# The efficacy of alveolar-decortication to reduce treatment time for orthodontic alignment of palatally impacted canines

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## ABSTRACT

### AIM

To investigate the efficacy of alveolar-decortication, in addition to surgical exposure, in reducing the time taken to align palatally impacted canines.

### NULL HYPOTHESIS

There is no difference in the velocity of tooth movement, whilst aligning an impacted canine, following the conventional or alternative surgical technique.

### DESIGN

Prospective Parallel Group Randomised Controlled Clinical Trial

### METHOD

Ethical approval was obtained. Participants were randomly allocated to control or test groups.

Measurements to record the distance from the tip of the canine to the line of the dental arch, and the time to various clinical endpoints were recorded to determine the velocity of tooth movement. Any pain and adverse events were recorded.

## RESULTS

Twenty-nine subjects were recruited, and 23 progressed to the primary endpoint. The addition of alveolar-decortication reduced the time to eruption, which was 34 and 21 weeks in the control and test groups respectively. There was little difference in the velocity from impaction to line of the arch, at 0.39mm/wk and 0.35mm/wk in the control and test groups. Alveolar-decortication is not associated with additional pain or discomfort.

## CONCLUSIONS

The use of alveolar-decortication does not reduce the treatment time to align palatally impacted canines. Alveolar-decortication does not increase the duration of surgery, and is not associated with increased pain or need for analgesics.

I would like to dedicate this thesis to my wonderful parents, David and Julia Bussell.

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# CONTENTS

# CHAPTER 1: LITERATURE REVIEW

# CHAPTER 2: SUBJECTS AND METHOD

# CHAPTER 3: RESULTS

# CHAPTER 4: DISCUSSION

# CHAPTER 5: CONCLUSIONS

# CHAPTER 6: APPENDICES

# LIST OF FIGURES

# LIST OF TABLES

# Chapter 1

# LITERATURE REVIEW

# CHAPTER 1: LITERATURE REVIEW

## 1.1 INTRODUCTION

An impacted canine may be defined as a canine that is prevented from erupting into its normal position by tooth, bone or fibrous tissue (Postgraduate Notes in Orthodontics, 2009).

Other terms within this subject area include ectopic canine and displaced canine. An ectopic canine is diverted from its normal path of eruption, and deviant from its normal functional position. A palatally displaced canine is characterised by developmental dislocation of the maxillary canine to a palatal side, often resulting in tooth impaction requiring surgical and orthodontic treatments (Peck et al., 1996).

Impacted canines have an incidence of approximately 2% (Ericson and Kurol, 1986; Thilander and Myrberg, 1973), however, they are seen frequently amongst a population who present for orthodontic treatment. Treatment is usually multi-disciplinary, with input from orthodontic, oral surgery, and occasionally paediatric and restorative departments.

The treatment duration for alignment of impacted canines is lengthily, and it is generally agreed that aligning the canine will add at least 6 months to any treatment plan. Fleming et al. (2009) reported that the mean treatment duration for alignment of an impacted canine was 26.31 months, with a standard deviation of 9.31 months.

Alveolar-decortication is a surgical technique, which when combined with conventional orthodontic treatment is reported to produce rapid tooth movement and reductions in orthodontic treatment time (Wilcko et al., 2001; Wilcko et al., 2008; Fischer, 2007).

Other terms used in the literature for this surgical technique include ‘corticotomy-assisted surgical technique’ (Fischer, 2007), ‘corticotomy-facilitated orthodontics’ (Suya, 1991), ‘corticotomy-assisted tooth movement’ (Lee et al., 2008), and ‘selective alveolar decortication-facilitated orthodontics’ (Wilcko et al., 2008).

An osteotomy is defined as a surgical operation to cut a bone into two parts followed by realignment of the ends to allow healing (Concise Colour Medical Dictionary). In comparison, corticotomy involves cuts being made in the cortical plate; and alveolar-decortication involves partial or selective corticotomy of the cortical plates of the alveolus.

Alveolar-decortication is essentially additional trauma to the bone, by making cuts and grooves in the cortex. Studies in animal models have shown that this additional trauma increases the physiological activity in the bone (Bogoch et al., 1993; Sebaoun et al., 2008). The density of bone is reduced (Bogoch et al., 1993; Lee et al., 2008;), and the metabolism is increased (Sebaoun et al., 2008).

Fischer (2007) has previously looked at the use of alveolar-decortication as an adjunct to surgical exposure and alignment of palatally impacted canines; his study reported a reduction of 28-33% in treatment time.

Raising a full mucoperiosteal flap and the use of a surgical bur is already indicated for exposure of impacted canines. Potentially a small modification to the surgical exposure may result in a clinically significant reduction in orthodontic treatment time. Therefore, allowing a reduction in the overall treatment duration and number of appointments, saving time for patients and potentially resources for the National Health Service (NHS).

## 1.2 NORMAL CANINE DEVELOPMENT AND ERUPTION

Calcification of the upper permanent canines starts by 1 year, and is usually complete by 5-6 years of age (Broadbent, 1941). At 3-4 years the canine migrates from its initial position, between the roots of the first primary molar, to lie on the labial side of the root of the lateral incisor (Miller, 1963). Growth and development of the maxilla provides additional space, and finally, the canine erupts along the distal aspect of the lateral incisor root.

Further to normal dental development, the upper permanent canines should be palpable in the buccal sulcus by 10-11 years of age (Ericson and Kurol, 1986), and will erupt at 11-12 years of age. Upper permanent canines may be considered late if they have not erupted by 12.3 years in girls and 13.1 years in boys (Hurme, 1949; Husain et al., 2010).

It is very rare for the upper permanent canines to be congenitally absent, and this has an incidence of only 0.3% (Gorlin et al., 1990). Congenital absence and impaction of the mandibular canines is far less common, with an incidence of 0.1% (Gorlin et al., 1990) and 0.35% (Dachi and Howell, 1961) respectively.

Upper permanent canines may become impacted, which prevents their normal path of eruption (Brin et al., 1986; Ericson and Kurol, 1986). It is therefore more common for an upper permanent canine, which appears missing, to be impacted rather than absent.

## 1.3 IMPACTED CANINES

An impacted canine gives an Index of Orthodontic Treatment Need, dental health component of 5i (Brook and Shaw, 1989), which currently makes a patient eligible for orthodontic treatment under the NHS.

Impactions are twice as common in females (Dachi and Howell, 1961), and occur bilaterally in 8% of cases (Bishara, 1992).

Most frequently an impacted canine lies palatal to the line of the arch (61.4%) followed by being present in the line of the arch (34.1%), and buccal to the line of the arch (4.5%) (Stivaros and Mandall, 2000).

There has been much debate over the aetiology of impaction, with both genetic and guidance theories having been proposed.

The guidance theory considers the distal aspect of the lateral incisor root guiding the canine along its path of eruption (Becker et al., 1981). Forty-two per cent of palatally displaced canines have been associated with anomalous or missing lateral incisors (Brin et al., 1986). In contrast, the genetic theory considers the familial tendency, sexual dimorphism, bilateral occurrence and association with other dental anomalies (Peck et al., 1994).

