is no impact on duration of treatment, although Class II malocclusions

extraction cases tended to have less duration of treatment, but the difference was not statistically significant (Popowich et al., 2005, Vig et al., 1990, Janson et al., 2007, Janson et al., 2012). The increase in the duration of treatment reported in the non-extraction cases in Class II malocclusions may be related to the treatment mechanics and appliance used in treating Class II malocclusions which may act as confounding factor altering the duration of treatment.

The second group of studies investigated the influence of extraction on border line extraction cases reported that extraction increased the duration of treatment (Lim et al., 2008, Xu et al., 2006, Germec and Taner, 2008). Limiting the sample in these studies to only border line extraction cases reduced the influence of the severity of malocclusion as a confounding factor on the duration of treatment. The results from the second group of studies were in agreement with several studies that were designed to identify factors that can influence the duration of treatment; it was reported that extraction was correlated to increased duration of treatment (Fink and Smith, 1992, Fisher et al., 2010, Skidmore et al., 2006).

It can be concluded from the available relatively weak evidence that extraction therapy in orthodontic treatment may increase the duration of treatment. However, the use of non-extraction mechanics to treat Class II malocclusions may still increase the duration of treatment in non-extraction cases when compared to extraction cases.

2.1.1.2.2. Scheduled appointment intervals (SAI)

There are very few studies in the literature that explored the influence of appointment intervals on the duration of orthodontic treatment. Vu et al. (2008) found that reduced visit intervals can significantly reduce the full duration of orthodontic treatment. On the same route Popowich et al. (2005) reported that increased appointments intervals in Class II malocclusion was associated with increased duration of treatment.

Alger (1988) suggested 6 weeks as visits interval during orthodontic treatment, however, this recommendation was not based on sound statistical data. No studies were found in the literature designed mainly to investigate the influence of appointments intervals on the duration of treatment.

2.1.1.2.3. Single phase vs. multiple phase treatment

For pre-adolescents with class II and III skeletal imbalance, growth modification is an option of treatment that sometimes is considered a separate phase of treatment. This early phase of treatment is usually followed by a second and presumably simpler later stage of tooth movement during adolescents. On the other side, some orthodontists prefer to delay treatment until full eruption of permanent teeth and undertake a single phase of treatment using a fixed appliance associated with class II or III elastics and a decision to extract or not. Both single phase and two-phase are considered proper approaches for correcting a class II and III imbalance in a growing patient. A controversy has developed in the orthodontic society on which approach is more effective.

(Tulloch et al., 1998) undertook a randomised clinical trial to compare the effectiveness of single-phase orthodontic treatment compared to two-phase treatment. The sample included 166 preadolescent patients with Class II malocclusions (overjet greater than 7 mm) and randomly allocated into two groups. First group treatment involved an initial phase of growth modification followed by a second phase of fixed appliance (two-phase treatment), while the second group treatment involved monitoring for the first period and then a single phase of fixed appliance treatment. The authors reported minimal difference in the outcome of treatment between the two groups at the end of the treatment. However, treatment duration was significantly increased in the two-phase treatment compared to the single phase. In agreement another randomised clinical trial designed by (Dolce et al., 2007) compared single phase and two-phase treatment using a larger sample (261 participants) reported that treatment duration was significantly increased in the two-phase group. Similarly, several retrospective studies were designed to compare the two protocols of treatment agreed that multiple phase treatment take longer treatment duration (Cancado et al., 2008; Berman et al., 2002; O'Brien et al., 1995; Livieratos et al., 1995).

(Cancado et al., 2008) designed a retrospective study to compare the duration and occlusal outcomes of one-phase and two-phase treatment protocols in Class II developing patients. The results showed no significant difference in the post-treatment PAR score between both groups indicating similar occlusal outcome. However, treatment duration was significantly shorter in the single-phase group. It is interesting to note that when ages of the patients in both groups were matched treatment duration was still significantly shorter in the single-phase protocol than

the two-phase protocol (2.17 and 3.49 years respectively). The authors concluded that similar treatment outcomes were obtained from both protocols, but the duration of treatment was significantly less in the single-phase. In addition, Bermen et al. (2002) constructed another retrospective study to compare the two protocols using dental developmental age to categorise patients (early mixed, late mixed and permanent dentition). It was reported that the duration of treatment decreased with progressing dental development and single phase treatment. Early mixed dentition mean treatment duration 57 months, late mixed dentition 33 months and permanent dentition 21months.

It can be concluded form the available satisfactory evidence that in Class II malocclusions treatment multiple phase treatment can significantly increase the duration of treatment.

2.1.1.2.4. Type of orthodontic fixed appliance

2.1.1.2.4.1. Self-ligating vs conventional brackets

Some self-ligating bracket systems were marketed as a superior system with several advantages, which include less duration of treatment. In the last decade several clinical trials were conducted to compare the effectiveness of treatment between self-ligating and conventional bracket systems. Two systematic reviews were conducted to collate the results from several studies and provide evidence to help clinicians in selecting the efficient bracket system (Fleming and Johal, 2010, Chen et al., 2010b).

Chen et al. (2010b) included in their eligibility criteria studies of all types of clinical trials including prospective and retrospective trials. On the other hand Fleming and Johal (2010) had relatively strict inclusion criteria which included only randomised and prospective controlled clinical trials. Despite the difference in the inclusion criteria for trial design between the two systematic reviews, meta-analysis conducted in both reviews agreed that there is no difference in the duration of treatment between the two types of bracket systems.

2.1.1.2.4.2. Bracket slot size influence on the duration of treatment

Two studies were published in the literature primarily designed to compare the duration of orthodontic treatment (Table 10). The two studies were retrospective in design with no criteria mentioned regarding case selection to reduce selection bias. Detterline et al. (2010) had large sample size of 828 patients (mean age 16.3 years) who were all treated by postgraduate students in a university teaching hospital, while Amditis and Smith (2000) study included only 64 patients(mean age 15.25 years) who were all treated in private practice by a single clinician.

Both studies found that the 0.022-inch bracket slot group had a statistically significantly increase duration of treatment compared to the 0.018-inch group. However, Detterline et al. (2010) reported more than double the mean duration difference of that found by Amditis and Smith (2000) 3.9 and 1.5 months respectively. This reported difference in the mean duration between the two groups can be explained by the difference in the total duration of treatment reported among the total sample (Table 10). It is interesting that the two studies agreed that

although the difference between the two bracket slot systems was statistically significant, this difference was considered by both authors not clinically significant.

Although, Amditis and Smith (2000) had a smaller sample size the authors managed to stratify the results according to the type of malocclusion. It was found that the 0.018-inch group finished treatment 2-3 months faster than the 0.022 in all types of Angle's malocclusion except Class II division 1 were the difference was minimal (0.2 months). It is important to stress that these finding were not supported by statistical tests due to the reduced sample size.

Amditis and Smith (2000) used the PAR index to evaluate treatment outcome between the two study groups but statistical tests for comparison between the two study groups were not published. Using a different index Detterline et al. (2010) used the ABO-OGS to compare occlusal outcome between the two groups; where it was reported using demonstrated statistical analysis that 0.018-inch group had better treatment outcome.

The results of the (Detterline et al., 2010, Amditis and Smith, 2000) two studies agree withVu et al. (2008) who designed a retrospective study to evaluate the outcome of orthodontic treatment in university teaching hospital. Vu et al. (2008) found that 0.022-inch bracket slot group had a statistically significant increase in the duration of treatment compared to the 0.018-inch bracket slot group (mean difference 9.5 months). However, it is important highlight that the authors mentioned that 0.022 represented only 20% of the sample and had more orthognathic cases which may have caused sample bias.

Table 10 studies that investigated the influence of bracket slot dimension on DT

Studies	**Amiditis and Smith 2000**	**Detterline et al. 2010**
Design	Retrospective	Retrospective
Clinic setting	Private practice	Teaching hospital
Operator	Single	Postgraduate students
Appliance prescription	Roth	Not mentioned
Sample(patients)	64	828
Age (years)	15.25	16.3
Types of Malocclusion	All	All
Extraction	79.7%	Not mentioned
Exclusion criteria	Not mentioned	Missing teeth Orthognathic treatment
Treatment duration	0.018 group= 20.2 0.022 group= 21.7	0.018 group= 30.2 0.022 group= 34.1
Mean difference in treatment duration (months)	1.5 total sample 2.5 Class I 3 Class II div 2 2.1 extraction cases	3.9 total sample
Occlusal outcome	PAR (but not presented)	ABO(OGS)
Scheduled appointment intervals	5 weeks	Not mentioned

All studies discussed in this section agree that patients treated using 0.018-inch bracket slot system had less duration of treatment when compared with 0.022-inch bracket slot system. However, the available evidence regarding the influence of the bracket slot dimension on the duration of treatment is weak represented in three retrospective studies with high risk of bias.

2.1.1.2.5. Operator variation and health management system

A retrospective study was designed to investigate the effect of change in the operating post-graduate clinician (trainee) on the treatment duration (McGuinness and McDonald, 1998). The records for 147 patients treated by a particular post-graduate clinician were investigated. Group 1 in the study consisted of thirty patients who had their treatment started and finished by the same postgraduate clinician. While group 2 consisted of thirty patients who had their treatment started by another operator and referred for the post-graduate trainee to finish treatment. The two groups were matched for the number of failed to attend appointments. It was found that the occlusal treatment outcome in the two groups was similar. However, study group 2 experienced statistically significant increase in the duration of treatment compared to the first group: 26.1 and 17.6 months respectively. It is important to mention that the authors described the selection of the patients' records investigated in both study groups as random, although they never explained the criteria of randomisation. This may have increased chance of selection bias, which may have influenced the results.

Mascarenhas and Vig (2002) designed a cohort study to compare the effectiveness of orthodontic treatment between educational and private practice settings. Two

hundred and eighteen patient's records were assessed for treatment duration and outcome using PAR index. The authors reported that there was a statistically significant increase in the duration of the treatment in the group of patients treated in private practice compared with those treated in teaching university hospital. No statistically significant difference was detected in occlusal outcome. However, more patients treated in private practice group started treatment earlier i.e. in the mixed dentition compared to the patients treated in the teaching university hospital.; this may have influenced the results reported.

Orthodontists are not the only clinicians treating malocclusions using fixed braces. It has been reported that more than 20% of the orthodontic treatment is performed by general dental practitioners with no certified orthodontic training (Wolsky and McNamara, 1996). This percentage may have increased recently due to the introduction of new clinicians to the speciality e.g. orthodontic therapist. The quality of treatment provided was compared between orthodontic specialists and general dental practitioner (Marques et al., 2012, Abei et al., 2004). Both studies reported that specialist orthodontists achieve better quality in less duration of treatment.

To summarise, it can be assumed that trained specialist orthodontist can provide more efficient orthodontic treatment; however, the evidence available for the influence of the operator on the duration of treatment is still week. Other factors including the health system management policy in covering treatment cost may also influence the duration of orthodontic treatment indirectly.

2.1.1.3. Factors influencing duration levelling and alignment stage

Fixed appliance orthodontic treatment can be generally categorized into three consecutive stages; initial alignment, space closure (correction of inter-arch relationship) and finishing (Proffit, 2013). Different theories of mechanics are considered in each stage depending on the treatment objectives and operator preference. Recognition of the factors that influence the duration of each stage can be useful in providing effective orthodontic treatment.

Levelling and aligning is usually the first orthodontic objective during the initial stages of treatment. It mainly involves tipping movements, which can be sufficient enough to align teeth and allow the clinician to insert the working archwire at the end of the aligning stage. However, unwanted teeth movements at this stage might increase the time and effort needed to complete the case later in treatment and can lead to loss of anchorage. It has been suggested that the effectiveness of this process of initial alignment may be dependent on several variables including:

- Severity of crowding/irregularity
- Archwire type
- Archwire sequence
- Bracket Slot dimension
- Bracket design / ligation
- Lacebacks

Some of the variables that affect the duration of levelling and alignment stage are largely outside the control of the orthodontist, while others depend on technical treatment factors that can directly influence the duration of treatment.

2.1.1.3.1. Severity of crowding/irregularity

The severity of crowding/irregularity and its relationship to the time taken for the initial alignment stage was reported by Pandis et al. (2007) & (2010) in two randomised clinical trials designed primarily to assess the effectiveness of conventional and self-ligating brackets in the alignment stage in the maxillary (2010) and mandibular (2007) arches. The authors used Little's irregularity index as a method for quantifying the severity of the irregularity in both studies. They reported that greater crowding in the anterior segment increased the mean time taken for the alignment stage in both bracket systems. They also suggested that greater irregularity prolonged treatment by an additional 20% for each unit of irregularity index in the mandibular arch. It is worth mentioning that Pandis et al (2007) noticed that in cases with moderate crowing (irregularity index <5) the self-ligating bracket system had 2.7 times faster aligning rate than the conventional bracket system.

Moreover, the same research group conducted a randomised clinical trial to compare the duration of treatment in aligning mandibular teeth between two different types of aligning archwires in self-ligating brackets (Pandis et al., 2009). The authors only included the mandibular arches with Little irregularity index score more than 2 mm and reported that by combining the sample from both groups higher irregularity index values (>5) were associated with increased duration for

alignment. However, it is important to mention that the Pandis and his co-workers used the terms “crowding and “irregularity” as synonyms. This may not be appropriate as the two terms differ in meaning because an arch does not have to be crowded to have teeth with broken point contacts i.e. irregularity.

It had been claimed by several authors who investigated the effectiveness of the alignment of new nickel titanium archwires that they can perform more efficiently when ligated into brackets of teeth with greater irregularities between contact points (Sebastian, 2012, Sandhu et al., 2012). This can be mechanically explained by the assumption that the shorter the inter-bracket spans in severe irregularities and contact point displacement the greater the stiffness of archwire segments (Cobb et al., 1998). This may be the chance for the super-elastic wires to function with less stiffness keeping low forces which may stimulate higher rate of tooth movement. However, several clinical studies failed to confirm this theory (Cobb et al 1998; Evans et al 1998).

2.1.1.3.2. Archwire type

During initial levelling and alignment, a great range of light forces are preferred. Two principal types of wires are commonly used; either multi-strand stainless steel wires or nickel titanium wires. The latter had been more popular in the last few decades with significant development in its mechanical properties (McNamara et al., 2010) . Several clinical studies were conducted to investigate the effectiveness of these two different types of aligning archwires.

Multi-strand stainless steel vs. Nickel titanium archwires

Five prospective clinical trials were designed in different research units to compare the effectiveness in alignment using multi-stranded stainless steel and different types of nickel titanium archwires (Table 11). Most trials were conducted in the last century where the popularity of both types of arch wires was still even. A recent survey suggested that less than 3% the orthodontists in U.K use multi-stand stainless steel archwires. However, a recent study was conducted to compare the effectiveness of the latter with nickel titanium archwires in alignment (Sandhu et al., 2012).

Three randomised clinical trials compared the 0.0155 multi-strand SS with different NiTi archwires. West et al. (1995) used 0.022-inch bracket slot edgewise system to compare the effectiveness of the 0.0155 multi-strand SS and 0.014 NiTi in aligning irregular teeth for 6 weeks. The authors reported that there was no statistically significant difference in the amount of teeth movement between the two archwire groups except in the lower teeth where the 0.014 NiTi was found to be more effective. On the other hand, Jones et al. (1990) compared the effectiveness of the same dimensions of two types of archwire using 0.018 bracket slot for 5 weeks. Although, the authors used the super elastic 0.014 NiTi they failed to find any statistically significant difference between the two groups.

Table 11 Clinical trials that compared the effectiveness of teeth alignment using multi-strand archwires with different types of nickel titanium archwires

Size of multi-strand SS	NiTi wire	Study	Investigation duration	Slot	Irregularity amount	Effect on rate of teeth movement
0.0155 ss	0.014 NiTi	West et al 1995	6 weeks	0.022	Not mentioned	No statistically significant difference. Except in the lower arch Niti group had more teeth movement.
	0.014 NiTi super elastic	Jones et al 1990	5 weeks	0.018	Not mentioned	No statistically significant difference
	-0.016x0.022 NiTi -0.016x0.022 NiTi	Evans et al 1998	8 weeks one visit for activation	Not mentioned	Not mentioned	No statistically significant difference
0.0175 ss	-0.016 NiTi -0.016 NiTi ion implemented	Cobb et al 1998	Until full alignment of anterior (mean 7 weeks)	0.018 & 0.022	7-8 mm	No statistically significant difference
	0.016 NiTi super elastic	Sandhu et al 2012	6 weeks	0.022& Begg	5-8 mm	Multi strand & Beg group had stat significant less teeth movement.

Evans et al. (1998) decided to conduct a study to compare two different types 0.016x0.022 rectangular NiTi arch wires with 0.0155 multi-strand SS in the effectiveness of alignment for 8 weeks. In agreement with Jones et al. (1990) no statistically significant difference was found between the study groups. However, Evans et al. (1998) did not specify the dimension of the bracket slot system used in the trial.

Moreover, two prospective clinical trials compared the effectiveness of 0.017s multi-strand SS archwire with different types of 0.016 NiTi archwire during periods ranging from 6-7 weeks (Table 10). Cobb et al. (1998) randomised 126 patients into three groups of archwires: 0.0175 multi-strand SS, 0.016 NiTi and ion implemented 0.016 NiTi. The authors predicted the importance of the effect of the bracket slot/archwire interaction and decided to stratify the randomisation of the archwires according to bracket slot size (0.018-inch and 0.022-inch). No statistically significant difference in the duration needed for teeth alignment was detected between the different archwires studied. However, the authors reported a statistically significant reduction in the duration of alignment in the 0.022-inch bracket slot groups compared to the 0.018-inch groups in the lower arch (mean difference 28 days).

Recently, Sandhu et al. (2012) conducted a non-randomised prospective clinical trial to compare the effectiveness of the 0.0175 multi-strand SS and super elastic 0.016 NiTi in combination with edgewise (0.022-inch slot) and Begg appliance to align the anterior mandibular teeth in 6 weeks. The authors reported that the multi-strand SS archwire with the Begg brackets group had a statistically significant less

reduction in the amount of irregularity. This difference reached the maximum (50% less) in severe irregularity cases. It is important to note that Sandhu et al. (2012) found a positive correlation between the amount of Little's irregularity index score and the amount of reduction of irregularity in the NiTi archwire group; however a negative correlation was found with the multi-strand SS archwire group when combined with Begg appliance. This may suggest that NiTi archwires perform better in severe anterior teeth irregularity in both types of brackets.

From the above mentioned 5 studies (Table 11) that investigated the effectiveness of multi-strand SS archwire it is obvious that only one study investigated the full duration of alignment achieving Little's Irregularity index score <2mm. The remaining 4 studies evaluated the difference between the different archwires in a range between 5-8 weeks. This may not be an adequate representation to the full alignment stage which may be extended up to 120 days (Ong et al., 2011). Moreover, it is important to note that the alignment stage may require a sequence of archwires to relieve the irregularity.

All five clinical trials agreed that there is no significant difference in the effectiveness of the different sizes (0.0155 and 0.0175) of multi-strand SS archwires and different types of NiTi (including round and rectangular) in alignment of teeth using edgewise bracket systems. However, Sandhu et al (2012) reported that the performance of multi-stranded SS can be negatively affected when used with the Begg appliance in mandibular anterior teeth. It is important to note that this study may have a relatively high risk of selection bias due to lack of

randomization which may have influenced the results; in addition to the bracket design (Begg) which may have a acted as a confounding factor.

It can be concluded that there is enough evidence to suggest that there is no clinical or statistical significant difference between multi-strand SS and NiTi arch wires in alignment of irregular teeth. This cannot explain the increased popularity of the different NiTi archwires among clinicians in the last decade considering their relatively expensive market price.

Different types of nickel titanium archwires

Since the introduction of the NiTi archwires to the orthodontic speciality in the early 1970s, several in-vitro studies were conducted to evaluate the mechanical properties of this group of archwires (Rock and Wilson, 1988, Ohura, 1984). In the last two decades and due to the continuous development and improvement in mechanical properties of the NiTi archwires several randomized clinical trials were conducted to evaluate the effectiveness of different types of NiTi archwires during the initial alignment stage (Table 12).

O'O'Brien et al. (1990) conducted the first randomised clinical trial to compare the effectiveness between to aligning NiTi archwires. Forty participants were randomized into either super-elastic Titinol or Nitinol 0.016 archwires. No difference was reported between the groups in the effectiveness of alignment of the upper and lower arches in 35 days. Cobb et al. (1998) compared the effect of ion implementation on the 0.016 NiTi archwires in the alignment of teeth. The authors recruited 126 patients with a mean irregularity of teeth 7-8 mm, where both 0.018-

inch and 0.022-inch bracket slot systems were used. The authors reported no significant difference in the amount of teeth movement between the ion implemented NiTi and the non-ion implemented NiTi nor the multi-strand SS archwires. In agreement, Evans et al. (1998) failed to find a statistically significant difference between two aligning active martensitic rectangular NiTi archwires (0.016x0.022 medium force and graded force). Both Evans et al. (1998) and O'Brien et al. (1990) did not specify in the published articles which bracket slot size were used.

Experimental studies suggested that the addition of Copper to NiTi alloys can alter the mechanical properties of the aligning archwire by increasing the strength of the wire and reducing hysteresis (Gil et al., 2004). Most importantly the addition of copper allows greater precision in the setting of the austenitic transformation temperature. Pandis et al. (2009) designed a randomised clinical trial to compare the effectiveness of super elastic 0.016 NiTi and 35 degrees transition CuNiti 0.016 for the complete alignment of the anterior mandibular arch. Sixty participants were randomised to one of the archwire groups and treated using 0.022 bracket slot system. The latter archwire failed to demonstrate any clinical superiority when compared to the former archwire. This may suggest the low impact of copper addition in NiTi arch wires on the clinical effectiveness of alignment. This is in agreement with a split mouth study Dalstra and Melsen (2004) which could not find a clinical significant difference between two groups of different temperature transition (27 and 40 degrees). It is important to note that the split mouth study was considered to have a high risk bias which may have influenced the results.

Sebastian (2012) published a recent randomised clinical trial to investigate the clinical effectiveness of coaxial super-elastic 0.016 NiTi compared to the 0.016 super elastic NiTi archwires. Twenty-four females were randomized to one of the mentioned archwire groups for alignment of the mandibular arch using 0.022-inch bracket slot for 12 weeks. The mean Little's irregularity index score for the sample was 8-9 mm. The coaxial super elastic archwire group was found to have statistically significant more alignment of the anterior teeth when compared with the super elastic 0.016 NiTi group. Although the authors mentioned that they had decided the sample size depending on a power calculation which was based on a pilot study, the sample was considered to be relatively very small (12 participants per group) when compared to previous mentioned studies comparing the effectiveness of different types of archwires (Table 12). The results from the pilot study were not published. The authors suggested that they were able to detect this difference in alignment between the two different types of archwires because the inclusion criteria for the sample recruited was LII score > 7mm. However, it was noticed that most of the studies in (Table 12) had similar LII score but couldn't detect any significant difference in alignment between the investigated NiTi archwires.

It can be conclude from the five RCTs presented in (Table 12) that different types of NiTi are similar in their effectiveness in aligning teeth except the coaxial NiTi archwires, which expressed superior properties in the clinical atmosphere in anterior mandibular arch

Table 12: Studies comparing different NiTi archwires

Study	Design	Archwires	Slot size	Sample size	Amount of irregularity	Findings
O'Brien et al. (1990)	RCT	Nitinol vs. Super elastic 0.016-inch	Not mentioned	20 archwires per group	Not mentioned	No statistically significant difference
Cobb et al. (1998)	RCT	Ion Implemented vs. Nitinol 0.016-inch	0.018 and 0.022	52 archwires per group	7-8 mm in (3-3)	No statistically significant difference
Evans et al. (1998)	RCT	Medium force vs. graded force 0.016x0.022-inch	Not mentioned	37 archwires per group	Not mentioned	No statistically significant difference
Dalstra and Melsen (2004)	Split mouth	(27 vs. 40 degrees transition temperature	Not mentioned	15 half archwire per group	Not mentioned	No statistically significant difference
Pandis 2009	RCT	CuNiTi vs. Super elastic 0.016-inch	0.022	30 archwires per group	5.5mm (3-3)	No statistically significant difference
Sebastian (2012)	RCT	Coaxial vs super elastic 0.016- inch archwires	0.022	12 archwires per group	8.7mm (3-3)	Coaxial 0.016 NiTi had more statistically significant alignment

Two systematic reviews were published recently to determine the effectiveness of initial arch wires in the alignment stage (Riley and Bearn, 2009) and (Wang et al., 2010). Riley and Bearn (2009) included both control clinical trials and randomised clinical trials; they suggested that there is insufficient evidence to make clear recommendations regarding the most effective arch wire for alignment. On the other hand, Wang et al. (2010) included only randomised clinical trials, they concluded that there is enough evidence to suggest that there is no difference in speed of teeth alignment using one initial aligning wire over the other. Despite, both studies did not agree on the quality of evidence available they both agreed that archwire material and dimension have no effect on the rate of teeth movement in this early stage of treatment. The two systematic reviews were done before the publication of the recent study that suggested that Coaxial NiTi archwire demonstrated superior alignment effectiveness in-vivo.

2.1.1.3.3. Archwire sequence

The rationale for archwire selection varies according to the clinician's treatment philosophy and experience. Rock and Wilson (1988) suggested that efficient alignment can be achieved using an archwire sequence that can move teeth faster with minimal iatrogenic damage and patient discomfort. Most of archwire sequence recommendations are based on clinician's preferences and judgment rather than evidence based clinical trials.

Two randomised clinical trials investigated the efficiency of several orthodontic archwire sequences (Mandall et al., 2006, Ong et al., 2011). Mandall et al. (2006) investigated the efficiency of three archwire sequences from the same manufacturer

(Ormco) in combination with 0.022-inch as the bracket slot system (Table 13). On the other hand, Ong et al. (2011) investigated the efficiency of three archwire sequences from different manufacturers in combination with 0.018-inch bracket slot system. Both trials were properly designed with a low risk of bias following the CONSORT guidelines.

Mandall et al. (2006) archwire sequence groups shown in (Table 13) indicate that there is no statistically significant difference in the duration of alignment between the study groups, however, one sequence of archwires had a significantly greater number of treatment visits than one of the two other comparison archwire sequences. The group which showed increased number of visits had also increased number (three) of aligning archwires, unlike the other two study groups which had only two archwires in sequence. This may have affected the results, although the difference was only detected between two groups only.

Ong et al. (2011) decided to only investigate the effectiveness of different archwire sequence on the mandibular arch. The results agreed with Mandall et al. (2006) that there is no statistically significant difference in the duration of alignment

It can be concluded from the two well-designed RCTs that there is reasonable evidence to suggest that archwire sequence does not have a significant impact on the duration of treatment.

Table 13: Studies that investigated the influence of archwire sequence on the duration of alignment

Study	Archwire Sequence	Bracket slot	Duration of alignment	Results
Ong et al. 2011	GP1(3M) 0.014 Nitinol, 0.017x 0.017 heat activated Niti GP2 (GAC) 0.014 Sentalloy, 0.016x0.022 Biforce GP3 (Oramco) 0.014CuNiti, 0.014x0.025CuNiti	0.018-inch conventional brackets	Mandibular arch 4 – 4.4 months	No statistically significant difference
Mandall et al 2006	GP1 0.016 Niti,& 0.018 x 0.025 Niti GP2 0.016 Niti,0.016 ss & 0.020 ss GP3 0.016 x 0.022 CuNiti & 0.019x 0.025 CuNiti	0. 022-inch conventional brackets	Maxillary arch= 6.7-7.9 months Mandibular arch= 6.8-9.3 months	No statistically significant difference

In conclusion, it is interesting to note that clinical trials do not usually support the claimed superior mechanical properties reported in laboratory- based studies for newly developed types of aligning archwires. This may suggest the irrelevance of in-vitro derived mechanical performance of the archwires in the intra-oral clinical environment. Moreover, the effect of the bracket/slot combination was not

considered in most of the studies, which may have an influence on the effectiveness of the alignment stages.

2.1.1.3.4. Bracket slot dimension

Since 1990, nineteen clinical trials have been designed to investigate the influence of several factors on the orthodontic levelling and alignment duration (Table 14). It was noticed that 14 studies used the 0.022-inch slot and 3 studies used 0.018-inch slot while 3 studies did not mention the slot size of the brackets used. This may reflect the popularity of the 0.022-inch bracket slot among clinicians. No study was designed with a primary aim to compare between the two bracket slot systems in the duration of the alignment stage.

Cobb et al. (1998) designed a randomised clinical trial to compare the duration of alignment between different types of arch wires. In this unique study the authors realised the importance of the influence of the bracket slot size interaction with different types of archwires and decided to stratify the randomisation of the sample recruited to different archwires according to the slot size. In other words, random allocation of participants was according to archwires and not to slot size. It was found that both the time for alignment and the rate of alignment were similar in the maxillary arch, but alignment was significantly faster in the 0.022-inch groups in the mandibular arch. A median difference of 28 days was found between the two bracket slot groups in the mandibular arch. The authors concluded that greater clearance between archwires and bracket slot in small interbracket spans (mandibular anterior segment) may result in faster alignment. However, the use of single wing 0.018-inch brackets in some of the participants in the mandibular arch

only may have affected the efficiency of alignment in this group. This may have acted as a confounding factor in one group which could have an impact on the results. This was the only study found in the literature to investigate the impact of slot size during alignment.

Mandall et al. (2006) and Ong et al. (2011) undertook to randomised clinical trials to compare the effectiveness of different archwire sequences during the alignment stage. The two studies used different bracket slots: 0.022-inch and 0.018-inch respectively. It is interesting to note that despite of the similarity in the pre-treatment characteristics between the samples in both studies, Mandall et al. (2006)reported more than 50% increase (about 3 months) in the duration of alignment compared to Ong et al. (2011). The latter suggested that the bracket slot dimension may have influenced the duration by the decreased play in the 0.018-inch bracket slot system. However, it is important to note that all the study groups in Mandall et al. (2006) study started with at least 0.016-inch archwire while Ong et al. (2011) study groups started with 0.014-inch archwires. This may have compensated for the difference in slot dimension resulting in similar play.

Two studies were found in the literature to mainly investigate the effect of bracket slot size on the duration of treatment (Amditis and Smith, 2000, Detterline et al., 2010). Both studies did not report the difference between the two slots on the alignment duration.

Table 14: Bracket slot size used in studies that investigated the factors influencing alignment duration

Study	**0.018 inch brackets**	**0.022 inch brackets**	
West et al. (1995)		Yes	
Jones et al. (1990)	Yes		
Evans et al. (1998)			Not mentioned
Cobb et al. (1998)	Yes	Yes	Both slots
O'Brien et al. (1990)			Not mentioned
Sandhu et al. (2012)		Yes	
Dalstra and Melsen (2004)			Not mentioned
Pandis et al. (2009)		Yes	
Ong et al. (2011)	Yes		
Mandall et al. (2006)		Yes	
Scott et al. (2008a)		Yes	
Fleming et al. (2009a)		Yes	
Ong et al. (2010)		Yes	
Miles (2005 & 2006)		Yes	
Pandis et al. (2007) & (2010)		Yes	
Wahab et al. (2012)		Yes	
Sebastian (2012)		Yes	

Amditis and Smith (2000) designed a retrospective study comparing the duration of fixed orthodontic treatment using edgewise brackets with 0.018 and 0.022 inch slots. The authors did not publish any data about the duration of levelling and alignment stage. However, from the tables of the archwires sequences published for each group the following was noticed: A mean duration of 12 months (360 days) was reported for the 0.018 inch slot bracket group from the start of treatment until use of a rectangular stainless steel arch wire (0.016x0.022). On the other hand, a

mean duration of 12.3 months (369 days) was reported for the 0.022-inch slot bracket group from the start of treatment until the use of 0.020 stainless steel arch wire. Treatment duration was similar for what could be assumed as the levelling and alignment stage in both systems. However, this assumption has to be considered with caution as the authors did not publish clear data about the levelling and alignment stage, as the study was mainly concerned with the whole length of treatment duration.

Detterline et al. (2010) conducted a study in teaching university orthodontic clinic to compare between the two bracket slots. Unlike Amditis and Smith (2000) the authors did not publish the sequence of the archwires used through treatment in the two study groups. The authors kindly responded to my enquiry regarding the sequence of archwires used in the two study groups by mentioning that data was collected retrospectively and they could not keep a track of the archwiire sequence (Appendix 4).

There seem to be a lack of evidence regarding the influence of bracket slot size on the alignment stage duration. This may suggest the need for adequately designed randomised clinical trial to investigate the effectiveness of both bracket slot systems in the alignment stage.

2.1.1.3.5. Bracket design

Some self-ligating bracket systems are marketed as being superior to other systems with several advantages which include less duration of treatment. In the last decade

several clinical trials were conducted to compare the alignment efficiency between self-ligating and conventional bracket systems of slot size 0.022 inch (Table 15).

Five prospective clinical trials compared the effectiveness between the self-ligating (active and passive) and conventional brackets for the alignment of mandibular teeth (Table 15). Pandis et al. (2007) and Fleming et al. (2009a) recruited patients with non-extraction treatment plan while Scott et al. (2008a) recruited patients who underwent extractions as part of their orthodontic treatment plan. Miles (2005) and Miles et al. (2006) recruited patients with extraction and non-extraction treatment plans. All five studies failed to find any statistically significant difference in the duration or rate of alignment between the two bracket systems in the mandibular teeth. In agreement, Hamilton et al. (2008) and Ong et al. (2010) reported no statistically significant difference between the two bracket systems for the alignment of both maxillary and mandibular arches. Although, Wahab et al. (2012) published a randomised clinical trial recently and reported that conventional brackets had a statistically significant higher rate of teeth alignment compared with the self-ligating brackets during the first 4 weeks, the authors failed to confirm this finding for the full alignment period suggesting no difference between the two groups in the rate of alignment.

Pandis et al. (2010) undertook an interesting randomised clinical trial to compare between active and passive self-ligating bracket systems in the alignment of maxillary arch. Seventy patients with non-extraction treatment plan were randomised into one of the study groups. The authors reported no statistically

significant difference between the two self-ligating bracket systems in the duration of alignment.

It is interesting to note that the mean duration to align the mandibular arch reported by Scott et al (2008) was 243 days (conventional brackets) and 253 days (self-ligating brackets) was more than double the mean duration reported by Pandis et al (2007) for both conventional (114 days) and (91 days) self-ligating systems and Pandis et al. (2010) for the passive and active ligating bracket systems (101 days). This variation may be due to the disagreement between the two studies on the standard for completion of the alignment stage. Pandis et al. (2007) and Pandis et al. (2010) used visual judgment while Scott et al. (2008a) decided that 0.019x0.025 inch stainless steel arch wire had to be inserted passively before the alignment stage is considered to be finished.

Table 15 Studies that investigated the alignment efficiency of self-ligating bracket systems.

	Design	**Type of brackets**	**Participants**	**Slot size (inch)**	**Duration**	**Statistical difference in duration of alignment**
Hamilton 2008	Retrospective	Active self-ligation vs. conventional brackets	762 patients (upper and lower arches)	Not known	15.7 months	No significant difference
Scott 2008	RCT	Passive self-ligation vs. conventional brackets	62 patients mandibular arch	0.022	243 CLB and 253 SLB days	No significant difference
Fleming 2009	RCT	Active self-ligation vs. conventional brackets	66 patients mandibular arch	0.022	8 weeks (1 visit)	No significant difference in rate of alignment
Ong 2010	RCT	Passive self-ligation vs. conventional brackets	50 patients maxillary and mandibular arches	0.022	20 weeks duration	No significant difference
Miles 2005	Prospective clinical trial	Active self-ligation vs. conventional brackets	58 patients mandibular arch	0.022		No significant difference
Miles 2006	Split mouth design	Passive self-ligation vs. conventional brackets	60 patients mandibular arch	0.022	20 weeks	No significant difference
Pandis 2010	RCT	Active & passive self-ligation brackets	70 patients maxillary arch	0.022	101 days	No significant difference
Wahab 2012	RCT	Passive self-ligation vs. conventional brackets	29 patients maxillary and mandibular arches	0.022	4 months	No significant difference
Pandis 2007	RCT	Passive self-ligation vs. conventional brackets	54 patients mandibular arch	0.022	114 CLB and 91 SLB days	No significant difference

2.1.1.3.6. Laceback

Laceback were first introduced by McLaughlin and Bennett to be used with the pre-adjusted edgewise appliance as it was though that the tip built in the brackets can procline anterior teeth during alignment and levelling leading to “round tripping of the anterior teeth”.

Irvine et al. (2004) undertook a randomised clinical trial to investigate the effect of lacebacks during alignment stage on the position of anterior and posterior teeth in the maxillary and mandibular arches. Sixty-two patients were recruited and randomly allocated to either the laceback group or control (no laceback). The authors investigated the time taken from the first archwire until the placement of the 0.018 stainless steel archwire where they assumed complete alignment of the anterior teeth. There was no statistically significant difference in the duration of treatment between the two study groups nor the position of the anterior teeth. It is interesting to note that although all participants in this study had premolar extractions the authors evaluated the amount of alignment by measuring crowding before and after the experimental duration. This method may not be considered a measure of alignment.

Only one study investigated the influence of lacebacks on the alignment stage duration, this was not the main outcome for the trial. The measurement of crowding was not the considered to be the appropriate measure for the alignment stage. This

may suggest that there is no sound evidence to evaluate the influence of laceback on the levelling and alignment duration.

Other factors that can influence the duration of treatment

Other factors may have an impact on the duration of treatment but were not investigated. This may include the use of advanced technology and non-conventional interventions to accelerate tooth movement and reduce the duration of treatment, which may include surgical interventions e.g. corticotomy and non-surgical interventions e.g. medication and Laser therapy (Bartzela et al., 2009, Long et al., 2013).

2.1.2. Orthodontically Induced Inflammatory Root Resorption OIIRR

Orthodontic treatment may have some biological side effects that may result from tooth movement or the physical presence of the orthodontic appliances on the tooth structure. These side effects could be called iatrogenic seqeualae of orthodontic treatment. This may include orthodontically induced inflammatory root resorption, loss crestal alveolar bone height and decalcification of the enamel structure. In the current study I will focus on OIIRR as a biological side effect of orthodontic treatment as it can be detected in the levelling and alignment stage.

Root resorption is defined as erosion of cementum and/or radicular dentine (Henry and Weinmann, 1951). It is a universal term that describes a process of multi-factorial aetiology. Root resorption can occur in individuals who have not had orthodontic treatment; a natural phenomenon of unknown cause called idiopathic root resorption. It had been reported in varying incidence with higher concentration towards the apex of the root (Henry and Weinmann, 1951, Han et al., 2005, Sogur et al., 2008).

Bishara et al. (1999) investigated the changes in root length in a longitudinal study of subjects between 25 and 45 years of age from orthodontically untreated population. They reported that there was no significant radiographic change in root lengths. This indicates that there is no radiographically detectable natural root shortening that takes place between early and mid-adulthood.

Root resorption can be classified into external and internal root resorption and or to surface root resorption, inflammatory resorption and replacement resorption (Tronstad, 1988). Generally, root resorption after orthodontic treatment is surface resorption or transient inflammatory resorption (Tronstad, 1988, Brezniak and Wasserstein, 1993). In the beginning of the last decade root resorption related to orthodontic treatment was termed by Brezniak and Wasserstein (2002) as "Orthodontically Induced Inflammatory Root Resorption".

Incidence

OIIRR is a common iatrogenic consequence of orthodontic treatment (Brezniak and Wasserstein, 1993). The reported incidence of OIIRR varies widely between investigations, which can be explained by the difference in the detection methods between studies. The incidence of OIIRR detected in ultra-structure studies is high reaching more than 90% of the treated teeth (Harry and Sims, 1982 and Han et al., 2005). However, radiographic studies had identified OIIRR with an incidence up to 73% using periapical and panoramic radiograph (Weltman et al., 2010). Recently published Cone beam CT studies reported OIIRR incidence ranging from 69% to 94% (Lund et al., 2012, Dudic et al., 2009).

It has been reported that the average amount of apical OIIRR in a tooth is less than 2.5 mm through a full period of comprehensive fixed orthodontic treatment (Linge and Linge, 1991b, Weltman et al., 2010). Severe OIIRR with more than 4mm or third of the root length is seen in 1% to 5% of teeth (Mirabella and Artun, 1995a, Weltman et al., 2010). Maxillary teeth are more sensitive to OIIRR than mandibular teeth (Kaley and Phillips, 1991, Weltman et al., 2010); whilst

Sameshima and Sinclair (2001a) reported that maxillary teeth were more severely affected than mandibular teeth by a factor of nearly two. It has been suggested that OIIRR of clinical significance is found in the anterior segment as the incisors are the teeth most affected by OIIRR in the maxillary arch (Harris and Baker, 1990, Sameshima and Sinclair, 2001a).

2.1.2.1. Factors that may influence OIIRR

In 1927, Ketcham published a striking report about apical root loss after orthodontic treatment where he used dramatic phrases that attracted the attention of the orthodontic society to OIIRR as an iatrogenic effect of orthodontic treatment (Ketcham, 1927). Since then, hundreds of studies had been undertaken and published trying to predict and identify the aetiology of OIIRR. It has been reported that several factors can influence OIIRR including patient related factors, treatment factors and combined aetiologies (Brezniak and Wasserstein, 2002, Sameshima and Sinclair, 2001a, Weltman et al., 2010).

2.1.2.1.1. OIIRR and patient related factors

2.1.2.1.1.1. Age

It has been suggested that the periodontium of adults is different in structure to that of adolescents (Weiss, 1972). Both cell population and vasculature are reduced in the adult periodontal ligament where a noticeable reduction in the number of fibroblasts and osteoblasts as well as cementobalasts had been reported (Grant and Bernick, 1972). This may explain the extended hyalisination period reported in adults during tooth movement (Weiss, 1972). Despite of the differences in

histological features due to age, clinical studies investigating the effect of age on OIIRR reported variable findings.

Harris and Baker (1990) conducted a retrospective study primarily designed to study the pattern of OIIRR in female adolescents (mean age 12years) and adults (mean age 27 years) with Class II division 1 malocclusions. The authors found no statistically significant difference in the severity of OIIRR between the two groups after orthodontic treatment. In this study OIIRR was investigated among anterior and posterior teeth using lateral cephalometric and orthopantomogram (OPT) radiographs, respectively. This may undermine the value of results reported as the types of radiographs used may not allow accurate evaluation of the severity of OIIRR among the teeth studied (Sameshima and Sinclair, 2001a).

Mavragani et al. (2002) conducted a retrospective study designed to investigate root length change in relation to the age of the patient and the developmental stage of the root in orthodontic patients using periapical radiographs. They reported that pre-treatment age was statistically significantly higher among patients showing root shortening in the maxillary lateral incisors. This difference was found to be not statistically significant in the maxillary central incisors. Moreover, the authors reported that most maxillary incisor teeth with incomplete root formation had statistically significant longer roots at the end of treatment when compared to teeth with complete root formation. This finding agrees with Hendrix et al. (1994) who suggested that teeth with incomplete root formation have a higher resistance for root resorption. Both studies recommended orthodontic treatment before complete root formation.

The studies by Harris and Baker (1990) and Mavragani et al. (2002) are the only two investigations found in the literature with a primary aim to study the effect of age on OIIRR. Harris and Baker (1990) used choronological age only, while Mavragani et al. (2002) used both choronological age and dental developmental to study their effect on OIIRR. The results of the two studies did not agree which can be explained by the different types of radiographs used for assessment. Harris and Baker (1990) used lateral cephalometric radiographs and OPTs to investigate OIIRR in anterior and posterior teeth, while Mavragani et al. (2002) used periapical radiographs for maxillary incisors. This makes the comparison between the results of the two studies difficult.

Several radiographic studies were conducted to identify and predict the factors that might influence OIIRR using multiple regression analysis. Most of these studies agreed that age has no significant effect on the severity of OIIRR (Linge and Linge, 1991a, Artun et al., 2009, McFadden et al., 1989). In contrast,Linge and Linge (1983) reported a high correlation between age and OIIRR in their retrospective radiographic study with a large sample size (719 patients). However, the authors used the same material after excluding patients who were less than 11.5 years pre-treatment in a later publication(Linge and Linge, 1991a) and it is interesting to note that the reduced sample (485 patients) altered the findings whereby age had no effect on the severity of OIIRR. Their results agree with Mavragani et al (2002) findings (mentioned in the previous paragraph) who reported that the group with no root shortening was younger (median 11.5 years) as compared with the group with root shortening (median 12.8 years).