The following aetiological factors have been documented in the literature:

- Familial tendency/inheritance (Zilberman et al., 1990; Peck at al., 1994)
- Displacement of the crypt (Bishara, 1998; Mitchell, 2007)
- Follicular disturbance/cyst formation/associated pathology (Bishara, 1998)
- Trauma (Brin et al., 1993)
- Long path of eruption (Coulter and Richardson, 1997)
- Alveolar cleft (Semb and Schartz, 1997)
- Lack of resorption of the deciduous canine (Thilander and Jacobsson, 1968; Ericson and Kurol, 1987)
- Absent/malformed/diminutive lateral incisors (Becker et al., 1981; Becker et al., 1984; Brin et al., 1986)
- Crowding (Thilander and Jacobsson, 1968; Jacoby 1983)
- Class II division 2 malocclusions (Mossey et al., 1994)

- Delayed dental development (Zilberman et al., 1990; Becker and Chaushu 2000; Chaushu et al., 2002)
- Environmental factors (Camilleri et al., 2008)

It is generally accepted that impacted canines have a multifactorial aetiology. Problems associated with an impacted canine include root resorption of adjacent teeth, and cyst formation.

Ericson and Kurol (1987) reported that 0.6-0.8% of 10-13 year olds have resorption of permanent teeth as a result of canine ectopia. However, this study did not have a control group. Resorption of adjacent incisors rarely starts after 14 years of age (Houston et al., 1992), and is most likely to occur between 11 and 12 years of age (Ericson and Kurol, 1988).

The more detailed the examination for resorption, the more likely it is to be detected. Root resorption was detected in 12% of permanent lateral incisors with plain film radiographs (Ericson and Kurol, 1988), and this value has increased to 66.7% with the use of cone-beam computed tomography (Walker et al., 2005).

## 1.4 TREATMENT OPTIONS

Jacoby (1983) stated that palatally impacted canines seldom erupt without some form of intervention. There are several treatment options for managing a palatally impacted canine and these can broadly be divided into:

- Interceptive treatment
- Surgical exposure and orthodontic alignment
- Surgical removal
- Transplantation
- No active treatment (leave and observe)

Several authors have reported on the success of interceptive treatment, by extracting the deciduous canine (Ericson and Kurol, 1988; Power and Short, 1993; Baccetti et al., 2008). However, the Cochrane review (2009) concluded that there was insufficient evidence to support extraction of the deciduous canine to facilitate the eruption of the palatally ectopic maxillary permanent canine (Parkin et al., 2009).

Surgical removal is carried out if a patient declines active treatment, is happy with their dental appearance, and in cases with severe root resorption. When the canine has been removed, the first premolar can be successfully camouflaged as the canine.

Transplantation is not usually considered, unless other options are inappropriate, or the position of the canine makes alignment impractical. Adequate space and alveolar-bone is required to accommodate the canine, and consideration should be given to the stage of root development.

No active treatment may be considered when there is no evidence of associated pathology, and the deciduous canine has a good long-term prognosis.
When interceptive treatment is ineffective or impractical, in a motivated patient with good dental health, alignment is generally the preferred treatment option (McSherry, 1998). There are few reports in the literature stating the success rate of aligning an impacted canine following surgical exposure. Becker and Chaushu (2003) reported that the success rate is 100% in young patients (12-16 years of age), and 69% in adult patients (20-47 years of age). There is a considerable age range of adult patients considered in this study, and the stage of root development was different in the 2 groups.

Factors to consider when planning the management of an impacted canine include:

- Age of the patient
- Medical history
- Patient co-operation and motivation
- General oral health
    - Oral hygiene
    - Root resorption of adjacent teeth

    - Prognosis of a retained deciduous canine
    - Suitability of the first premolar to replace the canine
- Skeletal variation
- Crowding/spacing
- Position of the canine
    - Palatal vs. buccal
    - Horizontal position
    - Vertical position
    - Angulation
- Experience of orthodontist and surgeon

Pitt et al. (2006) reported that the horizontal position, age of patient, vertical height, and bucco-palatal position, in descending order of importance, are factors that determine the difficulty of alignment. Fleming et al. (2009) reported that it is the horizontal position of the impacted canine, which is the main influencing factor on the overall treatment duration.

Surgical methods for exposing an impacted tooth can be divided into open and closed approaches.

The closed technique, which involves bonding an attachment prior to replacement of the mucoperiosteal flap, is associated with an increased risk of repeat surgery, and duration of surgical procedure (Pearson et al., 1997). There is currently no evidence to suggest that one method of exposure gives better periodontal health than the other (Burden et al., 1999). The Cochrane review (2008) has concluded that, there is no

evidence to support one surgical technique over the other in terms of dental health, aesthetics, economics and patient factors (Parkin et al., 2008).

More extensive bone removal has been associated with a long-term reduction in bony support (Kohavi et al., 1984). However, it is not known whether this is clinically significant, and cases will vary depending on the depth of impaction. In terms of periodontal health, an absence of significant differences in plaque index, gingival index, pocket depth, and attached gingiva following "radical' and "light" exposures were also reported by Kohavi et al. (1984).
Surgeons should take a conservative approach, and only expose enough tooth to allow placement of the attachment.

## 1.5 ALVEOLAR-DECORTICATION

### 1.5.1 HISTORICAL BACKGROUND

Recently, there has been a renewed interest in alveolar-decortication. However, the origins of the technique date back many years and are first attributed to L.C.Bryan in 1892 (cited by Suya, 1991).

In 1959, Köle described the use of corticotomy in conjunction with orthodontic treatment, which resulted in quicker tooth movement. His surgical technique involved a combination of corticotomy and osteotomy; vertical interdental bone cuts of the

cortical plate together with sectioning the bone horizontally beneath the apices of teeth (Köle, 1959). This created a block of bone, which could be mobilised to enable repositioning of the teeth (Köle, 1959; Suya, 1991).

Several modifications have been made, including elimination of the sub-apical cut (Wilcko et al., 2008), further elimination of the vertical cuts to the lingual cortical plate (Germec et al., 2006), the addition of perforations into the cortical plate (Wilcko et al., 2001), and most recently, complete elimination of the cuts and placement of perforations only (Fischer, 2007).

The evolution of the surgical techniques reflects the change in theory as to why this adjunct surgical procedure may allow more rapid tooth movement.
Initially, it was thought that the mobilisation of teeth within a block of bone accounted for the rapid tooth movement. However, research has shown that changes within the structure of bone and also at a cellular level accompany the cuts being made (Frost, 1989; Bogoch et al., 1993). Wilcko et al. (2001) first proposed that it is these changes, which result in an increase in the velocity of tooth movement.

### 1.5.2 BIOLOGY

In response to traumatic injury to bone (e.g. fracture or surgical trauma), a process of healing is initiated. Both physical and biochemical signals stimulate multicellular

mediator mechanisms within the surrounding tissues, which triggers the formation of cells required for repair.

The bone healing process proceeds as a cascade of events; fracture, temporary healing with granulation tissue, replacement with a temporary hard callus, replacement of the callus with oriented lamellar bone and finally recontouring of the bone to its normal shape.

As part of the healing process, bone turnover in the bone adjacent to the site of injury will be accelerated; a process referred to as the regional acceleratory phenomenon (RAP) (Frost, 1989). Theories of the RAP include release of cytokines, and hyperaemic effects (Bogoch et al., 1993).

The bone healing process, and therefore the RAP normally occurs following fractures, arthrodeses, osteotomies and bone grafting operations (Frost, 1989). During occurrence of the RAP, there is an increased bone turnover, whilst the volume of bone remains constant (Bogoch et al., 1993).

Frost (1989) suggested that the RAP begins within a few days of the injury, peaks at 1 to 2 months, and may take 6 to 24 months to subside.

In orthodontics, the application of a force initiates a cellular response within the periodontal ligament allowing tooth movement. Proliferation of cells, including

fibroblasts and osteoblasts occur, and osteoclastic activity is promoted resulting in resorption and apposition of bone.

Tooth movement occurs in four phases: initial, lag, acceleration and constant linear phases. The lag phase is associated with constriction of blood vessels; the compressed connective tissue has a structureless glassy appearance termed hyalinisation (Rygh, 1974). Efficiency of tooth movement might be improved by reducing the amount of hyalinisation that occurs, and eliminating this period has been shown to influence the velocity of tooth movement (Bohl et al., 2004).
Lino et al. (2007) reported less hyalinisation in the periodontal ligament in the early stages of tooth movement, and an apparent absence of the lag phase after corticotomy in adult Beagles.

In theory, intentional injury to the surrounding bone will reduce the density and increase bone turnover, thus enhancing orthodontic tooth movement.

### 1.5.3 ANIMAL STUDIES

Animal studies have demonstrated the occurrence of the RAP alongside bone healing (Bogoch et al., 1993; Lee et al., 2008; Mostafa et al., 2009; Sanjideh et al., 2010).

Bogoch et al. (1993) prepared sagittal cuts through the joint surface and cancellous bone in the femoral condyle of eleven rabbits; healing without fixation was permitted for a period of 28 days. Analysis of decalcified coronal sections revealed bone formation within the osteotomy ‘gap’, and an increase in the volume of calcein-labeled bone in the bone immediately adjacent to the injury. This demonstrated the increase in bone turnover induced by the nearby injury. The authors conclude that the regulatory processes that govern cancellous remodeling occur during the healing of the osteotomised bone.

In addition to this, other studies have suggested the RAP may occur without any direct surgical insult to bone. For example, Yaffe et al. (1994) reported the RAP in the mandible following mucoperiosteal flap surgery. Elevation and replacement without sutures of a mucoperiosteal flap was carried out in the premolar and molar region of the mandible in Wistar rats. A buccal flap, buccal and lingual flaps and a control group were compared. No additional surgical procedure was carried out, and the flap was reported to heal within 48 hours. Microradiography and histological sections revealed resorption of the adjacent alveolar bone. The increased rate of resorption in the experimental group was thought to be representative of the activation of the RAP, when accelerated resorptive activity is followed by further bone regeneration (Yaffe et al., 1994).

The RAP has also been described in response to orthodontic force (Verna et al., 2000), and suggested following normal tooth movement (Lee et al., 2008).

Lino et al. (2007) investigated the effects of corticotomy on orthodontic tooth movement in adult Beagles, and reported an increase in the velocity of tooth movement. Increased orthodontic tooth movement was reported for at least 2 weeks post-corticotomy, which was carried out following a mucoperiosteal flap being raised on both the buccal and lingual aspects of the cortical bone surrounding the third premolar tooth.
A reduction in hyalinisation was reported, which may also have promoted orthodontic tooth movement.

In contrast to this, Lee et al. (2008) reported little difference between normal tooth movement and corticotomy-assisted tooth movement in rats.
A study of decortication of buccal and lingual cortical plates in the maxilla of healthy adult rats, demonstrated how intentional injury can result in a significant increase in tissue turnover. These authors reported a three-fold increase in osteoclast count and apposition rate, together with a reduced calcified spongiosa. The increased tissue turnover was significantly increased by week 3, but reduced to a steady state by post-operative week 11. The study suggests negligible metabolic changes more than one tooth away from the test tooth (Sebaoun et al., 2008), although effects may be present in the adjacent tissues (Bogoch et al., 1993).

Increased bone turnover is a condition that promotes orthodontic tooth movement (Verna et al., 2000, 2003). In addition to the RAP, physical wounding of bone will cause a reduction of bone density and a transient osteoporosis, which has been reported to enhance tooth movement in rats (Goldie and King, 1984).

Sanjideh et al. (2010) considered the effects of corticotomy, including a repeat episode of corticotomy in mature foxhounds. A second corticotomy procedure was repeated 4 weeks after the initial surgery. The authors conclude that this maintained higher rates of tooth movement over a longer duration, but that this was not sufficient to justify a second corticotomy procedure.

### 1.5.4 CLINICAL STUDIES

Clinical studies are limited to case reports, case series and a single, very small, randomised controlled clinical trial.

Modified corticotomy techniques have been described in conjunction with a variety of orthodontic treatments: relief of crowding (Germec et al., 2006; Wilcko et al., 2001; Wilcko et al., 2008), intrusion of molars (Hwang et al., 2001; Akay et al., 2009), expansion (Wilcko et al., 2001, Ferguson et al., 2006) and alignment of ectopic teeth (Ferguson et al., 2006; Fischer, 2007).

Wilcko et al. have published several case reports (Wilcko et al., 2001; Wilcko et al., 2008; Wilcko et al., 2009) describing remarkable reductions in treatment duration. The reports describe class I crowded cases treated on a non-extraction basis. Therefore, crowding is relieved by expansion, and so the long-term stability of this may be questionable. In the most recent case reports, placement of a bone grafting

material is described following alveolar-decortication. The results of these case reports must be considered with caution, as they are not comparable to cases with impacted teeth treated by traditional methods.

A preliminary study published in 2007 reported a reduction of 28-33% in treatment duration (Fischer, 2007) in 6 patients with bilateral palatally impacted canines. This study lacked ethical approval and a power calculation. Conventional surgical exposure and corticotomy-assisted exposure carried out by a single surgeon was compared in a split-mouth design. No adverse side effects of loss of bone support or periodontal health were reported (Fischer, 2007), however, the information regarding the periodontal assessment was limited.

## 1.6 AVAILABLE EVIDENCE

A reduction of treatment time is likely to appeal to both patients and clinicians. Cases including alignment of impacted teeth are often challenging and result in prolonged treatment times.

If the RAP and its effects can be stimulated by intentional injury to bone, they may also be induced during any form of routine surgical procedure. The RAP may occur by raising a flap (Yaffe et al., 1994), placing an implant (Roberts, 1988) or, extracting a tooth (Buchanan et al., 1988). Infection and systemic change in the bone (Frost, 1989), the presence of an orthodontic appliance (Milne et al., 2009), and orthodontic

tooth movement (Verna et al., 2000) may all have an additional affect on local bone processes.

Systemic changes in the bone may override the advantages of the RAP and accelerated tooth movement. Tooth movement is delayed in adult patients, due to decreased proliferative activity in the periodontal ligament and alveolar bone (Verna et al., 2000). In addition non-steroidal anti-inflammatory drugs may influence bone metabolism, and animal studies suggest that they may inhibit tooth movement (Bartzela et al., 2009).

The full extent of corticotomy and alveolar-decortication contributing to the RAP remains unknown.