Severe OIIRR (more than 5mm in at least one tooth) occurs rarely; Linge and Linge (1983) and Mirabella and Artun (1995a) reported an incidence of 2% and 5% for severe OIIRR in adolescents and adults, respectively. This minimal difference can suggest that there is no clinical significant difference in server OIIRR between the two age groups.

It can be concluded from the available evidence that chronological age is not a factor that can significantly influence OIIRR. However, there is a lack of studies in the literature that are designed primarily to investigate the effect of age on OIIRR. Nevertheless, it seems that teeth with incomplete root formation may suffer less OIIRR. However, this suggestion does not have clear clinical implications as complete root formation occurs at different timings for different teeth.

2.1.2.1.1.2. Gender

As a baseline, it is worth mentioning that Bishara et al. (1999) reported no statistically significant difference in root length between males and females in a 26-year cohort study conducted on participants with no previous orthodontic treatment.

It has been reported in the literature that females represent a higher percentage of orthodontic patients than males (Harris and Glassell, 2011, Kerosuo et al., 2000). Gender as a patient-related diagnostic factor has been studied as a variable in several studies designed to identify the predisposing factors that can influence

OIIRR. However, no studies have been conducted with a primary aim to compare the severity of OIIRR in females and males.

Most studies concur that gender has no effect on either the severity of OIIRR, including radiographic and ultra-structure studies with a wide range of sample sizes ranging from as small as 4 patients to 1049 patients. In contrast, few studies reported significant difference in the severity of OIIRR between males and females (Horiuchi et al., 1998, Sameshima and Sinclair, 2001a, Kjaer, 1995b, Linge and Linge, 1991b, Newman, 1975).

Horiuchi et al. (1998); Newman (1975) and Kjaer (1995b) suggested that females are more susceptible to OIIRR than males. However, results from these studies should be interpreted with caution. Horiuchi et al. (1998) investigated OIIRR using lateral cephalometric radiographs which may not be accurate enough to study root OIIRR(Sameshima and Asgarifar, 2001). Using full mouth periapical radiographs Newman (1975) reported that the female to male ratio for patients with moderate to severe OIIRR from a sample was 3.7: 1. It is important to note that the authors did not describe the gender distribution in their original sample which may had an impact on their results if the majority of the original sample were females inducing sample bias. In other words, a comparison between the percentages of each gender with moderate to severe OIIRR would have been more representative.

In contrast, Spurrier et al. (1990) reported more OIIRR in males than females in a study designed to compare apical OIIRR in endodontically treated teeth and vital

control teeth. A statistically significant difference was only detected in the control group i.e. vital teeth.

From the evidence available it seems that the majority of studies, especially with large sample sizes had found that gender does not have a substantial impact on the severity or pattern of OIIRR (Sameshima and Sinclair, 2001a, Weltman et al., 2010). Despite of the existence of very few studies that suggest that gender may influence the severity of OIIRR, it seems that these studies could not agree which gender is more susceptible to OIIRR. Clinical trials with primary aim to study the effect of gender on OIIRR may be needed to confirm such suggestion.

2.1.2.1.1.3. Ethnicity

Only one study was found in the literature investigating the effect of ethnicity on OIIRR (Sameshima and Sinclair, 2001a). Using a large sample size (868 patients) the authors compared the severity of OIIRR among three ethnic groups: Asian, white and Hispanic. Full mouth periapical radiographs were used to evaluate the severity of OIIRR. Asians were found to have a lower risk for OIIRR than white and Hispanic ethnic groups.

2.1.2.1.1.4. Genetics and individual susceptibility

The clinical manifestation of OIIRR is highly variable between orthodontic patients (Weltman et al., 2010). Individual susceptibility has been suggested as the “hidden player” in several studies investigating the factors that can influence OIIRR (Marques et al., 2010, Artun et al., 2005, Smale et al., 2005). Despite of the assumption that genetics might be a first line suspect for OIIRR (Weltman et al.,

2010), only few studies have investigated this (Al-Qawasmi et al., 2003, Harris et al., 1997).

Familial clustering of OIIRR has been suggested by Newman (1975). A few years latter Harris et al. (1997) in a unique study design explored the hypothesis of the genetic influence on OIIRR; and a high heritability (h2=70%) was reported. Moreover, Al-Qawasmi et al. (2003) designed a study aimed at recognising the gene that is responsible for OIIRR. The authors reported that gene IL-1B significantly increased the risk of OIIRR. However, it was mentioned that this gene did not account for all or nearly all of the difference among patients at risk of OIIRR.

These studies indicate that more genetic-based studies are required to confirm the role of genetics in OIIRR and to help in recognising the patients with risk of OIIRR before orthodontic treatment is planned.

2.1.2.1.1.5. Systemic condition

The systemic condition of the orthodontic patient had been suggested to be an influencing factor for OIIRR. It was reported that asthmatic patients (medicated or non-medicated) may have an increased incidence of OIIRR (McNab et al., 1989; Owman-Moll and Kurol, 2000). Moreover, hormonal disease e.g. thyroid and para-thyroid had been suggested as one of the patient related factors that can increase the risk of OIIRR (Weltman et al., 2010, Poumpros et al., 1994). It has been suggested recently that bisphosphonate drugs for treatment of osteoporosis and bone tumours can reduce the severity of OIIRR. However, a recent systematic review was

designed to assess the effect of bisphosphonate on orthodontic patients stated that a debate exists between studies on the effect these drugs on OIIRR (Iglesias-Linares et al., 2010).

This may indicate that the medical systemic condition of orthodontic patients should be updated routinely to assess its influence on the effectiveness of orthodontic treatment and risk of OIIRR.

2.1.2.1.1.6. Dental anomalies

It is has been assumed that patients with dental anomalies may have an increased risk of OIIRR. The assumption probably is based on the fact that cementum and dentine are affected during the tooth formation process; thus possibly reducing the ability of the cementum and dentin to resist resorption in situations with exertion of pressure (Seow and Hackley, 1996).

Kjaer (1995b) and Lee et al. (1999) designed two retrospective studies to investigate the effect of dental morphological anomalies on the severity of OIIRR. Although, Kjaer (1995b) reported that presence of dental anomalies may lead to increased risk of severe OIIRR, the results from Lee et al. (1999) study did not agree.

Kjaer (1995a) collected a study sample by asking orthodontists involved in the study to send records of patients who were reported to suffer from severe OIIRR after orthodontic treatment. This method of sample recruitment may have resulted in selection bias, which could have influenced the results. The sample size was

reported as 107 participants; however, only 54 patients had complete radiographic material; which may indicate a small sample size in the absence of power calculation. Moreover, the radiographic measurement method of OIIRR was not standardised, as some of the measurements were taken from OPT and others from periapical radiographs. It was also noticed that no statistical tests were demonstrated in the publication to support the claimed conclusions.

Lee et al. (1999) undertook a retrospective trial, but with additional measures to reduce bias compared to Kjaer (1995b) study: 1) a larger sample size consisting of 84 consecutive patients with dental anomalies and 84 patients without anomalies (control group), 2) measurements taken from periapical radiographs and 3) investigators were masked to study groups when collecting data from the study radiographs. As a result, the risk of bias was considered to be relatively lower.

In addition, Kook et al. (2003) undertook a retrospective study to examine the pattern of OIIRR among peg shaped, small lateral incisors and normal shaped lateral incisors. The authors reported that there was no statistically significant difference in the severity of OIIRR between the peg shaped lateral incisors and normal shaped lateral incisors (1.09 and 0.88mm respectively). On the contrast a statistically significant difference in the severity of OIIRR between small lateral incisors (1.03 mm) and normal lateral incisors (1.62 mm) was found. However, this mean difference in OIIRR may be considered clinically insignificant, as this small difference could have developed due to measurement method error which was not investigated in this study.

From the available weak evidence, it can be concluded that there is insufficient evidence to suggest that dental abnormalities are a high risk for OIIRR.

2.1.2.1.1.7. Root morphology

Root morphology has been regarded as a risk factor for severe OIIRR by several studies (Linge and Linge, 1991a, Mirabella and Artun, 1995b, Marques et al., 2010). However, all these investigations were retrospective studies. In addition, the prevalence of abnormal root shapes among the samples studied varied between the studies; ranging from as low as 2.7%(Sameshima and Sinclair, 2001a) to as high as 31.5% (Marques et al., 2010). This can be explained by the difference in defining abnormal root shape by different investigators.

Brin et al. (2003) reviewed the records of patients of a previously designed randomised control trial investigating OIIRR in Class II malocclusion; with one- versus two-phase treatment protocols using OPT and post-treatment periapical radiographs. The authors suggested that teeth with abnormal root morphology were only slightly at risk of moderate to severe OIIRR; although, the results were not statistically significantly different. Recently, Artun et al. (2009) undertook an adequately designed prospective clinical trial involving 267 subjects to identify orthodontic patients at risk of severe OIIRR. The authors reported no statistically significant association between severe OIIRR and abnormal root morphology in the maxillary central incisors, however a significant association was found in the lateral incisors.

It is interesting to note that Weltman et al. (2010) in their published systematic review included only the results from Brin et al. (2003) study to investigate the effect of abnormal root morphology on OIIRR, as the study was considered to be of low risk of bias. Although the results reported from Brin et al. (2003) study were not statistically significant, it is surprising that Weltman et al. (2010) suggested that there is evidence that abnormal roots may be at slightly higher risk of moderate to severe risk for OIIRR when compared to normal roots. Moreover, Weltman et al. (2010) did not high light the error that might had influenced the results reported by Brin et al. (2003) due to the assessment of root morphology using OPT radiographs.

It is worth mentioning that the systematic review (Weltman et al., 2010) was submitted for publication before the article by Artun et al. (2009) was published.

It seems from the available studies reported in the literature that there is not enough evidence to support the proposition that abnormal root morphology has an impact on the severity of OIIRR.

2.1.2.1.1.8. Trauma

Traditionally, it has been accepted that all teeth with previous trauma are more susceptible to OIIRR than healthy control teeth. This was mainly based on retrospective studies (Brin et al., 1991, Linge and Linge, 1991b). However, other studies reported no statistically significant differences in the pattern of OIIRR in traumatised teeth when compared to control teeth (Brin et al., 2003, Malmgren et al., 1982).

Weltman et al. (2010) reported in their systematic review that the randomised clinical trials by Brin et al. (2003), Mandall et al. (2006) found that incisors with a history of trauma (but no signs of root resorption at the beginning of treatment) had the same prevalence of OIIRR as those without trauma.

In consequence, there is no sufficient evidence to support the suggestion that traumatised teeth are more prone to OIIRR. However, studies agree that traumatised teeth with root resorption before orthodontic treatment may have a higher risk of severe OIIRR during orthodontic treatment (Malmgren et al., 1982) (Levander et al., 1994).

2.1.2.1.2. Type and severity of malocclusion

The type and severity of malocclusion may have an impact on the outcome of orthodontic treatment (Vig et al., 1990), and whether this influences the severity of OIIRR is a question that only a few orthodontists tried to investigate.

Taner et al. (1999) designed a retrospective study to evaluate the severity of OIIRR in Class I and Class II division 1 extraction cases. The authors reported that the amount of root resorption was statistically significantly greater in Class II division 1 subjects when compared to those with Class I malocclusion. The mean difference in the amount of OIIRR between the types of malocclusion was 1mm. It is worth mentioning that Taner et al. (1999) used lateral cephalometric radiographs to measure the amount of OIIRR; which is not the ideal method recommended for measuring OIIRR (Sameshima and Asgarifar, 2001).

Kaley and Phillips (1991) undertook a retrospective radiographic study, where 200 consecutive completed cases were investigated for severe OIIRR. Twenty-one patients were found to suffer from severe OIIRR (more than 25% of the root length). Matched controls from the original sample were compared with the group suffering from severe OIIRR. Although the sample size was small, the authors reported that there was statistically significantly more Class III cases in the experimental group suffering from severe OIIRR. This finding has to be interrupted with caution due to the small sample suffering from severe OIIRR which may not allow sound statistical comparison.

Several retrospective studies (Sameshima and Sinclair, 2001a, Mirabella and Artun, 1995a, Harris, 1992) using multiple regression analysis reported that different types of malocclusions do not have a significant impact on the severity of OIIRR. Although, Taner et al. (1999) and Kaley and Phillips (1991) reported a higher risk of severe OIIRR in Class II division 1 and Class III malocclusions, respectively; the use of lateral cephalometric and panoramic radiographs in these studies may undermine the validity of the reported results.

Several orthodontists have recommended that specific features of different types of malocclusion may be considered risk factors. The most common feature associated with OIIRR is the increased overjet in Class II division 1 malocclusion and the need for horizontal tooth movement throughout orthodontic treatment. This will be discussed in more detail in the treatment factors influencing OIIRR section (2.1.2.1.3.3. Direction and type of tooth movement).

To summarise patient related factors may play an important role in the influence of the severity of OIIRR. However, this role may be more related to individual susceptibility and genetics rather than to the patient's demographics, root shape and type of malocclusion.

2.1.2.1.3. Treatment related factors

2.1.2.1.3.1. Treatment duration

The duration of treatment has been considered by some clinicians as one of the key variables that influences OIIRR i.e. severe root resorption is more likely for patients with longer treatment time (Sameshima and Sinclair, 2001b, Segal et al., 2004, Goldin, 1989). Harris and Baker (1990) suggested that there might be a threshold time at which the dynamic process is overwhelmed and significant resorption take place. Goldin (1989) reported that the amount of apical root loss during treatment is 0.9 mm/year, whereas Pandis et al. (2008) reported that the duration of treatment (independent of the fixed appliance type) is a significant predictor for OIIRR; with an average of 0.03 mm per month.

On the contrast, few radiographic studies failed to find any significant correlation between the duration of treatment and OIIRR (Baumrind et al., 1996, Mirabella and Artun, 1995b, Dermaut and Demunck, 1986).

On a different aspect, several ultra-structure studies found a correlation between the duration of orthodontic treatment and OIIRR (Harry and Sims, 1982, Stenvik and Mjor, 1970). However, it is important to mention that the experimental duration

applied in the microscopic studies (1-7 weeks) do not represent the normal length of duration for orthodontic treatment.

Systematic reviews would be expected to resolve an apparent debate in the literature; but only if the conclusions from these reviews agree. One systematic review (Segal et al., 2004) using meta-analysis suggested that total treatment duration is highly correlated with mean OIIRR. It is worth mentioning that all the included studies in the meta-analysis were retrospectively designs. A more recent systematic review (Weltman el al., 2010) applied strict inclusion criteria but did not report the duration of treatment as one of the factors that can influence OIIRR. It is interesting to note that the inclusion criteria applied by Weltman et al. (2010) were strict enough to exclude the retrospective studies that Segal et al. (2004) used to construct their meta-analysis that suggested that treatment duration is highly correlated with OIIRR.

The increased duration of treatment can be caused by several factors including complex treatment plans, lack of patient co-operation e.g.: patients missing appointments. Although, both factors can result in extended treatment duration, the influence of each on OIIRR might be different, for example, failed appointments will result in a relatively inactive appliances or decayed orthodontic forces, which can be different from active prolonged treatment duration with regular visits (Sameshima and Sinclair, 2001b). It is worth considering these factors when determining the influence of the duration of treatment on OIIRR.

There is a debate in the literature about the influence of the duration of treatment on the severity of OIIRR however, there is no strong evidence available to support that increased treatment duration can cause increased OIIRR.

2.1.2.1.3.2. Force magnitude

No orthodontic force can imitate the natural harmless physiologic force (Brezniak and Wasserstein, 2002). The magnitude of orthodontic forces is believed to be an important factor, not only for the amount of the tooth movement but also for any iatrogenic tissue damage. It is accepted that high force levels will cause increased damage to the dentoalveolar tissues (Kurol and Owman-Moll, 1998).

The optimum force necessary for physiologic tooth movement has long been debated (Ren et al., 2003). Schwarz (1932) suggested that the optimum force ranges between 20 and 26 gm/cm^2 and any applied force exceeding this level causes periodontal ischemia, which can lead to root resorption (Brezniak and Wasserstein, 1993).

It is interesting to note that there are no clinical radiographic studies in the literature that have investigated the influence of force magnitude on OIIRR. However, Costopoulos and Nanda (1996) with a prospective radiographic design study used a light force (15g per tooth) for intrusion of upper incisors using Burstone-type mechanics. The authors reported that intrusion using low forces can be effective in reducing overbite while causing only a negligible amount of apical root resorption (0.6mm) compared to a matched orthodontically treated control group (0.4mm) and this difference was statistically significant but not clinically

significant. The authors recommended further investigations to study the optimum force level that can result in minimal OIIRR.

Six split mouth randomised controlled studies had compared the effect of heavy and light forces on the pattern of OIIRR using volumetric microscopic analysis (Harris et al., 2006, Chan and Darendeliler, 2005, Chan and Darendeliler, 2006, Darendeliler et al., 2004, Barbagallo et al., 2008, Cheng et al., 2010). These studies were conducted by the same research group where the same magnitudes of heavy and light forces were applied (225g and 25g respectively). However, direction of tooth movement was not the same in all studies as most studies used buccal forces, while Harris et al. (2006) used intrusive forces. All these studies reported a statistically significant increase in the pattern of OIIRR in the heavy force group when compared to the light force group.

Faltin et al. (2001)in a transmission electron microscopy study applied a different range of intrusive forces (light =50g and heavy=100g). Although, the difference between the light and heavy forces is not clinically comparably large, the results of the study agreed with findings from the six volumetric analysis studies mentioned above.

These ultra-structure studies found that there is a statistically significant increase in the pattern of root resorption in all experimental groups (heavy and light forces) when compared to the control. The increase in the pattern of root resorption was reported in the heavy force group to range from 4 to 11.59 times that of the control, while in the light force ranged from 2 to 6 times that of the control. An exception to

these finding was reported by Chan and Darendeliler (2006) who found no statistically significant increase in the pattern of root resorption in the light buccally applied force when compared with the control group.

Moreover, Harry and Sims (1982) through a scanning microscopic study reported that the distribution of resorbed lacunae was directly related to the amount of stress using intrusive force on the root surface and the rate of lacunae development was more rapid with increasingly applied forces.

The available good quality evidence indicates that force magnitude can influence the pattern of OIIRR. However, this evidence has to be interpreted with caution because it is based on randomised clinical trials where the duration of applied force is relatively short ranging from 3 to 8 weeks. This duration does not simulate the average duration of orthodontic treatment.

2.1.2.1.3.3. Type of tooth movement

Orthodontic treatment may require a combination of different types of tooth movements including tipping, bodily movement, torque, rotation as well as intrusion and extrusion. Parker and Harris (1998) suggested that different types of tooth movements may produce different mechanical stresses at varying locations within the root. However, it is difficult to clinically isolate and evaluate specific types of tooth movements.

Vertical tooth movement

Rudolph et al. (2001) designed an interesting study which was undertaken to determine the types of orthodontic tooth forces that can cause high stress at the root apex. A 3-dimensional finite element model of a maxillary central incisor, its periodontal ligament, and alveolar bone was constructed on the basis of average anatomic morphology. The material properties of enamel, dentine, periodontal ligament, and bone and five different load systems (tipping, intrusion, extrusion, bodily movement, and rotational force) were tested. The authors reported that intrusive force can induce OIIRR mainly because the root shape concentrates pressure at the conical apex. Due to the potential for the high stress levels, intrusion is a movement that could increase the risk of apical OIIRR (Costopoulos and Nanda, 1996).

Ultrastructure studies that investigated the effect of intrusive force on the root surface agreed that there is a significant increase in the pattern of OIIRR when compared to the control reaching up to 4 times that of controls (Faltin et al., 2001, Harry and Sims, 1982, Han et al., 2005, Harris et al., 2006). Moreover, the systematic review byWeltman et al. (2010) confirmed these findings by suggesting that there is strong evidence to indicate that intrusive movements can cause increased OIIRR.

Several radiographic studies have agreed with these ultrastructure findings, reporting that intrusive tooth movements resulted in increased OIIRR when compared to an untreated sample (Parker and Harris, 1998, Dermaut and Demunck, 1986). However, Costopoulos and Nanda (1996) reported a clinically insignificant

increase in the amount of OIIRR (0.4mm) in their intruded group [using light force (15g)] when compared to their control group, which was a random sample of orthodontic patients. It is interesting to note that most radiographic studies that have investigated the effect of the amount of intrusion movement on OIIRR have reported no statistically significant correlation (Dermaut and Demunck, 1986, Costopoulos and Nanda, 1996).

It is worth mentioning that all the ultrastructure studies reported statistically significantly increased amount of OIIRR after the application of different types of vertical forces (extrusion and intrusion). An exception was the effect of extrusive forces as reported by Han et al. (2005) to cause an insignificant amount of OIIRR compared to their control teeth particularly when light forces were used.

Horizontal tooth movement

Mirabella and Artun (1995a) undertook a retrospective study design with a large sample size (343 patients) to assess OIIRR using lateral cephalometric and periapical radiographs. A multivariant regression analysis found that the amount of root movement is a significant risk factor for OIIRR. However, the authors reported that the horizontal root movement had the major impact as the amount of vertical movement in the study sample was relatively small. The findings from another retrospective study (Sameshima and Sinclair, 2001b) using the same type of radiographs agreed with the results of Mirabella and Artun (1995a) as they reported that only horizontal root movement to be significantly associated with OIIRR. This can explain the suggestion that malocclusions with increased overjet are more susceptible to increased OIIRR (Taner et al., 1999).

Moreover, Segal et al. (2004) reported in a systematic review using meta-analysis that the total apical displacement was highly correlated with mean OIIRR.

It can therefore be concluded from the available literature that there is sufficient evidence from randomized control ultrastructure studies that intrusive tooth movement significantly increases the severity of OIIRR (Weltman et al., 2010). Interestingly, most radiographic studies have failed to support the correlation between the amount of vertical root movement (intrusion) and OIIRR, whilst several radiographic studies have reported that the amount of horizontal root movement is correlated with increased OIIRR.

2.1.2.1.3.4. Bracket design

Self-ligating vs. conventional bracket system

The use of self-ligating brackets has been relatively popular in the last decade. However, clinical trials have not yet supported a number of the claims made by the manufacturing companies. Few studies have investigated the influence of self-ligating brackets on OIIRR.

Blake et al. (1995) designed a retrospective comparative study to investigate the effect of active self-ligating bracket system (Speed 0.018-inch) versus conventional edgewise (0.018-inch) bracket system on OIIRR in maxillary and mandibular incisors using periapical radiographs. The authors decided to express the OIIRR pattern as the percentage shortening per tooth. No statistically significant

difference in the percentage of root shortening between the two study groups was found.

Two clinical trials were reported in the same year investigated the influence of a passive self-ligating bracket system on OIIRR (Pandis et al., 2008, Scott et al., 2008a). Pandis et al. (2008) conducted a cohort study designed to investigate the effect of a self-ligating bracket system (Damon 2) on the severity of OIRR in maxillary incisors using panoramic radiographs. The authors reported that self-ligating bracket system group experienced increased OIIRR relative to the conventional bracket system with a mean of 0.37 mm; although this difference was not statistically significant. It is worth mentioning that although measurements for root length was performed on OPT films, the authors managed to calculate the magnification factor. This was done by placing a periodontal probe tip that was attached to the film during exposure.

Scott et al. (2008a) conducted a randomized clinical trial to investigate the alignment efficiency of self-ligating (Damon 3 0.022-inch) and pre-adjusted conventional bracket systems. Sixty-two patients were randomly allocated to treatment with either type of bracket systems. A change in root length of the mandibular incisors was one of the secondary outcomes for the trial. The authors reported no statistically significant difference between the study groups. Although, only the alignment stage was investigated this can still inform clinicians about the influence of bracket systems on OIIRR. It has been reported in the literature that orthodontic patients with detectable OIIRR during the first few months of active

treatment are more likely to experience resorption later through treatment (Artun et al., 2005).

In agreement with results from the previously mentioned studies a recent prospective clinical trial investigated the severity of OIIRR using CBCT between self-ligating and conventional brackets during the aligning stage; no statistically significant difference in the amount of OIIRR between the study groups (Leite et al., 2012).

It can be concluded from the available evidence that self-ligating bracket systems (active and passive) do not have a significant influence on the severity of OIIRR during the alignment stage or even the full course of orthodontic treatment.

Edgewise brackets

Janson et al. (2000) undertook a retrospective study which was designed to compare the amount of OIIRR in three different types of bracket systems: standard edgewise system, pre-adjusted edgewise system and Bioefficient therapy system. The authors used the same archwire sequence for both edgewise systems (standard and pre-adjusted), while different sequence and types of archwires were used for the Bioefficient therapy system. The amount of OIIRR was evaluated by using a scoring system (Malmgren et al., 1982). The authors reported no statistically significant difference in the amount of OIIRR between the three groups.

Mavragani et al. (2000) conducted a retrospective study to radiographically compare OIIRR after orthodontic treatment with standard and pre-adjusted

edgewise technique in Class II division 1 malocclusion. The amount of OIIRR was investigated by measuring root length. The maxillary central incisors showed significantly more severe OIIRR in the standard edgewise group than the pre-adjusted edgewise group. However, there was no statistically significant difference in the amount of OIIRR in the maxillary lateral incisors between the two study groups. This difference in the respond of the maxillary central and lateral incisors was explained by the authors to be due to the difference in the stage of root development between the two maxillary incisors. However, the mean age for the sample studies was 13.8 years, where the root development in the maxillary incisors would be expected to be completed.

Mohandesan et al. (2007) undertook a prospective clinical trial to measure the amount of OIIRR during the first 6 and 12 months of treatment. As a secondary outcome the authors investigated the influence of gender and treatment related factors on the degree of OIIRR. Forty patients were recruited and were treated using either standard edgewise bracket system or to pre-adjusted edgewise bracket system; both with 0.022 bracket slot system. OIIRR was assessed by measuring the amount of root shortening using periapical radiographs. The authors reported increased amount of OIIRR in the pre-adjusted edgewise patients; however, the difference was not statistically significant.

Reukers et al. (1998) undertook a randomized clinical trial to compare the degree of OIIRR in standard and pre-adjusted edgewise bracket systems. The authors agreed with the results from Janson et al. (2000), Mavragani et al. (2000) that there

is no statistically significant difference in the degree of OIIRR between the two groups.

It can be concluded from the available literature that different types of study designs using different techniques to assess OIIRR agreed that standard and pre-adjusted edgewise bracket systems have no significant influence on the amount of OIIRR.

Begg vs. conventional edgewise

Begg and edgewise bracket systems have different philosophies for orthodontic tooth movement. Begg brackets with the tipping followed by torquing mechanics may lead to “round tripping” of teeth which was thought to increase the risk of OIIRR (Beck and Harris, 1994). On the other hand edgewise bracket system with the use of rectangular archwires and extra-oral appliances was thought to increase the magnitude of force creating a higher risk of OIIRR (Reitan, 1970).

However, Beck and Harris (1994) failed to detect a significant difference in the amount of OIIRR between the two bracket systems in Class I malocclusion extraction cases in anterior and posterior teeth using lateral cephalometric and panoramic radiographs. Moreover, Malmgren et al. (1982) reported no statistical significant difference in the degree of OIIRR between the two types of bracket systems after orthodontic treatment in traumatized teeth.

However, McNab et al. (2000) results did not agree with Beck and Harris (1994) and Malmgren et al. (1982). McNab et al. (2000) reported that patients who had

orthodontic treatment using Begg appliance had 2.3 times higher incidence of OIIRR in posterior teeth than patient treated with the edgewise appliance. This retrospective study was designed mainly to investigate the influence of appliance type on the degree of OIIRR. However, the use panoramic radiographs to assess OIIRR in this study may query the accuracy of the results.

2.1.2.1.3.5. Bracket slot size

Reukers et al. (1998) designed a randomized clinical trial to evaluate OIIRR in two edgewise bracket systems using digital reconstruction and subtraction radiology. Fifty nine patients with Class II malocclusion were randomly allocated to either standard edgewise bracket system with 0.018–inch bracket slot group or pre-adjusted edgewise (Roth prescription) with 0.022-inch bracket slot group. Moreover, twist flex archwires and closing loops were used with the 0.018-inch bracket slot system, while nickel titanium archwires and sliding mechanics were used with the 0.022-inch bracket slot system.

On a different aspect, Alexander (1996) in a retrospective study investigated the difference in the extent of OIIRR between continuous and sectional arch mechanics in Class I malocclusion. 0.018-inch bracket slot system was used with the sectional archwire group, while 0.022-inch bracket slot system was used with the continuous archwire group. Both bracket systems used were pre-adjusted edgewise with Roth prescription.

The authors of both reported no statistically significant difference in the degree of OIIRR between the 0.018-inch and 0.022-inch bracket systems. However, these

finding should be interpreted with caution as the bracket slot size was not the only variable investigated in these trials; i.e. other mechanical variables (confounding variables) were not matched in both groups. In other words the authors were comparing the influence of bracket system philosophies rather than bracket slot size on OIIRR.

In addition, Artun et al. (2009) conducted a prospective clinical trial to identify patients at risk of increased OIIRR; where almost 65% of the participants were treated with 0.022-inch bracket slot system and 35% were treated using 0.018-inch bracket slot system. The authors reported no significant difference in the degree of OIIRR between the two bracket slot systems. Moreover, the results from a large sample retrospective study (Sameshima and Sinclair, 2001b) agreed with the findings from the previously mentioned studies reporting no statistically significant influence of bracket slot size on the degree of OIIRR.

The absence of studies in the literature designed primarily to investigate the influence of bracket slot size on the degree of OIIRR may demand high quality evidence based research in this topic.

It can be concluded that that there is not enough evidence to suggest that a specific orthodontic appliance (design/slot) is superior to others in reducing the amount of OIIRR.

2.1.2.1.3.6. Archwire sequence

Mandall et al. (2006) designed a randomized clinical trial to evaluate three different archwire sequences and their influence on OIIRR, patient discomfort and time needed to reach the working archwire. First archwire sequenc: 0.016 NiTi, 0.018 x 0.025 NiTi and 0.019 x 0.025 SS; Second archwire sequence: 0.016 NiTi, 0.016 SS, 0.020 SS, 0.019 x 0.025 SS; Third archwire sequence: 0.016 x 0.022 CuNiTi, 0.019 x 0.025 CuNiTi, 0.019 x 0.025 SS. Prior Sample size calculation was done for the study allowing for recruitment of 40 patients in each group. All three groups were treated with pre-adjusted edgewise appliances with a 0.022-inch bracket slot size. OIIRR was assessed by measuring root shortening in mm of the upper left central on periapical radiographs. The authors reported no statistically significant difference in the degree of OIIRR between the three groups. This study was adequately designed and considered to have low risk of bias. It was the only study found in the literature to investigate the influence of archwire sequence on OIIRR.

Several studies investigated the effect of the use of different archwires on the degree of OIIRR as a secondary outcome. Mirabella and Artun (1995a) and Sameshima and Sinclair (2001b) reported no correlation between use of rectangular archwires and the degree of OIIRR. Moreover, Artun et al. (2009) in a prospective clinical trial reported no correlation between the use of square archwires and OIIRR.

2.1.2.1.3.7. Extraction vs. non extraction treatment

Several studies reported, through multiple regression analysis, that patients who underwent extraction therapy for orthodontic reasons had more OIIRR than those patients who had no extractions (Sameshima and Sinclair, 2001b, Mohandesan et al., 2007, Blake et al., 1995, Jiang et al., 2010). Moreover,Sameshima and Sinclair (2001b) reported that patients who underwent first premolar extraction therapy had more OIIRR than those patients who had no extraction or had only maxillary first premolars removed. McNab et al. (2000) reported in a retrospective that orthodontic extraction patients are 3.72 times more prone to increased OIIRR than orthodontic non-extraction patients. This was explained by assuming that extraction subjects generally require larger tooth movement and apical displacement to correct malocclusion which may cause more pressure on the root leading to increased degree of OIIRR. However, other studies did not agree with these suggestions reporting no statistically significant difference between extraction and non-extraction orthodontic treatment (Baumrind et al., 1996, McFadden et al., 1989, Brin and Bollen, 2011).

Roberto de Freitas et al. (2007) designed a retrospective study to evaluate OIIRR in open bite patients treated with extraction and non-extraction. Records of 120 patients were used in this study. The authors reported statistically significant increase in the amount of OIIRR in the patients treated with premolar extractions. This is the only study found in the literature that investigated the influence of extraction on OIIRR as a primary outcome.

Brin and Bollen (2011) undertook a retrospective study to compare the degree of OIIRR in Class I malocclusion patients who were treated with serial extractions and with late extractions. The authors reported no statistically significant difference in the degree of OIIRR between the two groups. This may contradict with the suggestions that some clinicians make by assuming that extraction may lead to more movement of teeth, which in turn may lead to increased risk of OIIRR. However, this study is considered to be at high risk of bias.

According to the available weak evidence no definitive conclusion can be made in reference to this controversial issue. This may suggest the need for high evidence randomised clinical trial to investigate the influence of extraction in orthodontic patients on OIIRR. It seems that several authors are relating extractions in orthodontics to the amount of tooth movement, although this may vary within different type of malocclusion.

In conclusion, there seem to be dozens of factors that were suggested to influence OIIRR. Although, hundreds of articles had been published in this area but with the majority described as having high risk of bias; each suggesting different factors that can influence OIIRR. Studies using multivariate analysis concluded that the explained variance of the parameters in the final prediction model is less than 20% (Artun et al., 2009). The systematic review published by Weltman et al. (2010) is a reasonable collation of the available evidence. Magnitude of orthodontic force and intrusive tooth movement are the only factors proven to increase the risk of OIIRR. However, patient individual susceptibility is believed to play an important role in the risk of OIIRR; more high quality research is needed to confirm this.

2.1.2.2. **Detection and quantification of OIIRR**

Different methods have been used for detecting and studying OIIRR including radiographic, histological and ultrastructure investigations (Brezniak and Wasserstein, 2002).

2.1.2.2.1. Microscopic investigations

Histological and ultrastructure microscopic techniques for studying OIIRR had proven to be much more accurate and precise than radiographic techniques. However, these laboratory techniques cannot be used as a clinical diagnostic tool, which limits these techniques to research purposes.

Scanning electron microscopy S.E.M is the technique of choice for studying root surface and quantifying OIIRR when compared to earlier methods that involved analysing conventional histologic sections (Han et al., 2005, Chan and Darendeliler, 2005). Early detection of small craters of root resorption can only be achieved by S.E.M. In 1972, Kvam (1972) employing scanning electron microscopy reported small marginal root resorptions on the pressure side in all 40 experimental premolars after 10 days of applying orthodontic force. After 25 days resorption lacunae with involvement of dentin were seen in all experimental teeth. Recent technology has introduced several software programs and techniques that allowed for acceptable accuracy for calculations of the surface area and volume of the resorption craters.

It is interesting to note that the majority of ultrastructure studies investigating the effect of orthodontic force on the root surface reported 100% of experimental teeth experienced OIIRR (Han et al., 2005, Chan and Darendeliler, 2006, Harry and Sims, 1982). This high incidence of OIIRR could not be detected using conventional radiography due to the 2 dimensional limitation of the technique.

2.1.2.2.2. Radiographic detection and diagnosis of OIIRR

Conventional radiographs are considered to be the most common clinical diagnostic method for detecting OIIRR due to its non-invasive and relative low dose radiation exposure. In most clinical studies, OIIRR assessment is done using either panoramic or periapical or lateral cephalometric radiographs. However, it has been reported by many authors that conventional 2 dimensional radiographs are not precise tools to accurately assess and quantify OIIRR (Brezniak and Wasserstein, 2002, Weltman et al., 2010). In radiographic images only apical root resorption can be assessed, whereas root resorption areas on the middle and cervical parts at the mesial and distal root surfaces are not detected unless they are extensive. Buccal and lingual root resorption defects are not visible with currently used imaging techniques (Brezniak and Wasserstein, 2002). Moreover, it has been reported that OIIRR after seven weeks of treatment, detected microscopically are not visible in conventional radiographs (Owman-Moll, 1995).

Panoramic radiography

The advantages of panoramic film are less patient chair time, less operator time, and better patient cooperation (Sameshima and Asgarifar, 2001). There are few known limitations with panoramic radiography; the quality of the image is

dependent on the correct patient positioning and the machine used (Leach, 2001). Taylor and Jones (1995) reported that 40% of panoramic films lacked the clarity needed to visualize the premaxilla. They suggested that supplemental images are needed in many cases.

Sameshima and Asgarifar (2001) demonstrated that OPT films overestimated the amount of OIIRR by 20% or more compared to periapical films. The difficulty in identifying the Cementoenamel junction was given as the main reason for inability to measure on panoramic films. The mean resorption measured on panoramic films (0.92mm) was almost double that measured on periapical films (0.48mm), this difference is statistically significant. However, it was reported that the least observed difference was in the maxillary incisor region. Moreover, the authors suggested that it is much more difficult to correctly assess root shape on panoramic films.

In contrast to the finding suggested by Sameshima and Asgarifar (2001), Dudic et al. (2009) reported that OIIRR might be underestimated by panoramic films when compared to CBCT. This disagreement between the two studies can be explained by: First: the use of different gold standard image in the two studies. Second: the difference in the method of assessing OIIRR; Dudic et al. (2009) assessed OIIRR using a scoring system while Sameshima and Asgarifar (2001) assessed OIIRR using linear measurement of the tooth length.

Despite of this controversy, it has been suggested that panoramic radiographs are still sufficient enough to make initial diagnosis(Sameshima and Asgarifar, 2001).

However, accurate assessment of OIIRR using panoramic radiographs cannot be assured.

Lateral Cephalometry

Several studies used lateral cephalomertic radiographs to diagnose and assess OIIRR (Brin and Bollen, 2011, Taner et al., 1999). Although, in these studies the authors reported high reliability of the method, the validity of the method was not investigated. This may query the results of studies using lateral cephalometry to quantify and assess OIIRR.

Periapical radiographs

Periapical radiograph provides a more detailed view of the alveolar bone and root when compared to conventional extra oral radiographs. Sameshima and Asgarifar (2001) reported that periapical radiographs are more superior for fine details and less distortion especially in measuring tooth length.

The periapical radiograph has been the most widely used method to assess OIIRR (Levander et al., 1994, Artun et al., 2005). This may suggest that it is the recommended type of radiograph to detect OIIRR clinically. However, some orthodontist would depend on panoramic or even lateral cephalometric radiographs to clinically assess OIIRR. That is because the later radiographs are more commonly requested as the pre-treatment radiograph (Atchison et al., 1992).

On the other hand, Dudic et al. (2009) designed a study to validate the diagnostic accuracy of periapical radiographs in detecting OIIRR. The authors used the micro-

computed tomography as the gold standard. The authors reported that the OIIRR detected using periapical radiographs were underestimated. The results of the study suggest the limited accuracy of periapical radiographs for detecting OIIRR.

In addition, Andreasen et al. (1987) in an experimental study done on autopsy material from 5 jaw blocks reported that periapical radiographs are not sensitive enough to detect small simulated resorption craters (0.6mm diameter and 0.3mm depth). It is interesting to note that in this study the authors reported that there was no statistically significant difference in the sensitivity of detecting simulated root resorption in the three thirds of the root.

Radiography remains the only method for detecting OIIRR clinically. Several experimental studies may query the validity of conventional radiography in accurately detecting and measuring OIIRR when compared to computed tomography. However, due to the increased radiation dose with three-dimensional imaging the recommended clinical tool for detecting OIIRR is periapical radiography (Dudic et al., 2009, Dudic et al., 2008).

Standardization of periapical radiographs

Assessing and quantifying OIIRR usually requires data to be collected from pre-treatment radiograph and an additional radiograph taken through or after orthodontic treatment. Assessing OIIRR necessities standardization of the periapical radiographs to reduce magnification, orientation and procedural errors. Different techniques have been applied in several studies for standardization of

periapical radiographs (Costopoulos and Nanda, 1996, Levander et al., 1994, Linge and Linge, 1983). This include using the same x-ray machine, the same type of film (or receptor), film holder, patient position and angulation of the x-ray tube. It had been reported that paralleling technique produce fewer projection and procedural errors than the bisecting angle technique (Reynolds, 1967).

Three dimensional imaging

Cone beam CT (CBCT) radiographs provide highly detailed three dimensional imaging and high diagnostic capability. The diagnostic ability of CBCT has been studied experimentally and clinically with agreement on the high sensitivity in detecting OIIRR (Dudic et al., 2009, Lund et al., 2012, Liu et al., 2010, Ponder et al., 2013, Yu et al., 2012).

Ponder et al. (2013) demonstrated that CBCT images can be used to more accurately measure simulated OIIRR defects than periapical radiographs. However, CBCT expose patients to less radiation dose when compared to conventional CT, still due to the relative increased radiation dose, CBCT cannot replace conventional radiographs as a routine diagnostic method. CBCT is of obvious use in research and in special clinical conditions that requires accurate information for decision making. It is important to note that the radiation dose varies between CBCT units and parameters used (Lund et al., 2010).

2.1.2.3. Methods of measuring OIIRR

Scoring systems

An ordinal scoring system was originally developed by Malmgren et al. (1982) to assess the degree of apical OIIRR. This scoring system involves a subjective grading of apical root resorption on x-rays according to a scale. The underlying principle about this scoring system is that it allows for comparison between serial radiographs. Moreover, it is considered to be clinically a simple and quick method of assessing the degree of OIIRR clinically. Since the development of this OIIRR scoring system it has been used extensively in radiographic studies and modified to be used in 3 CBCT studies(Lund et al., 2010, Levander et al., 1994, Beck and Harris, 1994).

Linear measurements of the root shortening

This method involves a linear measurement of the root length from radiographs, which is falsely assumed to be a precise quantitative outcome in millimeters. Specific calculations (correction factor) need to be done to overcome the magnification error that may occur in radiographs. Different approaches or techniques have been used in studies to decrease the potential for the magnification error using the correction factor equation. It was first described by Linge and Linge (1983) to calculate the amount of apical OIIRR depending on the ability to detect the cementoenamel junction and measure crown length as a fixed factor in an equation to calculate the amount of root shortening . It is important to note that this technique relies on the assumption that the first radiograph has no image distortion and accurate spotting of the cementoenamel junction.

Several modifications to the method suggested by Linge and Linge (1983) were used by some authors. Dermaut and Demunck (1986) thought that the accuracy of the landmarks needed for constructing formula for correction factor was not accurate. Rather than using of absolute change in root length, they decided to calculate the proportional changes in root length. It was not clear if this improved the accuracy of the outcome. Costopoulos and Nanda (1996) described the use of a constructed wire jig that was attached to the incisor tooth via an acrylic block that was fitted on the incisal edge. This method is thought to allow more accurate calculation of the magnification factor for the radiographs. Levander et al. (1994) used digital periapical radiographs to measure the distance from the root apex to the base of the bracket.

Digital reconstruction/ subtraction

A relatively new technique of digital reconstruction/ subtraction is used to assess the small changes in root length. This is applied by using computer software to calculate root length by measurements of pixels on digital radiographs. It is achieved from the superimposition of unaltered anatomic structures represented by complex radiographic patterns that conceal the pathologic process.

This method was shown to be more sensitive than conventional radiography in detecting simulated root resorption on dry human mandible (Eraso et al., 2007, Westphalen et al., 2004, Kravitz et al., 1992). However, several experimental studies reported no statistically significant difference in the detection of simulated root resorption between the digital radiographs and digital subtraction radiographs

for lesions as small as 0.5mm (Ono et al., 2011). Moreover, this method may be time consuming for clinical application.

2.1.2.4. Early detection of OIIRR during the levelling and alignment stage

The limited number of the identified treatment risk factors for OIIRR suggests that the major variation in OIIRR might be explained by differences in individual predisposition. Levander and Malmgren (1988)suggested that the first six to nine months of fixed orthodontic treatment can be used to identify patients of risk of severe OIIRR. This can allow the clinician to apply different protocols to reduce the severity of the progressing OIIRR.

The authors (Levander and Malmgren, 1988) designed a retrospective study including records for 98 consecutive patients. It was found that the number of teeth with severe resorption after treatment was statistically significantly higher in teeth with evidence of minor OIIRR at six to nine months from start of treatment than teeth without early signs of OIIRR. None of teeth that suffered severe resorption at the end of treatment were diagnosed as free from OIIRR at the 6-9 months radiographs. The authors highlighted the importance of taking radiographs through treatment to identify patients that can suffer from severe OIIRR at the end of treatment.

Recently, a properly designed multicentre prospective study was conducted to address the same hypothesis. The authors aimed at investigating the predictive

value of the amount of OIIRR at 6-12 months from starting treatment for resorption at the end of treatment. Two hundred and sixty seven orthodontic patients were enrolled in the study, where linear measurements from periapical radiographs using digital reconstruction technique were used to quantify OIIRR. The authors reported that the odds of severe post-treatment OIIRR (defined as at least one incisor with more than 5 mm of root shortening) is about 3 times higher in patients with more than 1 mm of resorption and about 15 times higher in patients with more than 2 mm of resporption on individual incisors after about 6 months of orthodontic treatment.

The evidence available suggests that early treatment radiograph 6-12 months from start of treatment can be valuable for the prediction of severe OIIRR at the end of treatment. This allows the clinician to minimise the amount to tooth structure loss by applying the proper clinical guidelines for management of OIIRR.

Management of OIIRR

According to Schwarz (1932) when the pressure decreases below the optimal force (20 to 26 gm/cm ^{2}) root resorption ceases and a new layer of cellular cementum is deposited to full fill the resorption craters. Levander et al. (1994) demonstrated that interrupting active orthodontic treatment by setting the appliance in a passive mode for 2-3 months can reduce the severity of OIIRR in patients with evidence of OIIRR at 6-9 months of start of treatment.

Many scientists reported that, clinically root resorption associated with orthodontic treatment usually cease once active treatment is terminated (Weltman et al., 2010). This is expected since progressive root resorption is tissue-pressure related. OIIRR

rarely results in significant morbidity after orthodontic therapy (Marques et al., 2011, Remington et al., 1989).

2.1.3. Assessment of levelling and alignment stage outcome

In the last few decades there has been an increased interest in assessing the quality of orthodontic treatment outcome. This is necessary for several reasons including: comparing the effectiveness of different treatment modalities, establishing standards for orthodontic treatment, and for the support of decisions made by health service policy makers (Bergström and Halling, 1997).

The assessment of orthodontic treatment outcomes was historically carried out using the subjective opinion and experience of clinicians. This has been superseded by objective assessment of treatment outcome (Dyken et al., 2001). The outcome of the orthodontic treatment can be evaluated in an objective manner using several methods including indices.

2.1.3.1. Little's irregularity index LII

Different types of indices (Table 16)have been developed in an effort to quantify and/or categorise the severity of malocclusion, treatment need, treatment complexity and treatment outcome for individual patients and for populations (Firestone et al., 2002). It has been suggested that ideal occlusal index should possess the following properties (Deguzman et al., 1995):

- Reliability
- Validity
- Amendable to modification

- Yield quantitative data
- Easy to use

Table 16 Example of different types and uses of occlusal indices used in orthodontics

Use of Indices	**Example of indices used**
Diagnostic classification	Angle classification British Standard Institute
Treatment need	IOTN
Severity of Malocclusion	PAR ABO(DI) Little's Irregularity Index
Complexity of treatment	ICON
Outcome of treatment	PAR ABO(OGS) Little's Irregularity Index

Development of LII:

Little's irregularity index was developed in 1975 by Robert Little as a method of quantifying teeth irregularity in the mandibular anterior teeth from study casts (Little, 1975) . The scoring method involves measuring the horizontal linear distance between the anatomic contacts of adjacent teeth in the anterior teeth from canine to the contralateral canine, ignoring the vertical displacement. The sum of these measurements represents the amount/severity of irregularity in the mandibular teeth. This measurement suggests the amount of horizontal distance that the teeth need to move to achieve anterior teeth alignment. Little suggested the

use of a dial calliper parallel to the occlusal plane with 0.1 mm accuracy to measure the irregularity of the teeth.

Moreover, Little (1975) investigated the validity of the LII by correlating the subjective rating of a group of orthodontics for the severity of irregularity of dental study casts with their scores of the LII. The authors reported a correlation coefficient of R=0.81 which indicated a favourable correlation suggesting the validity of the LII.

Modifications of LII

When Little (1975) first developed the LII it was used only for the mandibular teeth and mainly as a method to quantify the amount of teeth movement due to relapse. However, it was used later by several studies to measure teeth irregularity in the maxillary teeth (Wahab et al., 2012, Kerosuo et al., 2013). Furthermore, it was modified by several investigators to be used for measuring the irregularity of both the anterior and posterior teeth and was referred to as the Index of Tooth Alignment ITA (Jones et al., 1990, West et al., 1995).

Use of LII to evaluate orthodontic levelling and alignment stage

LII is not only used as an index for quantifying relapse by measuring teeth irregularity during and after orthodontic retention i.e. relapse (Rowland et al., 2007, Edman Tynelius et al., 2013) . Several studies used LII to investigate the effectiveness of treatment modality (e.g. archwires or bracket designs) in reliving the irregularity of anterior teeth (Ong et al., 2010, Fleming et al., 2009a). This was

done by scoring the teeth before treatment and after treatment to calculate the amount of improvement in the irregularity of the teeth.

The use of LII recently to assess irregularity of teeth using photographic images has been investigated (Almasoud and Bearn, 2010) . The authors reported that measurements of the LII from digital photographs are reliable and valid. However, measurements from clinical photographs for an individual patient assessment level should be set with caution. Moreover, the use of LII for assessing teeth irregularity from three dimensional study models using different types of softwares has proven to be valid and reliable (Goonewardene et al., 2008).

Limitations of LII

Little (1975) demonstrated that LII is a valid and reliable index that can be used to assess the irregularity of the teeth. Interestingly, he claimed that the LII could be also used for assessing crowding. However, it is important to note that irregularity of teeth is not necessarily associated with crowding. This may suggest that LII is not an index that can be used to assess the amount of crowding or arch length analysis.

Moreover, LII was designed to consider only the horizontal dimension of the irregularity between contact points while giving absolutely no weight to the vertical dimension of irregularity. Robert Little realized that limitation although he claimed that the vertical displacement of contact points may not affect the anterior arch length; however, he did not demonstrate his theory.

Macauley et al. (2012) designed a study to assess the repeatability of scoring irregularities using LII on maxillary study models. It was found that the reproducibility of the individual contact point displacement used to calculate the LII score was poor. The authors discouraged the use of LII as a tool to evaluate the performance of orthodontic appliances or treatment modalities.

2.1.3.2. Working archwire as a guide for the end of the levelling and alignment stage

Several studies used the LII to quantify the amount of arch irregularity in the maxillary or mandibular arch for pre-treatment study models as a baseline record; however they did not use the same index at the end of the levelling and alignment stage. Instead the working archwire method was used (Mandall et al., 2006, Ong et al., 2011).

Clinically the ligation of a stiff stainless steel working archwire may indicate the end of the levelling and alignment stage and the start of the space closure stage or correction of inter-arch relation. Several studies that assessed the effectiveness of alignment of orthodontic appliances used the ligation of the working archwire as a guide to mark the end of the levelling and alignment stage (Mandall et al., 2006, Ong et al., 2011).

For the 0.022-inch bracket slot system the levelling and alignment stage is complete with the engagement of a stainless steel rectangular wire of 0.019x0.025 inch into a correctly place pre-adjusted 0.022- inch bracket system (Mandall et al.,

2006); whilst the placement of a 0.016x0.022 inch stainless steel wire is believed to be an equivalent working arch wire for the 0.018 inch slot bracket system.

This method necessitates the ideal positioning of the orthodontic brackets to assume complete levelling and alignment of the teeth by the engagement of the working archwire. It is considered to a simulation of the “real life” clinical scenario that a clinician would follow to start the next stage in treatment after levelling and alignment. Moreover, it bypasses the limitation associated with the use of LII.

2.1.3.3. Alternative methods

Several studies that evaluated the effectiveness of alignment of different orthodontic appliances or archwires did not investigate the whole levelling and alignment stage (Evans et al., 1998, O'Brien et al., 1990, Dalstra and Melsen, 2004). Alternatively, periods ranging from few weeks to few months were used to assess the amount/rate of teeth movement. These studies used different techniques to assess the amount teeth movement; below are examples that were published in the literature:

- O'Brien et al. (1990) used three dimensional contact point displacement with respect to anatomical landmarks in the maxillary arch (palatal rugue). This was done before and after using the investigated aligning archwires.

- Evans et al. (1998) measured the displacement of incisal edges anteriorly whilst effectively measuring inter-bracket span posteriorly. The irregularity was then summed to give a sum of inter-tooth distances. The authors

explained that difference in technique between anterior and posterior teeth due to the relatively increased error in measuring contact point displacement in the posterior segment.

- Dalstra and Melsen (2004) used computer aided photographic analysis in a split mouth technique to measure irregularity on each side of the mouth before and after ligation of aligning archwires. A custom made plexiglass plate was fitted over the palate which had a grid of lines drawn on it to act as a land mark for measurements on the photographs

2.1.4. Patient perception of orthodontic treatment

Orthodontic treatment differs from most dental treatment because it is often based on patient demand for treatment, and the success of orthodontic treatment requires adequate patient cooperation (Skidmore et al., 2006, Kerosuo et al., 2002). This explains why an assessment of treatment efficiency needs to include patient-centred outcome measures (McNair et al., 2006).

2.1.4.1. Importance of assessing patient perception of treatment?

The assessment of quality of care has long been based on the application of professional standards. Recently there has been ad trend to include measurements of patient perception (Haddad et al., 2000). Obtaining patient perceptions can be less expensive and yet more reliable than other methods of assessing quality, such as peer review (Rosenthal and Shannon, 1997).

The information about patient perception of orthodontic treatment is considered to be useful because it can help healthcare providers to improve the quality of the service that they deliver and so better meet patients' perceived needs and expectation (Lee et al., 2008).

Part of obtaining "informed consent" for a patient considering orthodontic treatment must include giving full information about what the treatment involves, including the benefits and risks. Evidence based knowledge in treatment perception can help to provide patients with realistic expectations of the likely experience that will be encountered during orthodontic treatment, and thus can help in gaining true "informed consent".

2.1.4.2. Methods for assessing patient perception of treatment

Evaluating patient perception towards treatment can be done using several methods including different types of questionnaires and interviews. There are few advantages and disadvantages for both approaches (Table 17).

Table 17 Comparison between questionnaires and interviews as a method for collecting information about patient perception to treatment.

	Questionnaires	**Interviews**
Advantages	-Cheap and can be done by mail -Less time consuming	- Expensive to administrator - More detailed response
Disadvantages	-- Higher rejection rate - Less detailed information	May be susceptible to interviewer bias

Most of the studies published in the literature used questionnaires as a form of collecting data about patient perception (Zhang et al., 2008, Scott et al., 2008b) while few studies used different types of interview (Al Jawad et al., 2012). Several questionnaires have been developed to assess patient perception of treatment. Some of these questionnaires were only designed to assess pain and discomfort using a visual analogue scale VAS or verbal rating scale VRS (Huskisso.Ec, 1974). This system is readily understood by most patients and is reliable, demonstrating good sensitivity between small changes and good reproducibility (Feldmann et al., 2012, Scott et al., 2008b).

Other studies used quality of life related questionnaires which are validated and more extensive (Table 18). These questionnaires assess oral health-related quality of life, to provide an insight into how individual oral health status affects overall quality of life (Chen et al., 2010a, Locker et al., 2001, McGrath and Bedi, 2001, Jokovic et al., 2002). Most of these extensive questionnaires cover domains like functional limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and any handicaps. However, most of these questionnaires were designed to assess the impact of oral health and not oral appliances on the quality of life.

Several studies have used customised questionnaires to compare patient perception to different types of treatment approaches or appliances (O'Brien et al., 2003, Feldmann et al., 2012). The two studies used extensive customised questionnaires in randomized clinical trials to assess patient experience with different types of orthodontic appliances.

Table 18: Examples of questionnaires used to assess oral health impact on quality of life.

Oral Impact on Daily Performances (OIDP)
Child perception questionnaire (CPQ)
Oral health impact profile (OHIP-14)
United Kingdom oral health-related quality of life (OHQoL-UK)

Previous studies

Orthodontic patient perception had been investigated by assessing patient perception to malocclusion before treatment, to orthodontic treatment procedures

and appliances during treatment, and to treatment outcome after treatment. In this literature review I decided to focus on patient experience in wearing orthodontic appliances during treatment as this is more related to the study topic which is effectiveness of different orthodontic appliance.

2.1.3.4. Patient perception of wearing orthodontic appliances

It is widely known that orthodontic appliances occasionally cause discomfort and pain in addition to functional limitations and emotional disturbance which may affect day-to-day living or quality of life (Sergl et al., 2000).

2.1.3.4.1. Pain and discomfort

Several studies have reported on the prevalence, magnitude, and duration of pain and discomfort associated with several orthodontic procedures including teeth separation, initial archwire alignment, insertion of microscrews and debonding (Scott et al., 2008b, Farzanegan et al., 2012, Lee et al., 2008).

Most of the studies that assessed patient perception of different types of orthodontic brackets and archwires focused mainly on the initial stage of treatment ranging from the first hours to the first few weeks (Scott et al., 2008b, Mandall et al., 2006).

A Fair number of RCTs were published in the literature to evaluate the effectiveness of different types of orthodontic appliance, archwires and modalities of treatment, where patient perception was assessed (Fleming et al., 2009a, Scott et al., 2008b, Pringle et al., 2009, Miles et al., 2006).

Four prospective controlled clinical trials were conducted in the last few years to compare patient perception between different types of self-ligation brackets and conventional brackets (Fleming et al., 2009a, Scott et al., 2008b, Pringle et al., 2009, Miles et al., 2006). All four studies except Miles et al. (2006) were randomized clinical trials and used VAS system for scoring pain and discomfort during the first few weeks of treatment, while Miles et al. (2006) using split-mouth study designed and simply asked patients which side of the mouth had more pain than the other . The findings from the four studies conflicted with two studies reporting less pain in the self-ligation brackets compared to the conventional brackets during the first week while the two other studies failed to find any significant statistical difference. To solve this debate in the literature, a properly designed systematic review managed to undertake meta-analysis by merging the results of these studies (Fleming and Johal, 2010). It was found that there is no statistically significant difference between the two brackets systems in regards to pain and discomfort during the first week of treatment.

Four prospective controlled clinical trials (of which were 3 RCTs) were conducted to investigate the influence of different types of aligning archwires and archwire sequences on patient perception to pain. All studies investigated pain and discomfort during the first week of archwire placement using different types of questionnaires. Mandall et al. (2006) and Ong et al. (2011) used “likert scale” type of questionnaires, while Fernandes et al. (1998) used VAS and Jones et al. (1990) used VRS questionnaires . Although, different results were reported a recent well-designed Cochrane review found that different aligning archwires did not influence

patient perception in regards to pain and discomfort in the initial stage of treatment(Wang et al., 2010).

Most studies agreed that pain starts a few hours after ligating the initial archwire in a fixed appliance and peaks at around 24 hours returning to a minimal level after 5-7 days (Scott et al., 2008b, Fernandes et al., 1998, Erdinc and Dincer, 2004). However, few studies have found that pain lasts for longer periods and extends periodically through treatment after appliance adjustment appointments (Scheurer et al., 1996, Brown and Moerenhout, 1991).

A wide range of individual response was reported when the same magnitude of force was applied on the teeth (Erdinc and Dincer, 2004) . Most studies agreed that gender did not affect perceived pain or discomfort during orthodontic treatment (Jones and Chan, 1992, Ngan et al., 1989, Fernandes et al., 1998). However, Jones and Chan (1992) and Erdinc and Dincer (2004) reported significantly higher discomfort in adults than younger patients.

2.1.4.3.2. Quality of life

While many studies had only assessed the experience of pain and discomfort among orthodontic patients, only a few studies have investigated the influence of wearing orthodontic appliances on quality of life of patients during treatment. The later studies used more extensive and structured questionnaires to provide an insight into how individual oral health status affected overall quality of life (Chen et al., 2010a, Locker et al., 2001).

Zhang et al. (2008) undertook a prospective cohort study that included 217 patients receiving fixed orthodontic appliance therapy to assess their perception of orthodontic treatment. The authors used Child perception questionnaire (CPQ), which is an extensive quality of life questionnaire to assess patient's perception to treatment 5 times over a period of 6 months. It was found that there was a significant overall deterioration in the oral health related quality of life through the investigated period. The greatest deterioration occurred during the first week of treatment especially in the oral symptoms and functional limitations. This deterioration was at worst during the first week, but as the treatment progressed the deterioration was reduced. In contrast the emotional well-being of the participants improved as treatment progressed. Kadkhoda et al. (2011) in a recent study used the translated form of the same questionnaire CPQ in Iranian population and reported similar finding like Zhang et al. (2008) suggesting that OHQoL was deteriorated poor during orthodontic treatment with no significant difference between head gear and functional appliance wear.

Liu et al. (2011) in a recent study used a slightly larger sample size (232 orthodontic patients) than Zhang et al. (2008) for a more extended period of investigation up to 18 months to assess patient perception to orthodontic treatment. The authors used two questionnaires for the assessments of quality of life (OHIP-14 and OHQoL-UK). It was found that the quality of life for the patients was generally deteriorated significantly especially in the first stage of treatment; however some domains like social well-being were improved. Moreover, it is worth mentioning that the authors found that as treatment progress the detrimental effects to the oral health related quality of life were reduced. Interestingly, the two

questionnaires used did not agree in some of the domains. This may high light the influence of the type of questionnaire used on the results. Chen et al. (2010a) used the Chinese version of the OHIP-14 questionnaire and reported similar findings.

Bernabe et al. (2008) used a relatively large sample size (357 orthodontic adolescent patients) to assess the prevalence, intensity, and extent of the impacts on daily performances related to wearing different types of orthodontic appliances using Oral Impact on Daily Performances OIDP questionnaire. The authors found that one in every four adolescents undergoing orthodontic treatment reported side effects, specific impacts on daily living, related to wearing orthodontic appliances. Such impacts were higher among adolescents wearing fixed rather than removable or a combination of fixed and removable orthodontic appliances.

O'Brien et al. (2003) used the “Smiles Better” questionnaire to evaluate patient experience with different types of functional appliances (Twin Block and Herbst appliances). The questionnaire included functional, oral symptoms, social, appearance and global domains. The authors used the questionnaire once through the whole period of treatment and reported no significant difference between the two types of functional appliances. However, no data was published about the general perception of patients to wearing functional appliances for the total sample.

Feldmann et al. (2012) used a different customised questionnaire to compare patient perception of different types of anchorage reinforcements. The questionnaire was used twelve times through the treatment from start of treatment until retention and assessed patient experience with pain intensity, discomfort,

analgesic consumption, and jaw function impairment. The authors reported very few significant differences between patients' perception of skeletal and conventional anchorage systems during orthodontic treatment.

Conclusion for the patient perception section

It can be concluded that there is sufficient evidence to suggest that orthodontic appliances have a negative effect on the patient's quality of life mainly physical pain and discomfort especially during the initial stage of treatment with reduction in severity as treatment progress. However, some of the studies found that some aspects were improved like social well-being.

2.2. Brackets and Archwires

2.2.1. History

Fixed orthodontic appliances were designed by pioneer orthodontists at the end of the 19th century. When Edward Angle introduced the edgewise appliance he used a horizontally orientated rectangular slot. At that time the bracket slot size was 0.022-inch which was appropriate for the gold alloys archwires that were used at that time which were resilient but expensive. By the beginning of the 1930s, stainless steel alloy was introduced into the speciality (Cash et al., 2004). Most clinicians started using this new inexpensive alloy, although some were concerned about potential high forces applied during tooth movement resulting from the increased stiffness of stainless steel archwires. This metallurgical advance allowed similar forces to be generated with smaller dimension archwires. Consequently, there was a demand to reduce the slot dimensions from 0.022 to 0.018-inch(Kusy, 2002). In the 1970s, advances in wire technology led to Nickel Titanium archwires being introduced to the speciality with wire stiffness close to that of the first gold alloys archwires (Rubin, 2001). This is one of the reasons why clinicians returned to the 0.022-inch bracket slot system.

Therefore the 20th century witnessed two changes in preference for bracket slot size. Interestingly, the debate is not yet settled and orthodontists around the world are divided according to their personal preference between the 0.018 and 0.022 inch bracket slot systems. Furthermore, it is clear from the history of bracket slot development that the key factor to the changes was the materials and dimensions of the archwires used and the philosophy of mechanics for tooth movement.

2.2.2. Edgewise brackets

In 1928, Angle introduced the standard edgewise bracket system, which was popular among orthodontist for several decades. However, few orthodontists followed P.Raymond Begg by changing to the Begg brackets system with its different treatment philosophy. The standard edgewise bracket system demanded skills in wire- bending and increased chair side time.

In 1972, Andrews (1976a) introduced the pre-adjusted straight wire appliance which demanded minimal wire-bending and chairside time. The new concept introduced by Andrews was to build into the bracket design the tip, torque and in-out movement required for each tooth to achieve Andrew's six keys of normal occlusion (Andrews, 1972). The work by (Andrews, 1972)was based on measurements from 120 non-orthodontic normal cases which were thought to have pleasant appearance and an occlusion which looked generally correct.

Andrews (1976a)introduced several modifications to the pre-adjusted edgewise brackets e.g. three different sets of incisor brackets with varying degrees of torque allowing a choice for a large range of bracket specifications for various clinical needs. Andrews produced brackets for non-extraction and extraction cases; where anti-rotation and anti-tip were incorporated in the extraction brackets(Andrews, 1976b). The second generation of pre-adjusted edgewise brackets was introduced by Roth who modified Andrews' bracket prescription and limited the number of bracket prescription variations (Roth, 1976, Roth, 1987). Roth prescriptions have

an increased tip for the canine brackets to help canine guidance and an increased crown tip on the lower buccal segments.

The third generation of brackets was introduced by McLaughlin, Bennett and Terevisi (MBT). This type of pre-adjusted edgewise brackets have a total of 10 degrees less distal root tip in the upper anterior segment and 12 degrees less distal root tip in the lower anterior segment when compared to Andrews' prescriptions (Thickett et al., 2007). The aim was to reduce the strain on molar anchorage and to avoid arch length increase that can occur during treatment. In addition, extra torque is incorporated in the incisors and molars region. MBT brackets provide three options for canine torque (-7, 0 and +7 degrees). Table (19 and 20) showing tip and torque in the three bracket generations.

Banks et al. (2010) reported that most orthodontists in the United Kingdom (UK) prefer the use of the pre-adjusted edgewise appliance (97.2%). The authors reported that in the UK 46% of the orthodontists use the MBT prescription while 41% use Roth prescription and the remainder use Andrews' prescription. However, Roth prescription brackets are dominating in the United States of America (55.9%); while MBT prescription is not that popular (6.6 %) (Keim et al., 2002). It is important to mention that the results from the survey conducted by Keim et al. (2002) should be considered with caution as it is more than a decade ago.

Table 19 Tip prescriptions (degrees) for different pre-adjusted edgewise bracket system

Upper	MBT	4	8	8	0	0	0	0
	Roth	5	9	13	0	0	0	0
	Andrews	5	9	11	2	2	5	5
	Tooth	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Lower	Andrews	2	2	5	2	2	2	2
	Roth	2	2	7	-1	-1	-1	-1
	MBT	4	8	8	0	0	0	0

Table 20 Torque prescriptions (degrees) in different pre-adjusted edgewise bracket system

Upper	MBT	17	10	-7	-7	-7	-14	-14
	Roth	12	8	-2	-7	-7	-14	-14
	Andrews	7	3	-7	-7	-7	-9	-9
	Tooth	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Lower	Andrews	-1	-1	-11	-17	-22	-30	-33
	Roth	-1	-1	-11	-17	-22	-30	-30
	MBT	-6	-6	-6	-12	-17	-20	-10

Did the introduction of the pre-adjusted edgewise brackets influence the choice of the bracket slot size?

There is a general feeling that the popularity of 0.018-inch bracket slot system is reducing by time. Keim et al. (2002) reported a decrease in the percentage of orthodontists using the 0.018-inch bracket slot system from 1986 (49.3%) to 2002 (40.5%). It can be assumed that the development of the edgewise bracket through

the last 3-4 decades from standard to pre-adjusted prescription may have influenced the choice of orthodontists regarding the bracket slot size. The use of the standard edgewise bracket system is usually associated with the need of wire bending to adjust the position (tip and torque) of the teeth. This may necessitate the use of a stiff archwire that can still deliver light forces and be easy for the clinician to bend. The 0.016 x 0.022 stainless steel as the working archwire for the 0.018-inch bracket slot system was convenient for orthodontists especially when closing loops mechanics were used as compared to the 0.019 x 0.025 stainless steel the working archwire of the 0.022-inch bracket slot system. The 0.019 x 0.025 stainless steel archwire was not easy to bend and can deliver unnecessary heavy forces.

In addition, the sliding mechanics philosophy which is popular in space closure mechanics in combination with pre-adjusted brackets may require the use of stiff archwire to maintain controlled teeth movements. Some clinicians believe that sliding mechanics can be more favourable in the 0.022-inch bracket slot system due to the relatively wider range of stiffer archwire used in comparison with 0.018-ich bracket slot system. However, there is no evidence to support these claims.

2.2.3. Distribution of bracket slot size use in the world

There is a consensus of opinion that the 0.022-inch bracket slot is more popular than the 0.018-inch bracket slot system worldwide. Clinicians in the United Kingdom (U.K) may have a significant preference for 0.022-inch bracket slot systems in comparison to orthodontists in mainland Europe who prefer the use of 0.018-inch bracket slot system (Rubin, 2001). In the United states of America there is a slight preference towards using the 0.022-inch(Keim et al., 2002).

Four surveys on diagnosis and treatment procedures among orthodontists were conducted by the Journal of Clinical Orthodontics in the United States of America in 1986, 1990, 1996 and 2002 (Keim et al., 2002). These four surveys targeted orthodontic speciality practitioners. The results from these surveys suggest that less than half (40.5%) the orthodontist in USA use 0.018-inch bracket slot system, while the remaining half prefers the use of 0.022-inch bracket slot system. However, it was noticed that the percentage of orthodontist using the 0.018-inch bracket slot system reduced from the first (1986) to the forth (2002) survey (49.3% and 40.5%, respectively). It is important to note that the response rate in the surveys was considered to be low. The survey conducted in 2002 (Keim et al., 2002) 8,812 orthodontist were contacted. The response rate was only 9% (789 orthodontists). However, the authors suggested that the results of the survey were valid when compared to previous surveys.

A recent survey was undertaken in the United Kingdom to investigate the use of fixed appliances among orthodontists (Banks et al., 2010). Nine hundred and thirty-five orthodontic specialists were contacted with an acceptable (66.3%) response rate. Data analysis investigated differences in clinical practice relating to varying provider groups, level of operator experience and geographic region. The authors reported that in total less than 9% of the orthodontist use the 0.018-inch bracket slot system, while more than 90% prefer the 0.022-inch bracket slot system. Interestingly, the higher percentages of clinicians favouring the 0.018-inch bracket slot system were noted to be in private practice (23.1%) and community units (24.1%) when compared to hospital services (4%). Moreover, it seems that more

orthodontists in Scotland (17.6%) and Northern Ireland (17.9) favour the 0.018-inch bracket slot system when compared to the rest of the United Kingdom (less than 9%). It is worth mentioning that the authors reported that 25 % of the senior orthodontists with more than 30 years of practice preferred to use a 0.018-inch bracket slot system.

Another recent survey was published in the same year (McNamara et al., 2010) with an aim to assess the clinician's view with regard to the choice of archwires during treatment. The survey was conducted in the south of England and involved 108 orthodontists in primary and secondary care units. Although, the planned target number of orthodontists in the survey was relatively low, the response rate was relatively high (more than 90%). The authors reported that all but one (99%) of the orthodontist preferred the use of the 0.022-inch bracket slot system.

The previously mentioned surveys may suggest that the preference of bracket slot system use in these two countries is different. United Kingdom orthodontists undoubtedly favour the 0.022-inch system while orthodontists in United States of America demonstrate almost no preference of one slot system over the other. None of the surveys investigated the clinical reasoning behind clinician preference.

Few assumptions can be concluded from these two surveys; service provider, geographic distribution, and seniority / experience appear to influence preference in slot size bracket system. No information is available regarding the preference slot size in other countries.

2.2.4. Influence of bracket slot on the levelling and alignment stage of treatment

Levelling and alignment of malpositioned teeth begins in the initial stages of orthodontic treatment and is accomplished with flexible archwires. When aligning teeth, a combination of labiolingual and mesiodistal tipping guided by the archwire takes place, however root movement does not normally take place at this stage (Proffit, 2013). A rectangular archwire is often used at the completion of the initial levelling and aligning stage, to express rotation control, and start torque control.

Proffit (2013) suggested that during the alignment stage there should be at least 0.002-inches clearance between the arch wire and the bracket slot. This would indicate that the largest round aligning archwire that is recommended to be used in the 0.018-inch bracket slot system is 0.016-inch NiTi archwire and for the 0.022-inch bracket slot system 0.018- inch NiTi archwire.

Force

Huang et al. (2005) stated that when using narrow bracket slots the play between the bracket slot and the wire is less than for wider slots and thus the force delivered is increased. This is important during the initial stages of treatment when the differences between bracket levels are significant. The authors also stressed that at that stage of treatment it is preferable to apply gentle forces for tipping movements. However, Proffit (2013)suggested that the introduction of super-elastic memory wires that have low force values over a wide range of activation makes the difference in force delivery in slot size systems less important than it was two or

three decades ago. However, this suggestion was based on laboratory studies and not evidence based clinical trials.

Although, Proffit (2013)recommended the use of an 0.016 inch NiTi as an aligning archwire when using an 0.022-inch bracket slot system, the authors also suggested the use of the same archwire or 0.014 NiTi for alignment in the 0.018-inch bracket slot system assuming the difference in play would not be clinically relevant. However, the use of an archwire with the same dimensions in a smaller slot would be likely to lead to greater control but higher forces and increased friction during the alignment stage (Kapila et al., 1990).

Friction

Kapila et al. (1990) reported that the amount of frictional force is increased when using 0.016 Niti archwire with 0.018 x 0.025-inch bracket slot combination (160gm) than with the same archwire in a 0.022 x 0.028-inch bracket slot combination (127gm). However, it is interesting to note that the frictional force from 0.018 NiTi archwire and 0.022-inch bracket slot combination (162 gm) is almost equal to that of 0.016 Niti and 0.018 x 0.025-inch bracket slot combination.

In other words friction in the two bracket slot systems will in part depend on the dimension of the wire used. This may highlight the influence of the bracket/archwire combination effect.

A recent systematic review (Ehsani et al., 2009) was designed to investigate the friction resistance in conventional and self-ligating bracket systems among in-vitro

studies. The authors reported that all the articles that met the inclusion criteria used the 0.022-inch bracket slot systems; therefore conclusions regarding the influence of bracket slot dimension on frictional resistance cannot be drawn in conventional and self-ligating bracket systems.

Clearance

Kapila et al. (1990) reported that the second order clearance permitted by the 0.016-inch Niti and the 0.022 -inch bracket slot is three times larger than the clearance between the same archwire and the 0.018-inch bracket slot (0.95 and 0.32 degrees respectively). On the other hand, double the clearance (0.64 degrees) was reported when using 0.018 archwire and 0.022-inch bracket slot combination, when compared to the 0.016 archwire and 0.018-inch bracket slot combination (0.32 degrees).

Table 21Clearance in the two bracket slot systems.

	0.18 slot size	**0.022 slot size**
0.016 archwire	0.32 degrees	0.95 degrees
0.018 archwire		0.64 degrees

Huang et al. (2005) suggested that, in practice, with two wires of the same stiffness the larger wire is preferred to the smaller because it has more control over tooth movement. Because the thicker archwire fills the bracket slot more fully, there is less play in the slot compared with the thinner wire. Therefore the primary aim of the levelling phase is to progress to archwires that fill the slot as fully as possible to as much control as possible.

In summary, if 0.016 NiTi archwire is used for the alignment stage in both the 0.018-inch and the 0.022-inch bracket slot systems, then more clearance between the archwire and the 0.022-inch slot will be available, although with reduced forces and friction when compared to the 0.018-inch bracket slot. On the other hand if 0.018 NiTi archwire is used in the 0.022-inch bracket system then a similar level of friction, greater clearance and increased force magnitude will exist (due to the increased stiffness of the wire) when compared to the 0.016 NiTi and 0.018-inch bracket slot combination.

The available information discussed above regarding the influence of bracket slot size on the levelling and alignment stage of treatment are mainly based on experimental studies with expert assumptions build on clinical experience. Experimental in-vitro studies are usually a primary level of investigation. It is essential that all these experimental findings are expressed in clinical outcomes in well-designed clinical trials so that the clinical significance of each variable could be evaluated as an evidence based criterion.

2.2.5. Aligning archwires and sequence

Archwires of low stiffness are preferred at the first stage of treatment while archwires of high stiffness are preferred latter through treatment. Rucker and Kusy (2002) suggested that initial aligning archwires require reasonable strength to prevent deformation, low stiffness to deliver low forces and high range of maximum activation. The materials commonly used for that stage of treatment are nickel titanium and stainless steel (twist flex) archwires. Nickel titanium archwires

are experimentally superior because they have low load-deflection ratio and better control of force magnitude (Koenig and Burstone, 1989, Burstone et al., 1985).

According to several surveys almost more than 80% of the clinicians favour nickel titanium aligning archwires (Banks et al., 2010, Keim et al., 2002, McNamara et al., 2010). In the last two decades manufacturers had developed several generations of the nickel titanium archwire, which explains its increased popularity despite of its relative high cost.

The most desirable physical properties in aligning archwires that can allow effective alignment (West et al 1995):

- Deliver light and continuous force
- Good spring back
- Biocompatibility
- Formability

Stainless steel archwires

Stainless steel archwires have good strength, corrosion resistance and relatively low cost. They have been used in the mid of last century as an aligning archwire with customised multi-loop bends to increase the springiness of the wire to align and level the malpositioned teeth (Evans et al., 1998). However, due to the increased chair side time needed for wire bending and the introduction of the multi-strand stainless steel arch wires (Twistflex) and Nickel titanium archwires, the use of this type of archwires during initial aligning almost vanished.

Multi-strand stainless steel archwires (Twistflex) offer a combination of acceptable strength and springiness(Jones et al., 1990). The properties of the multi-strand stainless steel archwire depend mainly on the characteristics of the wire strands and how tightly they are woven.

Five clinical trials investigated the effectiveness of multi-strand stainless steel archwire versus different types of nickel titanium arch wires (West et al., 1995, Jones et al., 1990, Evans et al., 1998, Cobb et al., 1998, Sandhu et al., 2012). All but one of these studies reported no statistically significant difference between the multi-strand and nickel titanium archwires using edgewise brackets. West et al. (1995) reported that the 0.014-inch superelastic nickel titanium was faster than the 0.0155-inch multi-strand stainless steel archwire in aligning teeth, although the clinical significance of the difference is questionable (Riley and Bearn, 2009, Wang et al., 2010).

Currently, less than 3% of orthodontist use multi-strand stainless steel archwires in the United Kingdom (Banks et al., 2010, McNamara et al., 2010) . However, clinical trials do not support reasons for the taking over of the nickel titanium alloys. It might be the influence of manufacturers marketing the results from in-vitro studies that pushes the clinicians to believe more in the effectiveness of the relatively expensive nickel titanium archwires.

Nickel titanium archwires

The development of the nickel titanium alloys has made significant progress since it was first introduced in the 1970s. Nowadays, different types of nickel titanium

archwire choices are available for the orthodontist by the manufacturers. Nickel titanium archwires can be classified according to structure into: 1) martensitic stabilised, which show a stable martensitic structure with minimal shape memory and no superelasticity; 2) martensitic active (thermoactive) in which an increase in temperature leads to transformation of the martensitic to austenitic structure; and 3) austenitic active with pseudoelastic behaviour when the martensitic structure transformation of these alloys is stress-induced, resulting from activation of the wire (Pandis et al., 2009, Gatto et al., 2013, Nakano et al., 1999).

Several in-vitro studies investigated the mechanical properties of these different types of nickel titanium archwires; suggesting superior mechanical properties of some over the others (Nakano et al., 1999, Kusy and Whitley, 2007). However, the clinical performance of these archwires was evaluated according to the rate of teeth movement in several randomised clinical trials with results that show no statistically significant difference (Mandall et al., 2006, Pandis et al., 2009, Ong et al., 2011). Discussed in previous section (Levelling and alignment duration).

Two recent systematic reviews were adequately designed to assess the efficiency of aligning archwires included a reasonable number of randomised clinical trials with relatively low risk of bias (Riley and Bearn, 2009, Wang et al., 2010). Both systematic reviews agreed that the available evidence suggest that no recommendation could be made on the most effective aligning archwire. This may suggest that in-vitro studies cannot fully simulate the intra-oral clinical situation.

It is essential to note that the influence of bracket slot size / arch wire combination was not highlighted in most of the previously mentioned clinical studies that investigated the efficiency of aligning archwires. Table (14) shows different clinical studies that were designed to compare the effectiveness of different archwires in teeth alignment and the bracket slot size system used. It is interesting to note that more than half of these studies did not mention the bracket slot size system used. Cobb et al. (1998) was the only study that involved the two bracket slot systems (0.018 and 0.022-inch) to compare the effectiveness of different aligning archwires. Patients were randomly allocated to different types of arch wires with stratification according to the bracket slot size. The authors mentioned that it is surprising to find no statistically significant difference between the archwires while there is a statistically significant difference between the two bracket slot systems; with the 0.022-inch bracket system having higher rate of teeth movement in the mandibular arch.

To summarise, it is interesting to note that clinical trials do not support the claimed superior mechanical properties reported in laboratory- based studies regarding the superior mechanical properties of newly developed types of aligning archwires. This may suggest the irrelevance of in-vitro derived mechanical performance of the archwires in the intra-oral clinical environment. Moreover, the effect of the bracket/slot combination was not considered in most of the studies, which may have an influence on the performance of the different archwires.

This topic was discussed in more details in a previous section (2.1.1.3. Factors influencing duration levelling and alignment stage).

2.3. Randomised clinical trials

2.3.1. Introduction and history:

The American Dental Association defines (ADA) evidence-based dentistry (EBD) as an approach to oral health care that requires the judicious integration of systematic assessments of clinically relevant scientific evidence, relating to the patient's oral and medical condition and history, with the dentist's clinical expertise and the patient's treatment needs and preferences.

Several authors have highlighted the importance of randomized clinical trials (RCTs) in evidence-based dentistry (Deeks et al., 2003; Moser. 1986). Well-conducted RCTs represent the gold standard for research when assessing the effectiveness of an intervention. Therefore, RCT is considered the second highest level in the hierarchy of evidence, with only well conducted systematic reviews of RCTs with meta-analysis being superior (Harrison, 2003) .

RCT study design is based on the principles that have been suggested for some considerable amount of time as the fundamentals for scientific human experimentation. These principles are:

- The hypothesis to be tested is formulated before collecting the data
- Variability in ‘disease’ and intervention outcomes being assessed by thorough statistical testing

- The assessment of casual relationship is based on comparison with a comparable group obtained by randomly assigning patients to treatment groups under study.

The RCT study design was first applied when streptomycin was evaluated as a treatment for tuberculosis (Crofton and Mitchison, 1948) . Since then the value of the method, which eliminated selection bias was clear for researchers, clinicians, policy makers and patients (Pandis et al., 2011).

2.3.2. CONSORT

The Consolidation Standards of Reporting Trials (CONSORT) statement was published in 1996 in an attempt to improve the quality of reporting of RCTs. The CONSORT guidelines were developed by a team of dedicated journal editors, epidemiologists and statisticians (Moher et al., 2001) . They determined the standards for reporting the findings of controlled clinical trials. CONSORT comprises a checklist which consists of 25 items that cover all key aspects of clinical trials and a flow diagram. It offers a standard way for researchers to report their findings and help improve the quality of reports of RCTs.

2.3.3. Advantages of an RCT

Selection/allocation bias

RCTs differ from non- randomised clinical trials as the assignment of subjects to particular intervention is made according to the laws of probability.
Selection/allocation bias is the most serious shortcoming of non- randomised clinical trials (Moser, 1986). It occurs when participants are preferentially assigned to one intervention group because some preference on the part of either investigator

or patients. This may allow confounding factors to influence the outcome of the intervention and lead to biased estimates of the intervention effect.

The RCT study design was developed mainly to eliminate selection bias. The concept behind randomising the allocation of the intervention into the participants in the study is of great importance. Random allocation ensures that each subject has a known chance of being assigned to each of the options for intervention.

Reduction of inter group heterogeneity

The baseline characteristics of the trial groups should ideally be as homogeneous as possible. This would enable the investigator to suggest that the treatment outcome is due to the intervention investigated. If an adequate sample size is recruited the law of chance invoke to maximize the likelihood that an equal proportion of subjects in each of the trial groups having similar baseline characteristics (Moser, 1986). This will also assure that the results of statistical tests of significance applied to the assessed outcome of the investigation are valid.

2.3.4. Disadvantage of RCTs

Although, the design of Randomised clinical trial is considered to be the cutting edge for clinical research still it is not without their problems

Generalizability (external validity)

One of the potential problems with RCT study design is the lack of generalizability of the results obtained from RCTs which in turn may undermine the external validity of the study (Weiner, 2009). Most patients selected (or consenting) for the

randomisation tend to be less sick, younger, better educated and of high educational status than the general population (Hannan, 2008) . There is evidence that RCT participants usually do not reflect the age, gender, and race distribution of the target population. (Svensson et al., 2012, Trauth et al., 2000). This results in selection bias. Moreover, within RCTs, patients and clinicians tend to adhere more rigorously to the treatment protocols. Whilst this assists with treatment quality and standardisation, it may not accurately reflect routine clinical practice (Hannan, 2008).

Ethical considerations

One of the tenets of ethics in medical research is that the clinician should do his/her best for every patient and cause no harm. Randomizing the patients into two or more groups should only be based on evidence that none of the interventions/treatments is superior to the other (Moser, 1986). Most important is a well-designed consent form that includes a patient information sheet, which is based on scientific evidence and not clinician(s) preference. This can explain why any ethical consideration may be a barrier in designing an RCT where there is no scientific evidence to support the intervention/ treatment to be investigated. In other words ethical arguments depend on prior evidence being available which can ideally be explored using systematic reviews(Jones et al., 2013). There are numerous situations in which RCTs are clearly ethical, while there are other situations in which RCTS can be considered to be to some degree unethical (Überla, 1981, Richter, 2006).

Cost and feasibility

RCTs are expensive to conduct especially when long term effects are investigated in a large sample population (Boissel, 1989). Slow recruitment might be one of the obstacles that might prolong the duration of RCTs and increase costs (Black, 1996).

2.3.5. RCTs and orthodontics

Gibson and Harrison (2011) designed an interesting study to investigate the type of studies published in four of the highest impact orthodontic journals in the period between 1999 and 2008. The authors reported that only 10.8% of the clinically based published studies used randomised control trial methodology; while more than 30% represented case report/ case series, which are considered to be of poor methodology. In addition, the authors noticed that there was no statistically significant increase in the percentage of published RCT between the beginning and end of the last decade. It is important to note that the authors clearly mentioned that the aim of the study was not to assess the quality of the reported RCTs.

However, Pandis et al. (2011) designed a study to evaluate the quality of RCTS published in high impact dental journals using the modified CONSORT checklist. The authors reported that the quality scores for the RCTs were unfortunately suboptimal.

In summary, RCTs are the most robust method of gaining valid information regarding the effectiveness of interventions from a scientific point of view (Faulkner et al., 2008). Limiting bias by random allocation, allocation concealment, blinding and accounting for loss of follow up makes the study results of high

quality valid (Pandis et al., 2011). The benefits from the sound high quality evidence supplied by this type of study design outweigh the drawbacks of conducting RCT.

Systematic reviews and meta-analysis aggregate the results from multiple RCTs and therefore represent the highest evidence available. However, in order to produce them, the core studies (RCTs) must be undertaken and published. Moreover, many of the orthodontic systematic reviews published recently suggested that there are not enough studies to support clinical recommendations (Bollen, 2008, Fleming and DiBiase, 2008, Fleming et al., 2013). It is clear that the field of orthodontics requires a greater number of RCTs for clinicians to inform their clinical decisions using the evidence-based dentistry principles.

Chapter 3: Aims, Objectives and Hypothesis

3.1. Aim

The aim of the current study is to examine the effectiveness of the levelling and alignment stage of orthodontic treatment in the 0.018-inch and 0.022-inch bracket slot systems.

3.2. Objectives

The primary objective

- Investigate if there is any difference between the 0.018-inch and 0.022-inch conventional pre-adjusted Victory brackets in terms of the duration of levelling and alignment stage of orthodontic treatment in months.