The additional trauma required to stimulate the RAP and associated effects may be of concern. The amount of bone removed will vary amongst cases; an increase in bone removal during surgical exposure of maxillary canines is not considered to reduce the resultant bone support (McDonald and Yap, 1986). However, the amount of surgical bone removal could be an important factor to the long-term periodontal health (Becker et al., 1983). To date, there are no reports of undesirable side effects, but the risks verses benefits of the intentional injury to the bone remain inconclusive.

The extent and duration of the effects of surgical injury are unknown, and therefore it is unclear whether there is a need to raise flaps on both the labial and palatal aspects, or whether there is a need to repeat the injury to maintain the desired

increase in bone turnover during orthodontic treatment. Several studies (Lino et al., 2007; Hwang, 2001; Wilcko et al., 2001) have raised a flap to allow access and surgery to both labial and palatal aspects, perhaps to maximise the effects.

Since the duration of the effects are unclear, it is not known how soon after surgery orthodontic traction should be applied, and for how long after surgery a benefit of corticotomy in terms of increased velocity of tooth movement can be expected. Authors have suggested that orthodontic forces should be applied immediately after corticotomy; otherwise it looses effectiveness (Hwang, 2001; Lee et al., 2008). In the absence of strong evidence to the contrary, this seems to be a reasonable recommendation, as delaying movement may allow the alveolar bone to heal. Following injury to bone, the initial cellular responses occur within 7 days, and mineralisation of the granulation tissue within 1 to 4 months (Frost, 1989).

During bone healing, the RAP results in an increased bone turnover, which has been shown to encourage tooth movement.
In orthodontics increased tooth movement, without undesired side effects would be beneficial to both the patient and clinician.

Recently, there have been several case reports and one clinical trial suggesting that alveolar-decortication when combined with conventional orthodontic treatment results in rapid tooth movement and reduced treatment duration (Wilcko et al., 2001; Wilcko et al., 2008; Fischer, 2007).

Many studies have been carried out on animal models, the findings of which are limited due to differences in the structure and physiology of bone. Unfortunately, due to the small number of human studies, it is difficult for direct comparisons between studies to be made.

At present, the evidence supporting this theory is limited, and many unanswered questions regarding its use remain. Sound evidence, including randomised control clinical trials are required in this subject area.

Questions regarding the use of alveolar-decortication:

1. How soon should the orthodontic traction be applied?
2. What is the duration of the desired changes allowing increased tooth movement?
3. Over what area of bone does the RAP have an effect?
4. Is there a need to raise flaps on both aspects of a tooth?
5. Can systemic changes in the bone reduce the efficiency of the technique?

## 1.7 STUDY AIMS

The primary aim of this study was to investigate the efficacy of alveolar-decortication, in addition to surgical exposure, in reducing the time taken to align palatally impacted canines.

The secondary aims were to establish whether the addition of alveolar-decortication increases the surgical time, whether it is associated with any adverse events, increased pain and increased analgesic consumption.

## 1.8 NULL HYPOTHESIS

There is no difference in the velocity of tooth movement whilst aligning an impacted canine, following conventional surgical exposure or the use of alveolar-decortication in addition to surgical exposure.

Chapter 2

# SUBJECTS AND METHOD

# CHAPTER 2: SUBJECTS AND METHOD

## 2.1 STUDY DESIGN

The study was designed as a prospective parallel group randomised controlled clinical trial. Patients requiring surgical exposure and bonding of an attachment, to a palatally impacted canine, as part of their orthodontic treatment at Birmingham Dental Hospital were invited to take part.

Participants were randomly allocated to either the control (conventional surgical exposure) or test group (alveolar-decortication in addition to surgical exposure) at the time of surgery. The orthodontic treatment, which followed was carried out irrespective of group allocation. The treating orthodontist was blinded with respect to the surgical treatment received.

Clinical impressions, and the linear distance from the tip of the canine to the line of the dental arch were measured with a calliper in order to determine the velocity of tooth movement.

A pain diary was given to each participant in order to record any discomfort experienced, and analgesics taken following surgery.

## 2.2 ETHICAL APPROVAL AND RESEARCH AND DEVELOPMENT APPROVAL

Ethical approval was gained from South Birmingham Research Ethics Committee. Reference number: 09/H1207/108

Local NHS Research and Development approval was gained from Birmingham and the Black Country Comprehensive Local Research Network. Reference number: 1282

The trial was registered on clinicaltrials.gov. Reference number: NCT01093352

## 2.3 SAMPLE SIZE

Published evidence regarding alveolar-decortication in orthodontics is limited to several case reports (Wilcko et al., 2001; Wilcko et al., 2008) describing the technique, and one preliminary study of 6 patients (Fischer, 2007). Therefore, reliable estimates of effect size and variability were not available.

Fischer (2007) investigated the effect of alveolar-decortication on the treatment duration for aligning bilateral palatally impacted canines. This study observed a marked difference in velocity of tooth movement of 0.08mm/week (mm/wk) with a standard deviation of 0.04mm/week.

The following tables give the power for various effect sizes, and standard deviations conservatively based on the data by Fischer (2007), assuming a two-tailed $\alpha=0.05$ and a sample size of n=15 per group and n=13 per group (allowing for drop-outs), respectively. Drop-outs were unlikely to be a problem, due to the patients committing to a course of fixed appliance therapy; a possibility was if patients relocated away from the area.

The following tables show the power calculations carried out, using the *Sampsi* procedure in STATA 10 (STATA Corp., College Station, TX, USA).

**If n=15 per group**

| Difference in velocity (mm/wk) | SD=0.04 | SD=0.05 | SD=0.06 |
|---|---|---|---|
| 0.08mm/wk | >99% | 99% | 95% |
| 0.07mm/wk | >99% | 97% | 89% |
| 0.06mm.wk | 98% | 91% | 78% |

Table 2.3.1 Power calculation (n=15 per group)

SD = standard deviation

**If n=13 per group**

| Difference in velocity (mm/wk) | SD=0.04 | SD=0.05 | SD=0.06 |
|---|---|---|---|
| 0.08mm/wk | >99% | 98% | 92% |
| 0.07mm/wk | 99% | 95% | 84% |
| 0.06mm/wk | 97% | 86% | 72% |

Table 2.3.2 Power calculation (n=13 per group)

A difference in velocity of tooth movement of 0.06mm/week to 0.08mm/week would be clinically relevant. In the study by Fischer (2007), the average velocity in the control group was 0.18mm/week, resulting in an average duration of treatment of 67 weeks (average distance of 12mm). A difference in velocity of 0.06mm/week or

0.08mm/week would result in reductions of treatment time by 17 and 21 weeks, respectively. These differences were considered to be clinically meaningful.

The required sample size was calculated to be 15 participants per group (30 participants in total), based on the following parameters:

- Power of 95%
- Significance level of 0.05
- To detect a difference of 0.08mm/week in tooth movement with a standard deviation of 0.06mm/week

## 2.4 RANDOMISATION PROCESS

www.randomisation.com was used to perform the randomisation process.

Sealed opaque envelopes with group assignment were kept in a locked office. Enrolled participants were assigned a study number at the time of surgery. While the surgeon could not be blinded for obvious reasons, group assignment was not disclosed to the patient or orthodontist. Once the participant had been randomised, based on the principles of an intention-to-treat analysis, any data generated was included in the final results.

## 2.5 SUBJECTS

Thirty participants were recruited between April 2009 and February 2012 from the orthodontic department at Birmingham Dental Hospital. An additional 5 potential participants were identified, who declined participation in the study.

### 2.5.1 INCLUSION CRITERIA

- Patients at Birmingham Dental Hospital
- Patients with a palatally impacted canine*, and treatment planned for surgical exposure (closed technique)
- Patients who had orthodontic appliances fitted, such that orthodontic traction could be applied as soon as possible following surgical exposure
- Patients with bilateral impacted canines; in these cases both canines were treated using the same surgical technique determined by allocation into either the control or test group
- Informed consent

* All palatally impacted canines were considered, irrespective of the severity of impaction.

### 2.5.2 EXCLUSION CRITERIA

- History of periodontal disease
- Radiographical evidence of pathology associated with the impacted canine

- Patients already participating in a research study

## 2.6 METHOD

Potential participants were approached during the orthodontic treatment planning stage, and invited to participate. The nature of the study was fully explained and all potential participants were given a written information sheet. For those patients under 16 years of age, a separate patient information sheet was also given to the parent (Appendix 1). Participants (and a parent when appropriate) were asked to sign a consent form prior to enrolment into the study.

Following informed consent, and placement of a fixed appliance, patients attended a standard oral surgery consultation appointment in preparation for the surgical exposure of their palatally impacted canine/s.

The orthodontic treatment progressed as standard care, and when the patient had a rigid archwire in place, they attended their surgical appointment in the oral surgery department.

Participants were randomly allocated to the control or test group. The envelope was opened after completion of the surgical exposure, but prior to flap closure.

For both groups baseline measurements were taken at the time of surgery:

- A sterile impression* of the upper arch
- The linear distance (mm) from the tip of the impacted canine to the desired position in the line of the dental arch

*A sterile impression material ('Elite implant heavy') traditionally used for impressions during surgery for dental implants was identified, and obtained from 'Zhermack'.

Callipers were used to measure the following distances on the study models:

- The direct distance from the tip of the impacted canine to the desired position of the tip of the canine in the line of the upper arch (DD)
- Horizontal distance, parallel to the occlusal plane, from the tip of the impacted canine to its desired position in the upper arch (HD) (figure 2.6.5)
- Vertical distance from the tip of the impacted canine to the overlying mucosa (VD)

Both groups completed a pain diary in order to record any discomfort experienced and analgesics taken in the week, which followed surgery (Appendix 3). Any adverse events e.g. infection were also noted.

Participants were given an appointment with the orthodontic department within 2 weeks of the surgical exposure. At this appointment, the pain diary was collected, and adjustments were made to the fixed appliance including the application of traction to the gold chain (bonded to the impacted canine during surgery).

The orthodontic treatment, which followed was carried out irrespective of the patient being involved in the study. Participants continued regular appointments until completion of treatment.

**Control group**

The participants in this group had their canine tooth exposed in the standard way. A palatal mucoperiosteal flap was raised, and bone removed to access the canine (figures 2.6.1 and 2.6.2), a bracket with gold chain was attached to the tooth and the flap was closed.

**Test group**

In addition to the standard surgical technique, described above, small cuts were made in the alveolar-bone (buccal and palatal) surrounding the exposed tooth prior to closure. A buccal flap was also raised to allow perforations to be placed buccally (figure 2.6.3). A 1mm diameter bur (figure 2.6.4) was used, similar to the 1.5mm diameter bur described by Fischer (2007). The surgeons were asked to make as many cuts as possible in the surrounding bone, without putting the adjacent teeth at risk. The surgeons were asked to make the cuts approximately 1.5mm apart, based on the method used by Fischer (2007).