The secondary objectives

- Investigate if there is any difference between 0.018-inch and 0.022-inch conventional pre-adjusted edgewise Victory brackets in terms of
  - The number of scheduled alignment stage appointments.
  - Severity of OIIRR.
  - Patient experience in wearing the fixed appliance.
- Conduct validity studies to investigate
  - The agreement of conventional film and digital periapical radiographs in measuring simulated orthodontically induced apical root resorption.
  - The accuracy of the bracket slot dimensions the 0.018-inch and 0.022-inch conventional pre-adjusted Victory brackets using SEM.

3.3. Null hypothesis

The null hypotheses to be tested are:

Ho1:

There is no significant difference in the time taken to complete the levelling and alignment stage of treatment in terms of number of months of treatment using 0.018-inch or 0.022-inch conventional pre-adjusted edgewise Victory brackets.

Ho2:

There is no significant difference during levelling and alignment stage of treatment in terms of number of scheduled appointments using 0.018-inch or 0.022-inch conventional pre-adjusted edgewise Victory brackets.

Ho3:

There is no significant difference in the severity of orthodontically induced inflammatory root resorption OIIRR at 9 months from the start of treatment using 0.018-inch or 0.022-inch conventional pre-adjusted edgewise Victory brackets.

Ho4:

There is no significant difference in patient perception of the experience of wearing fixed orthodontic appliance during the levelling and alignment stage of treatment using 0.018-inch or 0.022-inch conventional pre-adjusted edgewise Victory brackets.

Ho5:

There is no agreement between the conventional film and digital periapical radiographs in simulated orthodontically induced apical root resorption.

Ho6:

There is no difference in the bracket slot dimensions in the 0.018 and 0.022-inch bracket slot conventional pre-adjusted Victory brackets measured using SEM and the manufacturer published dimensions.

Chapter 4: Subjects and Methods

4.1. Study design

This was a multicentre non-stratified randomised clinical trial designed in line with the CONSORT principles. It was a single blind (masked), parallel group trial with equal randomisation (1:1 for two groups) to compare the effectiveness of 0.018-inch and 0.022-inch pre-adjsted edgewise bracket slot systems during the aligning and levelling stage of orthodontic treatment. The study was conducted in Scotland, United Kingdom. The study is a part of an on-going trial comparing the effectiveness of orthodontic treatment between the 0.018-inch and the 0.022-inch bracket system.

The study was sponsored by the University of Dundee. Ethical approval for the study was gained from NHS Tayside A Committee (East of Scotland Ethics Service) on Medical Research Ethics in October 2009. Research and Development (R&D) approval was given from NHS Tayside Research and Development (November 2009). Three sites were involved in the study within Tayside NHS: Dundee Dental Hospital & School (DDH&S), Perth Royal Infirmary (PRI) and Springfield Medical Centre (SMC).

4.2. Participants

4.2.1. Eligibility criteria for participants

Eligible participants were all patients with any type of malocclusion aged 12 years or over seeking orthodontic treatment.

Inclusion criteria

Patients with malocclusion scheduled to undergo dual arch fixed appliance orthodontic treatment at Dundee Dental Hospital, Perth Royal Infirmary, and Springfield Medical Centre were invited to participate in this trial by the study operator planning to conduct their orthodontic treatment.

Exclusion criteria

- Patients who had undergone previous orthodontic treatment including fixed, removable and functional appliances.
- Patients less than 12 years old at the beginning of the study.
- Patients with orofacial clefting, severe hypodontia, and special needs patients.
- Patients undergoing orthognathic surgery as part of their overall orthodontic care.

4.2.2. Study settings

This was a multi-centre study conducted in secondary care settings NHS Tayside in Scotland, United Kingdom.

Table 22: Study centres

Sites	NHS centre	Care Setting
Dundee Dental Hospital & School	Tayside	Secondary care
Perth Royal Infirmary	Tayside	Secondary care
Springfield Medical Centre	Tayside	Secondary care

The three sites involved in the study were hospital based Consultant-led Orthodontic units, treating NHS patients. All the clinicians treating the patients were either on the GDC Specialist List for Orthodontics or training to become Specialists in Orthodontics.

The participants were selected according to the above mentioned criteria, and were invited to participate in the study between January 2010 and March 2012.

4.3. Interventions

All patients had the following procedures routinely undertaken at the first appointment (Figure 2) as a part of their routine orthodontic care, prior to informed consent for the study being obtained:

1. Orthodontic diagnostic sheet used routinely in the three study centres for orthodontic assessment for each patient. It involved extra-oral and intra-oral assessment.

2. Maxillary and mandibular dental arch alginate impressions using orthodontic impression trays. Wax bite occluding in the maximum inter-

cuspal position. These impressions were used to construct orthodontically trimmed plaster/ dental stone study models.

3. Extra-oral and Intra-oral colour photographs taken by the medical illustration department.

4. Radiographic investigation as clinically indicated. This may include any of the following: bitewing, periapical, occlusal, panoramic or cephalometric radiographs.

The relevant patient/parent information sheet was provided and the nature of the study was explained.

4.3.1. Information sheet

Patients who met the recruitment criteria for the study were given the patient information sheet and the parent information sheet if relevant (Appendix 1) by one of the clinicians study team. The information sheet was designed especially for this trial in the form of a serious of questions and answers that explained to the participant/parent all the information needed about the study in a lay language. The study process was explained to the participants and they were asked to take the patient information sheet home and make their decision about participating in the study on the following visit. The following visit was at least two weeks after the first visit.

On the following appointment any enquires by the patient/parent were explained by one of the research team to make sure that all the patients had sufficient

information about the trial.

An independent clinician (Dr. D. Evans) who was not part of the trial research group, agreed to be an independent reference for participants/ parents if required in case there were any further queries regarding the study. His contact information was included in the patient/parent information sheet.

4.3.2. Consent process

Once the patient/parent agreed to participate in the study, informed consent form was obtained and the study consent form was signed. Only one of the five eligible study research team clinicians who had been trained in "Good Clinical Practice" were allowed to obtain informed consent form for this study. The researcher was to make sure that the patient/parent had enough time to read the patient/parent information sheet and understand it. The consent form was signed in triplicate (Appendix 2) by both the patient/parent and the researcher. One of these signed consent forms was given to the patient/parent to keep, the second was kept in the patient's notes, and the third signed consent form was kept in the trial site file.

4.3.3. Intervention procedures

4.3.3.1. Initial procedures

Fig (2) shows the flowchart for the steps and procedures undertaken during the first two appointments for each participant. During the second appointment (once the informed consent form had been signed), the following procedures were undertaken for participants if they had not been previously undertaken at the first appointment (as part of the routine clinical assessment).

- Long-cone paralleling periapical radiograph of the maxillary central incisors using either a conventional film radiograph [F speed film].(www.carestream.com)] or a digital (PPS) radiograph [Dürr Dental (www.duerr.co.uk)]. The distance of the source of the x-ray to the film was standardized at 40 cm.

  An identification yellow dot sticker was placed by the clinician on the radiographic request form for all participants in the trial at Dundee Dental Hospital. That allowed the radiographer to identify that the patient was a participant in the study and to record the radiographs according to an agreed standardized protocol.

- IOTN pre-treatment aesthetic component (Richmond et al., 1994). This is an index used routinely in orthodontic clinics for rating the attractiveness of patients' teeth against a validated scale before treatment. The index is in the form of standardised ten coloured intra-oral photographs for teeth in occlusion. The participants were asked to pick the photograph that most resembled their own dental attractiveness.

On reaching this stage, all initial records were completed. Participants were then randomly assigned to be treated using either the 0.018-inch bracket slot system Victory series MBT prescription or the 0.022-inch bracket slot system Victory serious MBT prescription (3M-Unitek, Monrovia, USA) using the sealed opaque

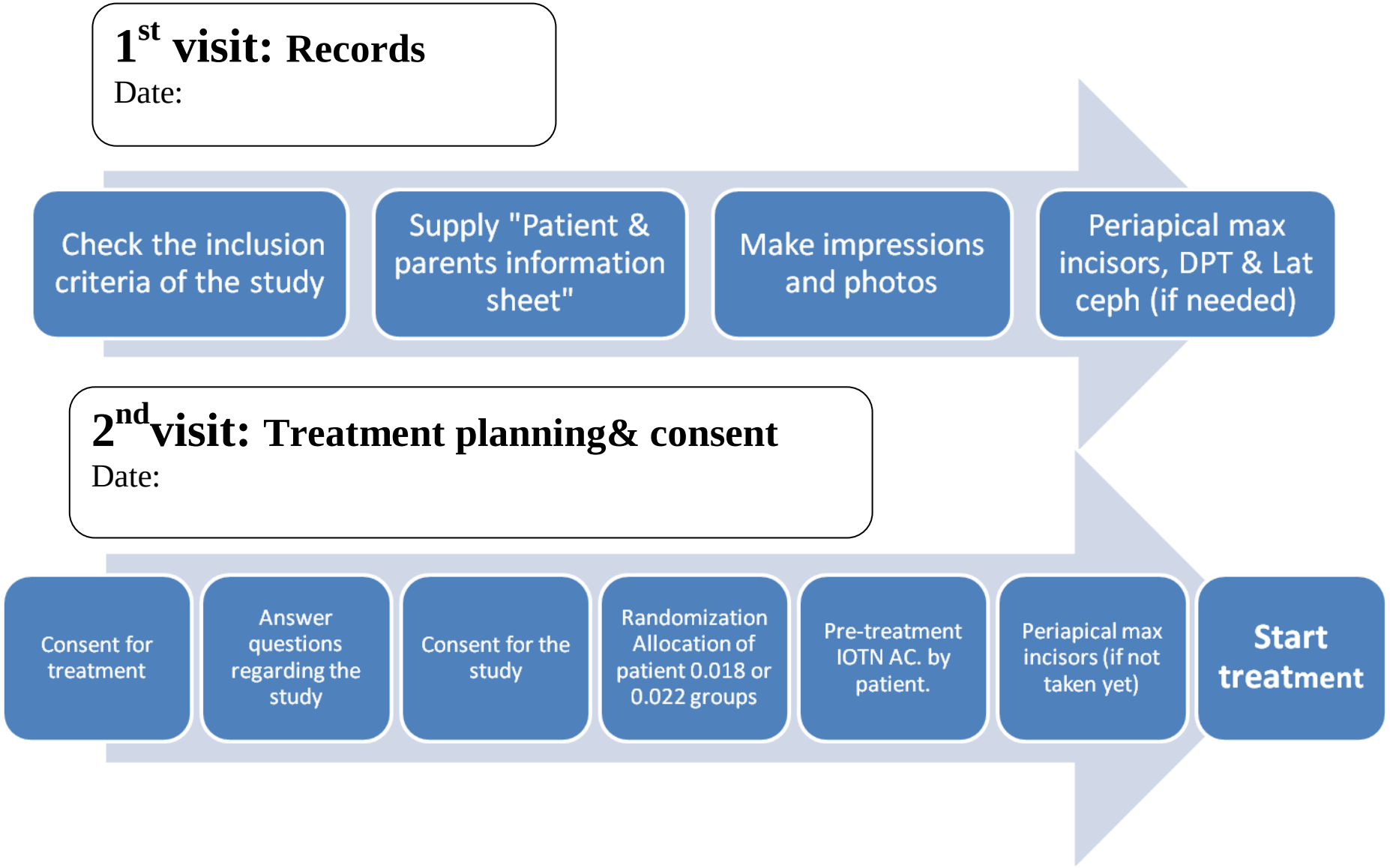

Figure 2 Flow chart for the first and second appointments for the patients participating in the study

envelope method of randomisation. The slot size was then documented in the case notes for future reference throughout treatment.

After the participants were allocated randomly to one of the two groups the orthodontic fixed appliance was placed. The bonding/banding method was standardised for both groups. All teeth underwent pumice / water prophylaxis immediately before bonding / banding. The teeth were then prepared using selfetching primer (Transbond (TM) Plus Self Etching Primer, 3M-Unitek, Monrovia, USA). Depending on the allocation card inside the participant's envelope, either 0.018-inch slot or 0.022-inch slot Victory Series MBT prescription adhesive pre-coated (APC) brackets / buccal tubes (or bands, where appropriate) [APC™ II Victory Series™ Twin MBT™, 3M-Unitek, Monrovia, USA] were placed.

The following standardised archwire sequence was followed where possible:

<u>0.018-inch bracket slot system</u>

- 0.016 inch super elastic nickel titanium archwire
- 0.016 x 0.022 inch super elastic nickel titanium archwire
- 0.016 x 0.022 inch stainless steel archwire

<u>0.022-inch bracket slot system</u>

- 0.016 inch super elastic nickel titanium archwire
- 0.019 x 0.025 inch super elastic nickel titanium archwire
- 0.019 x 0.025 inch stainless steel archwire

The recommended archwire sequences for each bracket slot system were encouraged. However, the decision about the most appropriate archwire to be ligated at each appointment was left to the clinician to decide according to clinical appropriateness. In addition, canine lacebacks were used where necessary to control the positions of the maxillary and mandibular canines.

4.3.3.2. Treatment procedures

During the routine orthodontic treatment appointments all the procedures of treatment were recorded in the patient's notes. These included:

- Archwires used at each appointment,
- Debonded brackets/tubes,
- Unscheduled emergency appointments,
- Cancelled or failed appointments
- Auxiliaries used
- Any relevant clinical finding

At each appointment, the clinician checked the type of appliance (written in the notes) used for each patient (0.018 or 0.022 inch slot) as a reminder to follow the recommended arch wire sequence when possible.

The following additional procedures were undertaken for all participants in the study during the period of orthodontic treatment:

- After 6 months from the start of treatment in both groups the "Smiles Better" patient questionnaire was completed by the patient while waiting in the reception area before the regular orthodontic treatment appointment. The "Smiles Better" is a questionnaire which assessed the patient's experience during wearing the orthodontic fixed appliance.

1. After 9 months from the start of treatment in both groups, a long-cone periapical digital/conventional radiograph was taken for the maxillary central incisors. The purpose of this radiograph was to investigate the severity of apical orthodontically induced inflammatory root resorption (OIIRR). For standardisation purpose, the same technique was used as in the initial (pre-treatment) periapical radiograph in each study centre, where possible. Further maxillary incisors periapical radiographs for monitoring the participants who suffered from significant amount of OIIRR were taken according to routine clinical protocols.

4.4. Outcomes

<u>The primary outcomes:</u>

The duration of orthodontic treatment measured in months required to finish the stage of aligning and leveling teeth in both the maxillary and mandibular arches.

The starting point of this stage was the date (D1) the first orthodontic archwire was ligated into the fixed appliance; the end point for the alignment and leveling stage was determined to be the date (D2) of the full ligation of a working stainless steel arch wire. For the 0.022-bracket slot system it was the ligation of 0.019 x 0.025 inch stainless steel archwire; and for the 0.018-inch bracket slot system it was the ligation of 0.016 x 0.022 inch stainless steel archwire.

The secondary outcomes:

1. Number of appointments during the alignment and leveling stage. This only included scheduled appointments. Additional appointments for emergency reasons were not considered unless a different archwire was ligated.

2. The severity of apical (OIIRR) affecting the maxillary central incisors after 9 months from the start of orthodontic treatment was assessed from the periapical radiographs using the index suggested by Malmgren et al. (1982) Fig (3).

3. Patient perception for orthodontic treatment was evaluated using the "Smiles Better" questionnaire which patients were asked to complete at 6 months from the start of treatment.

4.5. Changes in outcomes

The outcomes used in this study were a part of a multi-centre randomised clinical trial comparing the effectiveness of the 0.018-inch and the 0.022-inch in the whole orthodontic treatment stages. Unexpected delays occurred due to:

- Obtaining ethical approval (12 months)
- Difficulties in recruitment which led to extending the planned recruitment phase (24 months)

Due to the mentioned factors, a decision was made in conjunction with the thesis monitoring committee to analyse the levelling and alignment stage of treatment of the study for this thesis. However, the final outcome data will be analysed and published once the whole trial is completed.

The additional final outcomes are:

1. Duration of treatment for the whole orthodontic treatment.
2. Occlusal outcome after treatment as measured using PAR index.
3. Inclination of anterior teeth at the end of treatment using lateral cephalometric radiograph.
4. Patient satisfaction with treatment using pre-treatment and post-treatment questionnaires.

4.6. **Sample size**

Sample size calculation

The primary outcome for the study was to detect a difference in the duration of treatment for the alignment and levelling stage between the two groups. A sample size calculation was undertaken in order to detect a difference of one month between the study groups in the mean treatment duration for the alignment and levelling stage. The value of one month [equivalent to almost one appointment interval] was determined to be clinically important as Scott et al. (2008a) suggested that more than 20 days difference in the duration of alignment and levelling between two groups would be considered clinically significant.

Data from Table 23 was used for the sample size calculation. This determined that a sample size of 42 participants in each group would have 80% power to detect a difference of 1 month assuming that the common standard deviation is 49 days using ANOVA with a 0.05 significant difference level. Given an anticipated dropout rate of 20%, 105 participants were therefore planned to be recruited in this study.

Post hoc sample size calculation for the appropriate sample needed for statistical analysis to assess the severity of OIIRR between the two groups. This determined that a sample size of 16 participants in each group would have 80% power to detect a difference of 0.5mm (equivalent to score 1) with a 0.05 significant difference level.

4.7. Interim analyses and stopping guidelines

Stopping rule

During the 9 months periapical radiographic assessment, if there was concern that severe apical OIIRR [score 3 or more(Malmgren et al., 1982)] in the majority of participants in one group, whilst the other group showed minor changes, then the data monitoring committee would be convened to consider if the study should be terminated.

Table 23 Studies from the literature used for sample size calculation.

Study	Aim of study	Total Sample size	Alignment and levelling stage duration (mean)	SD
Pandis et al 2007	Compared self-ligating and conventional brackets for alignment and levelling duration.	54 patients	Group 1= 114 days Group 2= 91 days	46.44 31.94
Scott et al 2008	Compared self-ligating and conventional brackets for alignment and levelling duration	62 patients	Group 1= 243 days Group 2= 253 days	82.5 63.6
Ong et al 2011	Compared different sequences of aligning arch wires on the alignment and levelling duration.	132 patients	Group 1 = 120 days Group 2 = 132 days Group 3 = 120 days	1.2 1.2 1.2
Cobb et al 1998	Compared duration for alleviation of arch irregularity using 3 different types of archwires	126 patients	Median Maxillary 51 and Mandibular 46 days	Not detailed

Trial monitoring committee

A trial monitoring committee was composed of three investigators: Mr Ahmed El-Angbawi, Professor David Bearn and Dr Grant McIntyre. This committee had regular meetings every three months to monitor and discuss the progress of the study.

Monitoring visits

Regular monitoring visits were made to the study centres to ensure that the study protocol was followed and to help resolve any difficulties in running the study. Trial monitoring visits form was completed on each visit and kept in the trial master file.

4.8. Randomisation

Sequence generation

Simple randomisation was accomplished with no stratification using a restricted (10 number block) random number using www.graphpad.com/quickcalcs/randomn2.cfm to ensure equivalence of numbers in each group. The odd numbers were allocated to group 1 and the even numbers to group 2. In every ten number block from the random table, the sequence was checked to ensure the even numbers were equal to the odd numbers. Each number in the random table was given a study number and assigned into one of the study groups.

A table for the allocation of the participants in the study was composed and kept in a sealed envelope. All the documents used for the randomisation and

allocation sequence generation were kept in a box in a locked office (A.E.) away from the clinical environments in DDH&S.

Allocation concealment mechanism and implementation

Numbered, identical, opaque and sealed envelopes were prepared by an investigator (A.E.) with no clinical involvement in the trial. The allocation envelope contained the treatment allocation card either group 1 or group 2. The allocation envelopes were kept in a labelled box in an agreed location in the clinical environments.

After the clinician obtained the informed consent from the patient, the Dental Nurse was asked to identify the next allocation envelope in sequence. The allocation was only revealed at the time of appliance placement. Then the allocation envelope was opened in front of the participant. Both the participant and the clinician were informed about the group allocation for the participant.

The numbers on the sequenced envelopes used for allocation were then also used as the study ID number for each participant in the study. The participant study ID number and the unique identification number (hospital number) for the participant were then both registered in a special form named “List of study participants” at each trial site. This list did not detail which group the participants were allocated to. Patients who declined to participate in the study were registered in a separate form named “list of patients who declined to participate in the study”. Both forms were kept in the trial investigator site file.

4.9. **Blinding (masking)**

This randomised clinical trial was single masked. It was not possible for the study to be double masked. Once the numbered random envelopes used for random allocation was opened and the clinician and participant knew which appliance type (either 0.018-inch slot or 0.022-inch slot) was to be used, the appliance was clearly specified on the proforma kept within the patient's case notes. This was to remind the clinician (orthodontist) of what type of appliance was used in treatment. This allowed the clinician to adhere to the recommended standard arch wire sequence for each type of appliance.

The study ID number label (from the random allocation envelopes) for each participant was attached to all the documents related to the trial. It is important to note that this label did not show which group the participant was allocated to. During data collection from patients records all the participants documents were coded (using the model box number) to ensure masking of the data investigator.

During the sequence generation procedure at the beginning of the trial an allocation table was undertaken by one of the trial researchers (A.E.). The table included the participant study ID number and the group allocation. This allocation table was kept locked in box in A.E.'s office before recruitment started. This was the only document that could unmask the allocation of participants in this trial; and was kept away from clinicians, data collectors and analysts. The allocation table was only used after complete data collection and during statistical tests analysis.

Participant study package

A unique study label was placed on the front cover of each participating patient's case notes. This label did not specify which group the patient was allocated to. The study label had a list of all the additional data to be collected for the trial with 'tick boxes' for each step. This was to illustrate the patient was participating in the study; and to remind the clinician to undertake the additional procedures required for the trial. A study file containing all the study documents needed for each patient was attached to each set of patient case notes.

Participant study package included:

1. Flow chart for the study
2. First and second visit procedures chart
3. Smiles better patient questionnaire
4. Study ID labels
5. Consent forms

4.10. Data Collected

4.10.1. Study cast analysis

The data collection sheet template was designed to collect all the information needed from the pre-treatment study casts (appendix 3). An investigator guide for data collection from the study casts was constructed to help investigators collect data in a standard pattern. The study casts were coded to mask the investigator collecting the data. Data collection was performed by one investigator A.E. Twenty study models were randomly selected and re-measured by the same investigators at two weeks interval to evaluate intra-investigator reliability using ICC.

Irregularity assessment

The irregularity of teeth in each of the maxillary and mandibular arches before the start of treatment was measured on the pre-treatment study models using the Index of Tooth Alignment (ITA) (West et al., 1995). The method is based on Little's Irregularity Index of which was originally used for quantifying dental irregularity in the mandibular anterior teeth (Little, 1975) . The main difference from Little's index is that the ITA can be used for assessing irregularity in either the maxillary or mandibular anterior and posterior teeth. Measurements were taken from the distal and mesial anatomic contact points for all teeth mesial to the first molars.

Measurements were made on the pre-treatment study models using a fine-tip digital calliper which was manufacturer calibrated to a tenth of a millimetre (Mitotoya, Digimatic micrometer, Japan). The linear horizontal displacement of

the adjacent contact points of the teeth was determined. The sum of these linear measurements represented the ITA for a single dental arch. Impacted teeth were given a score of 5 on each contact point with adjacent teeth, to compensate for the difficulty in measuring the irregularity of teeth in segments with impacted tooth.

Data collection was performed by one investigator A.E. Twenty study models were randomly selected and re-measured by the same investigators at two weeks interval to evaluate intra-investigator reliability using ICC.

Crowding assessment

The amount of crowding of teeth in each of the maxillary and mandibular arches before the start of treatment was also assessed on the pre-treatment study models. Crowding was calculated as the difference between the sum of the teeth width (mesio-distally) and the arch circumference. To allow accurate measurement of the arch circumference, each arch was divided into four segments: the anterior segment represented two segments measured from the distal contact point of the lateral incisor on one side to the midline and from the midline to the distal contact point on the opposite side. The two buccal segments were measured from the distal contact area of the lateral to the mesial contact area of the first permanent molar. The measurements from the four segments were added to represent the arch circumference for the whole dental arch. The severity of the crowding was then categorised as follows: mild 0.1-

4mm, moderately severe 4.1-8 mm, with severe crowding being more than 8.1 mm (Proffit, 2013).

Peer assessment rating PAR score

The Peer assessment rating PAR (British weighted) was used to objectively quantify the severity of malocclusion for the patients on the study casts before treatment (Richmond et al., 1992a). The scoring was done by the Orthodontic Technicians in the Dental Laboratories in the trial centres who were calibrated. The PAR scoring for orthodontic casts is part of their everyday job and they were masked for the study groups.

Index for orthodontic treatment need IOTN score

The Dental Health Component of the Index for Orthodontic Treatment Need (IOTN) was scored for all the participants in the study. Scoring was based on the information from the study casts in addition to relevant information needed from clinical notes and radiographs. The study investigators received prior training and calibration for the use of the IOTN; and were masked for the study groups.

4.10.2. Periapical radiograph analysis

Apical OIIRR was evaluated in this study by assessing the severity of apical root resorption affecting the maxillary central incisors using long cone periapical radiographs. Pre-treatment radiographs were taken for all trial participants before the start of treatment (T0) and 9 months after the start of treatment (T1). All periapical radiographic request forms for the study were

given a colour code (yellow dote sticker) to ensure standardisation of the radiographs. Radiographic films were placed using a film holder with a forty cm film-source distance. The radiographs were generated at 60 kv and 7 mA Dc, 0.20 sec.

The periapical radiographs taken in this study were of two types depending on availability in the study centres

- Digitised conventional film: conventional film radiographs [F speed film (www.carestream.com)] were digitised using a flatbed scanner [Epson perfection v750PRO (www.epson.com)] as 16 bit grayscale images at 300 dpi.

- Digital radiographs: taken using the phosphor plate (PPS) radiograph [Dürr Dental (www.duerr.co.uk)].

All digital images were stored in a password secured computer located in the orthodontic department. The images were saved on JPG form and imported for measurements into Image J Link 1.4 software (http://rebweb.nih.gov/ij/index.html).

Section 5.1 includes a published article for in-vitro study that was undertaken by the study research team to investigate the validity and agreement of measurements from digital periapical radiographs produced by scanning

conventional films in measuring root shortening when compared to the phosphor plate digital imaging.

Investigators were masked for the study groups during radiographic analysis for assessing apical OIIRR as all the radiographs were coded in advance of being assessed. The process was performed by two investigators D.B. & G.M. All the radiographs were rescored by the same main investigator (G.M.) after an interval of several weeks to evaluate intra-investigator error.

Method of assessing apical OIIRR from periapical radiograph

The severity of OIIRR was assessed using a scoring index Fig (3) that was adapted from Malmgren et al. (1982).

- Grade 0: absence of apical root resorption
- Grade 1: irregular apical root contour
- Grade 2: minor apical root resorption, small area of root loss amounting to less than 2mm.
- Grade 3: severe apical root resorption from 2mm to one third of the original root length
- Grade 4: extreme apical root resorption exceeding one third of the original root length.

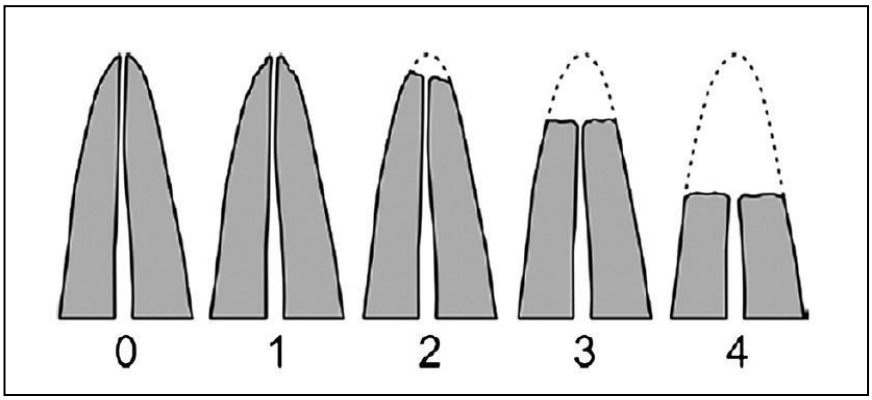

Figure 3: Scoring index for apical OIIRR (Malmgren et al., 1982)

Method of assessing pre-treatment root morphology

The root morphology was assessed for abnormality in the pre-treatment periapical radiograph using the index suggested byLevander and Malmgren (1988) Figure 4.

Score 0: Normal root morphology

Score 1: Short root

Score 2: Blunt root

Score 3: Root with apical bend

Score 4: Root with apical pipette shape

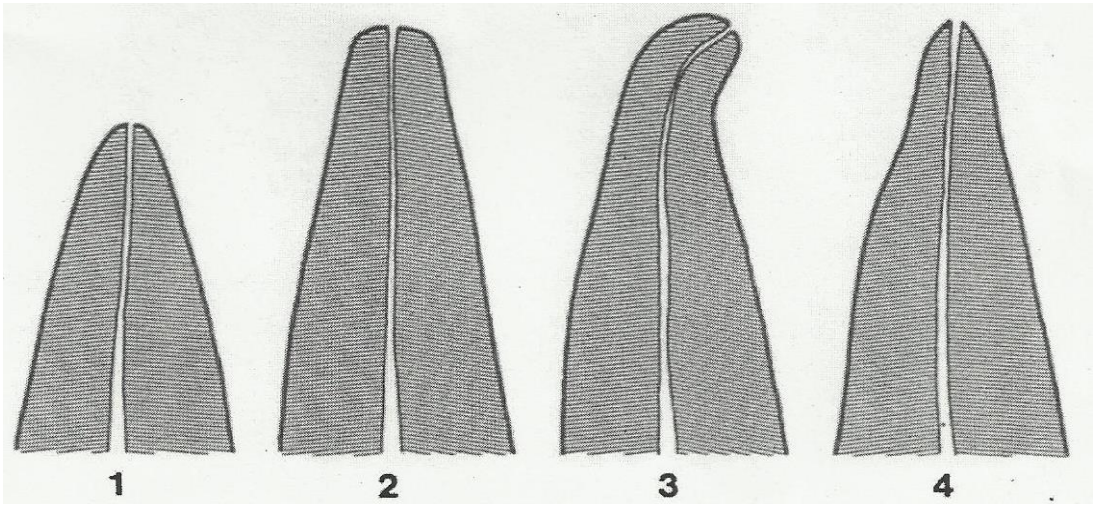

Figure 4: Scoring index for abnormal root morphology Levander and Malmgren (1988)

4.10.3. Patient perception analysis

Participants were asked to complete a questionnaire “Smiles better” about their experience with wearing the fixed orthodontic braces and its impact on their life (appendix). The questionnaire was used by a research group in University of Manchester to compare the effectiveness of two functional appliances (O'Brien et al., 2003). The Smiles better questionnaire was completed by the participants at 6 months from the start of treatment during one of the routine brace adjustment appointments.

The scores for questions related to school work, family relationship, friendship and hobbies were added to give a single score for each topic. This score was then used to rate that topic into either improved, same or worse. The last open question in the questionnaire which is related to the overall experience of the participants was ranked by the study investigators into either positive comment, negative comment or not sure. The data from the questions were classified into five domains which include:

- Oral symptoms
- Functional limitations
- Appearance
- Social impact
- Global experience

4.11. Data Collection sheet

The data collection sheet (Appendix 4) was designed specifically for the study to collect data for the full duration of treatment. This included data before the start of treatment, during the levelling and alignment stage of treatment and at the end of orthodontic treatment. In this thesis data collection was planned only up to the levelling and alignment stage. The data for the end of treatment stage and full duration of orthodontic treatment is still in progress and will be analysed and assessed for publication in a peer reviewed journal.

4.12. Statistical analysis methods

Descriptive data

Descriptive statistics for demographic (age, gender and race) and clinical baseline measurements were tabulated by treatment group. For each outcome variable descriptive statistics were presented by treatment group. For continuous variables, means and standard deviation were presented in each group. For non-normally distributed data, median was presented. Shapiro test was used to test for the normality of the data.

Two group comparison

Data was transformed into Log10 if it was found to be not normally distributed. Comparison between the two study groups were conducted using the one-way ANOVA or chi-square test, depending on the nature of the data (numeric or categorical) as shown in Table (24).

The mean difference between the two study groups regarding the primary outcome along with an appropriate 95% confidence interval was estimated. A *P* value less than or equal to 0.05 was accepted as significant. Similar analyses were performed on the secondary outcomes using the SPSS version 21.

Regression analysis

Multiple linear regression analysis was constructed using the whole study sample to determine and predict the effect of selected independent variables on the duration of alignment and levelling stage in orthodontic treatment.

Table 24: Statistical tests used

Outcome measure		**Type of Variable**	**Statistical test *P*<0.05**
Primary outcome	Duration of alignment stage for the upper and lower arches	Continuous, assuming normal distribution	One-way ANOVA test
Secondary outcomes	Number of visits required.	Continuous, assuming normal distribution	One-way ANOVA test
	Patient perception	Categorical data	Chi-square test
	Severity of OIIRR	Categorical data	Chi-square test or Friedman test

Intra-investigator reliability

To assess the intra-investigator and inter-investigator reliability of the measurements obtained from the dental casts and the periapical radiographs, Intra class correlation (ICC) and Bland and Altman plot were used. Cohen's Kappa test (not weighted) was used for categorical agreement.

Chapter 5: Validity Studies

5.1. Radiographic validity experimental In-vitro study

Film and digital periapical radiographs for the measurement of simulated orthodontically induced apical root resorption

Introduction

Orthodontically induced inflammatory root resorption (OIIRR) is a frequent but undesirable consequence of orthodontic treatment (Hartsfield et al., 2004). Apical root shortening in the maxillary incisor region is usually the most evident manifestation of OIIRR; and the gold standard method for detecting and measuring root shortening during orthodontic treatment is periapical radiography(Sameshima and Asgarifar, 2001). Conventional film periapical radiographs have been used for almost a century with developments in film speed and collimation improving image quality and minimising dose. With the introduction of digital imaging in 1986, digital periapical radiography became an alternative image modality(Berkhout et al., 2003).

Over the last 25 years, digital radiographic developments have led to improved image quality, reduced working time from image capture to display and reduced radiation dose to patients(Berkhout et al., 2003, Wenzel and Møystad, 2010).In contrast to a radiographic film, digital imaging requires either a wired sensor placed in the patient's mouth or a phosphor plate sensor (PPS) to temporarily store the radiographic energy of the latent X-rays. The latter is scanned before the radiographic image

can be displayed on-screen. Despite the availability of digital radiography, conventional radiographic film is still commonly used as it is an inexpensive and reliable image receptor (Bhaskaran et al., 2005).

An alternative option to a fully digital system is to convert conventional film radiographs to digital images by scanning (Schmitd et al., 2008). This allows image quality to be enhanced (when necessary) and the images can be quantitatively analysed using on-screen software (Dudic et al., 2008). However, it has been suggested that valuable diagnostic information can be lost during the digitisation procedure, with artefacts and noise being introduced (Versteeg et al., 1997). In addition, the radiation dose for the patient and the working time are not reduced as the radiographic technique is not altered.

Several experimental studies have compared the accuracy of diagnosing simulated external root resorption between conventional and digital radiographs(Kamburoğlu et al., 2008, Westphalen et al., 2004, Levander et al., 1998, Borg et al., 1998). Westphalen et al. (2004) found that conventional film was inferior to digital peripical radiographs for the detection of simulated root resorption. Interestingly Levander et al. (1998) and Borg et al. (1998) reported that conventional film and digital periapical images had a similar level of sensitivity for the detection of resorption, but up to one quarter of lesions were not detected on either the conventional film or digital periapical radiographs. Kamburoğlu et al. (2008) on the other hand determined that the presence of simulated apical root resorption was more difficult to identify using either conventional

film or digital periapical radiographs in comparison to simulated resorption cavities elsewhere on the root surface. No study has yet compared the accuracy and validity of measuring simulated orthodontically induced apical root resorption using film and digital periapical radiographs.

The objective of this investigation was therefore to compare the accuracy and agreement between scanned film and digital (PPS) periapical radiographs for the measurement of simulated orthodontically induced apical root resorption.

The null hypothesis tested:
There is no agreement between the conventional film and digital periapical radiographs in simulated orthodontically induced apical root resorption.

Materials and methods

A sample size calculation determined that in order to be able to detect a clinically significant difference of 0.5 mm in tooth length between the two groups at a power of 80 percent where $p<0.05$, six sound extracted maxillary incisor teeth would be required. These were collected from the Oral Surgery Department at Alexandria University, Egypt and were judged to be caries free by observation with no obvious root defects. The teeth were sterilized and storedin 10 % formalin in a sealed container.

The true length of each of the six incisors was measured from the tip of the root to the midpoint (mesio-distally) of the incisal edge. The measurements were performed using digital calipers [Mitutoyo digital calliper (Mitutoyo.co.uk)] equipped with a Vernier scale accurate to 0.01 mm. The teeth were measured on two separate occasions and the mean length of each tooth was taken as the pre-trimming true length (PreT-TL). Each tooth was placed into the central maxillary incisor region in a typodont (consisting of acrylic teeth in a wax base used for orthodontic fixed appliance training). Heavy body polysiloxane (Lab Putty, www.coltene.com) was used with a radiographic film holder for each mounted tooth to construct an index for the tooth for all four radiographic exposures of each tooth. Whilst the extracted incisor tooth was not fixed, it could be repositioned in a reproducible manner. A single small metal rod was placed in the wax of the typodont, mesial to each mounted tooth, for calculation of the magnification factor.

Radiographs

Long-cone periapical radiographs were recorded (60 kv and 7 mA Dc, 0.20 sec) for each tooth in the typodont using the film holder polysiloxane index on two separate occasions by a single experienced dental radiographer, using a conventional film radiograph [F speed film (www.carestream.com)] and a digital (PPS) radiograph [Dürr Dental (www.duerr.co.uk)]. The distance of the source of the x-ray to the film was standardized at 40 cm.

The teeth were then removed from the typodont. All teeth had the root apex trimmed by 1mm using a new tungsten carbide bur in a slow speed dental hand piece. Each tooth was then measured using the same digital caliper twice and the mean length was taken as the post-trimming true length (PostT-TL).

The teeth were then remounted using the film holder index and two further long cone periapical radiographs (conventional and PPS) were taken for each tooth using the same technique as before.

Measurements on the radiographs

The conventional radiographs were then digitised using a flatbed scanner [Epson perfection v750PRO (www.epson.com)] as 16 bit gray scale images at 300 dpi and no automatic adjustments. Both the scanned film and digital (PPS) periapical images were imported into Image J Link 1.4 software (http://rebweb.nih.gov/ij/index.html) for measurement. The total length of each tooth was measured from the apex of the root to the midpoint (mesio-distally) of the incisal edge. The true length of the metal rod and the length of the metal rod on the radiograph were used as a correction factor for the magnification to calculate the length of the tooth on the radiographs in millimeters. Each radiograph was measured by two observers (AE and GM), separately. Measurements were recorded on a second occasion two weeks later by one of the observers (A.E).

Statistical analysis:

- Intra-class correlation (ICC) was used to determine the inter-observer and intra-observer reliability.
- The level of accuracy of the two radiographic groups was evaluated in relation to the true length using ICC and Bland and Altman plots.
- The level of agreement between the two groups was determined using ICC and Bland and Altman plots.
- The ability to detect the change in tooth length was determined using paired t-rests for each group. The level of significance was set at $P<0.05$.

Results

The mean true tooth length measurements of the teeth pre-trimming and post-trimming are listed in table (25).

Intra-observer and inter-observer reliability

A high level of intra-observer and inter-observer agreement (ICC 0.978-0.997; reliability coefficient 0.992-0.999) was found for the measurements obtained from both scanned film and digital (PPS) radiographs.

Table 25: Mean true length measurements in millimeters of the experimental teeth before and after trimming using a digital caliper.

Tooth number	Pre-trimming mean true teeth length (PreT-TL) mm	Post-trimming mean true teeth length (PostT-TL) mm
1	20.03	18.97
2	19.53	18.55
3	19.70	18.76
4	20.28	19.21
5	19.85	18.80
6	23.04	22.01

Accuracy and agreement

A high level of agreement was found between the scanned film and digital (PPS) periapical radiographs and the true length of the teeth (Table 26 and Figures 5, 6). Moreover, a high level of agreement was found between the measurements from the scanned films and digital radiographs (Table 26 and Figure 7).