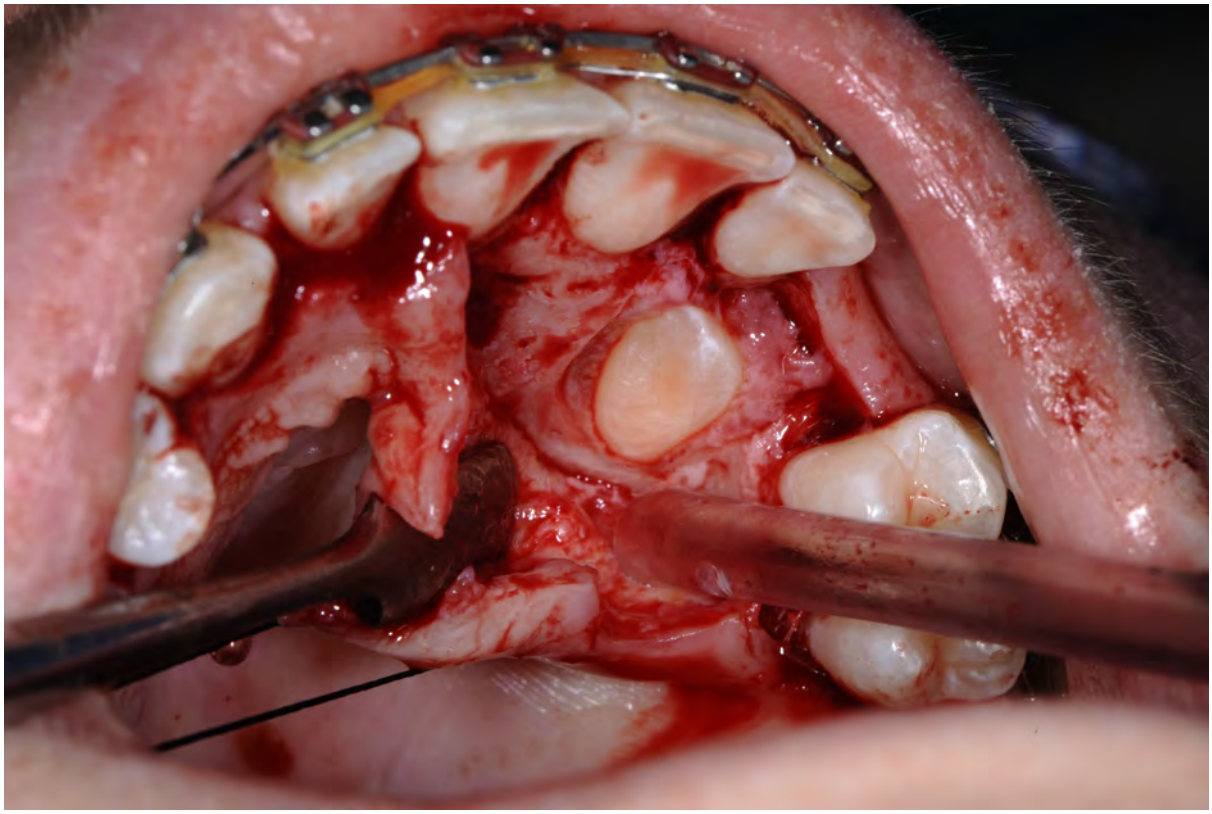

Figure 2.6.1 Standard surgery

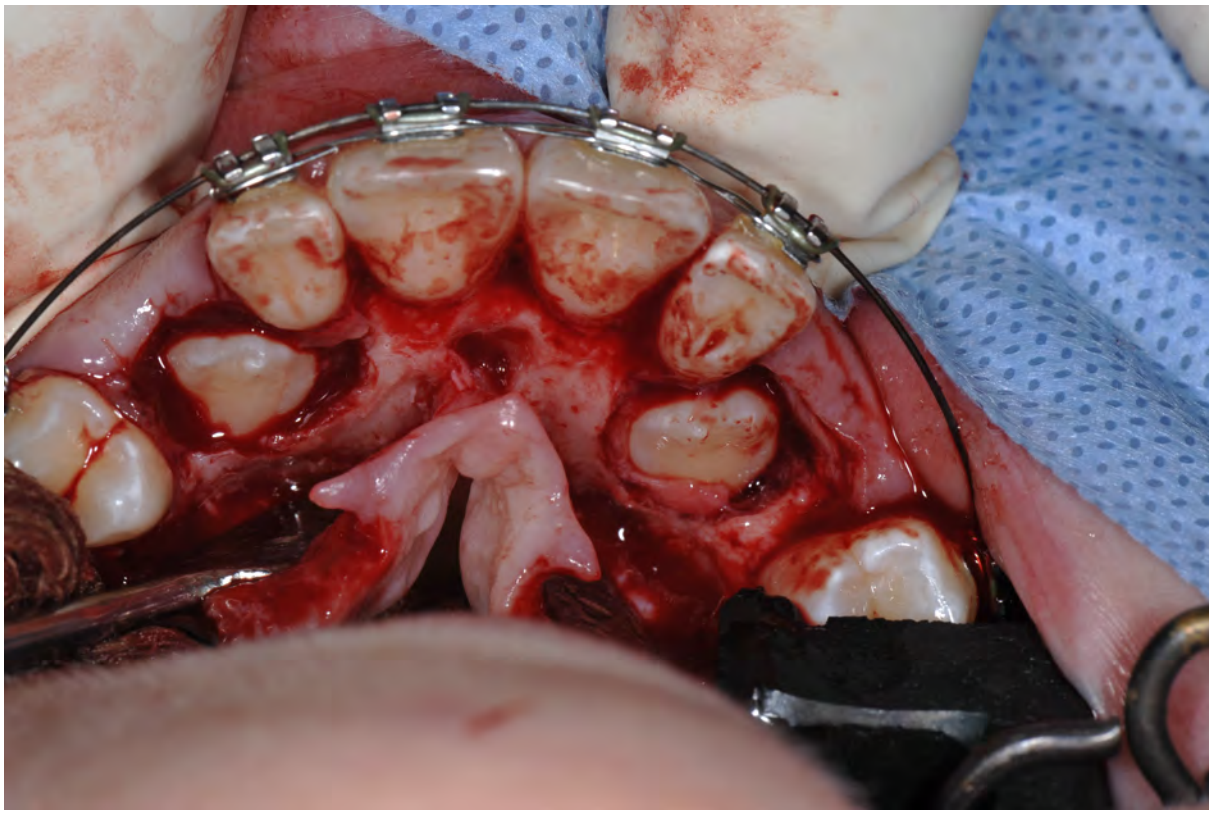

Figure 2.6.2 Standard surgery (bilateral case)

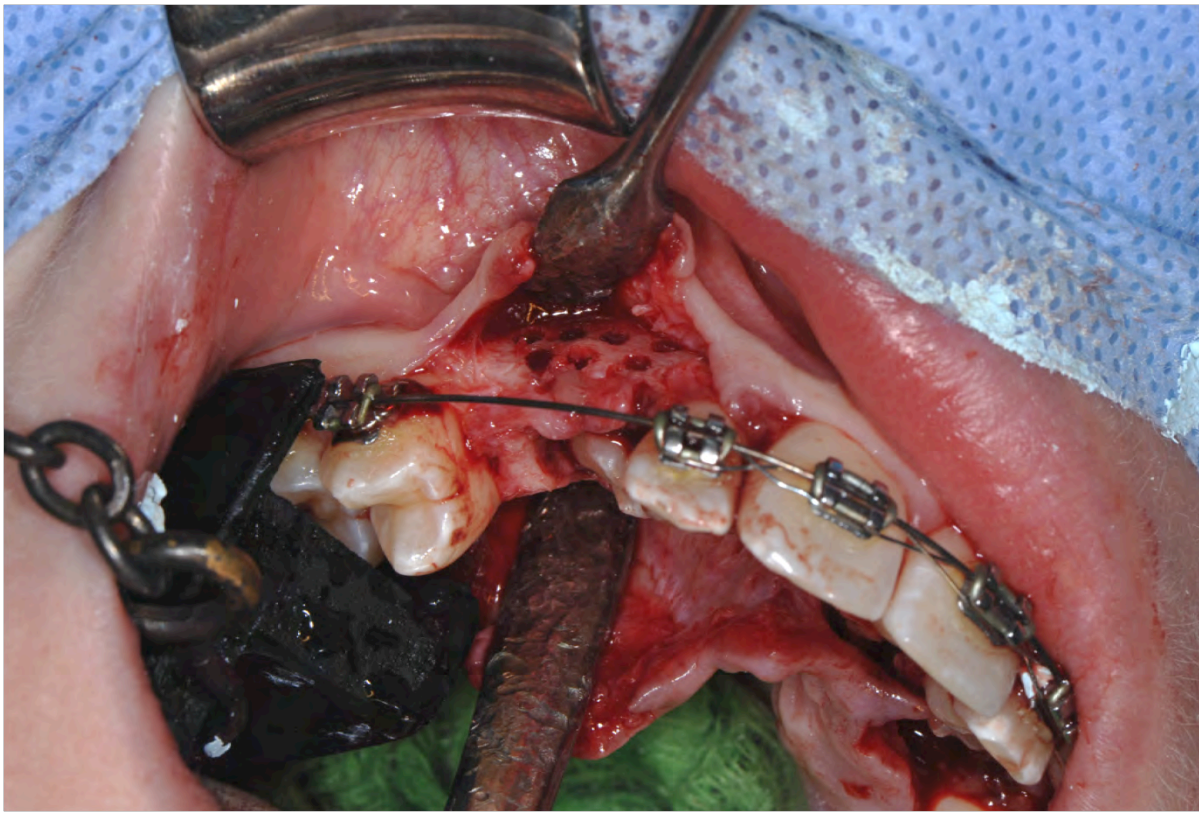

Figure 2.6.3 Alveolar-decortication. Cuts/perforations made with a 1mm diameter bur in the bone surrounding the impacted canine during surgery. Perforations were made in all of the available exposed bone, approximately 1.5mm apart (as described by Fischer, 2007)

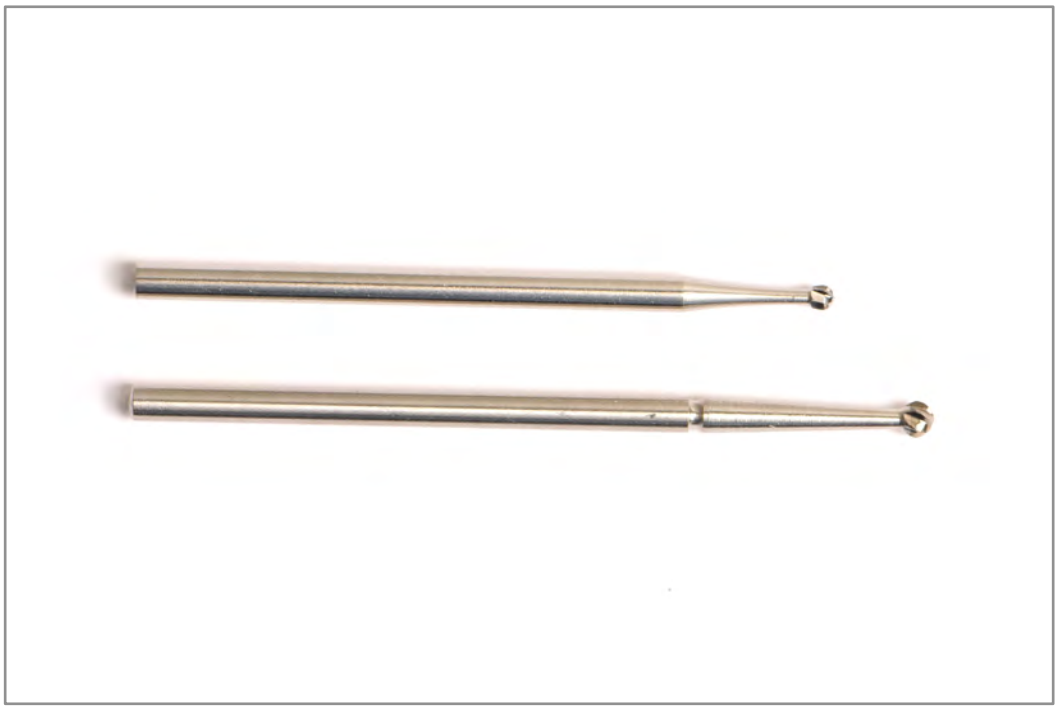

Figure 2.6.4 Surgical burs. Small surgical bur with a diameter of 1mm (top) used to make cuts/perforations (alveolar-decortication), and the standard surgical bur with a diameter of 2.3mm used for bone removal

Figure 2.6.5 Callipers used to measure distance from impaction to line of the arch, parallel to the occlusal plane (HD)

## 2.7 ENDPOINTS

**Primary endpoint:**

- Velocity of tooth movement (determined using the distance from the tip of the canine at its point of impaction to its desired position in the line of the upper arch, when viewed from the occlusal plane)

**Secondary endpoints:**

- Surgical time
- Any adverse effects of alveolar-decortication
- Time for canine to erupt into the mouth
- Time to placement of working archwire
- Total treatment time (from fitting the fixed appliance to debond)

## 2.8 DATA COLLECTION

Paper case report forms (CRFs) were developed for the surgical procedure and clinical follow-up visits (Appendix 2). The CRFs for the surgical procedure were kept separate in a locked office, and were not accessible by the orthodontic clinicians.

Information recorded on the surgical CRF and/or obtained from hospital notes:

- Hospital sticker and study number

- Date of surgery
- Surgeon
- Method of anaesthesia
- Extraction of retained deciduous canine, or adjacent premolar
- Length of procedure (from raising flap to closure) (minutes)
- Distance from tip of impacted canine to its desired position in the line of the arch (mm)
- Number of perforations in the surrounding bone
- Any complications encountered

Information recorded on the orthodontic CRF and/or obtained from hospital notes and study models:

- Hospital sticker
- Orthodontist
- Date of bond-up of upper fixed appliance
- Date first seen after surgery
- Method of applying traction to impacted canine
- Date canine first visible in mouth
- Distance from tip of canine to its desired position in the line of the upper arch
- Date canine tip in the line of the upper arch
- Date of placement of working archwire
- Any complications encountered

- Total number of orthodontic appointments from surgery to debond
- Number of failed orthodontic appointments after surgery
- Date of debond

## 2.9 PAIN DIARY

All participants were asked to rate the severity of any discomfort experienced, in the week after surgery. Participants were asked to place a cross to mark the point corresponding to their level of pain on a numerical rating scale labelled with the numbers 0 – 10, and with the extremes ‘no pain’ and ‘worst pain’.
Participants were also asked to record any analgesics taken (type and dose). The pain diary was returned by post, or collected by the orthodontist at the follow-up appointment.

## 2.10 STATISTICAL ANALYSIS

The online statistical programme R was used for statistical analysis. Summary statistics were calculated for the control and test groups.

Differences between the experimental groups were tested with two-sided non-parametric tests at $\alpha=0.05$ as appropriate.

The intra-examiner reliability for the study model measurements was calculated using intraclass correlation coefficient (ICC) following 3 repeat measurements on all of the study models.

# Chapter 3

# RESULTS

# CHAPTER 3: RESULTS

## 3.1 BASELINE DATA

The results presented in this thesis are preliminary results for this on-going clinical study. At the time of writing up, 30 participants had been recruited, and 29 had undergone surgery; with 14 in the control group (group 1) and 15 in the test group (group 2). Twenty-three participants had reached the primary endpoint (the tip of their canine was in the line of the upper arch, when viewed from the occlusal plane).

Fifteen females (50%) and 15 males (50%) made up the desired sample of 30 participants. The control group had 5 females and 10 males, whilst the test group had 10 females and 5 males.

Five participants had bilateral palatally impacted canines, whilst 11 were affected on the right side, and 14 on the left. Table 3.1.1 shows how the site of impaction varied between control and test groups.

The age of participant at the time of surgery ranged from 13 years, 9 months to 30 years, 1 month. The mean age of participant was 17 years. The mean age of participant was 18 years and 17 years in the control and test groups respectively, and so the groups were evenly matched with regards to age of participant.

| | | **Control group (group 1)** **n=15** | **Test group (group 2)** **n=15** | **Total** **n=30** |
|---|---|---|---|---|
| **Age (years)** | Mean (SD) | 18 (2.63) | 17 (4.21) | 17 (3.46) |
| | Median | 18 | 16 | 17 |
| | Minimum | 14 | 14 | 14 |
| | Maximum | 24 | 30 | 30 |
| | | **n=15** | **n=15** | **n=30** |
| **Gender** | Male (%) | 10 (66) | 5 (33) | 15 (100) |
| | Female (%) | 5 (33) | 10 (66) | 15 (100) |
| **Site of impaction** | | | | |
| | Left (%) | 8 (57) | 6 (43) | 14 (100) |
| | Right (%) | 4 (36) | 7 (64) | 11 (100) |
| | Bilateral (%) | 3 (60) | 2 (40) | 5 (100) |

Table 3.1.1 Baseline data

SD=Standard deviation

## 3.2 SURGICAL DATA

A total of 6 oral surgeons were involved with the study. Various methods of anaesthesia were used, 7 participants had a general anaesthetic, 18 a local anaesthetic and 4 local anaesthetic with intra-venous sedation, as shown in figure 3.2.1.