Table 26: Intra-class correlation for measurements from the scanned films, digital (PPS) radiographs and the true length of the teeth

	Intra-class correlation	Reliability coefficient	Mean difference (mm)	Standard Deviation	Limit of agreement *Mean diff ± 1.96 SD*	
Scanned film vs. True	0.979	0.989	-0.083	0.346	0.596	-0.763
Digital (PPS) vs. True	0.979	0.989	0.006	0.292	0.579	-0.565
Digital (PPS) vs. Scanned film	0.991	0.997	0.090	0.163	0.411	-0.231

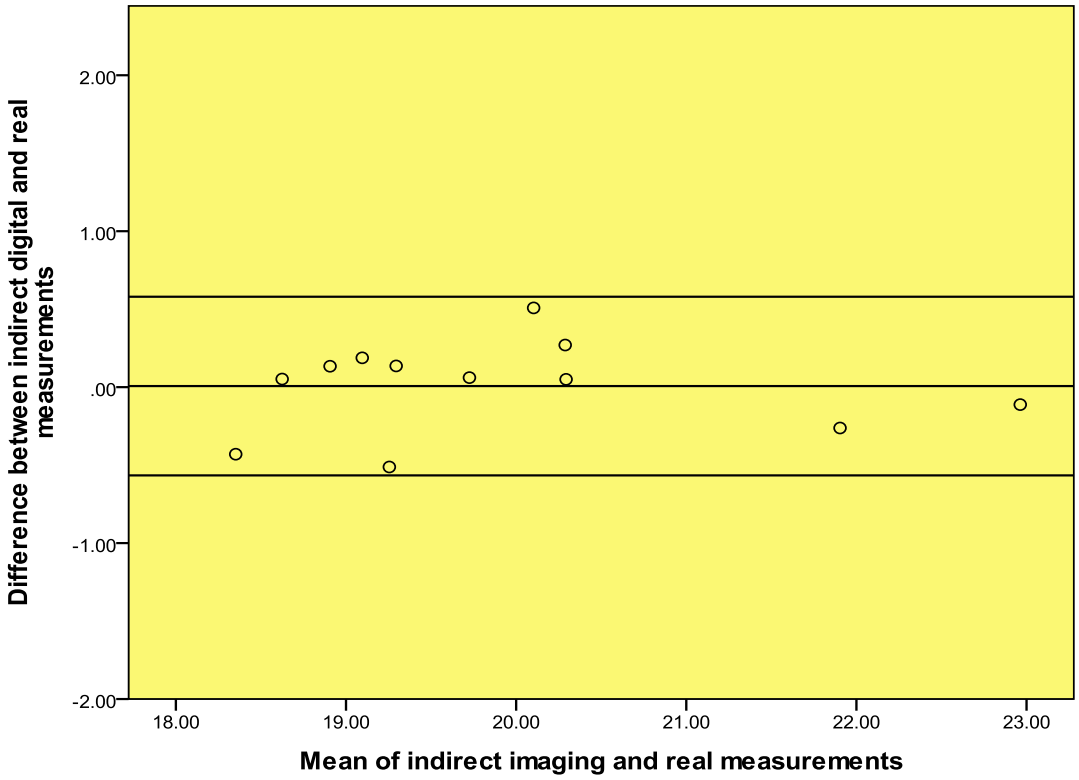

Figure 5 Bland and Altman plot of real tooth length vs. scanned film measurements

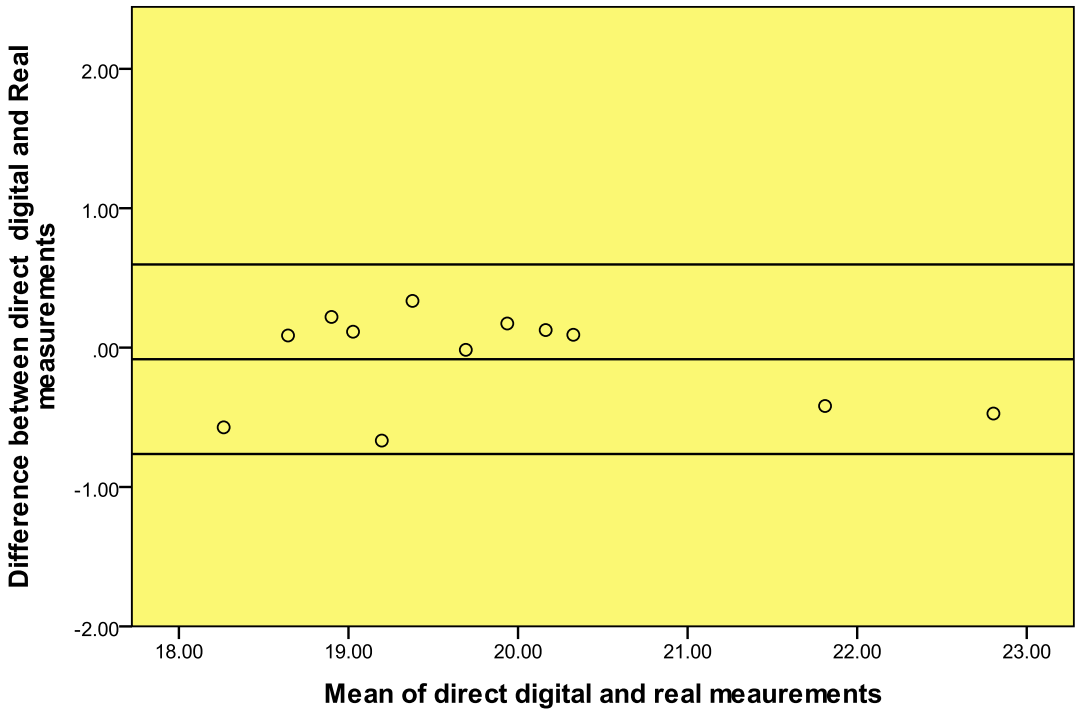

Figure 6 Bland and Altman plot of real tooth length vs. digital (PPS) measurements

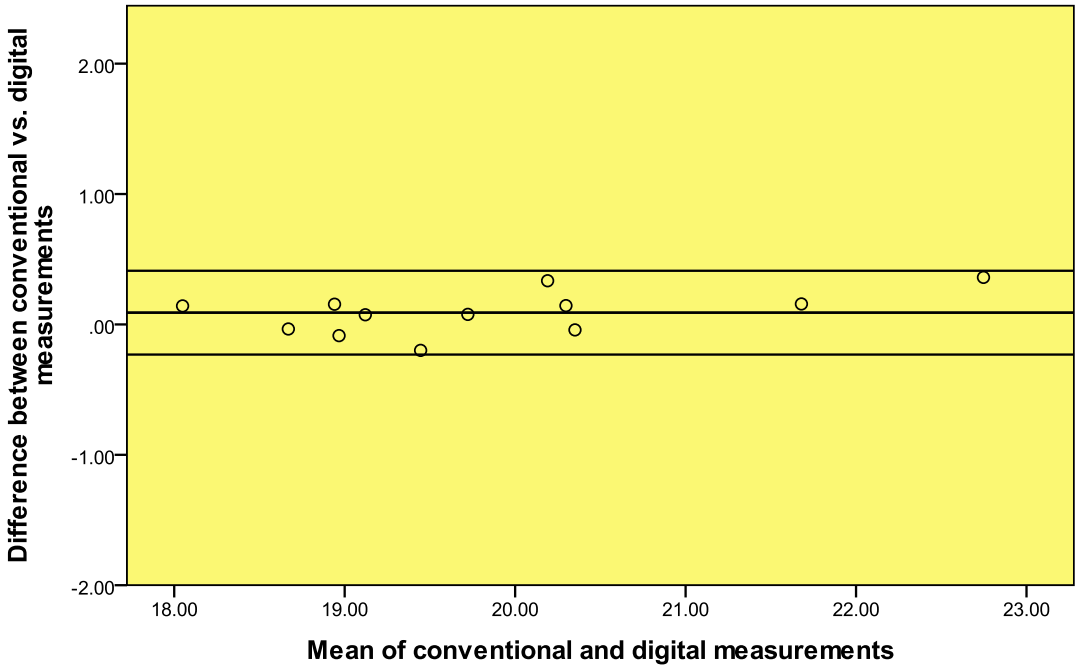

Table 7 Bland and Altman plot of scanned film vs. digital (PPS) measurements

Radiographic measurements of apical root shortening

The pre- and post- shortening measurements of the six teeth for each observer for conventional film measurements and digital (PPS) measurements were analyzed with paired t-tests to determine if the radiographs were able to detect a 1 millimeter change in root length at a statistically significant level (Table 27). In all cases the change in tooth length was statistically significant ($P<0.01$).

Table 27: Results of paired t-tests for apical tooth shortening.

	Mean difference (mm)	Standard deviation	Upper 95% Confidence Interval of the Difference	Lower 95% Confidence Interval of the Difference	P-value
Scanned Film Observer 1	1.14	0.32	0.80	1.47	<0.001
Scanned Film, Observer 2	1.19	0.37	0.80	1.57	0.001
Digital (PPS) Observer 1	0.97	0.24	0.72	1.22	<0.001
Digital (PPS) Observer 2	0.86	0.28	0.56	1.15	0.001

Discussion

The objective of this study was to compare the accuracy of scanned film and digital (PPS) radiographs for the measurement of tooth length before and after simulated apical OIIRR. We found that scanned film and digital (PPS) radiographs are accurate methods for measuring tooth length and moreover, there were high levels of agreement between scanned film and digital (PPS) periapical radiographs. Therefore the null hypothesis was rejected. The difference in the means between the two groups (0.16 mm) was clinically insignificant(Levander et al., 1998), and suggests that scanned film and digital (PPS) periapical radiographs are both appropriate for the measurement of OIIRR.

Apical OIIRR was simulated in the current study by trimming the root apex by 1mm, which is the level at which it becomes clinically significant (Levander et al., 1998). We found that both conventional film and digital (PPS) radiographs were able to statistically significantly ($p<0.01$) detect the 1 millimeter change with the sample size of six teeth. This supports the use of both these imaging modalities to detect changes due to OIIRR. Simulated apical OIIRR was assessed rather than resorption concavities as used by Kamburoğlu et al. (2008), Westphalen et al. (2004), Levander et al. (1998) and Borg et al. (1998). This was because we aimed to investigate the accuracy of the different radiographic methods for the linear measurement of tooth length rather than the sensitivity of detecting root resorption using subjective scoring systems. Three studies have compared linear measurements of root length using film and digital radiographs for endodontic purposes and found that the two types radiographs were comparable (Cederberg et al., 1998, Ong and Pitt Ford, 1995, Velders, 1995). Although these studies were not designed to assess simulated root resorption, it is noteworthy that our findings are in accordance with their findings.

We carried out a sample size calculation to determine the number of teeth that would be required. As only six teeth were required we were concerned that this could lead to random error obscuring the actual difference between the measurements made on the scanned film and digital (PPS) images. For this reason, we assessed the repeatability of the measurements for each group and compared the results to the true tooth

length. Any systematic error could also bias the results and we aimed to minimize this by making the radiographs as standardized as possible. A silicon impression material index was used to customize the film holder for each study tooth to eliminate any difference in radiographic angulations between the study groups. Moreover, a single metal rod of known length was placed in the typodont close to the root of the experimental teeth to allow the magnification of each radiograph to be calculated.

In conclusion scanned film and digital (PPS) periapical radiographs are accurate methods for measuring tooth length with a high level of agreement.

5.2. Validity of Bracket slot size SEM study.

Background

Pre-adjusted edgewise orthodontic brackets are mainly available in two slot dimensions 0.018 x 0.025-inch and 0.022x 0.028-inch. A wide variety of orthodontic archwires are used clinically in combination with the different bracket slot systems aiming for an ideal tooth movement in three dimensions.

The accurate dimensions of the bracket slot size and archwire allow the clinician to predict the tooth movement in all dimensions (Demling et al., 2009, Kusy and Whitley, 1999). A discrepancy in the dimensions of the bracket slot or/and archwire this may lead to improper interaction between them which can cause unpredicted tooth movement(Bhalla et al., 2010).

There has long been an assumption by clinicians that the dimensions of orthodontic brackets slots and archwires are accurate when compared to the manufacturer's published dimensions. Several studies have reported discrepancies between the manufacturers published and actual dimensions of orthodontic brackets slots and archwires (Joch et al., 2010, Cash et al., 2004). These discrepancies may have an influence on the efficiency of tooth position during orthodontic treatment (Bhalla et al., 2010).

Different methods have been used to measure the variability of the bracket slot dimensions (Table 28). Several studies reported significant difference in the

bracket slot dimension in comparison to the manufacturer's published dimensions. It was found that the bracket slot dimensions were oversize (Joch et al., 2010, Demling et al., 2009).

Table 28 Studies that instigated the accuracy of bracket slot dimensions

Study	**Method of measuring**	**Sample**	**Archwire**
Joch et al 2010	Leaf gauges	50 brackets	Micrometre 60
Cash et al 2004	Moxtascan	55 brackets	Not done
Bhalla et al 2010	S.E.M	30 brackets	Not done
Steve et al 2010	S.E.M	240 brackets	Not done
Demling et al 2009	Precision pin gauges	240 brackets	Not done
Kusy et al 1999	Optics of micro hardness tester	24 brackets	Micrometre 26 archwires

Aim of the study

- To determine the accuracy of pre-adjusted conventional (3M Victory Series MBT). 0.018x0.022-inch and 0.022x0.028-inch bracket slots when compared to the manufacturer's published data
- To determine the accuracy of the dimensions of some of the archwires used in combination with the two brackets slot systems when compared to the manufacturer's published data.

Null hypothesis

There is no difference in the bracket slot dimensions in the 0.018 and 0.022-inch bracket slot conventional pre-adjusted Victory brackets measured using SEM and the manufacturer published dimensions.

Materials and methods

Twenty-four upper central incisor brackets 3M-Unitek Victory Series MBT prescription, (www.solutions.3m.com) with 0.018 x 0.025-inch and 0.022 x 0.028-inch slots were investigated using scanning electron microscopy (JEOL 7400 FEGSEM & EDS). The brackets were assessed using the SEM at standardized magnification (x80); and Images were captured perpendicular to the mesial aspect of the bracket (side view).

The height and depth of each bracket slot were measured from the SEM images using ImageJ (www.rsbweb.nih.gov). The scale on the SEM image was used as a magnification factor to calculate the measurements made. The height of each bracket slot was measured from three points representing bracket inner, middle and outer height. The depth of the bracket was measured from the base of the slot wall to line x (Figure 9& 10).

The dimensions of the recommended archwires for the levelling and alignment stage for each bracket slot system were assessed (Table 29). The height and width of each archwire was measured using a digital caliper with0.001 accuracy (Mitotoya, Digimatic micrometer, Japan).

The brackets slots images and archwires were measured on two occasions by two investigators at 2 weeks interval. Measurements were compared with the manufacturer's published dimensions

Sample size calculation was done to detect a difference of 0.003mm (0.00011 inch) assuming a standard deviation of 0.002 mm with a 90% power and a significance level of $P<0.05$.

Table 29 Summary of the study sample

	Types	Sample needed	Method of measurement
Bracket slot	0.018 x 0.025-inch	12	SEM
	0.022x 0.028-inch	12	
Archwire dimensions	0.019x 0.025-inch nickel titanium	12	Digital calliper
	0.016x 0.022-inch nickel titanium	12	
	0.016x 0.022 -inch stainless steel	12	
	0.016 -inch nickel titanium	12	
	0.019x 0.025-inch stainless steel	12	

Results

A high level of agreement was found for the intra-investigator and inter-investigator bracket slot measurements using the Intra-class correlation test (0.995 and 0.997 respectively).

Brackets slot dimension results

Measurements form SEM images for both bracket slot systems are shown in Table 30. The mean slot height was 5.4% greater for the 0.018-inch brackets, and for the 0.022 slot group was 1.9% greater. Whilst the mean slot depth for the 0.018-inch group was increased at 3.6%, mean slot depth was smaller for the 0.022 slot group at 11.1%.

Scanning electron microscopy images are shown for the 0.018 bracket slot (Figure 8) and the 0.022-inch bracket clot (Figure 9). Figures 10 and 11 showing the working archwires ligated in the 0.018-inch and 0.022-inch bracket slots.

Table 30 Results for the SEM brackets slots dimensions

Bracket slot dimensions	Mean height	Inner height	Middle height	Outer height	Mean depth
0.018-inch	0.01896	0.01854	0.01904	0.01911	0.02592
SD	0.0003	0.00032	0.00038	0.00047	0.0018
0.018-inch Manufacturer published	0.018	0.018	0.018	0.018	0.025
Percentage difference 0.018 group	+5.4%	+3%	+5.7%	+6.1%	+3.6%
0.022-inch	0.02243	0.02205	0.02249	0.02253	0.02493
SD	0.00036	0.00039	0.00035	0.00043	0.00259
0.022-inch Manufacturer published	0.022	0.022	0.022	0.022	0.028
Percentage difference 0.022 group	+1.9%	+0.2%	+2.2%	+2.4%	-11.1%

Archwire dimensions results

A high level of agreement was found for the intra-investigator and inter-investigator bracket slot measurements using the Intra-class correlation test (0.985 and 0.927 respectively).

Measurements form digital caliper for the archwires are shown in Table 31. The percentage difference from the published size ranged from -1.22% to 0.77%.

Table 31: Results for the archwires measurements

Archwire	Mean width (inch)	Percentage difference	Mean Height (inch)	Percentage difference
0.016 NiTi	0.01580	-1.22%		
0.016x0.022 NiTi	0.02217	0.77%	0.01602	0.12%
0.016x0.022 SS	0.02200	0%	0.015940	-0.37%
0.019x0.025NiTi	0.025140	0.56%	0.018900	-0.53%
0.019x0.025SS	0.024835	-0.67%	0.019035	0.15%

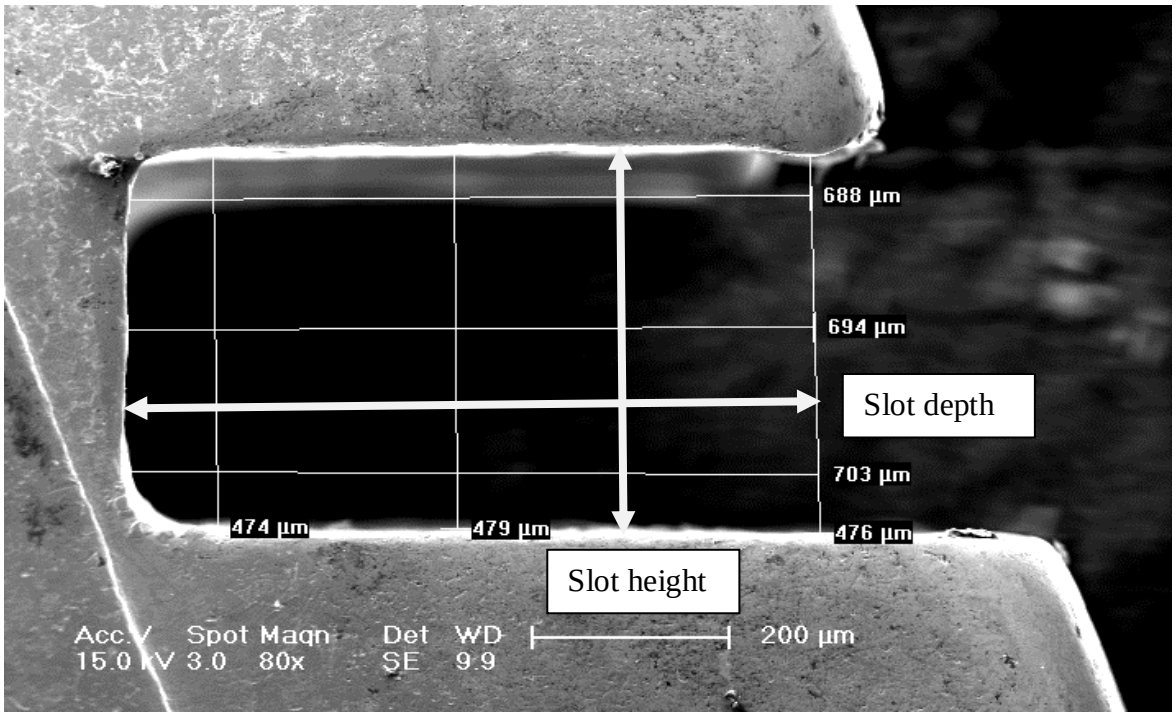

Figure 8 SEM image of 0.022 bracket slot

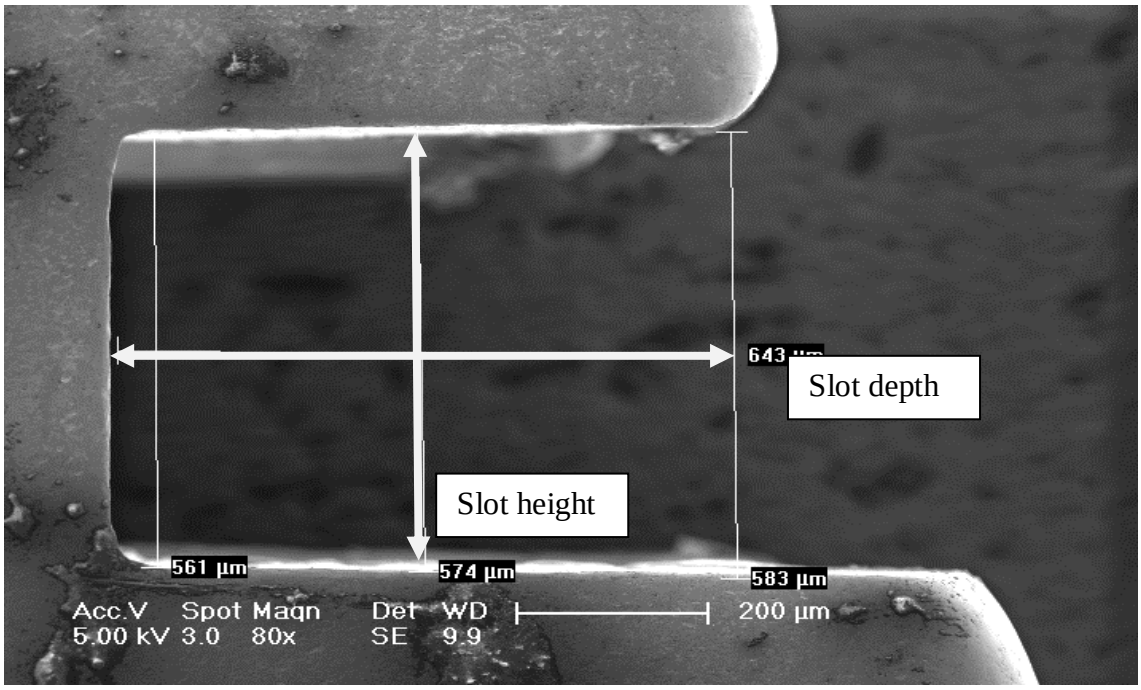

Figure 9 SEM image of 0.022 bracket slot

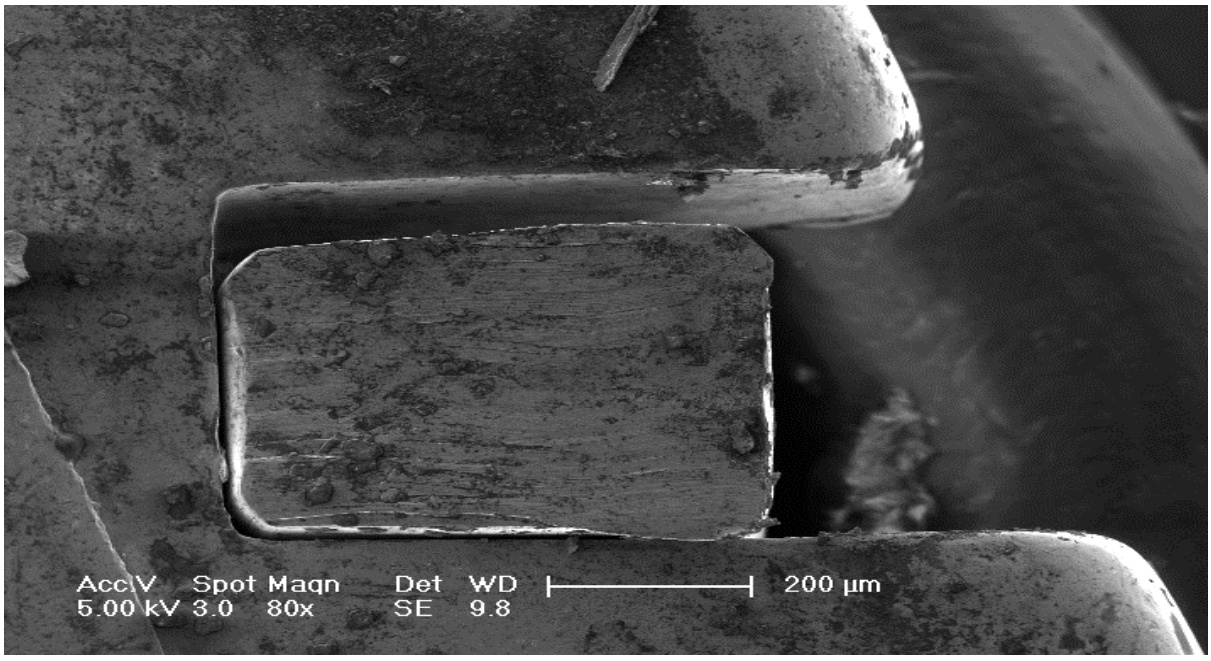

Figure 10 SEM image for 0.016x0.022 stainless steel arch wire ligated in a o.018 bracket slot

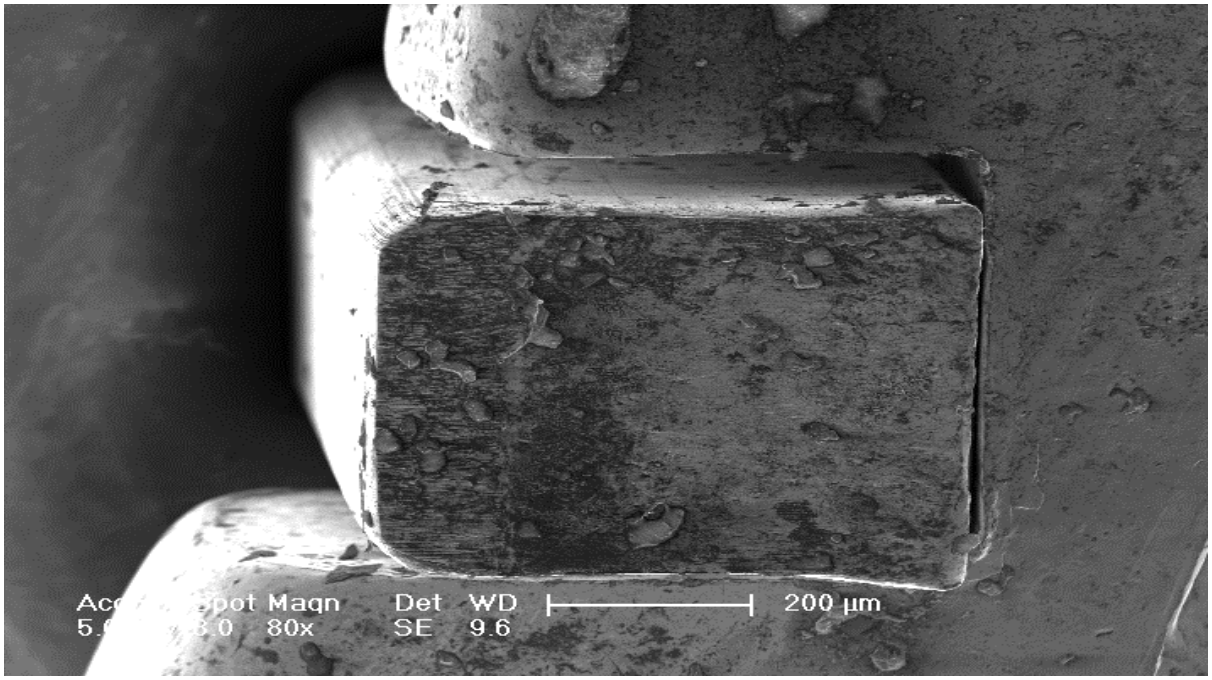

Figure11 SEM image for 0.019x0.025 stainless steel arch wire ligated in 0.022 bracket slot

Discussion

The use of SEM to measure the bracket slot dimensions provided a high degree of accuracy. The slot heights for both the 0.018-inch and 0.022-inch brackets were oversized when compared to the manufacturer's stated specification: 5.4% and 1.9% respectively. However, this increase is still within the tolerance of the DIN (1998) (10%). This agrees with several studies that have used different measuring methods (Fischer-Brandies et al., 2000, Joch et al., 2010, Bhalla et al., 2010). It is interesting to note that the height of the slot increases from the inner (base) to the outer aspect of the slot increased (Table 30).

Whilst the slot mean depth for the 0.018-inch group was increased compared to the manufacturer's published dimensions, the mean slot depth was smaller for

the 0.022 group at 0.0249-inch or 11.1% smaller. Therefore the large dimensions archwire recommended for 0.022 brackets may not be fully seated in the bracket slot. Therefore the null hypothesis was rejected.

The variation in the dimensions of the archwires assessed in comparisons to the manufacturer's published dimensions is minimal ranging from -1.22% to 0.77%.

Conclusion

The dimensions of the 0.018-inch and 0.022-inch 3M Victory Series bracket slots were greater than the manufacturer's dimensions but within the DIN standards tolerance limit except the slot depth in the 0.022 brackets which was significantly decreased.

Chapter 6: RESULTS

6.1. Baseline descriptive data of the study participants

One hundred and twelve orthodontic patients who met the inclusion criteria were invited to participate in the study between the three trial centres. Seven patients refused to participate and therefore there were 105 participants in the study. Thirteen participants were excluded from the analysis due to the various reasons shown in Table 1 leaving 92 patients included in the analysis.

Table 32: Frequency and distribution of dropouts

	Number	Study centre	Study group
Did not receive allocated intervention			
Patient withdrew before appliances provided	3	DDH&S	Group 1= 3 Group 2=0
Clinician used wrong appliance	1	SMC	Group 1=1 Group 2=0
Total	4	DDH&S=3 SMC=1	Group 1 =4 Group 2 = 0
Lost to follow up			
Patient did not finish alignment due to failure to attend multiple appointments	3	DDH&S	Group 1=1 Group 2=2
Patient could not be identified	3	DDH&S	Group 1=3 Group 2=0
Patient abandoned treatment	2	1 DDH&S 1 PRI	Group 1=1 Group 2=1
Patient moved away from the area	1	DDH&S	Group 1=0 Group 2=1
Total	**9**	DDH&S= 8 PRI= 1 SMC= 0	**Group 1=5** **Group 2=4**

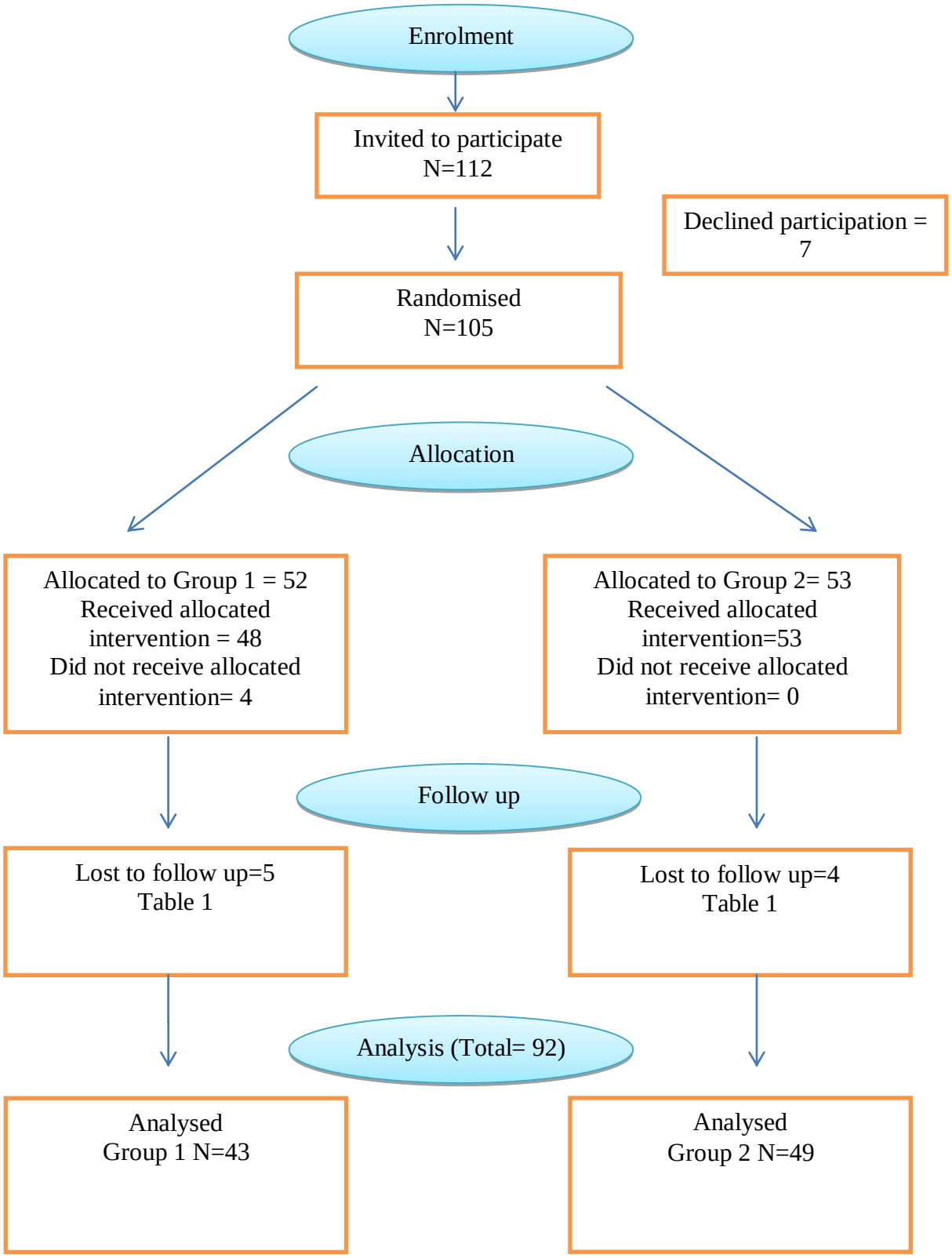

Figure 12: CONSORT flowchart for subjects invited to participate in the study.

The CONSORT flowchart was constructed to show the flow of subjects through the trial (Figure 12). Of the ninety two participants available for data analysis, 43 were in the 0.018 group and 49 were in the 0.022 group.

The percentage of drop outs in each category of data is shown in Table 33.

Table 33 Drop out in each category of data in the sample

Source of data collection	**0.018 group**	**0.022 group**	**Sample analysed**	**Total recruited**	**Missing**
Demographic data	49	53	102	105	3(2.8%)
Clinical notes data	43	49	92	105	13(12.7%)
Study models data	46	46	92	105	13(12.7%)
Smile's better questionnaire data	40	48	88	105	17(16%)
Maxillary (right and left added) central incisors data from Radiographs	56 Teeth	80 Teeth	136	105	74(35.7%)

The descriptive statistics for age are shown in Table 34 and 35.

Table 34: Descriptive statistics for age for the total sample

Total sample	Age (years)						
Number	Range	Mean	SD	Median	Percentiles		
					25%	50%	75%
102	12 - 48	19.55	8.60	16	14	16	21

Table 35: Descriptive statistics for age for the study groups

Age (years)				
Study groups	Number	Range	Mean	SD
0.018 group	49	12 - 42	19.69	9.10
0.022 group	53	13 - 48	19.42	8.20
Total sample	102	12-48	19.55	8.60

The distribution of gender in each study group and the total sample are shown in Table36.

Table 36: Distribution of gender in study groups

	Male	Female	Total
0.018 group	13(26.6%)	36(73.4%)	49(100%)
0.022 group	19(36.5%)	34(63.5%)	53(100%)
Total sample	32(31.2%)	70(68.8%)	102(100%)

The descriptive statistics for the severity of the malocclusion pre-treatment using the PAR index, and upper and lower dental arch irregularity scores performed using the ITA in each group and the total sample are shown in Table 37. High level of intra-investigator reliability was found (ICC= 0.960) for the scoring the amount of arch irregularity using the ITA score for the upper and lower arches.

Table 37: Descriptive statistics for PAR index and ITA

	0.018 group				0.022 group				Total sample			
	N	Range	Mean	SD	N	Range	Mean	SD	N	Range	Mean	SD
PAR score	46	10-56	34.21	11.2	46	19-68	36.23	10.17	92	10-68	35.27	10.67
Maxillary arch irregularity (ITA)	46	5- 38	16.65	6.23	46	6-40	18.09	8.12	92	5-40	17.37	7.24
Mandibular arch irregularity (ITA)	46	5-28	14.80	5.71	46	5-27	14.89	5.31	92	5-28	14.85	5.48

The distribution for malocclusion type and frequency of extractions in each study group and for the total sample are shown in Table 38, 39 and Figure 13.

Table 38: Distribution of malocclusion using BSI Incisor classification

		0.018 group	0.022 group	Total sample
Type of malocclusion	Class I	15(30.6%)	19(35.8%)	34(33.3%)
	Class II div 1	13(26.5%)	16(30.3%)	29(28.5%)
	Class II div 2	10(20.5%)	7(13.2%)	17(16.7%)
	Class III	11(22.4%)	11(20.7%)	22(21.5%)
	Total	49(100%)	53(100%)	102(100%)

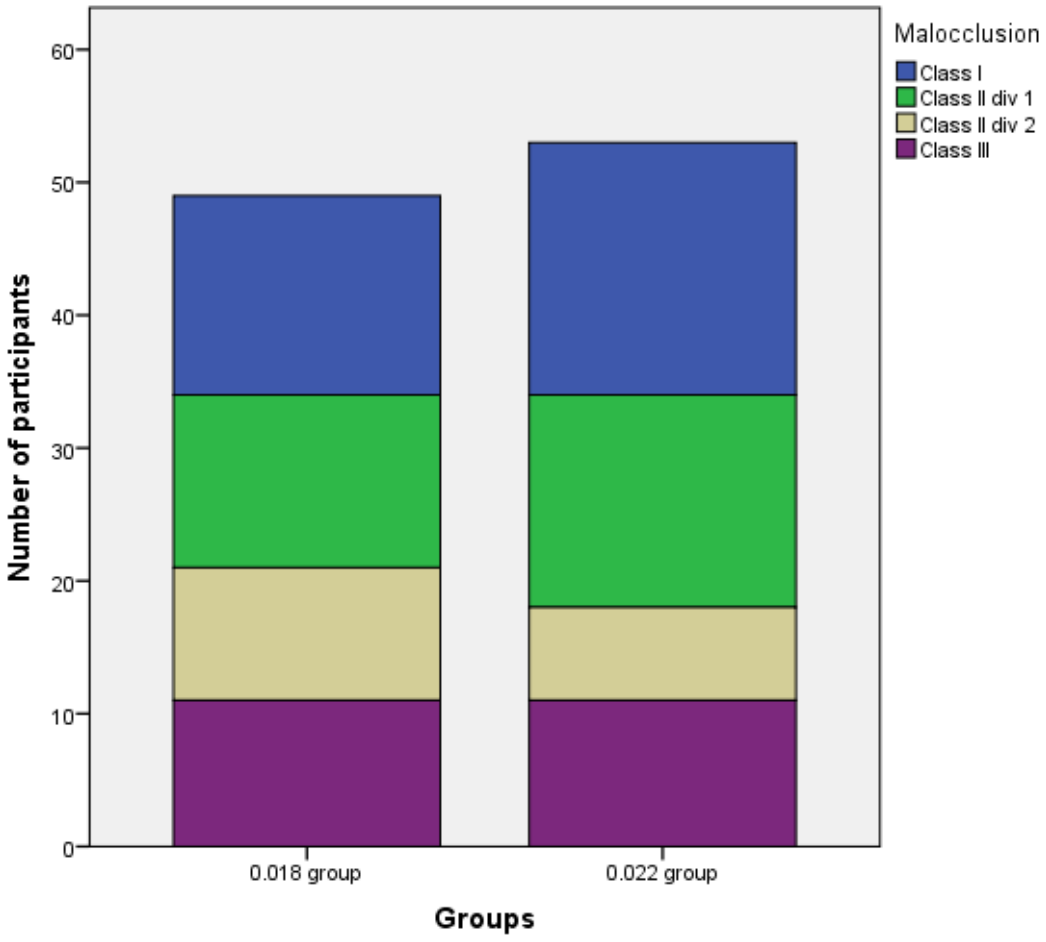

Figure 13 showing bar chart for malocclusion distribution among study groups

Table 39 Distribution of extractions

		0.018 group	0.022 group	Total sample
Extractions Maxillary arch	Extraction	33(68.8%)	36(68%)	69(68.3%)
	Non-extraction	15(31.2%)	17(32%)	32(31.7%)
	Total	48(100%)	53(100%)	101(100%)
Extractions Mandibular arch	Extraction	23(48%)	29(54.7%)	52(51.4%)
	Non-extraction	25(52%)	24(45.3%)	49(48.6%)
	Total	48(100%)	53(100%)	101(100%)
Extractions (maxillary or mandibular arches)	Extraction	33(69.8%)	37(69.8%)	70(69.3%)
	Non-extraction	15(31.2%)	16(31.2%)	31(30.7%)
	Total	48(100%)	53(100%)	101(100%)

One participant data was not included in Table 39 because it was not clear in the clinical notes if the participant had extraction done as part of treatment.

The distribution of patients with ectopic teeth that were orthodontically aligned in each group and the total sample is shown in Table 40.

Table 40: Distribution of upper and lower arches with orthodontically aligned ectopic teeth

		0.018 group	0.022 group	Total sample
Ectopic teeth in maxillary arch	Yes	5(10.2%)	6(11.3%)	11(12.0%)
	No	44(89.8%)	47(88.7%)	91(88.0%)
	Total	49(100%)	53(100%)	102 (100%)
Ectopic teeth in mandibular arch	Yes	0(0%)	2(3.9%)	2(1.9%)
	No	49(100%)	51(96.1%)	100(98.1%)
	Total	49100%)	53(100%)	102(100%)

The distribution of crowding/spacing in each group and the total sample is shown in Table 41and Figure14 and 15.

Table 41: Frequency distribution and percentage of crowding and spacing

		0.018 group	0.022 group	Total sample
Crowding maxillary arch	No crowding/ no spacing	0(0%)	1(2.2%)	1(1.3%)
	Mild crowding	20(43.4%)	14(30.5%)	34(36.9%)
	Moderate crowding	9(19.6%)	13(28.3%)	22(24%)
	Severe crowding	9(19.6%)	10(21.7%)	19(20.6%)
	Spacing	8(17.4%)	8(17.3%)	16(17.2%)
	Total	46(100%)	46(100%)	92(100%)
Crowding mandibular arch	No crowding/ no spacing	3(6.5%)	2(4.3%)	5(5.43 %)
	Mild crowding	18(39.1%)	18(39.2%)	36(39.2%)
	Moderate crowding	12(26.1%)	7(15.2%)	19(20.6%)
	Severe crowding	7(15.2%)	8(17.3%)	15(16.4%)
	Spacing	6(13%)	11(24%)	17(18.5%)
	Total	46(100%)	46(100%)	92(100%)

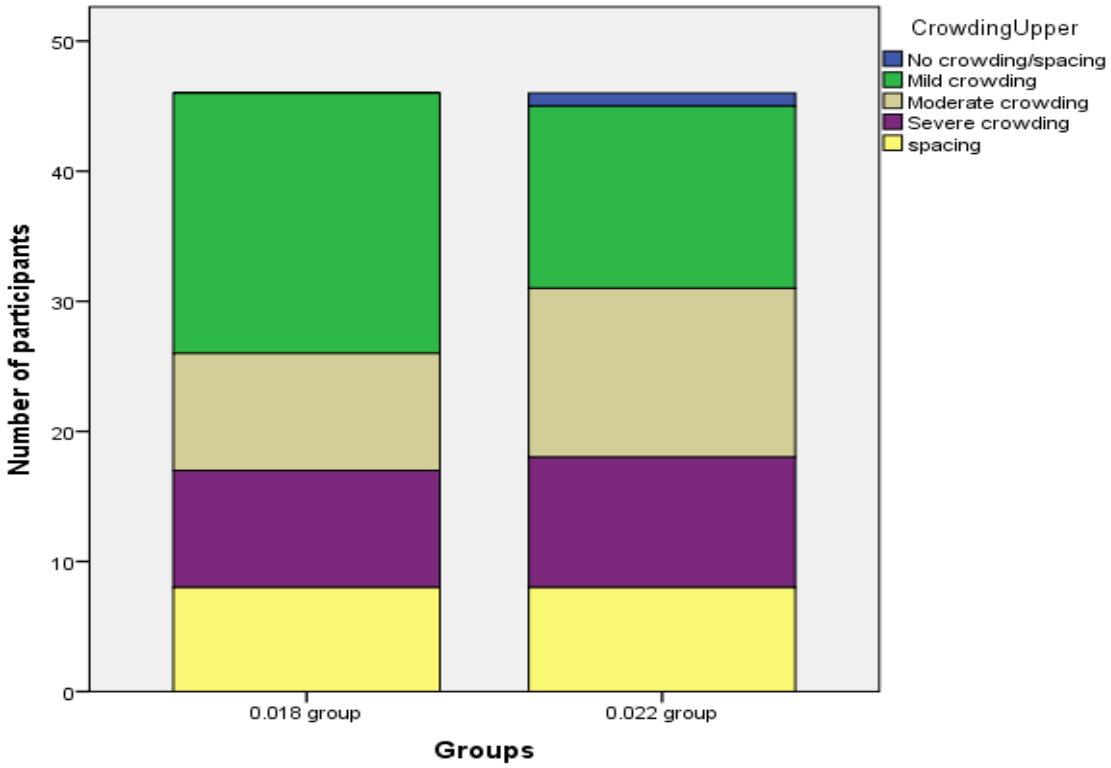

Figure 14 Distribution of severity of crowding in the upper arch

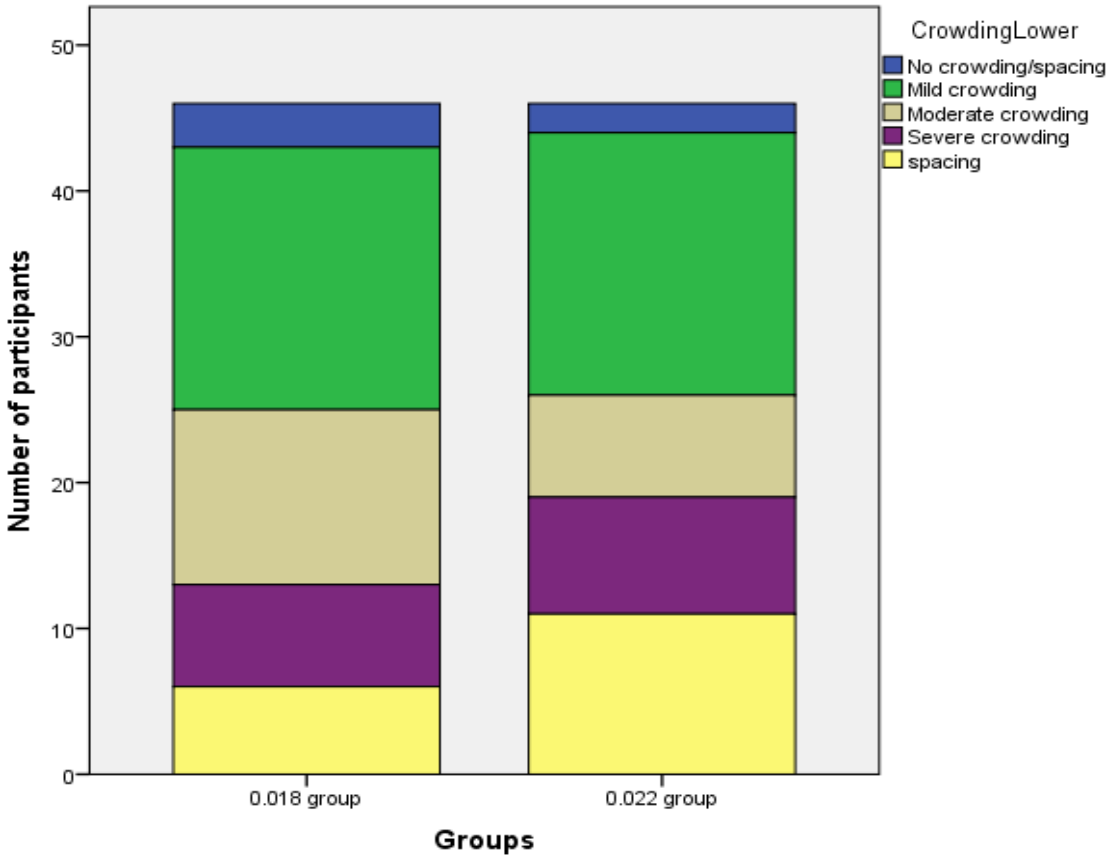

Figure 15 Distribution of the severity of crowding in the lower arch

The distribution of patients with history of trauma in maxillary anterior teeth and variation in root morphology in study groups and the total sample is shown in Table 42.

Table 42: Distribution of patients with history of trauma and root morphology of upper central incisors

History of trauma to maxillary incisors		0.018 group	0.022 group	Total sample
	Yes	13(26.5%)	8(15%)	21(20.55%)
	No	36(73.55)	45(85%)	81(79.45%)
	Total	49(100%)	53(100%)	102(100%)
Root morphology maxillary centrals (right and left teeth added)	Abnormal morphology	10(17.7%)	10(12.5%)	26(14%)
	Short root	2(3.5%)	2(2.5%)	4(3%)
	Blunt root	3(5.35)	5(6.25%)	8(5.8%)
	Apical bend	2(3.5%)	1(1.25%)	3(2.2%)
	Pipette shape	3(5.35)	1(1.25%)	4(3%)
	Normal	46(82.3%)	70(88.75%)	116(86%)
	Total	56(100%)	80(100%)	136(100%)

The descriptive data for scheduled appointments intervals (SAI) per group and total sample are shown in Table 43. The descriptive data for failed scheduled appointments and number of debonded brackets for each participant are shown in Table 44 and 45 and Figure 16.

Table 43: Descriptive data for scheduled appointment intervals (months)

Scheduled appointments intervals (months)				
Group	Arch	Number	Mean (months)	SD
0.018	Maxillary	43	1.442	0.442
	Mandibular	43	1.481	0.423
0.022	Maxillary	49	1.382	0.310
	Mandibular	49	1.406	0.319
Total sample	Maxillary	92	1.409	0.374
	Mandibular	92	1.441	0.370

Table 44: Descriptive data for number of failed appointments.

	Number of failed appointments				Number of participants who failed appointments		
Group	Number	Mean	SD		None	Up to 2	More than 2
0.018	43	1.07	1.880		27(62.8%)	9(20.9%)	7(16.3%)
0.022	49	0.78	1.331		30(61.2%)	15(30.6%)	4(8.2%)
Total sample	92	0.92	1.609		57(61.9%)	24(26.1)	12(12%)

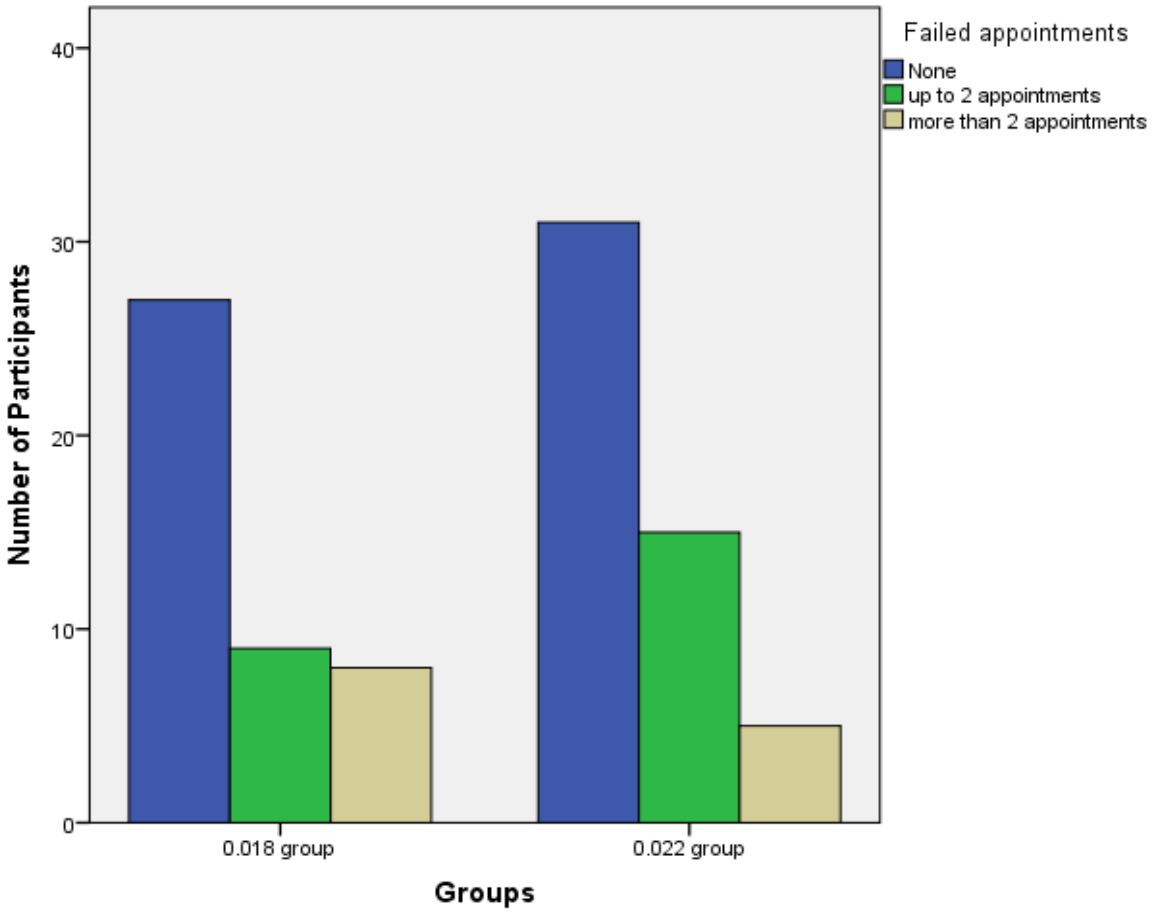

Figure 16 Distribution of number of failed appointments per patient in each group

Table 45 Descriptive data for number of debonded brackets.

Number of debonded brackets during alignment stage					
Group	Arch	Number	Range	Mean	SD
0.018	Maxillary	43	0-5	1.2	1.45
	Mandibular	43	0-5	0.70	1.2
0.022	Maxillary	49	0-7	1.40	1.64
	Mandibular	49	0-6	1.04	1.43
Total sample	Maxillary	92	0-7	1.22	1.56
	Mandibular	92	0-6	0.88	1.36

Comparison of the descriptive baseline variables between the two groups was performed using independent t-tests for continuous data and Chi square tests for ordinal and categorical data. No statistically significant differences were found between the two groups.

6.2. Treatment outcomes

6.2.1. Duration of alignment and number of treatment appointments

6.2.1.1. Descriptive statistics for duration of alignment and number of treatment appointments

Descriptive data for duration of treatment and number of visits for the study groups and the total study sample is shown in Table 46 and Figures 17 and 18.

The mean duration of alignment for the upper arch was 8.19 (SD+/-4.61) and 8.90 (SD+/-4.52) months for the 0.018 and 0.22 groups respectively; with a mean difference of 0.71 months. In the lower arch the duration of alignment was 8.21 (SD+/-3.51) and 8.67(SD+/- 3.98) months for the 0.018 and 0.22 groups respectively; with a mean difference of 0.46 months.

The number of scheduled alignment appointments for the upper arch was 5.65 (SD+/-2.56) and 6.37 (SD+/-2.58) visits for the 0.018 and 0.22 groups respectively; with a mean difference of 0.72 visits. In the lower arch the number of scheduled alignment appointments was 5.53 (SD+/-1.9) and 6.12 (SD+/- 2.26) for the 0.018 and 0.22 groups respectively; with a mean difference of 0.59 appointments.

Table 46: Descriptive data for the duration of alignment (months) and number of scheduled alignment appointments

	0.018 group				0.022 group				Total sample			
	N	Range	Mean	SD	N	Range	Mean	SD	N	Range	Mean	SD
Duration of alignment maxillary arch (months)	43	2- 22	8.19	4.61	49	3-23	8.90	4.52	92	2-23	8.57	4.55
Duration of alignment mandibular arch (months)	43	2-18	8.21	3.51	49	3-20	8.67	3.98	92	2-20	8.46	3.76
Number of maxillary alignment scheduled appointments	43	2-13	5.65	2.56	49	3-13	6.37	2.58	92	2-13	6.03	2.58
Number of mandibular alignment scheduled appointments	43	2-10	5.53	1.90	49	3-14	6.12	2.26	92	2-14	5.85	2.11

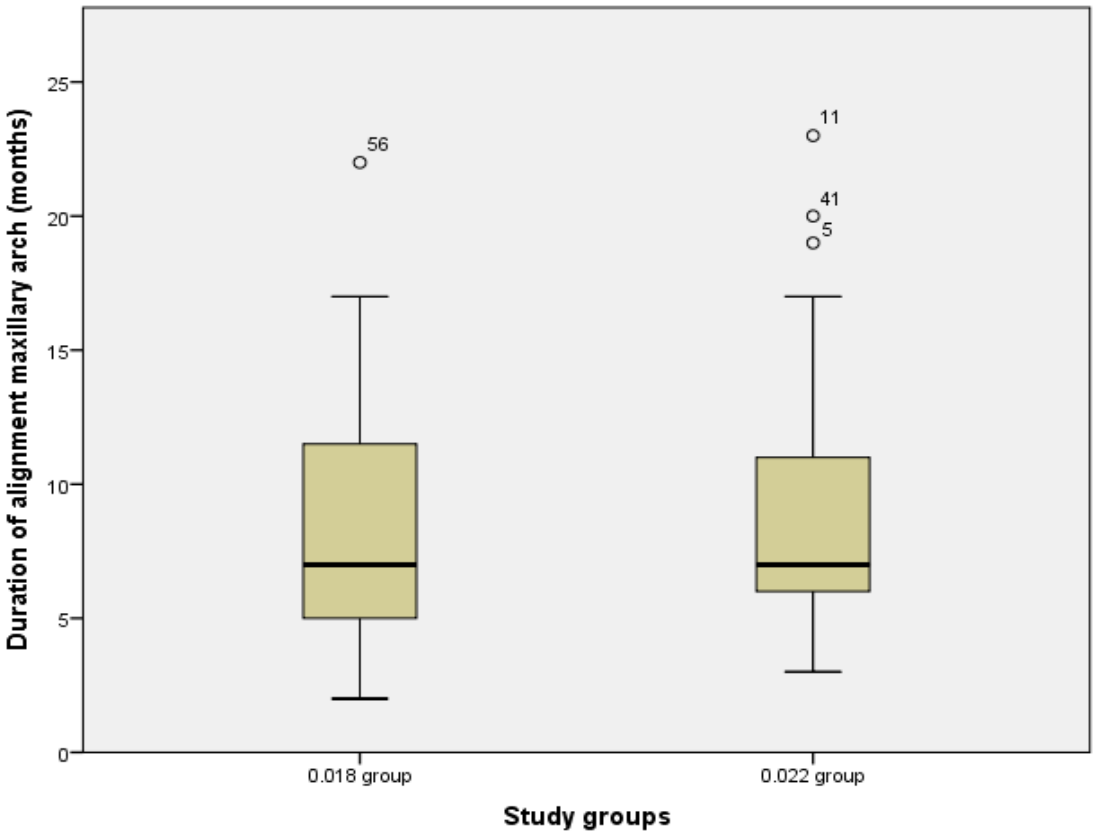

Figure 17 Boxplot for the duration of treatment in the upper arch (months)

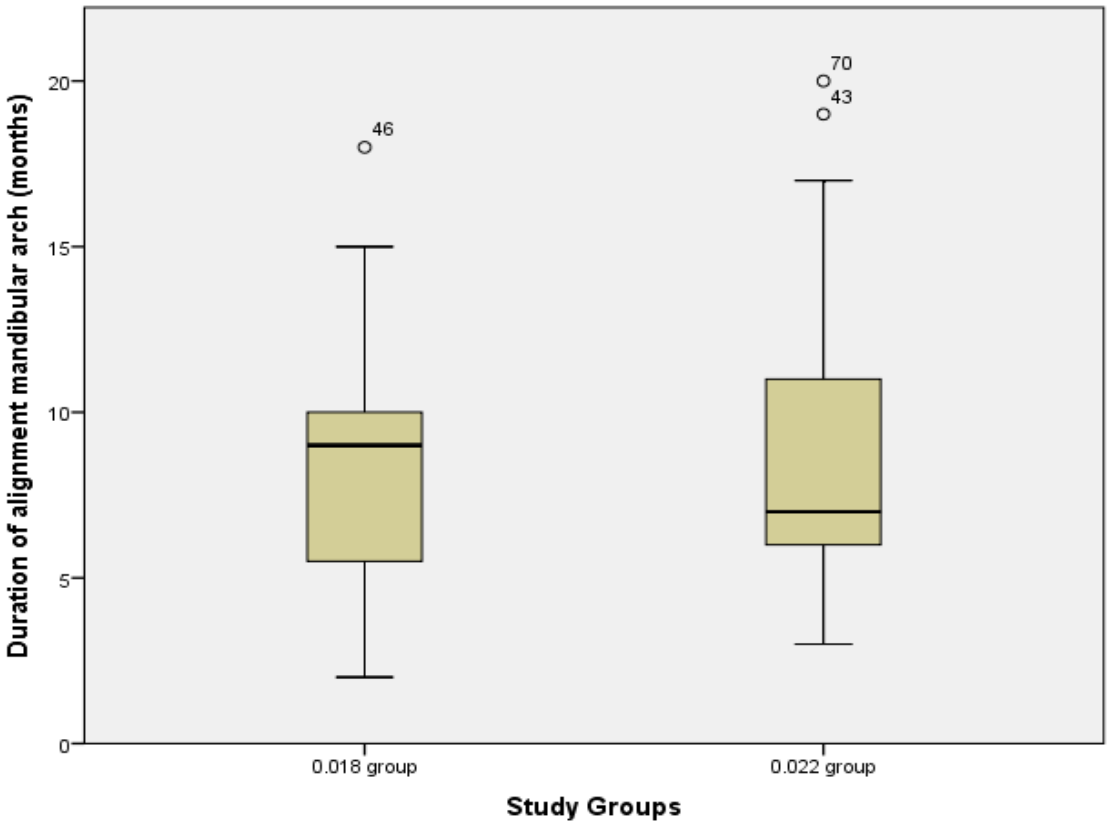

Figure 18 Boxplot for the duration of treatment in the lower arch (months).

It was noticed that the outliers for the duration of levelling and alignment stage presented in Figure (17 & 18) were due to extended duration for alignment of ectopic canines, deviation from the recommended archwire sequence and patient's failure to attend appointments.

There was homogeneity of variance between groups as assessed by Levene's test for equality of error variances (Table 47). A Shapiro-Wilk test was used to examine the normality of the distribution of the data representing the duration of alignment and the number of appointments for the alignment stage. The duration of alignment and the number of scheduled alignment visits were found to be non-normally distributed (Table 47). The data from both variables were transformed by multiplying by Log10 which was then found to be normally distributed (Table 48).

Table 47: Shapiro-Wilk test and Levene's test for normality and equality of data for duration of alignment and number of scheduled alignment visits

	Arch	Levene's test	Shapiro-Wilk test			
			Group	Statistic	df	Sig.
Duration of alignment	Maxillary arch	0.609	0.018	0.904	43	0.002*
			0.022	0.878	49	0.000*
	Mandibular arch	0.418	0.018	0.960	43	0.140
			0.022	0.913	49	0.001*
Number if scheduled alignment appointments	Maxillary arch	0.952	0.018	0.898	43	0.001*
			0.022	0.904	49	0.001*
	Mandibular arch	0.427	0.018	0.945	43	0.039*
			0.022	0.921	49	0.003*

Table 48: Shapiro-Wilk test for normality of data for Log10 duration of alignment and Log10 number of scheduled alignment visits

		Shapiro-Wilk test			
	Arch	Group	Statistic	df	Sig.
Log10 Duration of alignment	Maxillary arch	0.018	.974	43	.443
		0.022	.974	49	.356
	Mandibular arch	0.018	.935	43	.057
		0.022	.978	49	.477
Log10 Number of scheduled alignment appointments	Maxillary arch	0.018	.956	43	.102
		0.022	.954	49	.054
	Mandibular arch	0.018	.963	43	.183
		0.022	.964	49	.135

6.2.1.2. Comparison of mean duration of alignment and number of visits between 0.018-inch slot and 0.022-inch slot groups

ANOVA test was used to examine the effect of bracket slot size on mean log10 duration of alignment and mean log10 number of scheduled alignment visits (Table 49). There was no statistically significant difference in the mean log10 duration of alignment between 0.018 and 0.022-inch slot bracket groups. For the upper arch, *P*=0.255 (CI -0.145 to 0.039) and for the lower arch, *P*=0.630 (CI -0.110 to 0.057). Therefore, the null hypothesis for the influence of bracket slot size on the duration of alignment was accepted.

There was no statistically significant difference in the mean log10 number of scheduled alignment appointments between the 0.018 and 0.022-inch slot bracket groups. For the upper arch, *P*=0.115 (CI -0.133 to 0.014) and for the lower arch, *P*=0.269 (CI -0.106 to 0.022). Therefore, the null hypothesis for the influence of bracket slot size on the number of scheduled alignment visits was also accepted.

Table 49: ANOVA test to compare the mean Log10 duration of alignment and mean Log10 number of scheduled alignment visits between the 0.018 and 0.022 groups.

	ANOVA				
	Arch	Group	Mean	95% confidence interval	Sig. (p value)
Log10 Duration of alignment	Upper arch	0.018	0.847	-0.145 to 0.039	0.225
		0.022	0.901		
	Lower arch	0.018	0.869	-0.110 to 0.057	0.630
		0.022	0.895		
Log10 Number of scheduled alignment appointments	Upper arch	0.018	0.711	-0.133 to 0.014	0.115
		0.022	0.770		
	Lower arch	0.018	0.717	-0.106 to 0.022	0.269
		0.022	0.759		

The mean difference is significant at *P*< 0.05 level.

In addition to the results of the ANOVA tests reported above, a Mann Whitney U test was undertaken to examine the difference between the mean duration of alignment and number of scheduled alignment visits on the untransformed data (this was used as it is a non-parametric test because of the non-normally distributed data). No statistically significant difference was found (Table 50).

Table 50: Mann Whitney U test for duration of alignment and number of scheduled alignment visits

	Mann Whitney U				
	Arch	Group	Number	Mean Rank	Sig.
Duration of alignment (months)	Upper arch	0.018	43	43.38	0.292
		0.022	49	49.23	
	Lower arch	0.018	43	45.62	0.765
		0.022	49	47.28	
Number if scheduled alignment visits	Upper arch	0.018	43	41.81	0.111
		0.022	49	50.61	
	Lower arch	0.018	43	43.06	0.241
		0.022	49	49.52	

The rate of teeth alignment was calculated for each arch by dividing the amount of arch irregularity (ITA) by the duration of alignment in months (Table 51).

Table 51: Rate of teeth alignment in each arch.

Arch	Group	Rate of alignment mm/ months	
Maxillary arch	0.018	2.03	2.03 mm/months
	0.022	2.03	
Mandibular arch	0.018	1.8	1.75mm/months
	0.022	1.71	

6.2.1.3. Regression analysis for factors influencing duration of levelling and alignment

Initially univariate analysis was done for each independent variable that may influence the Log10 duration of alignment (Table52). The R^2 was calculated for each variable. Three independent variables out of eleven were found to have a statistically significant influence on the Log10 duration of alignment for the

maxillary arch; while six independent variables were found to have a statistically significant influence on the duration of alignment in the mandibular arch.

Table 52: Univariate analysis for factors that can influence Log10 duration of alignment

Independent variables	**Maxillary arch**		**Mandibular arch**	
	Sig.	R^2	Sig.	R^2
Age	0.129	0.04	0.035*	0.53
Gender	0.533	0.019	0.891	0.05
Type of Malocclusion	0.331	0.025	0.433	0.011
PAR score	0.312	0.023	0.080	0.039
Square root teeth irregularity MLII	0.051	0.055	0.026*	0.061
Crowding	0.732	0.010	0.386	0.010
Alignment of ectopic tooth	0.007*	0.091	0.551	0.008
Extraction	0.279	0.027	0.016*	0.067
Number ofFailed visits	0.000*	0.142	0.039*	0.051
SAI	0.000*	0.368	0.000*	0.376
Number of debonded brackets	0.977	0.014	0.030*	0.055
Bracket slot size	0.255	0.014	0.535	0.04

*Significance level at <0.05

A general multiple linear regression analysis to detect independent variables that can influence the duration of alignment for the maxillary arch was then undertaken by including independent multiple variables in the same model. Five independent

variables were found to significantly influence the duration of alignment in the upper arch with an R^2 value of 0.496: alignment of ectopic tooth, number of failed appointments, bracket slot size, scheduled appointments intervals and gender (Table 53).

Table 53: Multiple regression analysis of Log10 duration of alignment maxillary arch

Multiple regression analysis for Log10 duration of alignment maxillary arch				
	df	Mean Square	F	Sig
SAI	1	0.820	30.252	0.000*
Number of failed appointments	1	0.184	6.901	0.011*
Alignment of ectopic tooth	1	0.302	11.142	0.001*
Age	1	0.106	3.921	0.51
Gender	1	0.128	4.724	0.033*
Bracket slot size	1	0.193	7.115	0.009*

*significance level at <0.05; R^2=0.496

A general multiple linear regression analysis to detect factors that can influence the duration of alignment for the mandibular arch was undertaken by including independent multiple variables in the same model. Three factors were found to significantly influence the duration of alignment in the mandibular arch with R^2 value of 0.508: amount arch of irregularity, Scheduled appointments intervals and number of debonded brackets (Table 54).

Table 54: Multiple regression analysis of Log10 duration of alignment mandibular arch

Multiple regression analysis for Log10 duration of alignment mandibular arch				
	df	Mean Square	F	Sig
SAI	1	1.299	62.650	0.000*
Number of debonded brackets	1	0.344	16.605	0.000*
Arch irregularity	1	0.088	4.256	0.042*
Bracket slot size	1	0.008	0.372	0.544

*Significance level at <0.05; R^2=0.508

6.2.1.4. Comparison between the study centres

A T-test was used to compare the duration of alignment between the two main study centres as shown in Table 55.

Table 55 t-test to compare Log 10 duration of alignment between the two main study centres

	Centre	Number	t	df	Sig.
Log 10 Duration of alignment maxillary arch	DDH&S	71	1.428	88	0.157
	PRI	19			
Log 10 Duration of alignment mandibular arch	DDH&S	71	476	88	0.635
	PRI	19			

*Significant level at <0.05

6.3. Orthodontically induced inflammatory root resorption

6.3.1. Reliability of the results for OIIRR

Two investigators scored the periapical radiographs taken for the study participants at T0 and T1. A Kappa test was used to examine the agreement between the two investigators. The results suggest that there was substantial agreement (0.749) between the two investigators (*P*=0.000).

A Kappa test was also used to examine the intra-observer agreement across the two scoring sessions by the main investigator. The results from the kappa test indicate that there was high agreement (0.938) between the two episodes *(P*=0.000).

6.3.2. Descriptive data for OIIRR

Descriptive data for root resorption at start of treatment (T0) and 9 months in treatment (T1) for both study groups and the total study sample are shown in Tables 56 and 57and Figure 19.

Table 56: Descriptive data for root resorption at T0 (pre-treatment)

	Pre-treatment (T0) Root resorption affecting maxillary central incisors							
	N	Missing	Valid	Root resorption score				
				0	1	2	3	4
0.018 group	104 (100%)	48 (46.1%)	56 (53.9%)	53 (94.6%)	3 (5.4%)	0 (0%)	0 (0%)	0 (0%)
0.022 group	106 (100%)	27 (25.4%)	79 (74.6%)	75 (95.1%)	2 (2.5%)	1 (1.2%)	1 (1.2%)	0 (0%)
Total sample	210 (100%)	75 (35.7%)	135 (64.3%)	128 (94.8%)	5 (3.7%)	1 (0.7%)	1 (0.7%)	0 (0%)

Table 57: Descriptive data for OIIRR at T1 (9 months in treatment)

	Nine months in treatment (T1) OIIRR affecting maxillary central incisors							
	N	Missing	Valid	OIIRR score				
				0	1	2	3	4
0.018 group	104 (100%)	48 (46.1%)	56 (53.9%)	34 (60.7%)	12 (21.5%)	10 (17.8%)	0 (0%)	0 (0%)
0.022 group	106 (100%)	26 (24.5%)	80 (75.5%)	54 (67.5%)	17 (21.2%)	7 (8%)	2 (3.1%)	0 (0%)
Total sample	210 (100%)	74 (35.2%)	136 (64.8%)	88 (64.7%)	29 (21.3%)	17 (12.5%)	2 (1.2%)	0 (0%)

6.2.2.3. **Comparison of the severity OIIRR at T0 and T1**

The data for scoring OIIRR for the right and left maxillary central incisors were combined to represent a single dependent variable “upper central incisors OIIRR score”. The Friedman test for repeated ordinal variables was used to compare OIIRR score between T0 and T1 for the total sample and each study group (Table 58 and Figure 19). There was a statistically significant increase in the severity of OIIRR in T1 compared with T0 in the total sample and in each study group (P=0.000).

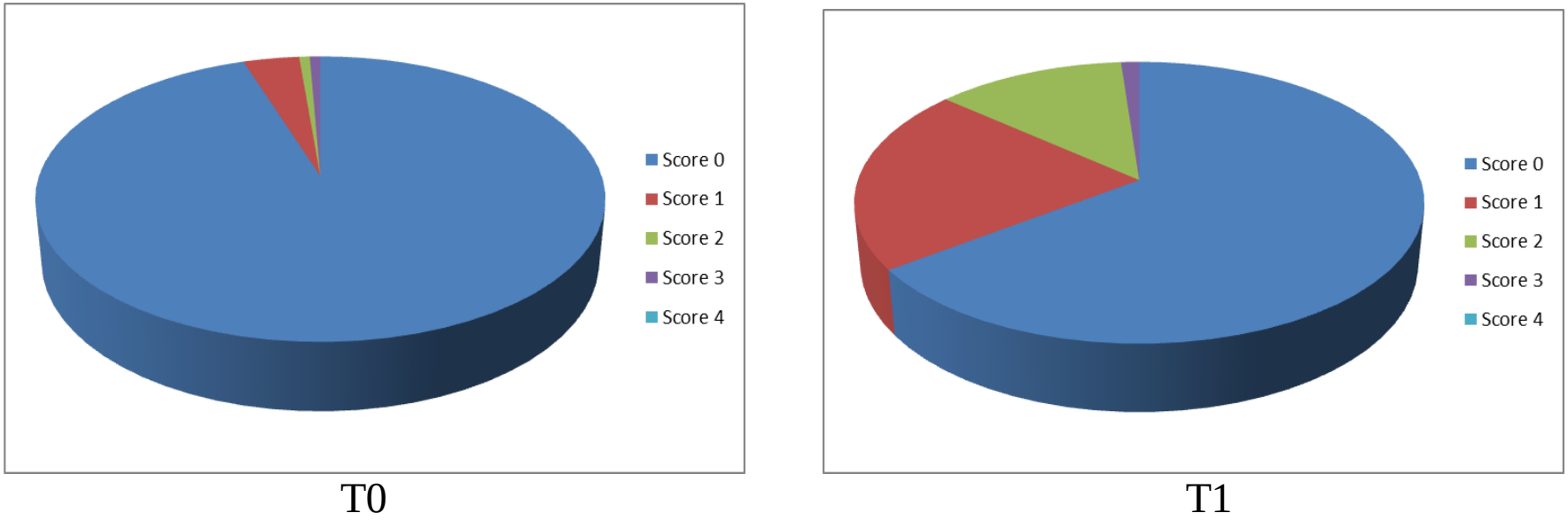

Figure 19 Percentage distribution of OIIRR T0 (LHS) and T1 (RHS) for the total sample.

Table 58: Friedman test for comparison of OIIRR between T0 and T1

		Number	Mean rank	Chi-square	df	Sig
0.018 group	T0	112	1.33	19.000	1	0.000*
	T1	112	1.67			
0.022 group	T0	158	1.37	21.000	1	0.000*
	T1	158	1.63			
Total sample	T0	270	1.35	40.00	1	0.000*
	T1	270	1.65			

*Significance level <0.05

6.2.2.4. Comparison of the severity OIIRR between 0.018 and 0.22

The severity of OIIRR was compared between 0.018 and 0.022 study groups at T0 and T1. No statistically significant difference was found between the two groups at T0 or T1 (Table 59). Therefore the null hypothesis was accepted.

Table 59: Kruskal Wallis test to compare OIIRR between 0.018 and 0.022-inch slot groups

	Group	Number	Mean rank	Chi square	Df	Sig.
T0	0.018	56	68.06	0.002	1	0.968
	0.022	79	67.96			
T1	0.018	56	71.59	0.816	1	0.366
	0.022	80	66.34			

Correlation between OIIRR at T1 with history of trauma to maxillary incisors and abnormal morphology was tested using Spearman's test (Table 60). No statistically significant correlation was found between OIIRR at T1 with history

of trauma to maxillary incisors and abnormal root morphology (*P*= 0.677 and *P*=0.155 respectively).

Table 60 showing correlation between OIIRR at T1 with history of trauma and abnormal root morphology

Correlation with the OIIRR at T1		
	Correlation coefficient R	Spearman's test Sig
History of Trauma to maxillary central incisors	0.036	0.677
Abnormal root morphology	0.136	0.115

6.2.3.Patient perception of treatment

6.2.3.1. Descriptive statistics

Descriptive statistics for the frequency distribution and percentage of the answers to the Smiles Better questionnaire for the total sample are contained in Tables 61-63.

Table 61: Distribution of the patients' answers to questions related experience of wearing fixed appliance for the the total sample

	Total study sample						
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	105(100%)	17(16%)	88(84%)	3(3.4%)	70(79.5%)	14(15.9%)	1(1.1%)
Eating	105(100%)	17(16%)	88(84%)	5(5.7%)	44(50%)	34(38.6%)	(5.7%)
Drinking	105(100%)	17(16%)	88(84%)	6(6.9%)	76(86.3%)	5(5.7%)	1(1.1%)
Sleeping	105(100%)	17(16%)	88(84%)	1(1.1%)	82(93.1%)	3(3.5%)	2(2.4%)
Appearance	105(100%)	17(16%)	88(84%)	36(40.9%)	40(45.4%)	11(12.5%)	1(1.1%)
Teasing	105(100%)	17(16%)	88(84%)	16(18.1%)	65(73.9%)	6(6.9%)	1(1.1%)
	Number	**Missing**	**Valid**	**Not at All**	**A little**	**A lot**	
Sore teeth	105(100%)	17(16%)	88(84%)	9(10.2%)	69(78.5%)	10(11.3%)	
Sore mouth	105(100%)	17(16%)	88(84%)	26(29.5%)	55(62.5%)	7(7.9%)	
Sore rubbing	105(100%)	17(16%)	88(84%)	22(25%)	55(62.5%)	11(12.5%)	
Embarrassed	105(100%)	17(16%)	88(84%)	70(79.5%)	16(18.1%)	2(2.4%)	
Dribbling	105(100%)	17(16%)	88(84%)	65(73.9%)	23(26.1%)	0(0%)	
Cleaning braces bother you?	105(100%)	17(16%)	88(84%)	35(39.0%)	45(51.1%)	8(9%)	

Table 62: Distribution of the patients' answers to questions related experience of wearing fixed appliance for the the total sample

Total study sample					
Do you feel that your teeth are moving?			Not at All	A little	A lot
Number= 105(100%)	Missing= 17(16%)	Valid= 88(84%)	7(8%)	33(37.5%)	48(54.5%)
Is it important for you whether or not your teeth are moving?			Not at All	A little	A lot
Number= 105(100%)	Missing= 18(17.1%)	Valid= 87(82.9%)	6(6.9%)	16(18.45)	65(74.6%)
Have you had extra visits because your brace was broken?			Yes	No	
Number= 105(100%)	Missing= 18(17.1%)	Valid= 87(82.9%)	47(54%)	40(46%)	
Did extra visits bother you?			Not at All	A little	A lot
Number= 105(100%)	Missing= 29(27.6%)	Valid= 74(72.4%)	46(62.1%)	26(35.1%)	2(2.8%)
Is wearing a brace what you expected?			Yes	No	Not sure
Number= 105(100%)	Missing= 18(17.1%)	Valid= 87(82.9%)	43(49.4%)	24(27.5%)	20(22.1%)
Overall experience with brace?			Positive	Negative	Neutral
Number= 105(100%)	Missing= 48(45.8%)	Valid= 57(54.2%)	36(63.1%)	13(22.8%)	89(14.1%)

Table 63: Distribution of the patients' answers to questions related experience of wearing fixed appliance for the total sample.

Total study sample						
How did your experience with braces affect your:						
	Number	Missing	Valid	Improved	Same	Worse
School work	105(100%)	23(21.9%)	72(78.1%)	3(4.1%)	68(94.4%)	1(1.5%)
Family relationship	105(100%)	17(16.1%)	88(83.9%)	6(6.1%)	80(91%)	2(2.9%)
Friendship	105(100%)	17(16.1%)	88(83.9%)	10(11.3%)	76(86.3%)	2(2.9%)
Hobbies	105(100%)	40(38.1%)	65(61.9%)	7(10.7%)	50(76.9%)	8(12.4%)

Descriptive statistics for the frequency distribution and percentage of the Smiles Better responses for the 0.018 group are shown in Tables 64-66.

Table 64: Distribution of the patients' answers to questions related experience of wearing fixed appliance for the 0.018 group.

	0.018 group						
Patient's experience regarding	Number	Missing	Valid	Improved	Same	Slightly worse	Much worse
Speech	52(100%)	12(23%)	40(77%)	2(5%)	33(8.5%)	4(10%)	1(2.5%)
Eating	52(100%)	12(23%)	40(77%)	4(10%)	19(47.5%)	15(37.5%)	2(5%)
Drinking	52(100%)	12(23%)	40(77%)	4(10%)	35(87.5%)	1(2.5%)	0(0%)
Sleeping	52(100%)	12(23%)	40(77%)	0(0%)	38(95%)	2(5%)	0(0%)
Appearance	52(100%)	12(23%)	40(77%)	15(37.5%)	20(50%)	5(12.5%)	0(0%)
Teasing	52(100%)	12(23%)	40(77%)	6(15%)	29(72.5%)	4(10%)	1(2.5%)
	Number	Missing	Valid	Not at All	A little	A lot	
Sore teeth	52(100%)	12(23%)	40(77%)	0(0%)	37(92.5%)	3(7.5%)	
Sore mouth	52(100%)	12(23%)	40(77%)	13(32.5%)	24(60%)	3(7.5%)	
Sore rubbing	52(100%)	12(23%)	40(77%)	11(27.5%)	23(57.5%)	6(15%)	
Embarrassed	52(100%)	12(23%)	40(77%)	32(80%)	8(20%)	0(0%)	
Dribbling	52(100%)	12(23%)	40(77%)	32(80%)	8(20%)	0(0%)	
Cleaning braces bother you?	52(100%)	12(23%)	40(77%)	19(47.5%)	17(42.5%)	4(10%)	

Table 65: Distribution of the patients' answers to questions related experience of wearing fixed appliance for the 0.018 group.

0.018 group					
Do you feel that your teeth are moving?			Not at All	A little	A lot
Number= 52(100%)	Missing= 12(23.1%)	Valid= 40(76.9%)	4(10%)	15(37.5%)	21(52.5%)
Is it important for you whether or not your teeth are moving?			Not at All	A little	A lot
Number= 52(100%)	Missing= 13(25%)	Valid= 39(75%)	2(5.1%)	8(20.5%)	29(74.4%)
Have you had extra visits because your brace was broken?			Yes	No	
Number= 52(100%)	Missing= 12(23.1%)	Valid= 40(76.9%)	19(47.5%)	21(52.5%)	
Did extra visits bother you?			Not at All	A little	A lot
Number= 52(100%)	Missing= 18(34.6%)	Valid= 34(65.4%)	20(58.8%)	12(35.25)	2(5.8%)
Is wearing a brace what you expected?			Yes	No	Not sure
Number= 52(100%)	Missing= 12(23.1%)	Valid= 40(76.9%)	21(52.5%)	9(22.5%)	10(35%)
Overall experience with brace?			Positive	Negative	Neutral
Number= 52(100%)	Missing= 28(53.9%)	Valid= 24(46.1%)	16(66.6%)	6(25%)	2(8.3%)

Table 66 Distribution of the patients' answers to questions related experience of wearing fixed appliance for the 0.018 group

0.018 group						
How did your experience with braces affected:						
	Number	Missing	Valid	Improved	Same	Worse
School work	52(100%)	19(36.5%)	33(63.5%)	1(3.2%)	31(95.4%)	1(3.2%)
Family relationship	52(100%)	13(25%)	39(75%)	2(5%)	37(95%)	1(2.5%)
Friendship	52(100%)	12(23.1%)	40(76.9%)	2(5%)	37(92.5%)	1(2.5%)
Hobbies	52(100%)	23(44.2%)	29(55.8%)	3(10.3%)	22(75.8%)	3(14.2%)

Descriptive statistics for the frequency distribution and percentage of the Smiles Better responses are shown in Tables 67-69.

Table 67: Distribution of the patients' answers to questions related experience of wearing fixed appliance for the 0.022 group.

	0.022 group						
Patient's experience regarding:	Number	Missing	Valid	Improved	Same	Slightly worse	Much worse
Speech	53(100%)	5(9.5%)	48(90.5%)	1(2%)	37(77%)	10(20%)	0(0%)
Eating	53(100%)	5(9.5%)	48(90.5%)	1(2%)	25(52.5%)	19(39.5%)	3(6%)
Drinking	53(100%)	5(9.5%)	48(90.5%)	2(4%)	41(84.8%)	4(8.2%)	1(2%)
Sleeping	53(100%)	5(9.5%)	48(90.5%)	1(2%)	44(92%)	1(2%)	2(4%)
Appearance	53(100%)	5(9.5%)	48(90.5%)	21(43.8%)	20(41.6%)	6(12.5%)	1(2%)
Teasing	53(100%)	5(9.5%)	48(90.5%)	10(20%)	36(76%)	2(4%)	0(0%)
	Number	Missing	Valid	Not at All	A little	A lot	
Sore teeth	53(100%)	5(9.5%)	48(90.5%)	9(18.7%)	32(66.6%)	7(14.7%)	
Sore mouth	53(100%)	5(9.5%)	48(90.5%)	13(27%)	31(64.8%)	4(8.2%)	
Sore rubbing	53(100%)	5(9.5%)	48(90.5%)	11(23%)	32(66.6%)	5(10.4%)	
Embarrassed	53(100%)	5(9.5%)	48(90.5%)	38(79.4%)	8(16.6%)	2(4%)	
Dribbling	53(100%)	5(9.5%)	48(90.5%)	33(68.8%)	15(31.2%)	0(0%)	
Cleaning braces bother you?	53(100%)	5(9.5%)	48(90.5%)	16(33.5%)	28(58.3%)	4(8.2%)	

Table 68: Distribution of patients' answers to questions related to fixed appliance experience for the 0.022 group.

0.022 group					
Do you feel that your teeth are moving?			Not at All	A little	A lot
Number= 53(100%)	Missing= 5(5.7%)	Valid= 48(94.3%)	3(6%)	18(37.5%)	27(56.5%)
Is it important for you whether or not your teeth are moving?			Not at All	A little	A lot
Number= 53(100%)	Missing= 5(5.7%)	Valid= 48(94.3%)	4(8%)	8(16.6%)	36(75.4%)
Have you had extra visits because your brace was broken?			Yes	No	
Number= 53(100%)	Missing= 6(11.4%)	Valid= 47(88.6%)	28(60%)	19(40%)	
Did extra visits bother you?			Not at All	A little	A lot
Number= 53(100%)	Missing= 13(24.5%)	Valid= 40(75.5%)	26(65%)	14(35%)	0(0%)
Is wearing a brace what you expected?			Yes	No	Not sure
Number= 53(100%)	Missing= 6(11.4%)	Valid= 47(88.6%)	22(37%)	15(32%)	10(31%)
Overall experience with brace?			Positive	Negative	Neutral
Number= 53(100%)	Missing= 20(37.7%)	Valid= 33(62.3%)	20(60.5%)	7(21.3%)	6(18.2%)

Table 69: Distribution of the patients' answers to questions related to the impact of the effect of fixed appliance for 0.022 group.

0.022 group						
How did your experience with braces affected:						
	Number	Missing	Valid	Improved	Same	Worse
School work	53(100%)	14(26.45%	39(73.6%)	2(5%)	37(95%)	0(0%)
Family relationship	53(100%)	5(9.3%)	48(90.7%)	4(8%)	43(90%)	1(2%)
Friendship	53(100%)	5(9.3%)	48(90.7%)	8(16.6%)	39(81.4%)	1(2%)
Hobbies	53(100%)	16(30.1%)	37(69.9%)	4(10.8%)	28(75.6%)	5(13.6%)

A list of examples of some of the common positive and negative comments written by the study participants for the open questions in the Smiles Better questionnaire asking about the overall experience and the advice for someone who is about to start orthodontic treatment are shown in Table 70.

Figure 70: Some of the common positive and negative comments from Smiles Better questionnaire.

Positive comments	**Negative comments**
"Do it because it is worth it in the end"	"It is sore for a couple of days"
"It is not as bad as you think it is. It helps improve your smile"	"it is more painful than I thought , it affect my lifestyle, but it is worth it"
"it is nothing to worry about "	"it is not an easy undertaken "
"It is not affecting me much"	"Ulcers, sore gums and teeth. Worth it at the end"
"not as bad as people say, I like my brace it made such a good difference"	"have plenty of pain killers at hand"

5.2.2. Comparison of patient perception of fixed orthodontic between 0.018 and 0.022 groups

A Chi-square test was used to compare patient's perception to fixed orthodontic braces through the Smiles Better questionnaire responses between the 0.018 and the 0.022 groups (Table 71). No statistically significant difference was found between the two study groups for any of the questionnaire aspects except the soreness of teeth due to wearing braces. (*P=0.006).* Therefore the null hypothesis was rejected.

Figure 71: Chi-square test to compare between 0.018 and 0.022 for Smiles better questionnaire.

Patient's experience regarding	Study group	Number	Person Chi square Value	df	Sig.
Speech	0.018	40	3.43	3	0.329
	0.022	48			
Eating	0.018	40	2.58	3	0.461
	0.022	48			
Drinking	0.018	40	3.24	3	0.356
	0.022	48			
Sleeping	0.018	40	3.07	3	0.381
	0.022	48			
Appearance	0.018	40	1.37	3	0.711
	0.022	48			
Teasing	0.018	40	2.71	3	0.438
	0.022	48			
Sore teeth	0.018	40	10.32	2	0.006*
	0.022	48			
Sore mouth	0.018	40	0.309	2	0.857
	0.022	48			
Sore rubbing	0.018	40	0.843	2	0.656
	0.022	48			
Embarrassed	0.018	40	1.804	2	0.406

	0.022	48			
Dribbling	0.018	40	1.403	1	0.232
	0.022	48			
Cleaning braces	0.018	40	2.237	2	0.327
	0.022	48			
Do you feel that your teeth are moving?	0.018	40	0.442	2	0.802
	0.022	48			
Is it important for you whether or not your teeth are moving?	0.018	39	1.707	3	0.635
	0.022	48			
Have you had extra visits because your brace was broken?	0.018	40	1.268	1	0.260
	0.022	47			
Did extra visits bother you?	0.018	34	4.140	4	0.387
	0.022	40			
Is wearing a brace what you expected?	0.018	40	0.966	2	0.617
	0.022	47			
Overall experience with brace?	0.018	24	1.128	2	0.569
	0.022	33			
School work	0.018	33	1.372	2	0.504
	0.022	39			
Family relationship	0.018	39	0.393	2	0.822
	0.022	48			
Friendship	0.018	40	2.950	2	0.229
	0.022	48			
Hobbies	0.018	29	0.119	2	0.942
	0.022	37			

***Significant level at <0.05.**

Chapter 7: DISCUSSION

The main aim of the current study was to compare 0.018-inch and 0.022-inch bracket slot systems in terms of the effectiveness of levelling and alignment stage. The results of the current study will be discussed in this chapter with referral to the relevant studies published in the literature to allow the reader to have a reasonable understanding of the position of the current findings in relation to the evidence available.

7.1. Description of the sample

In the current study 105 participants were recruited with 52 participants in the 0.018-inch group and 53 participants in the 0.022-inch group. The current sample per group is relatively higher than most of the RCTs published in the literature that investigated the effectiveness of the levelling and alignment stage (ranging from 12- 44 participants) with the exception of Mandall et al. (2006) who recruited 52 participants in each study group(Scott et al., 2008a, Fleming et al., 2009a, Sebastian, 2012).

Thirteen participants were excluded due to various reasons accounting for 12.3% drop out in the current study; leaving 43 participants in the 0.018 group and 49 participants in the 0.022 group for analysis as shown in the flow chart. This drop out percentage is slightly higher than most of the RCTs published in the literature (ranging from 0% - 5.7%) that investigated the effectiveness of the levelling and alignment stage. However, Mandall et al. (2006) reported higher dropout rate (16.5%). It is important to note that the drop out percentage in the current study

did not exceed the predicted drop out percentage suggested from the prior sample size calculation. This will be discussed in section 7.4. (study strengths and weakness).

Age

It was decided in this study to limit age in the inclusion criteria to patients 12 years and older on the day of recruitment to ensure the complete root formation of the maxillary anterior segment teeth to limit the effect of root development when assessing the severity of OIIRR. The mean age of participants in the study was 19.55 years (range 12-48); with 25% being adult patients. This is in accordance with several studies that have reported a gradual increase in the proportion of adult orthodontic patients over the last two decades (Nattrass and Sandy, 1995).

Most studies which have investigated the duration of alignment have excluded adult patients during recruitment (Mandall et al., 2006, Sebastian, 2012). However, a few studies have had no restriction on the recruitment of adult patients. These have reported a relatively similar mean age 14.4-16.7 years (Riley and Bearn, 2009, Cobb et al., 1998, Ong et al., 2011, Jones et al., 1990). This indicates that the current sample in terms of age is relatively more diverse and includes more adult patients when compared to previous studies reported in the literature. In spite of this, the age distribution in both study groups did not significantly differ. Moreover, there is no evidence to suggest that age differences can significantly influence the duration of orthodontic treatment in general, including the alignment stage (Robb et al., 1998).

Gender

In the current study more female than male patients were recruited, at 68.2% and 31.8% respectively. There was no statistically significant difference in the gender distribution between the two study groups. This agrees with several studies that investigated the duration of alignment (West et al., 1995, Wahab et al., 2012, Ong et al., 2011, Mandall et al., 2006)and as such was an expected finding. Although, no statistically significant difference in the prevalence of malocclusion between females and males exists (Brunnelle et al., 1996, Harris and Glassell, 2011) it has been reported in the literature that female patients seek orthodontic treatment more than males (Kerosuo et al., 2000, O'Brien et al., 1996, Harris and Glassell, 2011).

Malocclusion groups

All types of malocclusion were recruited in the current study sample with Class I and II division 1 representing almost two thirds of the sample, with 16.7% having a Class II division 2 malocclusion and Class III malocclusion accounting for one fifth of the sample . This distribution of malocclusion is slightly different from that reported by several studies (Beckwith et al., 1999, Skidmore et al., 2006, Vu et al., 2008) with a relatively increased proportion of subjects with Class III malocclusion. This may be explained by the increased prevalence of Class III malocclusion in Scotland (Luffingham and Campbell, 1974) .

Severity of malocclusion

The severity of malocclusion was evaluated in this study using several methods that included PAR score, severity of crowding and amount of irregularity in the upper and lower arches. The mean PAR score for the total sample studied was 35.27 SD +/- 10.67 which was higher than that reported by several previous studies with PAR scores between 24 – 29 (Turbill et al., 2001, McGuinness and McDonald, 1998, Mascarenhas and Vig, 2002, Firestone et al., 1999). This may be explained by the referral policy within NHS Tayside for only complex cases to be accepted for treatment in consultant-led clinics. Although the increased PAR score can reflect the severity of malocclusion, it does not necessarily indicate the severity of tooth irregularity in each arch.

Irregularities in the upper and lower arches were measured from the mesial surface of the first molar to the contralateral tooth using ITA index (17.37 SD+/- 7.24 and 14.85 SD+/- 5.48 respectively). These finding are comparable to that reported byFleming et al. (2009a) who included anterior and posterior teeth with mean overall irregularity of 16.7mm (SD+/- 5.81).

Most of the studies that have evaluated the severity of irregularity have only included the six anterior teeth (Pandis et al., 2007, Cobb et al., 1998, O'Brien et al., 1990). This method can be misleading because it ignores the irregularity in the posterior segments. West et al. (1995), Jones et al. (1990), Evans et al. (1998) assessed irregularity in both the anterior and posterior segment however, none of

these studies reported the severity at the pre-treatment stage. This makes the comparison of the severity of irregularity between the current study and previous studies not possible.

Extraction / non-extraction

Extraction as part of orthodontic treatment was undertaken for more than two thirds (69.3%) of the total sample with more extractions in the upper arch than the lower arch at 68.3% and 51.4% respectively. The literature is not consistent about the percentage of cases requiring orthodontic extractions with several studies reporting a relatively low extraction rate at less than one third of the cases (Beckwith et al., 1999, Vu et al., 2008) while other studies have reported much higher extraction rates at almost more than three quarters of subjects (Amditis and Smith, 2000). This had been reported by Weintraub et al. (1989) in a pilot study that the extraction rate among five orthodontic practices in the United States ranged from 25% to 80%. During the last two decades there has been an increase in the proportion of non-extraction cases in orthodontics and therefore the proportion of extraction cases in this study is relatively high. This can be explained partially by the increased severity of malocclusion in the sample where the mean PAR score was 35.27 (SD +/- 10.67) with more than one third of the arches having either moderate or severe crowding. Moreover, the nature of the treatment setting (a consultant-led dental teaching hospital) can also explain in part the complex nature of the cases refereed and the tendency towards a conventional type of treatment plan. Although, as mentioned in section 2.1.1.2.1. Extraction vs. non extraction of the literature review there is controversy about the

influence of extraction on the full duration of orthodontic treatment, there is no evidence to suggest any effect of extraction on the duration of the levelling and alignment phase.

Comparison of the descriptive baseline variables between the two study groups indicated that there is no statistically significant difference. This ensured that the randomization process of the recruited sample was effective in producing study groups with similar pre-treatment characteristics. This reduced the influence of confounding factors when comparing between the two study groups and indicate that the results are valid and unlikely to be caused by any factor other than the intervention being investigated.

Treatment outcome

The main aim for this study was to compare the duration of alignment in months and number of scheduled visits between the 0.018-inch and 0.022-inch bracket slot systems. The results showed that there was no statistically significant difference between the two brackets slot systems in neither the alignment stage duration nor the number of scheduled alignment visits. Therefore the null hypothesis was rejected.

In the current study the end point outcome for the alignment stage was the ligation of the working archwire. This is in agreement with Ong et al. (2011) and Mandall et al. (2006). Although, this method may not be a precise technique to measure the

change in contact point displacement between teeth, it was considered applicable to the “real life” scenario in the orthodontic clinic where the clinician decides to ligate the working archwire when the teeth are aligned. On the other hand, several studies measured the change in contact point displacement after alignment period using LII (Wahab et al., 2012, Sandhu et al., 2012) . However, poor reliability of the LII in measuring orthodontic treatment outcome has been reported (Macauley et al., 2012).

7.2. Duration of alignment

Alignment – time

The duration of alignment of the upper and lower arches were found not to be normally distributed. This reflects the individual variation in the rate of tooth movement which could be explained by differences among individuals in the rate of bone remodelling and metabolic turn over. The mean duration of upper arch alignment for the total sample was 8.57 months (SD +/- 4.55); while the mean duration for lower arch alignment was 8.46 months (SD 3.76). These results are similar to that reported by Scott et al. (2008a) and Mandall et al. (2006) where alignment duration in the upper and lower arches ranged from 6.7 to 7.9 months and from 6.8 to 9.3 months respectively. However, Pandis et al. (2007); Pandis et al. (2010), Pandis et al. (2009) and Ong et al. (2010) reported less mean alignment duration for the upper and lower arches ranged from 3 to 4.4 months.

The reduced alignment duration in the studies by Pandis et al. (2007), Pandis et al. (2009) and Pandis et al. (2010) might be explained by the subjective evaluation of the completion of the alignment stage after clinical visual inspection of the contact points. This was not applied in the current study where the ligation of the working archwire was determined to be the end of the alignment stage.

Although, Ong et al. (2011) used the ligation of the working archwire as a determinant of the end of the alignment stage, the duration of alignment was still found to be shorter when compared to the current study. This may be explained by the different exclusion criteria applied and the treatment setting in private practice. The exclusion criteria involved excluding patients with missing teeth, ectopic teeth and severe crowding that did not allow bonding of brackets at the initial appointment. This exclusion criteria may have influenced the duration of alignment as it has been reported in the literature that orthodontic treatment involving the alignment of severely irregular teeth and ectopic canines can take longer (Pandis et al., 2007, Stewart et al., 2001). It is worth mentioning that the authors mentioned that the patients were seen for fixed appliance adjustment at 10 weeks intervals; and as described by the authors at least 2 visits were required for each patient to complete the archwire sequence recommended. This would necessitate that each patient would have alignment treatment duration of at least 5 months. This makes the reported mean alignment duration phase 4- 4.5 months questionable. However, the authors mentioned that visits intervals were reduced where necessary to allow archwire progression.

Moreover Cobb et al. (1998) reported a median duration of alignment of 51 and 46 days for the upper and lower arches respectively. It is important to mention that the alignment for the arches was done using a single aligning archwire and alignment was determined as reduction of irregularity to less than 2mm in the anterior segments.

It is worth mentioning that several studies that evaluated the effectiveness of alignment of different orthodontic appliances or archwires did not investigate the whole levelling and alignment stage (Evans et al., 1998, O'Brien et al., 1990, Dalstra and Melsen, 2004). Alternatively, periods ranging from few weeks to few months were used to assess the amount/rate of teeth movement. This makes comparison with these studies difficult.

Alignment – number of visits

The number of scheduled alignment visits in the current study for the upper and lower arches was 6.03 (SD+/- 2.58) and 5.85 (SD+/- 2.11) respectively. That was found to be similar to the only study found in the literature to report the number of visits during the alignment phase with a mean 6.12 visits for the upper arch and 6.5 visits for the lower arch (Mandall et al., 2006).

Scheduled appointments intervals

The mean interval between scheduled alignment phase visits in the current study was found to be 1.42 months (5.7 weeks). This was calculated by dividing the duration of the alignment phase by the number of scheduled alignment visits. The

visit interval was left for the clinician to decide. However, 6 weeks was the general visit interval followed by most of the clinician in the study centres. The visits intervals for the 0.018 and 0.022 study groups were very similar, 1.46 and 1.40 months respectively.

The visit interval in the current study was similar to Scott et al. (2008a) study who reported 6 week intervals, and longer than Cobb et al. (1998) study who reported 4 week visit intervals. However, it is shorter than Ong et al. (2011) study who reported 10 weeks for visit intervals. Several studies did not report the visit intervals followed by the clinicians.

There are very few studies in the literature that explored the influence of visit intervals on the duration of orthodontic treatment. Vu et al. (2008) found that reduced visit intervals can significantly reduce the full duration of orthodontic treatment. Alger (1988) suggested 6 weeks as visit interval during orthodontic treatment, however, this recommendation was not built on statistical conclusions. No studies were found in the literature designed mainly to investigate the influence of visit intervals on the alignment stage.

Rate of alignment

The rate of tooth movement (alignment) was calculated in this study by dividing the mean duration of alignment with the mean irregularity (ITA) in each arch. The rate of alignment for the upper and lower arches was 2.03 and 1.75 mm/months respectively. The comparison of the rate of alignment for the current study with

many studies in the literature is misleading because most of the studies measured the irregularity only in the anterior segment using Little's irregularity index (Sebastian, 2012, Pandis et al., 2009, Wahab et al., 2012).

Study centres

Comparison between the two main centres involved in the study demonstrated no statistically significant difference in the duration of alignment phase in the upper or lower arches. Springfield Medical Centre was excluded from the comparison due to the small number of participants recruited (3 patients). The lead consultants in PRI and SMC were based in DDH&S which allowed standardization and limited scope for the effect of the variation in clinician on the duration of treatment

Comparison between 0.018 vs. 0.022 duration of alignment

There was no statistically significant difference found in the duration of alignment phase and number of scheduled alignment visits between the 0.018 and 0.022 groups in the upper and lower arches. No study was found in the literature conducted mainly to compare the duration or rate of teeth alignment between the two bracket slot systems.

The results of the current study in part agree with the findings reported by Cobb et al. (1998) who investigated the effectiveness of different aligning archwires in a randomized clinical trial after stratification of the sample according to the bracket slot size system (0.018-inch and 0.022-inch). The authors reported no significant difference in the duration of alignment between the two bracket slot systems in

combination with different types of aligning archwires in the upper arch; while in the lower arch the 0.022 group was found to have statistically significantly faster rate of alignment (median difference 28 days). Although, this study is the only published clinical trial comparing the two bracket slot systems duration of alignment the results have to be considered with caution because:

- Randomization was not done on the level of bracket slot (only for archwires). This could give a scope for selection bias at the slot size level.

- The brackets design was not standardized in the lower arch as some of the brackets were twin wing and others were single wing in the 0.018 group. This may have introduced a potentially effective confounding factor in the alignment of the lower arch.

- The full alignment stage was done using a single archwire in 51- 46 days. This is not usual practice as usually a sequence of aligning archwire is needed for completion of the levelling and alignment stage.

- The median difference reported (28 days) between the 0.018 and the 0.022 was more than half the median alignment duration for the lower arch (46 days).

Amditis and Smith (2000) and Detterline et al. (2010) reported through retrospective trials that the 0.018-inch bracket slot system had statistically

significant shorter full treatment duration than 0.022-inch bracket slot system (mean difference 1.5 and 3.9 months respectively). Although, the mean difference between the bracket slot groups reported by Amditis and Smith (2000) and Detterline et al. (2010) represented 6.6 % and 11.4% of the full orthodontic treatment duration respectively both studies agreed that the difference was not clinically significant. This reported difference was calculated for the full orthodontic treatment duration and no data was published in both publications regarding the levelling and alignment phase duration.

Based on the findings from the above mentioned two retrospective studies there is fragile evidence to support that 0.018-inch bracket slot system has a shorter duration for the full treatment, however, it cannot be assumed that this difference exists in the levelling and alignment stage. In an attempt to calculate the duration of levelling and alignment phase I decided to assess the sequence of archwires used in both studies (Amditis and Smith, 2000, Detterline et al., 2010). Amditis and Smith (2000) published the sequence of archwires for each bracket slot system. However, it was difficult to decide from the sequence published the end of the levelling and alignment stage. While Detterline et al. (2010) did not publish the sequence of archwires, the corresponding author responded to my enquiry about the sequence of archwires (Appendix 4). The corresponding author explained that due to the retrospective nature of the study the sequence of archwires was not assessed as it varied among clinicians. Therefore, it was not possible to calculate the duration of the aligning and levelling stage for the only two studies available in the literature that compared the two bracket slot systems.

It is important to note that Amditis and Smith (2000) mentioned that 75% of the difference in the treatment duration between the 0.018-inch group and 0.022-inch group was found before the ligation of stainless steel arch wires. This may suggest that the levelling and alignment stage had the highest impact on the difference between the bracket slot systems.

Brackets and archwires

Victory Series twin MBT prescription 3M-Unitek brackets were used in current trial because it had been reported as the most common bracket prescription type used in the UK (Banks et al., 2010). An ultrastructure validity study was undertaken as part of this research using SEM to investigate the accuracy of the bracket slot dimensions in the 0.018 x 0.025-inch and 0.022 x 0.028-inch bracket slot systems. The bracket slot dimensions for both slot systems were found to be increased but within the tolerance limit (DIN standards) except the depth of the 0.022 x 0.028-inch bracket slot which was found to be significantly reduced (-11%). It is important to note that the bracket slot depth for both the 0.018 and 0.022 brackets were found to be almost identical (0.0259-inch and 0.0249-inch respectively). This was discussed in more details in the current study in section 5.2.

The results of the ultrastructure investigation indicated that the 0.022 is larger than the 0.018 slot only in the bracket height and not the depth. This could potentially

reduce the expected play between archwires and the 0.022 bracket slot; allowing for more friction and controlled aligning movements which may have influenced the aligning duration. However, these findings do not affect the validity of the current trial as the aim of the study was to clinically compare effectiveness of what was marketed and sold to clinicians as 0.018x0.025-inch and 0.022x0.028-inch bracket systems.

The difference between the two bracket slots is not only about the size, but the combination of the bracket slot and the archwires used which makes the comparison between the two different bracket slot/ archwire systems.

Super elastic NiTi archwires (3M) were used in this trial in combination with the studied 3M bracket systems. The aligning archwire dimensions were found to be within the tolerance limit according to the DIN standards. This means that the variation in the 0.022-inch bracket depth reported was not compensated by the size of the aligning archwires.

The first recommended aligning archwire in the current study was common for the two bracket slot systems. This was based on the suggestion by Profit (2013) who recommended the use of 0.016 inch NiTi archwires for 0.022-inch brackets and the same for the 0.018-inch brackets unless there was a short inter-bracket span. Kapila et al. (1990) calculated the second order clearance between the 0.016 archwire and the 0.018-inch and 0.022-inch to be 0.32 and 0.95 degrees respectively. This suggests that 0.022-inch bracket slot had more play and less

friction with the archwire. However, this play is reduced in the current study due to the reduced depth found in the 0.022-inch brackets.

The use of 0.019x0.025 NiTi in the 0.022-inch group and the 0.016x0.022 NiTi in the 0.018-inch group suggested higher forces of alignment in the 0.022-inch group due to the increased thickness of the aligning archwire. However, it can be concluded from the current trial results that the difference in the magnitude of forces generated by the two different bracket slot/archwire systems did not have a significant influence on the rate of tooth movement or the duration of alignment.

Archwire sequence

A recommended archwire sequence was suggested for each study group for the clinicians to follow during the alignment stage to reach the working archwire. However, it was agreed to allow for flexibility for the archwire selection according to the clinician's judgment to best treat the individual case. Most of the participants that had variation in the sequence of archwire were treated with special mechanics (e.g. Piggy back technique) for aligning ectopic canines.

The variation in the sequence of archwire according to each patient's clinical need was not considered to be a violation of the protocol of the study for two reasons:

- This resembles the "real world" clinical environment where the clinician would use the most suitable mechanics to meet the needs of each case.

- The clinician would give priority to the patient benefit in his/her decisions.

Two RCTs have been designed to investigate the effectiveness of different archwire sequences, in combination with 0.022-inch bracket slot system (Mandall et al., 2006) and the 0.018-inch (Ong et al., 2011). The latter used 3M Victory serious MBT prescription, while the former did not mention which bracket prescription was used. Both studies agreed that the effect of different archwire sequences on the duration of alignment was found to be not statistically significant in both bracket slot systems. This is in agreement with two well-designed systematic reviews that were conducted to investigate the effectiveness of aligning archwires (Riley and Bearn, 2009, Wang et al., 2010). Both reviews found no significant influence of different archwires on the rate of tooth movement.

Ong et al. (2011) using 0.018-inch bracket slot reported half the mean duration of alignment reported by Mandall et al. (2006) using the 0.022-inch brackets for the lower arches (4.0-4.4 and 6.8-9.3 months respectively). The archwire sequences investigated in the two studies were not similar. It is worth mentioning that unlike the current study Ong et al. (2011) used 0.014 archwire as the first aligning archwire. Ong et al. (2011) claimed that the shorter alignment duration compared to Mandall et al. (2006) was due to the difference in bracket slot system and the decreased play between the archwire and bracket slot. However, other factors may

have influenced the results of Ong et al. (2011) which include different exclusion criteria of patients, and applying different protocols for stepping into the next archwire in sequence to reach the working archwire.

Factors influencing the duration of alignment stage

Univariate regression analysis was undertaken to detect factors that influenced the duration of alignment in the upper and lower arches. When each variable was considered solely three factors were found to have a significant influence on the duration of the upper arch alignment stage (alignment of ectopic tooth, number of failed visits and scheduled alignment visit intervals). While six variables were found to have a significant influence on the alignment duration of the lower arch (age, arch irregularity, extraction in lower arch, number of failed visits, number of debonded brackets, and scheduled appointments intervals).

However, when these variables were put together with bracket slot size to construct a multiple linear regression model, different combination of factors were found to explain the variance in the duration of alignment in the upper (R^2= 0.496) and lower (R^2= 0.508) arches. This indicated that confounding variables might have caused bias when each variable was considered alone, but when the confounding factors were controlled these factors demonstrated different influence on the variation of levelling and alignment duration in the upper and lower arches.

The regression model suggested that 49.6% of the variance in the alignment duration of the upper arch can be explained by five factors: alignment of ectopic tooth, scheduled appointment intervals, gender, bracket slot size system and the number of failed appointments. While 50.8% of the variance in the alignment duration of the lower arch can be explained by three factors: scheduled appointment intervals, severity of lower arch irregularity and the number of debonded brackets.

Difference between upper and lower arches

Although, the mean duration of alignment in the upper and lower arches were almost identical for the total sample 8.57 SD+/-4.55 and 8.46 SD+/-3.76 months, the factors influencing the alignment duration stage varied between the two arches. This can be explained by the:

- Difference in the biology of the supporting alveolar structure in the maxilla and the mandible (Samrit et al., 2012).
- Difference in the morphology and size of the upper and lower teeth which has an effect on the inter-bracket distance.
- Different orthodontic mechanics used in each arch depending on the type of malocclusion eg: laceback, bracket prescription and archwire forms.

- Increased prevalence of ectopic canines in the upper arch (Ericson 1986).

None of the studies found in the literature investigating the duration of the alignment stage have published regression model analysis for the factors influencing the alignment duration. This did not allow for comparison of the current regression analysis results with other studies.

Alignment of ectopic tooth

The influence of aligning ectopic teeth explained 9.1% of the variation in the duration of alignment in the maxillary arch. The number of participants experienced alignment of ectopic teeth in the maxillary arch was almost five times larger than that in the mandibular arch. This can be explained by the well documented higher prevalence of ectopic maxillary canines (Ericson and Kurol 1986). This reduced the number of participants with ectopic teeth in the mandibular arch (two participants) which explains the insignificant effect reported for aligning ectopic teeth in the mandibular arch.

The significant influence of aligning ectopic tooth on the duration of alignment was expected due to the long distance that an ectopic tooth needs to move to be in the line of the arch. Moreover, the routine mechanics (piggy back) used by the clinicians to align ectopic teeth involved a longer sequence of archwires which is expected to take longer to complete alignment.

Several studies that investigated the duration of the alignment stage excluded patients who required alignment ectopic teeth (Ong et al., 2011, Cobb et al., 1998, Sebastian, 2012) while others did not consider its influence on the alignment duration in the statistical analysis. This makes the comparison with these studies impossible.

The results of the current study in part agrees with several studies which reported a statistically significant increase in the full duration of treatment due to orthodontic alignment of ectopic maxillary canines (Stewart et al., 2001, Fleming et al., 2009b). Although, in the current study only the alignment stage was considered, still the correction of ectopic teeth is routinely undertaken during the alignment stage which is usually expressed by an increase in the full duration of orthodontic treatment.

It has been reported by several studies that the severity of impaction of ectopic maxillary canines can influence the duration of treatment (Fleming et al., 2009b, Becker and Chaushu, 2003). Due to the small sample available for patients with ectopic teeth in the current study subgroup statistical analysis was not possible.

Arch irregularity

The increased severity of irregularity in the mandibular teeth was found to explain 6.1% of the variation in the alignment duration of the lower arch. This may be explained by the assumption that increased irregularity suggests that the teeth

need to move a greater distance to be aligned, which may then require alonger alignment duration. This is in agreement with results from the RCT conducted byFleming et al. (2009a) who reported that alignment efficiency was correlated to pre-treatment arch irregularity, however the authors reported that it represented almost 10 times (60%) the variation in alignment duration than that found in the current study.

This is in agreement with two randomized clinical trial results (Pandis et al., 2007, Scott et al., 2008a) which reported a significant influence of increased arch irregularity on the duration and rate of alignment in the mandibular arch. Moreover, Pandis et al. (2007) suggested that severe irregularity (>5 mm) can prolong alignment duration by 20% for each mm unit. It is important to note that unlike the current study the authors only considered the severity of arch irregularity in the anterior segment and the terms “irregularity” and “crowding” were used as synonyms.

Increased tooth irregularity may lead to decreased inter-bracket distance which may cause incomplete ligation of the archwire in the bracket slot and also increase the binding of the archwire with the bracket slot (Cobb et al., 1998); this may explain the increased alignment duration. Recent advanced technology claims to improve the clinical properties of new aligning archwires to perform more effectively in severe irregularities between the teeth (Sebastian, 2012).

Moreover, increased irregularity is routinely associated with increased crowding which makes lack of space in and thus in non-extraction treatment cases a challenge for tooth movement. However, extraction of posterior teeth and the use of lacebacks tend to move the canines distally and allow for more space for alignment in the crowded segments.

In the current study it was found that unlike the mandibular arch, the severity of arch irregularity did not significantly influence the maxillary arch alignment duration. This did not agree with Pandis et al. (2010) results who reported that higher Little's irregularity index was associated with prolonged alignment duration in the maxillary arch. This difference in the maxillary arch may be explained by:

- The influence of the tooth morphology (increased mesio-distal width) in the maxillary arch to counteract the reduced inter-bracket span in severe arch irregularities.

- More extractions were done in the maxillary arch (68.3% of sample) when compared to the mandibular arch (51.4% of sample). Extractions can create space in a crowded arch and potentially allow for unobstructed tooth movement in segments with severe irregularities during the alignment stage.

- Ectopic tooth is a form of severe contact point displacement in three dimensions i.e. severe irregularity. It had been demonstrated in the current study that alignment of ectopic teeth was correlated with

significantly prolonged alignment duration. This overlap between alignment of ectopic tooth variable and arch irregularity variable may explain why the irregularity of teeth was found to be marginally significantly (P = 0.051) associated with increased alignment duration in the maxillary arch when tested solely, but was not expressed in the regression models when the other factors were controlled.

Scheduled appointment intervals (SAI)

Mean SAI in the current study was found to be 1.42 months (5.7 weeks). SAI was found to statistically significantly influence the duration of levelling and alignment stage (= P = 0.000) which was found to explain 36% and 37% of the alignment duration in the maxillary and mandibular arches. SAI in the current study was left for the clinician to decide, however, 6 weeks was the general visit interval followed by most of the clinician in the study centres

In agreement with the current resultsVu et al. (2008) found that reduced appointment intervals can significantly reduce the full duration of orthodontic treatment. Moreover, Popowich et al. (2005) found that increased treatment duration was significantly associated with increased visit intervals in Class II malocclusion. No studies were found in the literature designed to investigate the influence of visits intervals on the alignment stage.

Increased SAI can be due to a combination of clinician's planned interval between appointments or due to failed appointments owing to lack of patient's compliance. From the patient compliance aspect it has been well documented that lack of patient compliance can prolong treatment duration. While planned prolonged SAI can give chance for bone remodelling with less OIIRR (Aras et al., 2012) it can also prolong alignment duration due to minimal activation of the fixed appliance towards the end of the interval. However, the optimal SAI for the alignment stage remains unidentified.

Patient co-operation

Patient co-operation was evaluated in this study through the number of failed visits and the number of debonded brackets during the alignment stage. Patient co-operation had been reported as a vital factor affecting the duration of orthodontic treatment (Beckwith et al., 1999; Fink and Smith.1992; Skidmore et al., 2006). However, no studies were found in the literature designed to specifically investigate the influence of patient cooperation on the alignment duration.

The mean number of failed visits in the current study was 0.92 (SD +/- 1.60), with more than 25.3% of the participants missing up to 2 visits and 13.7% missing more than 2 visits. The number of failed visits was found to explain 14.2% of the alignment duration in the maxillary arch. This is in agreement with Beckwith et al (1999) and Fink and Smith (1992) who in retrospective studies found that failed visits explained 17.6% and 5.2% of the variance in the full duration of orthodontic treatment. Moreover, O'Brien et al (1995) reported that missing appointments is

one of two factors that exerted the greatest effect on the duration of treatment. However, other studies failed to find significant correlation between failed visits and prolonged treatment duration in class II malocclusion (Popowich et al., 2005). It has been estimated from regression models undertaken by several studies that a single missed appointment can increase the duration of treatment by 0.8 to 1.4 months (Beckwith et al., 1999; Fink and Smith.1992; Skidmore et al., 2006).

The increased number of debonded brackets was found to explain 5.5% of the alignment duration in the mandibular arch. This is in agreement with the results of several retrospective studies that reported significant correlation between bracket debonds and prolonged duration of treatment (Popowich et al., 2005, Beckwith et al., 1999, Skidmore et al., 2006). However, unlike the current study and Skidmore et al. (2006) most of the studies did not differentiate between a debonded bracket due to patient breakage and due to repositioning by the clinicians which might have influenced the results reported.

Bracket slot size

The influence of the bracket slot size on the levelling and alignment duration was the main aim for the current randomised clinical trial. The 0.018 group was found to have a decreased alignment duration than the 0.022 group in the maxillary arch (8.19 SD +/- 4.61and 8.90 SD+/- 4.52 months respectively) and the mandibular arch (8.21 SD +/- 3.51and 8.67 SD+/- 3.98 months respectively). The results from the ANOVA test suggest that the difference was not statistically significant.

However, when controlling the confounding factors using multiple regression analysis the bracket slot dimension variable was found to have a statistically significant (P = 0.009) influence on the alignment duration in the maxillary arch. This may explain that the uncontrolled confounding factors biased the results when using the ANOVA test to compare between the two study groups.

Based on the multiple regression analysis the bracket slot size was found to significantly influence the duration of alignment in the maxillary arch but not in the mandibular arch. In contrast, Cobb et al. (1998) found a significant difference between the bracket slot systems in the mandibular arch only. Moreover,Cobb et al. (1998) found that 0.022 group had a statistically significant decreased alignment duration than the 0.018 group in the mandibular arch, while in the current study the 0.018 group was found to have a decreased alignment duration than the 0.022 group in the maxillary arch. However, the results from the Cobb et al. (1998) were subjected to bias due to the difference in the bracket design between the maxillary and mandibular arch as some of the 0.018-inch brackets used in the mandibular arch were single wing brackets.

The bracket slot size system was found to have a significant influence on the duration of levelling and alignment stage in the maxillary arch due:

- The increased inter-bracket span due to the wide crown morphology in the maxillary teeth might have allowed complete engagement of the archwire in the bracket slot augmented with minimal aligning

continuous forces from the recommended archwires which allowed for more effective alignment.

- In the mandibular arch almost identical amounts of arch irregularity was found in the 0.018 and the 0.022 groups (mean ITA 14.80mm and 14.89mm respectively), while in the maxillary arch less arch irregularity was found in the 0.018 group than the 0.022 group (mean ITA 16.65mm and 18.09mm respectively). This relative decrease in the severity of maxillary arch irregularity in the 0.018 group may explain the reduced alignment duration compared to the 0.022 group (Pandis et al., 2010).

- Less play between the 0.016-inch NiTi archwire as the recommended initial archwire and the 0.18 slot than the 0.022 slot which may allow more controlled tooth movement.

- The rectangular aligning archwire used was less stiff for the 0.018 slot system compared to the 0.022 slot system which could allow faster progress to reach the working archwire.

- In some of the participants with 0.022 slot the clinician could not use only two aligning archwires to reach the working archwire. An additional aligning archwire was used between the 0.016 NiTi and the 0.019x0.025NiTi.

Gender

Gender was found to be a factor that significantly influenced the alignment duration in the maxillary arch; where females were found to have increased alignment duration than males. These results might have been influenced by the uneven gender distribution in the study with the females representing more than two thirds of the sample. This did not agree with several studies in the literature which suggested no effect of gender on the duration of treatment (Fink and Smith, 1992, Popowich et al., 2005, Vig et al., 1990) and other studies who found that males take longer in treatment due to their reduced co-operation through treatment (Skidmore et al., 2006, Al Yami et al., 1998).

7.3.Orthodontically induced inflammatory root resorption

In the current study the biological side effect of orthodontic treatment was evaluated during the levelling and alignment stage by assessing the severity of OIIRR after 9 months from inserting the initial continuous archwire in the upper central incisors.

Central incisors

Evaluation of OIIRR in the current sample was done by the assessment of the severity of OIIRR in the maxillary central incisors. This is in agreement with several studies who evaluated OIIRR during the alignment stage (Mandall et al.,

2006, Scott et al., 2008a, Mohandesan et al., 2007, Artun et al., 2005). However, Scott et al. (2008a) assessed OIIRR in mandibular incisors while Beck and Harris (1994) evaluated OIIRR in several maxillary and mandibular (anterior and posterior) teeth.

In the current study it was decided to evaluate the severity of OIIRR by assessing the maxillary central incisors only for the following reasons:

- It had been reported that maxillary incisors have the highest prevalence of OIIRR (Brezniak and Wasserstein, 2002, Weltman et al., 2010, Beck and Harris, 1994);
- To minimize any unnecessary radiation exposure to the study participants by reducing the number of teeth exposed;
- Following the British Orthodontic Society guidelines which mainly relied on evidence from Levander and Malmgren, and Artun et al research teams series of publications for early detection of patients with severe OIIRR, by radiographically assessing the maxillary incisors (Artun et al., 2005, Artun et al., 2009, Levander and Malmgren, 1988).

Periapical radiographs

Periapical radiographs were used in the current study to assess OIIRR as it was reported as being the gold standard conventional radiograph for detecting OIIRR (Sameshima and Asgarifar, 2001). This is in agreement with several studies that evaluated OIIRR during the aligning stage (Artun et al., 2005, Mandall et al., 2006, Scott et al., 2008a). However, other studies relied on less accurate radiographs for a more generalized view of the dentition (OPT and lateral cephalometry) to assess the severity of OIIRR (Beck and Harris, 1994, Pandis et al., 2008) .

However, there are a few limitations in the diagnostic capabilities of periapical radiographs (Brezniak and Wasserstein, 2002, Weltman et al., 2010). Only apical OIIRR can be assessed, whereas root defects on the middle, cervical, lingual and buccal aspects of the root surfaces are not detected unless they are extensive (Brezniak and Wasserstein, 2002). This explains the use of the index scoring system which focuses mainly on the apical OIIRR in the current study.

Moreover, it has been reported that periapical radiographs have limited diagnosis facility for OIIRR when compared to the three dimensional imaging using CBCT (Dudic et al., 2008). However, considering the risks and benefits for the study participants, the relative increased radiation dose from CBCT could not be justified.

Conventional film and digital periapical radiographs were used for the maxillary central incisors in the current study. To minimize the influence of the type of radiographic image on the results, a reliability error study to test the agreement of the tooth length measurements between the two types of radiographic images was conducted. High agreement was found between the two types of radiographic images, which indicated an insignificant influence of the type of radiographic image on the reliability of the results (Chapter 5).

Quantifying OIIRR

Several techniques have been described in the literature to quantify OIIRR during and after orthodontic treatment including linear measurements, subjective scoring indices and digital reconstruction (Malmgren et al., 1982, Linge and Linge, 1983, Levander et al., 1994, Eraso et al., 2007). In agreement with several studies (Lund et al., 2012, Beck and Harris, 1994) it was decided in the current trial to use the OIIRR scoring index suggested by Malmgren et al. (1982) . However, other studies that investigated OIIRR during the alignment stage used linear measurements for quantifying the severity of OIRR (Mandall et al., 2006, Scott et al., 2008a), while others used the digital construction technique. (Artun et al., 2005, Artun et al., 2009).

It has been reported in the literature that even with adequate standardization in the radiographic technique potential errors in comparison of OIIRR between consecutive radiographs can still occur for several reasons including tooth

movement during orthodontic treatment. This may necessitate the use of a magnification correction factor. A range of mean error was reported from different studies using different methods of correction factors within 0.45 mm (Linge and Linge, 1983). This potential systematic measurement error can be considered significant in view of the minimal OIIRR expected at 9 months from start of treatment. However, attempts to reduce this potential error may necessitate the use of complicated measures as suggested by several authors such as customized metal jigs for each participant or digital reconstruction of images (Artun et al., 2005, Costopoulos and Nanda, 1996).

The use of digital reconstruction technique had been reported to be an accurate method in quantifying the amount of OIIRR(Artun et al., 2005). However, several experimental studies reported no statistically significant difference in the detection of simulated root resorption between the digital radiographs and digital subtraction radiographs for lesions as small as 0.5mm (Ono et al., 2011); this difference was thought to be clinically insignificant. Moreover, this method may be time consuming for clinical application.

The scoring index system used in this study was subjective, depending mainly on morphological description in combination with measurement guidance. The use of this index in the current study was planned to avoid the error created from the linear measurements. Although the scoring index used is subjective, the high intra- and inter examiner agreement of the OIIRR scores suggest high reliability

of the results (0.938 and 0.749 respectively). Moreover, there were concerns about the sensitivity of the scoring index in detecting OIIRR after the first 9 months of treatment with more than 80% of the sample scoring 0 and 1. However, the systematic error reported in using the linear measurements from periapical radiographs could not allow for valid detection of minimal OIIRR. It was felt that the scoring index had more clinical utility in describing OIIRR severity which justified its use in the current study.

Root resorption at T0 pre-treatment

In the current study 94.8% of the maxillary central incisors did not show any sign of pre-treatment root resorption. While five teeth (3.7%) had a score of 1 and a single tooth each had a score of 2 and 3. had. This minimal percentage of idiopathic root resorption has been reported in the literature (Han et al., 2005, Sogur et al., 2008). It was impossible to compare the current baseline results with the studies that evaluated the severity of root resorption using linear measurements because they assume that there is no root resorption at the baseline records.

OIIRR at 9 months

It has been reported that OIIRR can be detected microscopically after 15 days (Stenvik and Mjor 1970) and using conventional radiographs after seven weeks of orthodontic treatment (Owman-Moll, 1995). However, several studies detected OIIRR of varying severities after 6 months of orthodontic treatment (Artun et al.,

2005, Smale et al., 2005, Levander and Malmgren, 1988, Stenvik and Mjor, 1970).

It has been decided to assess OIIRR at 9 months as a representative period for the estimated duration for the levelling and alignment stage and to identify patients that suffered from increased OIIRR and who might be at risk of severe OIIRR through the full duration of treatment (Artun et al., 2009, Levander and Malmgren, 1988).

In the current study out of 210 maxillary central incisors only 136 (64.8%) had a complete set of periapical radiographs at T0 and T1. The increased percentage of dropouts in the OIIRR assessment was mainly because the clinicians did not remember to take the radiographs at 9 months. It was found that almost two thirds of the sample (64.7%, 88 teeth) did not experience any detectable OIIRR with score zero, while 21.3% (29 teeth) were given score 1, 12.5% (17 teeth) score 2, and 1.2% (2 teeth) score 3, while none of the teeth had a score of 4.The results from the current study seem to agree with that reported by Smale et al. (2005) who used the same scoring index for assessing OIIRR after 6 months from the start of treatment in a prospective study using a relatively large sample size. They reported 57.3% of the teeth with score zero, 25.7% had score 1, 13.7% score 2, 3% score 3, while none of the teeth had a score of 4. Although in the current study the participants were exposed to a longer duration of orthodontic treatment than in Smale et al. (2005) this was not reflected on the severity of OIIRR. However, the same sample from Smale et al. (2005) was followed for a further 6 months in

treatment and radiographs were taken again after an overall period of 12 months (Artun et al., 2005). The authors reported a statistically significant increase in the severity of OIIRR (mean 0.48 and 0.84 mm at 6 and 12 months respectively). Unfortunately the authors did not use the scoring index for OIIRR in the 12 months radiograph study which made the comparison with the current study difficult.

Levander and Malmgren (1988) investigated the severity of OIIRR at 6-9 months from the start of treatment and reported different degrees of OIIRR that did not agree with the current results. The authors reported significantly less teeth that did not experience any detectable OIIRR (score zero 28.9%) which is equivalent to less than half the percentage reported in the current trial (64.7%). Moreover, the authors reported an increase in the percentage of teeth that scored 1,2, and 3. However, in agreement with the current trial the authors found no teeth to suffer from extremely severe OIIRR with score 4.

This reported decrease in the severity of OIIRR in the current study and Smale et al. (2005) when compared to (Levander and Malmgren, 1988) might be explained by the difference of more than two decades of improving the properties of aligning archwires which theoretically could allow for continuous delivery of lighter forces during the alignment stage.

Other studies have been conducted to evaluate the severity of OIIRR during the first 6 – 12 months of treatment. However, none of these studies used the scoring

index system. Most of these studies used either the linear tooth measurements (Scott et al., 2008a, Mandall et al., 2006, Mohandesan et al., 2007, Ramanathan and Hofman, 2009) or the digital reconstruction technique(Artun et al., 2005, Smale et al., 2005, Artun et al., 2009). This makes the comparison with the current results difficult. The range of mean OIIRR reported by the mentioned studies was 0.48 – 1.67 mm for the maxillary incisors. This range reported for the maxillary incisors OIIRR fall in to score 1 and 2 in the index scoring system used in this study. However, the reported data did not show the severity distribution which could have a better clinical value.

OIIRR. Pre- treatment vs. 9 months in treatment.

There was a statistically significant increase in the severity of root resorption at 9 months of treatment when compared to pre-treatment for the total sample and the two study groups. This confirms that root resorption detected was initiated by orthodontic tooth movement. This is in agreement with all radiographic, ultrastructure and three dimensional studies that evaluated the impact of orthodontic treatment on the root surface (Lund et al., 2012, Levander and Malmgren, 1988, Han et al., 2005). However, the majority of the sample experienced no to very minimal irregularity of the root apex.

Comparison of OIIRR between 0.018 vs. 0.022

To ensure that the sample available after 35.2% drop outs was sufficient for statistical analysis to compare between the two study groups, a post hoc power calculation was undertaken (appendix). The power calculation suggested that the sample available was adequate for statistical analysis.

There was no statistically significant difference in the severity of OIIRR between the 0.018 and 0.022 groups for the radiographs taken pre-treatment (P= 0.968) and at 9 months from the start of treatment (P= 0.366). This indicate that the two groups started treatment with no difference as there was minimal root resorption in the two groups and then both groups experienced the same severity of OIIRR after 9 months.

No study was found in the literature designed to investigate the difference in severity of OIIRR between the 0.018 and 0.022 bracket slot systems during the alignment stage. However, Smale et al. (2005) and Artun et al. (2005) using the same sample found no statistically significant difference between the patients treated with 0.018 slot and 0.022 slot after 6 and 12 months from starting treatment. These finding agree with the results from the current study, however the statistical tests were not reported in the published articles. Also, there might be a risk of selection bias due to lack of randomization allocation in these two studies which could have influenced the results.

The difference in bracket slot size between the study groups allowed the use of larger dimension rectangular aligning arch wires in combination with the 0.022 bracket slot system when compared with the 0.018 bracket slot system. This increase in the aligning arch wire dimension might have caused an increase in the amount of aligning forces applied on the teeth. From the results of the current study it seems that this expected difference in the aligning force magnitude had no significant influence on the severity of OIIRR.

In part the current study results agree with the results reported from randomized clinical trial that investigated the difference in severity of OIIRR between the 0.018 and 0.022 bracket slot systems for the full orthodontic treatment duration (Reukers et al., 1998) The authors found no statistically significant difference between the 0.018-inch partially programed edgewise bracket system and 0.022-inch fully programed edgewise brackets. Although, Roth prescription brackets were used in this study it still agrees with the finding in the current study were MBT prescription was used. Although, the results from (Reukers et al., 1998) was for radiographs taken after full duration of treatment, which is not the similar to the current study (9 months in treatment), it is still an evidence-based predication for the pattern and severity of OIIRR at the end of the treatment (Artun et al., 2009, Levander and Malmgren, 1988).

This may suggest the insignificant influence of the difference in slot size of the orthodontic brackets on the severity of OIIRR during the alignment stage after 9 months in treatment. This agrees with several studies that investigated the

influence of different bracket types and design on the severity of OIIRR during the alignment stage (Scott et al., 2008a, Pandis et al., 2008, Leite et al., 2012) and after full orthodontic treatment duration (Reukers et al., 1998, Blake et al., 1995).

Factors influencing OIIRR

Due to the relatively low percentage of patients who had significant OIIRR (14%) and after obtaining statistical advice, it was decided that it would not be appropriate to perform regression analysis to detect variables that influenced the severity of OIIRR. However, the influence of trauma to anterior teeth and abnormality in root morphology are discussed briefly.

Relation between OIIRR and trauma to anterior teeth

In the current trial 20.5% of the participants reported history of trauma to the upper anterior teeth. This percentage is similar to that reported by Brin et al. (2003). No statistically significant correlation was found (P=0.667) between severity of OIIRR at 9 months of treatment and history of trauma to the anterior teeth. This is in agreement with (Smale et al., 2005, Artun et al., 2005) who found no significant association between history of trauma and the severity of OIIRR at 6 and 12 month from the start of treatment.

The current results are also in agreement with Weltman et al. (2010) who reported in a systematic review based on the Cochrane guidelines that incisors with a

history of trauma (but no signs of root resorption at the beginning of treatment) had the same prevalence of OIIRR as those without trauma.

However, the results from the current study have to be considered with caution because a detailed history of trauma was not taken from the patients.

Relation between OIIRR and abnormal root morphology

In the current study 14% of the maxillary central incisors had some form of abnormality in root morphology. Due to this low percentage it was decided to dichotomise the finding of root morphology into normal and abnormal. This percentage is higher than that reported by Sameshima and Sinclair (2001a) at 2.7% and lower than that reported by Brin et al. (2003) and Marques et al. (2010) (35.5% and 31.5% respectively). This relatively large variation in the prevalence of abnormal root morphology among orthodontic patients can be explained by the different criteria used in the subjective scoring indices for root morphology in each study.

No statistically significant (P=0.115) correlation was found in the current study between the teeth with abnormal root morphology and severe OIIRR at 9 months. However, the relatively small percentage of teeth with abnormal morphology may have an influence on the results.

Comparison between the current study results and previous studies was found difficult due to the different criteria and indices used in defining and categorizing abnormal root morphology. The results from the current study did not agree with the two studies found in the literature that explored the influence of abnormal root morphology on OIIRR during the initial stages of treatment (Artun et al., 2005, Levander and Malmgren, 1988).

In a prospective clinical trial a multinational research team using the same sample reported in a serious of publications a significant influence of abnormal root morphology (pointed and deviated in shape) on the severity of OIIRR after 6 months from the start of treatment (Artun et al., 2005, Artun et al., 2009, Smale et al., 2005), however the authors failed to find this positive relation at 12 months from start of treatment (Artun et al., 2005). The authors also reported no significant influence of blunt and short roots on the severity of OIIRR. It is interesting to note that the same authors published a third article using the same sample after completion of treatment and reported a significant association between pointed deviated roots with severe OIIRR in maxillary lateral incisors only. In addition, Levander and Malmgren (1988)in a retrospective trial reported that blunt and pipette shaped roots are significantly associated with severe OIIRR.

The lack of agreement in the results reported between the two published articles for the same sample in 6 and 12 months(Smale et al., 2005, Artun et al., 2005), and the lack of agreement between the Smale et al. (2005) and Levander and Malmgren (1988) studies on which type of root morphology (blunt or pipette

shape) was associated with severe OIIRR suggest that one should consider these results with caution.

An obvious debate exists in the literature about the influence of abnormal root morphology on the severity of OIIRR for the full duration of orthodontic treatment (Linge and Linge, 1991a, Mirabella and Artun, 1995b, Marques et al., 2010, Artun et al., 2009). Comparison between the results from the current study and these studies should be considered with caution due to the difference in treatment duration investigated.

The results from the current study did not agree with findings from Weltman et al. (2010) systematic review who reported that there is evidence that abnormal roots may be at slightly higher risk of moderate to severe risk for OIIRR when compared to normal roots. Weltman et al. (2010) based their finding on the results from the a single randomized clinical trial (Brin et al., 2003) which surprisingly failed to demonstrate statistical tests to demonstrate significant influence of root morphology on the severity of OIIRR.

Although, the data available from the current study is only for the initial stage of treatment, there is enough evidence in the literature to support the significant correlation between the severity of OIIRR at 6-12 months from start of treatment and the severity of OIIRR at the end of treatment.

It has been well documented that the aetiology of OIIRR is multifactorial (Weltman et al., 2010). The findings from the current study suggest that the effect of bracket slot size on the severity of OIIRR is insignificant.

7.4. Patient perception of wearing fixed appliances

In the current study patient perception was assessed using the "Smiles Better" questionnaire which was completed once by the participants after 6 months of treatment. The response rate to the questionnaire was 84%. This is an acceptable response when compared to studies that evaluated patient perception of treatment during the initial stages which range from 78% (Lee et al., 2008, Pringle et al., 2009) to 96.8% (Scott 2008).

Questionnaire design and delivery

The "Smiles Better" questionnaire aimed at evaluating the whole experience of wearing fixed appliances and its impact on the patient's life using, rather than pain and discomfort only experienced during the first few days of treatment which was assessed by several studies using VAS questionnaires (Mandall et al., 2006, Scott et al., 2008b), .

Several studies have been published using validated quality of life questionnaires and indices (e.g. oral health related profile (OHIP-14) or oral health related quality of life (OHQoL)) to assess to the impact of wearing orthodontic appliances

(Zhang et al., 2008, Liu et al., 2011, Bernabe et al., 2008). However, these indices and questionnaires were originally designed to evaluate the effect of malocclusion or oral health, not orthodontic appliance wear, on the quality of life. Moreover, several studies required the participants to complete the questionnaires several times through the observation period and compared the results between the different time intervals (Zhang et al., 2008, Liu et al., 2011) . In contrast, the current study is a cross sectional assessment of the patient perception to the orthodontic treatment during the alignment stage.

It was decided to ask the participants to complete the questionnaire after 6 months from the start because it was believed that this period is appropriate for realistic assessment for patient experience during a substantial component of treatment for the following reasons:

- Six months can be a reasonable representative period for the alignment stage experience
- It is reasonably less biased by the first weak pain and discomfort experienced by most patients.
- The patient should have accommodated with the fixed appliance.
- It is not too far into treatment progress were patient starts to loss motivation and waiting for the braces to be debonded.

- Six months is usually a reasonable period were patients can start to notice improvement and progress in the alignment of the teeth. This can make them feel the benefits of treatment.

The questionnaire was mainly composed of closed questions with a single open question at the end to describe the experience of wearing fixed appliances. This questionnaire has been used by two multicentre randomised clinical trials in the United Kingdom to compare the effectiveness between different functional appliances (Appendix 6). As far as can be determined the "Smiles Better" questionnaire has never been used before to evaluate patient perception to fixed orthodontic appliances.

The outcome from this questionnaire can be categorized into five sections that include: functional limitation, oral symptoms, social impact, apperance and global experience.

1. Functional limitation

The majority of the participants reported that speech, drinking and sleeping did not change through treatment with only a few patients reporting mild improvement or deterioration. Almost half the participants (44.4%) found that eating was worse, although most of them rated it as 'slightly worse'. A quarter of the participants reported a little dribbling due to the fixed braces and more than half the participants thought that keeping the braces clean was a nuisance.

This reported functional limitation in the current study agrees with several studies published in the literature (Zhang et al., 2008, Liu et al., 2011, Al Jawad et al., 2012, Scheurer et al., 1996) who found that biting and chewing were the most painful everyday activities affected in the week after insertion of appliances. Zhang et al. (2008) and Liu et al. (2011) used different types of oral health related quality of life questionnaires and reported statistically significant increase in the functional limitation of orthodontic patients at six months and twelve months from start of treatment. The two studies assessed the patient perception of fixed appliances at several intervals during treatment.

Functional limitations for the current study participants was localised in difficulty in eating, increased dribbling and cleaning the braces. This is in agreement with Al Jawad et al. (2012) and Brown and Moerenhout (1991) who reported masticatory problems due to difficulty in eating and chewing which led the patients to shift into soft diet. Al Jawad et al. (2012), Bernabe et al. (2008) reported also that the majority of the participants found difficulty in cleaning and brushing the fixed braces and keep good oral hygiene.

In contrast to the finding in the current study Bernabe, Sheiham et al. (2008) reported speech problems in a large sample (1657 adolescents). However, this difference in results may be explained by the difference in the inclusion criteria as Bernabe, Sheiham et al. (2008) included patients wearing both fixed and removable orthodontic appliances. Removable appliances are usually more bulky and extended to the palate which can interfere with speech; Sergl et al. (2000)

suggested that different orthodontic appliances might have different impacts on patients.

2. Oral symptoms

In the current study most of the patients experienced soreness related to teeth, mouth, and rubbing. However, the majority of these participants rated this soreness as "a little" while few participants rated the soreness as "a lot" (7.9-12.5%). This finding is in agreement with almost all the studies that investigated patient perception to wearing different types of braces (Scott et al., 2008b, Mandall et al., 2006).

Most of the studies that assessed pain or soreness related to wearing different types of orthodontic brackets and archwires focused mainly on the very early stage of treatment ranging from hours to the first few weeks (Scott et al., 2008b, Mandall et al., 2006). Unlike the current study these studies mainly focused on pain perception and discomfort which was evaluated using a VAS (Scott et al., 2008b, Pringle et al., 2009). While few studies evaluated physical pain and soreness using Oral health quality of life questionnaires and indices for longer periods through the progress of fixed orthodontic treatment (Liu et al., 2011, Zhang et al., 2008)

In the current study the majority of young participants found that wearing fixed orthodontic braces did not affect school work. This accords with the finding that the functional limitations reported by the participants due to the appliances were

mainly related to eating, cleaning and dribbling and it would not be expected that these would extend to affecting school work.

One of the oral symptoms that was evaluated in the current study was patient perception to tooth movement; where majority of the participants (92%) felt that their teeth were moving. More than half the participant rated movement of the teeth as “a lot”. This can be considered a positive sign that the participants were aware of the progress in treatment during the initial aligning and levelling stage of treatment. Interestingly, more than 90% of the participants indicated that it was important for them that the teeth were moving.

3. Social impact

The majority of the patients reported that family relationship, friendship and hobbies were not affected. Moreover, most participants did not feel embarrassed due to wearing the orthodontic appliances.

It can be concluded from the above results that patient experience with fixed orthodontic appliances in the first 6 months did not significantly affect their social life. This is in agreement with Bernabe et al. (2008) who using Oral Impact on Daily Performances questionnaire found that orthodontic appliances did not have an impact on social contact. In contrast, Zhang et al. (2008) and Liu et al. (2011) reported improvement in the social well-being during the treatment using CPQ and OHQoL questionnaire respectively. This disagreement reported among different studies may be explained by the use of different types of questionnaires.

4. Appearance

In the current study almost half the participants reported no change in appearance. Only few of the participants (13.6%) reported that appearance got worse, however almost three times as many participants (40.95%) reported improvement in appearance. Moreover, 18.1% of the participants reported that teasing improved. These results along with patients' awareness of tooth movement (mentioned in oral symptoms section) may suggest that treatment progress had caused a perceived improvement in appearance. Alternatively this improvement in appearance may be due to its increased popularity and acceptability in society.

No studies in the literature were found that assessed the impact of orthodontic appliances on the patient perception to appearance during the initial phase of treatment. This makes comparison of the results of this domain with other studies impossible.

5. Global experience

The "overall global experience" was found to be positive for the majority of the participants as the positive comments given suggested that they would recommend the treatment for someone who is about to start orthodontic treatment.

It is interesting to note that only half the participants found that wearing the braces was what they were expecting. Moreover, repeated comments were noticed like

“not as bad as people say” and “it is more painful than I thought” may suggest that patients did not have accurate information about the expected experience of wearing fixed braces.

Comparison between 0.018 and 0.022 groups

There was no statistically significant difference found between the 0.018 and 0.022 groups in any of the “Smiles Better “questions except for the soreness of teeth. It was found that all patients in the 0.018 group reported a degree of sore teeth, while in the 0.022 group 18.7% of the participant did not experience sore teeth. However, more patients (14.7%) in the 0.022 group reported “a lot” of sore teeth when compared to the 0.018 group (7.55%).

Although, from the available data a statistically significant difference was found between the two study groups in the reported soreness of teeth, due to the nature of the data it was found difficult to identify which bracket system caused less or more sore teeth. Therefore, further investigation may be needed in this area.

No studies were found in the literature that investigated the difference in patient perception between the 0.018 and 0.022 bracket slot systems. This did not allow comparison with other results.

7.5. Study strengths and weakness

This section will outline the perceived strengths and weaknesses of this study. It will begin by listing the most beneficial factors that the investigator has observed followed by a summary of limitations of this study. On the basis of this a list of recommendations for further research has been suggested

Strengths of the study

1. This study is original and unique study as it is the only RCT designed primarily to compare the effectiveness of the levelling and alignment stage of orthodontic treatment between the 0.018-inch and 0.022-inch bracket slot systems.

2. This is a randomized clinical trial which is considered the gold standard study design to compare between two interventions. In this study the CONSORT guidelines were followed to reduce the risk of bias.

3. The current study was a multicentre RCT that aids in successful recruitment of a wider range of population and gives increased generalizability to the findings.

4. The sample recruited in the current study for comparing between the two study groups was supported by a power calculation with estimated drop out (20%) to reduce the effect of sample attrition.

Ninety two participants out of 105 completed the study against an estimated power calculation of 84 for both study groups.

5. In this study the effectiveness of the 0.018-inch and 0.022-inch bracket stot systems was done by assessing three domains: levelling and alignment duration, OIIRR and patient perception of treatment.

6. In the current study the investigators were blinded (masked) to the group allocation using codes during data collection from study models, radiographs and questionnaires to reduce investigator bias.

7. In the current study inter-investigator and intra-investigator agreement were assessed to ensure reliability of the results.

8. This study was supported by validity study for the accuracy of the bracket slot dimensions using scanning electron microscopy. To ensure that the bracket slot sizes used in the current study had the accurate dimensions as published by the manufacturers.

9. Due to the use of both conventional film and digital periapical radiographs in the study to assess OIIRR, an in-vitro study was undertaken to assess the agreement between the two types of radiographs in measuring tooth length. This was to reduce the influence of the type of radiographs as a confounding factor on the OIIRR results.

10. Trial monitoring committee meetings were done several times through the study to ensure that trial management and progress was in accordance with Good Clinical Practice and to identify of any of the stopping rules needed to be applied.

The list above refers to the key strengths of this study. It is significant to observe that this study was carried out in multicentres and designed to cover the effectiveness of the performance of the two bracket slot systems in several relevant aspects in orthodontics. This can allow the clinician to grab a complete picture for the comparison between the two study groups.

Weakness of the study

1. It is important to high light that the current study investigated only the levelling and alignment stage of orthodontic treatment. The finding of the current study cannot be a representative for the full phases of orthodontic treatment.

2. In the United Kingdom the 0.022 bracket slot system is by far the most popular bracket slot dimension among clinicians. This may have influenced the perception of the clinicians to the study groups as the clinician was not blinded to the bracket slot system allocation. However, before commencing the study and during departmental

meeting the protocol of the study was discussed with the clinicians to answer any query about using the 0.018-inch system and the archwire sequence recommended.

3. Thirteen participants did not complete the study when the data was collected which may be a source of attrition bias. Four of these participants were excluded before they received the allocated intervention. There was a similar number of drop outs in each study group for those participants who received the allocated treatment (Table 32). However, there was still appropriate sample size available for analysis to meet the sample size determined by the prior power calculation for the study.

4. One of the study centre dropped out after recruiting three participants for the current study. The clinic lead in this centre found it difficult to manage running the recruitment and keeping the required records for the study.

5. More than one third of the study sample did not have periapical radiographs taken at 9 months from the start of treatment. This sample attrition regarding the assessment of OIIRR could have an influence on the results. However, post hoc sample size calculation was done to ensure that the sample available for analysis for the comparison of severity of OIIRR between the study groups.

6. This study was single blinded (investigator) as it was impossible to mask the clinician to the type of bracket slot used for each participant due to difference in each archwire sequence recommended for each group. However, the study investigators were blinded during data collection and analysis.

7. The current study was undertaken in a hospital teaching environment which might be a different setting from the realistic practice in the high street.

8. There are some limitations in using 2 dimensional radiographs in assessing OIIRR. However, 3D CBCT technology was not used in this study due to the relative high radiation dose exposure to participants.

9. Comparison for the study main outcomes between the operators was not possible due to the limitation for the sample size. However, comparison between the two main study centres was done.

10. Appointment intervals were not standardized in this study, as it was left to the clinicians' decision.

11. Archwire sequence decision was recommended by the study protocol however, flexibility was given to the clinician to decide about the best archwire sequence used for each participant.

12. The comparison between the 0.018-inch and 0.022-inch bracket slot in this study was done for the MBT bracket description type. Comparison of different types of bracket prescription between the two bracket slot systems was not possible due to sample size limitation.

It is clear that neither of the above study limitations relate directly to the primary outcomes of this study. It is therefore evident that the main objectives have been achieved in this study with minimal impact from the stated limitations.

7.6. Recommendation for Further work

Based on the experience and findings from carrying out this study the following recommendations can be made:

- Investigation of the full orthodontic treatment effectiveness between the 0.018-inch and 0.022-inch group include assessment of the different phases of treatment.

- Investigation of the effectiveness of treatment of the bracket slot systems in a multicentre RCT that include high street practice and overseas centres to allow for more generalization of the findings.

- Stratification of the sample recruited according to schedualed appointments intervals, gender, age, alignment of ectopic teeth to allow for

limiting confounding factors when comparing between the bracket slot systems.

- With advanced technology hopefully the radiation dose of 3D imaging will be reduced in the future and this may allow for 3D assessment of OIIRR and alveolar bone changes between the two bracket slot systems.
- Investigation of different types of bracket description and ligation between the 0.018-inch and the 0.022-inch systems.
- Investigate the appointments interval as a potential factor that can influence the duration of different stages of orthodontic treatment.
- Investigation of other biological side effects (e.g. decalcification and alveolar bone loss) between the bracket slot systems.
- Investigate the clinician's perception and experience after using both bracket slot systems in treatment.
- Sample size in the future should allow for comparison between study operators in different centres.

Chapter 8: Conclusions

The main aim of this study was to examine if there was any difference between 0.018-inh and 0.022-inch bracket slot 3M Victory fixed appliance systems in terms of duration and number of visits for the levelling and alignment stage. The secondary objectives were to investigate if there is a difference in severity of OIIRR and assess patient perception of treatment between the two bracket slot systems.

The findings are:

1. There is no statistically significant difference in the duration of the levelling and alignment stage in the maxillary and mandibular arches between the 0.018-inch and 0.022-inch conventional pre-adjusted bracket slot systems (3M Victory).

2. There is no statistically significant difference in the number of scheduled appointments for the levelling and alignment stage in the maxillary and mandibular arches between the 0.018-inch and 0.022-inch conventional pre-adjusted bracket slot systems (3M Victory).

3. According to the regression analysis the alignment of ectopic teeth, scheduled appointment intervals, number of failed appointments, gender and bracket slot dimension can significantly influence the duration of levelling and alignment stage in the maxillary arch. In the mandibular arch scheduled appointment intervals, number of debonded brackets and

severity of arch irregularity significantly influence the duration of levelling and alignment.

4. There is a significant amount of maxillary central incisor OIIRR evident at 9 months from the start of treatment for the total study sample. However, there is no statistically significant difference in the severity of OIIRR between the 0.018-inch and 0.022-inch bracket slot systems.

5. Bracket slot size does not have a significant impact on patient perception of wearing fixed orthodontic appliances except for the soreness of teeth. Patients treated with 0.022-inch system may experience increased soreness of teeth as compared to 0.018-inch system.

6. Functional and oral symptom domains were affected negatively in the form of difficulty in eating and cleaning the fixed appliance, dribbling and different forms of oral soreness. However, improvement in appearance, teasing and embarrassment overweighed the negative symptoms as the participants gave more positive global comments and recommended the treatment for others.

7. It was noticed that patients' expectations about wearing the braces were not precise, which may indicate that patients may not have been given enough or accurate information to give an informed consent form for fixed orthodontic treatment.

Validity studies:

1. Scanned film and digital (PPS) periapical radiographs are accurate methods for measuring tooth length with a high level of agreement.
2. The dimensions of the 0.018-inch and 0.022-inch 3M Victory Series bracket slots were greater than the manufacturer's dimensions but within the DIN standards tolerance limit except the slot depth in the 0.022 brackets which was significantly decreased.

It can be concluded that there is no significant difference in the effectiveness of the levelling and alignment stage between the 0.018 and 0.022-inch bracket slot systems except for the soreness of teeth. However, regression analysis suggests duration of L&A stage in maxillary arch may be influenced by the bracket slot size when confounding factors are controlled.

Clinical implications

- This study does not provide sufficient evidence to change clinical practice in terms of clinical selection of slot size for the L&A stage of orthodontic treatment in terms of duration and OIIRR.
- There is some evidence that there is a difference in patient perception of teeth soreness.

Flow of research work in 0.018 vs. 0.022-inch systems

Past work

Retrospective studies comparing the duration and treatment outcome between the 0.018 and 0.022 slot systems

Current work

RCT comparing the effectiveness of the alignment stage

- Duration of levelling and alignment stage
- OIIRR
- Patient perception of orthodontic appliance wear

Future work

Continue RCT comparing effectiveness of full orthodontic treatment

- Full duration of treatment
- Occlusal outcome
- Maxillary incisor inclination
- Patient perception to treatment outcome

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• APPENDICES

The following appendices contain relevant documentation developed for the current study:

1. The Patient Information Sheet
2. Study Consent Form
3. The Case Record Form (CRF)
4. Correspondence
5. List of publications from the current study
6. Smiles better questionnaire

Appendix 1: Patient information sheet

Is the 0.018-inch slot or the 0.022-inch slot bracket system more effective in orthodontic treatment?

Patient Information Sheet (Version 2)

We invite you to participate in a research project. We believe it to be of potential importance. However, before you decide whether or not you wish to participate, we need to be sure that you understand firstly why we are doing it, and secondly what it would involve if you agreed. We are therefore providing you with the following information. Read it carefully and be sure to ask any questions you have, and, if you want, discuss it with outsiders. We will do our best to explain and to provide any further information you may ask for now or later. You do not have to make an immediate decision.

THE BACKGROUND TO THE STUDY

- What is the research about?

Investigating two types of orthodontic brace currently used in NHS Tayside.

- Why is the research being done?

We do not know which type is better.

- Who is sponsoring it, and are they paying the researcher or his/her department to do the research?

University of Dundee. None of the researchers is being paid to do this research.

- Why have I been chosen as a possible participant in the research?

You or your child's orthodontic treatment could be carried out using either orthodontic brace

- How many other people have been asked to consider participating?

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WHAT DOES THE STUDY ENTAIL?

- Will I have to come back to the clinic more often or remain in hospital longer than would normally be the case?

No

- What will I be asked to do at each visit?

At each routine visit nothing additional to the usual adjustment of the braces, except for at the start and end of treatment when you will be asked to give a score to your smile using a simple questionnaire in the clinic.

- How long will my participation in the study last?

Until completion of your orthodontic treatment

- What procedures will I be asked to submit to and what will they be like?

1. You will have normal brace treatment with one of the two types of brace currently used in NHS Tayside, which includes having moulds of your teeth and photographs and x-rays taken.

2. Two additional small close-up x-rays for your upper front teeth will be taken at the start of treatment and after 9 months as part of this research. These have been approved by the Clinical Radiologist at Dundee Dental Hospital and by the Medical Physics Department.

- What treatment will I get if I do take part?

The same high quality of orthodontic treatment we provide on a routine basis at Dundee Dental Hospital, Perth Royal Infirmary & Springfield Medical Centre.

- Will this be different from the treatment I would get otherwise?

No

- Will the decisions about my treatment be made by my usual doctor or by someone else?

Yes, by the Consultant or his/her deputy

- What are the names and amounts of drugs which I will be given (if any) and by what route?

No drugs are involved in this study.

- Will all patients receive active treatment, or will some receive dummy medication? Is so, what is the chance that I would receive dummy medication?

All patients will receive active treatment

- Were I to feel severe discomfort or pain during the study, would I be able to take any relief medication?

Yes, as recommended by the clinician

- Is there any chance that the proposed research will be of benefit to me personally, or to future patients with the same condition?

We hope to help orthodontists choose the best brace type for future patients.

- Are there any factors, which would exclude me from participating, like pre-existing illness, the possibility of becoming pregnant or other drugs being taken?

Yes, if you fall into one of the following categories:
You have undergone previous orthodontic treatment.
You are less than 12 years old at the beginning of the study.
You have a cleft lip or palate, multiple missing teeth or have special needs.
You are having jaw surgery as part of their treatment.
If you suffer from hypothyrodism, hypopituitarism or hyperpitutarism.

- Were the new treatment to be of benefit to me, could I continue to take it after the trial?

Your full treatment will be covered by the study.

WHAT ARE THE DISCOMFORTS, RISKS AND SIDE EFFECTS?

- Will there be any discomforts, such as additional needle pricks or biopsies, or pain, and if so, how much and for how long?

No

- Are there likely to be side effects from what will be done to me in the research, and if so what are they?

None

- Who should I contact if I am worried about any side effects that I experience?

Chief investigator: Prof David Bearn.
Professor of Orthodontics, University of Dundee Dental School Park Place
Dundee DD1 4HN
Tel: 01382 635978, e: d.bearn@dundee.ac.uk.

- Is there any chance of anything going wrong, and if so, what are the risks compared to everyday activities?

Only the same risks as undergoing brace treatment not as part of the research.

- Would I be withdrawn from the study if my condition became worse or if any extra risks came to light during the course of it?

Yes, and we will continue your care.

- Are there any activities I should refrain from during and in the period following the research and for how long, eg, blood donations, taking other medication, exposure to sunlight, driving, taking part in other studies?

Only those that all patients undergoing brace treatment should avoid.

If you agree to participate in this study, you will be entered into the trial register (held on computer) and will be allocated the next available study number. The study number will correspond with a numbered sealed envelope, which will be opened when your treatment is about to begin. Each envelope will contain a sheet with the details regarding the type of brace that will be used for your orthodontic treatment and will have been allocated in advance using a computerised random number generator.

WHAT WILL HAPPEN TO THE INFORMATION COLLECTED IN THE STUDY?

- How will my confidentiality be protected, ie, who will have access to the records generated and what steps will be taken to ensure that they will only be seen by those authorised to see them?

Only the named researchers involved in this study will have access to the data that will be recorded.

- Will my dentist be told that I am taking part in this study, and the results of my participation?

We will inform your dentist that you are participating in the study.

- If any illness of which I am presently unaware is found as a result of the study, will I be told and receive any treatment for it?

Yes.

- If the research may result in me or my relatives being made aware for the first time of our susceptibility to an illness, what arrangements have been made for counselling?

This will not happen in this study.

- Will I be informed of the results of the study?

No – this study is not being funded by any outside body. Therefore we believe the resources involved in contacting individual patients should be used for continuing patient care in dealing with our lengthy waiting list.

WHAT ARE MY RIGHTS?

- How can I obtain more information if I wish?

Contact one of the researchers involved in this study – we would be delighted to discuss any aspect with you

- Can I discuss the study with friends and relatives, or my GP before deciding whether to take part?

Yes

- Can I refuse to take part or change my mind later even if I agree to take part now?

You can refuse to take part, although your orthodontic treatment will involve one of the two orthodontic braces we are investigating in this study anyway. Once treatment is underway, it would not be appropriate to remove your orthodontic brace unless there are clinical reasons for doing so.

- If I do refuse to take part or change my mind later, will I still get the treatment my usual doctor thinks is right for me?

If you agree to participate, your orthodontic treatment will be identical to that if you refused to take part, as we treat all our patients to high and exacting clinical standards.

- If something went wrong, how and from whom would I obtain compensation?

As an NHS patient being treated in NHS Tayside, you should initially address any complaint to the Consultant in charge of your orthodontic treatment.
If you believe you have been harmed in any way by taking part in this study. You have the right to pursue a complaint and seek any resulting compensation through the University of Dundee who are acting as the research sponsor. Details about this are available from the research team. Also, as a patient of the NHS, you have the right to pursue a complaint through the ususal NHS process. To do so you can submit a written complaint to the Patient Liaison Manager, Complaints Office, Ninewells Hospital (Freephone 0800 027 5507). Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against NHS Tayside but you may have to pay your legal costs.

- Will I get travelling expenses or other payment?

No.

Participation in this study is entirely voluntary and you are free to refuse to take part or to withdraw from the study at any time without having to give a reason and without this affecting your future medical care or your relationship with medical staff looking after you.

The Tayside Committee on Medical Research Ethics, which has responsibility for scrutinising all proposals for medical research on humans in Tayside, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from NHS Tayside and the Regulatory Authorities.

Thank you for reading this Information Sheet and considering your participation in this study

Appendix 2: Consent form

NHS Tayside

CONSENT FORM (Version 2)
Is the 0.018-inch or the 0.022-inch bracket slot system more effective in orthodontic treatment?

Name of researcher:

Please Initial Box

1. I confirm that I have read and understood the information sheet dated 1/10/2009(version 1.1) for the above study. I have had the opportunity to consider the consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at anytime without giving any reason, without any medical care or legal rights affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from University of Dundee Dental School and Hospital and Tayside NHS where it is relevant to my taking part in this research. I give permission to these individuals to have access to my records. ☐

4. I agree for my dentist to be informed of my participation in this study. ☐

5. I agree to take part in the above study. ☐

Name of participant	Date	Signature
Name of parent/guardian *(if appropriate)*	Date	Signature
Name of person taking consent	Date	Signature

When complete, 1 for the participant; 1 for research site file;,1 (original) to be kept in medical notes

Appendix 3: Participant Data collection sheet

NHS Tayside

Data collection sheet for participants in 0.018 vs. 0.022 trial

Check list:

- **Data from Notes**

☐ Alignment stage ☐ Full treatment

- **Data from Models**

☐ Pre-treatment ☐ Post treatment

- **Data from Radiographs**

☐ Pre-treatment ☐ Mid treatment ☐ End of treatment

- **Questionnaires**

☐ Pre-treatment ☐ 6 months ☐ End of treatment

1. Patients notes

Study I.D /Code			
Date of birth			
Gender			
History of trauma to incisors			
Oral Hygiene			
Gingival inflammation			
Type of Malocclusion			
Mandibular displacement			
Extraction upper arch			Tooth number=
Extraction Lower arch			Tooth number=
Date of bonding Upper arch			
Date of bonding Lower arch			
Date of starting rectangular wire upper			
Date of starting rectangular wire Lower			
Date of using working archwire upper			
Date of using working archwire Lower			
Use of lace backs upper arch			
Use of lace backs Lower arch			
URA			
Anchorage reinforcement			
Alignment of ectopic teeth Upper			
Alignment of ectopic teeth Lower			
Number of broken brackets (Alignment) Upper			
Number of broken brackets (Alignment) Lower			
Number of repositioned brackets (Alignment) Upper			
Number of repositioned brackets (Alignment) Lower			
Number of visits (Alignment Upper)			
Number of visits (Alignment Lower)			
Number of cancelled appt(Alignment)			
Number of emergency appt(Alignment)			
Date of starting space closure upper arch			
Date of starting space closure Lower arch			
Date of end of space closure Upper arch			
Date of end of space closure Lower arch			

Date of debond upper arch	
Date of debond Lower arch	
Total number of visits Upper arch	
Total number of visits Lower arch	
Number of cancelled appt Total	
Number of emergency appt Total	
Mechanics of space closure Upper arch	
Mechanics of space closure Lower arch	
Use of inter-maxillary elastics	
Duration of intermaxilllary elastics II	
Duration of intermaxilllary elastics III	
Number of broken brackets (total) Upper	
Number of broken brackets (total) Lower	
Number of repositioned brackets (total) Upper	
Number of repositioned brackets (total) Lower	
Visits intervals alignment	
Visits intervals space closure	
Visit intervals finishing	
Visits intervals total	

Sequence of arch wire upper	Arch wire type	Code	Sequence	Date
	0.012-inch NiTi	1		
	0.014-inch NiTi	2		
	0.016-inch NiTi	3		
	0.016-inch SS	4		
	0.018-inch NiTi	5		
	0.018 -inch SS	6		
	0.020 -inch SS	7		
	0.020x0.020 TNiTi	8		
	0.016x0.022-inch NiTi	9		
	0.016x0.022-inch SS	10		
	0.017x0.022-inch NiTi	11		
	0.017x0.022-inch SS	12		
	0.018x0.022-inch NiTi	13		
	0.018x0.022-inch SS	14		
	0.019x0.025-inch NiTi	15		
	0.019x0.025-inch SS	16		
		17		
		18		
		19		
		20		

		21		
Sequence of arch wire Lower	Arch wire type	Code	Sequence	Date
	0.012-inch NiTi	1		00/00/00
	0.014-inch NiTi	2		
	0.016-inch NiTi	3		
	0.016-inch SS	4		
	0.018-inch NiTi	5		
	0.018 -inch SS	6		
	0.020 -inch SS	7		
	0.020x0.020 TNiTi	8		
	0.016x0.022-inch NiTi	9		
	0.016x0.022-inch SS	10		
	0.017x0.022-inch NiTi	11		
	0.017x0.022-inch SS	12		
	0.018x0.022-inch NiTi	13		
	0.018x0.022-inch SS	14		
	0.019x0.025-inch NiTi	15		
	0.019x0.025-inch SS	16		
		17		
		18		
		19		
		20		
		21		

2. Models

Pre-treatment models

1. Study ID/code	
2. Box number	
3. Date on the model	
4. IOTN (DH)	
5. PAR score	
6. Irregularity index Upper arch	
7. Irregularity index Lower arch	
8. Crowding/spacing Upper arch	
9. Crowding/spacing Lower arch	
10. Curve of Spee	
11. Overjet	
12. Overbite	
13. Type of malocclusion	
14. Molar relationship RHS	
15. Molar relationship LHS	

Post-treatment models

1. Study ID/code	
2. Box number	
3. Date on the model	
4. IOTN (DH)	
5. PAR score	
6. Irregularity index Upper arch	
7. Irregularity index Lower arch	
8. Crowding/spacing Upper arch	
9. Crowding/spacing Lower arch	
10. Curve of Spee	
11. Overjet	
12. Overbite	
13. Type of malocclusion	
14. Molars relationship RHS	
15. Molars relationship RHS	

3. Radiographs

3. A. Periapical Radiographs

Periapical radiographs Pre-treatment

Date on the radiograph	
Type of radiograph	
Root resorption index	
Abnormal root morphology	
Quality of image	

Periapical radiographs 9 month from treatment

Date on the radiograph	
Type of radiograph	
Root resorption index	
Abnormal root morphology	
Quality of image	

3. B. OPT pre-treatment

Date on the radiograph					
Type of radiograph					
Missing teeth		Tooth number	Tooth number	Tooth number	Tooth number
Number of missing teeth					
Number of teeth with caries					
Wisdoms Upper arch					
Wisdoms Lower arch					
Quality of image					

3. C. Lateral Cephalometry

Lateral cephalometry Pre-treatment

Date on the radiograph	
Type of radiograph	
SNA	
SNB	
ANB	
Max/Mand Pl	
Lower incisors to Mand Pl	
Upper incisors to Max Pl	
Inter-incisal angle	
Quality of radiograph	

Lateral cephalometry Post-treatment

Date on the radiograph	
Type of radiograph	
SNA	
SNB	
ANB	
Max/Mand Pl	
Lower incisors to Mand Pl	
Upper incisors to Max Pl	
Inter-incisal angle	
Quality of radiograph	

Appendix 4: Correspondence with Detterline et al. (2010)

-----Original Message-----
From: Kula, Katherine S.
Sent: 04 March 2010 20:29
To: Ahmed ElAngbawi
Subject: RE: Clinical outcomes if 0.018-inch and 0.022-inch bracket
slot using the ABO objective grading system

Dear Dr. El-Angbawi,

The sequence of wires was chosen by the faculty who treated the cases.
Since this was a retrospective study, we did not have a chance to
control the wire sequence. They varied among the patients.
Thank you for your interest in the study.

Sincerely,
Katherine Kula, MS, DMD, MS
Chair and Program Director
Joseph R. and Louise Jarabak Endowed Professor Dept. Orthodontics and
Oral Facial Genetics Indiana University School of Dentistry
1121 W. Michigan St.
Indianapolis, IN 46202
kkula@iupui.edu
317-278-9915

-----Original Message-----
From: Ahmed ElAngbawi
Sent: Thursday, March 04, 2010 2:41 PM
To: Kula, Katherine S.
Subject: Clinical outcomes if 0.018-inch and 0.022- inch bracket slot using the ABO objective grading system

Dear Dr Katherine

I enjoyed reading the article published 2009 in the Angle Orthodontist.
"Clinical outcomes if 0.018-inch and 0.022- inch bracket slot using the
ABO objective grading system".
Going through the materials and methods, I wonder which

arch wire
sequence did you use for each bracket slot system?

Thank you in advance for your kind cooperation.

Ahmed El-Angbawi

Appendix 5: List of publications from this study

- **El-Angbawi A, McIntyre G, Bearn D, Thomson D. Film and digital periapical radiographs for the measurement of apical root shortening. J Clin Exp Dent. 2012;4(5):e281-5.**

- **Variability in Bracket slot dimensions (poster presentation in the British orthodontic Conference 2012)**

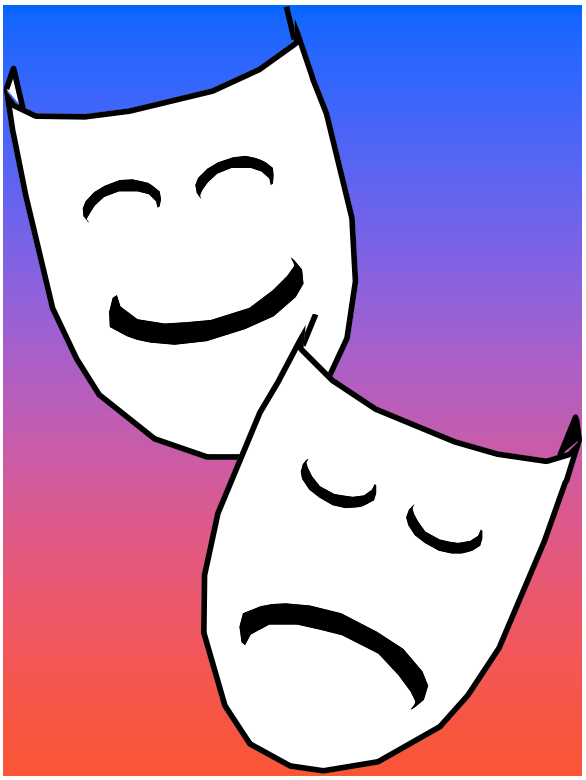
Appendix 6: Smile better questionnaire

NHS Tayside

Affix
Unique Study I.D.
label here

Smiles Better

A few questions about you and your brace



A Few Questions About You And Your Brace

We would like to know how you feel about wearing your brace. By answering these questions, YOU can help to make wearing a brace better for people in the future.

Please circle the answer, which is nearest to how you feel, like this :

If you think wearing a brace has improved your smile put a ring around improved
or
How often do you play sport Not at all (A little) A lot

*Please tell us about how you feel **NOW**, not about when your brace was new.*

---

1. How much have the following things changed because of wearing your brace?

Speech	Improved	Same	Slightly worse	Much worse
Eating	Improved	Same	Slightly worse	Much worse
Drinking	Improved	Same	Slightly worse	Much worse
Sleeping	Improved	Same	Slightly worse	Much worse
Appearance	Improved	Same	Slightly worse	Much worse
I am teased	Less	Same	Slightly more	Much more

2. Now you are wearing a brace, how have the following affected you?

Sore teeth	Not at all	A little	A lot
Soreness in your mouth	Not at all	A little	A lot
Soreness from rubbing	Not at all	A little	A lot
Feeling embarrassed	Not at all	A little	A lot
Dribbling	Not at all	A little	A lot
Keeping the brace clean is a nuisance	Not at all	A little	A lot

We would like to know if wearing a brace can affect other things in your life.

SCHOOLWORK

3a. How have the following things associated with wearing a brace affected your schoolwork?

For example, if you think your schoolwork is better you would put a ring around **improved**

How have any changes in your speech affected your schoolwork ?	Improved	Same	Worse	Much Worse
How have any changes in your eating affected your schoolwork ?	Improved	Same	Worse	Much Worse
How have any changes in how you drink affected your schoolwork ?	Improved	Same	Worse	Much Worse
How have any changes in your sleep patterns affected your schoolwork ?	Improved	Same	Worse	Much Worse
How have any changes in your appearance affected your schoolwork ?	Improved	Same	Worse	Much Worse
If you have experienced teasing how has it affected your schoolwork ?	Improved	Same	Worse	Much Worse

3b. How have your experiences of the following affected your schoolwork?

Sore teeth	Not at all	A little	A lot
Soreness in your mouth	Not at all	A little	A lot
Soreness from rubbing	Not at all	A little	A lot
Feeling embarrassed	Not at all	A little	A lot
Dribbling	Not at all	A little	A lot
Keeping the brace clean	Not at all	A little	A lot

GETTING ON WITH FRIENDS

4a. How have the following things associated with wearing your brace affected your friendships?

For example, if you think it is easier to get on with your friends because of the way your brace has changed your smile, you would put a ring around improved

How have any changes in your speech affected your friendships ?	Improved	Same	Worse	Much Worse
How have any changes in your eating affected your friendships ?	Improved	Same	Worse	Much Worse
How have any changes in how you drink affected your friendships?	Improved	Same	Worse	Much Worse
How have any changes in your sleep patterns affected your friendships ?	Improved	Same	Worse	Much Worse
How have any changes in your appearance affected your friendships?	Improved	Same	Worse	Much Worse
If you have experienced teasing how has it affected your friendships ?	Improved	Same	Worse	Much Worse

4b. How have your experiences of the following affected the way in which you get on with your friends?

Sore teeth	Not at all	A little	A lot
Soreness in your mouth	Not at all	A little	A lot
Soreness from rubbing	Not at all	A little	A lot
Feeling embarrassed	Not at all	A little	A lot
Dribbling	Not at all	A little	A lot
Keeping the brace clean	Not at all	A little	A lot

FAMILY RELATIONSHIPS

5a. How have the following things associated with wearing a brace affected how you get on with your family?

For example, if you think you argued a lot more with your parents because of your brace, you would put a ring around much worse

How have any changes in your speech affected your relationship with your family? Much Worse	Improved	Same	Worse
How have any changes in your eating affected your relationship with your family? Much Worse	Improved	Same	Worse
How have any changes in how you drink affected your relationship with your family? Much Worse	Improved	Same	Worse
How have any changes in your sleep patterns affected your relationship with your family? Much Worse	Improved	Same	Worse
How have any changes in your appearance affected your relationship with your family? Much Worse	Improved	Same	Worse
If you have experienced teasing how has it affected your relationship with your family? Much Worse	Improved	Same	Worse

5b. How have your experiences of the following affected your relationship with your family?

Sore teeth	Not at all	A little	A lot
Soreness in your mouth	Not at all	A little	A lot
Soreness from rubbing	Not at all	A little	A lot
Feeling embarrassed	Not at all	A little	A lot
Dribbling	Not at all	A little	A lot
Keeping the brace clean	Not at all	A little	A lot

HOBBIES / INTERESTS

6. If you feel that wearing a brace has had any effect on your hobbies please tick the appropriate box.

For example:

If you feel that wearing a brace has meant that you get the lead roles in the school play you would tick the **I enjoy doing more** *box beside* **drama**

Activity	I enjoy doing more…….	No different	I do less…….
Music			
Sport			
Drama			
Singing			
Going to clubs eg Scouts or guides			

If you think wearing a brace has affected other hobbies or interests please write them in the activity column and say in what way by ticking the appropriate boxes.

TOOTH MOVEMENT

Now that you are wearing a brace do you feel that your teeth are moving?	Not at all	A little
A lot		
Is it important to you whether or not your teeth are moving?	Not at all	A little
A lot		

YOUR EXPERIENCE OF WEARING A BRACE

Is wearing a brace what you expected?	Yes	No
Not sure		
Have you had any extra visits to the hospital because your brace has broken?	Yes	No
If you have had to make extra visits because your brace has broken, has this bothered you?	Not at all	A little
A lot		

YOUR ADVICE TO OTHER PATIENTS

Based upon **YOUR** experience of wearing a brace, what would **YOU** say to someone who was about to have a brace fitted?