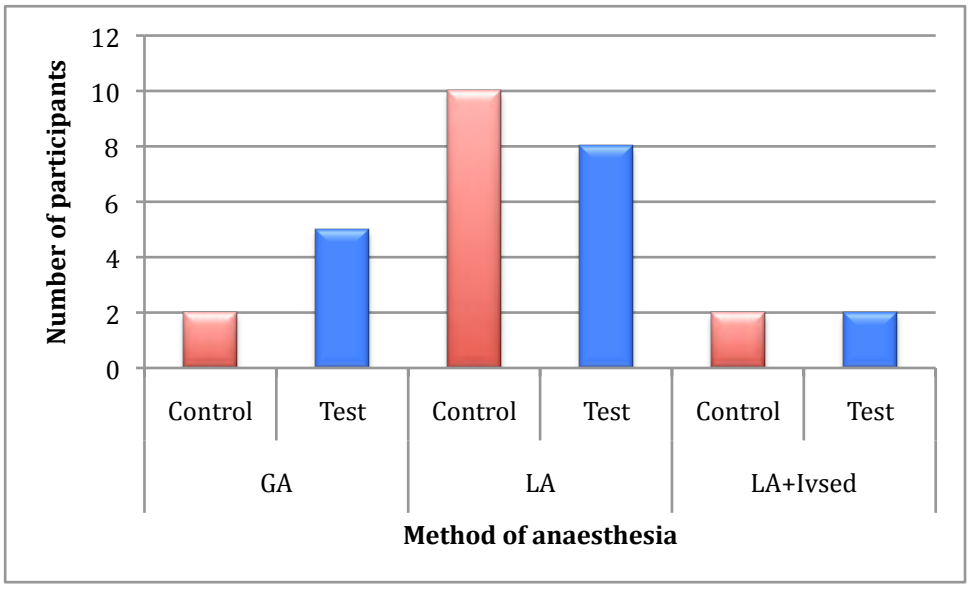


Figure 3.2.1 A graph to show the distribution of type of anaesthetic between the control and test groups

Eight participants had their retained deciduous canine extracted at the time of surgical exposure of the permanent canine. Four of these were in the control group, and 4 in the test group.

### 3.2.1 CLINICAL MEASUREMENTS

At the time of surgery, the surgeon measured the direct distance, with a calliper, from the tip of the impacted canine to the desired position of the tip of the canine in the line of the upper arch. This distance may be considered “as the crow flies” between 2 points.

The mean clinical distance was 12.1mm in the control group and 12.8mm in the test group, as shown in table 3.2.1. There was no significant difference between these measurements, and so the groups were evenly matched with regards to distance from impaction to desired position in the upper arch.

| | | **Control group (group 1) n=14** | **Test group (group 2) n=14*** | **Total n=28*** |
|---|---|---|---|---|
| **Clinical distance (mm)** | Mean (SD) | 12.14 (2.91) | 12.79 (4.00) | 12.46 (3.45) |
| | Median | 11.5 | 14 | 12 |
| | Minimum | 9 | 6 | 6 |
| | Maximum | 17 | 20 | 20 |

Table 3.2.1 Clinical distance measured at time of surgery: direct distance from the tip of the impacted canine to its desired position in the upper arch

* For 1 participant the clinical distance was not measured at the time of surgery

### 3.2.2 ALVEOLAR-DECORTICATION

The number of cuts/perforations made in the bone surrounding the impacted canine ranged from 6 to 13, with a median of 7 cuts.

### 3.2.3 TIME TAKEN FOR SURGICAL PROCEDURE

The mean time taken for the surgical procedure (from raising flap to closure) was 42 minutes with a range of 20 to 90 minutes. The mean surgical time was 40 minutes and 44 minutes in the control and test groups respectively, as shown in figure 3.2.2. There was no clinically or statistically significant difference between the groups. The Wilcoxon rank-sum analysis was used to determine the statistical difference, and a p-value of 0.2961 was calculated. As expected, the mean surgical time for bilateral cases was higher at 59 minutes.

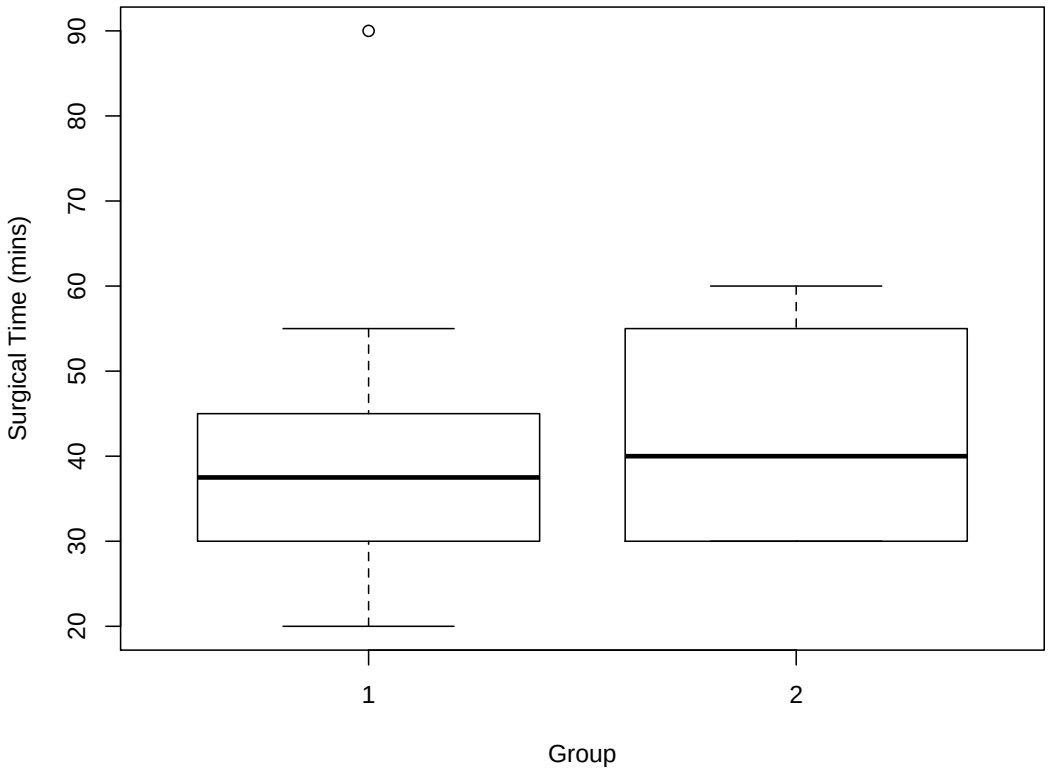


Figure 3.2.2 A box and whisker plot for the time taken to carry out the surgical procedure (from raising flap to closure)

The box represents the 25$^{th}$ to 75$^{th}$ percentiles with the median (50$^{th}$ percentile) indicated by the black line. The whiskers indicate the range, up to 1.5 times the inter-quartile range and any values 1.5-3 times the inter-quartile range are classified as outliers (as shown by the dot).

The plot shown on the right hand side of the figure only has one whisker: this is due to the minimum value being equal to the 25$^{th}$ percentile in the test group (group 2).

### 3.2.4 ADVERSE EVENTS

Adverse events following surgery were reported for 2 participants. One participant (subject number 5 in the control group) required a repeat surgical exposure with an apically repositioned flap to expose the canine from the buccal aspect. One participant (subject number 18 in the test group) suffered with flap necrosis and wound infection of the palatal mucosa.

### 3.3 ORTHODONTIC DATA

A total of 9 orthodontic specialist registrars were responsible for the orthodontic treatment, and were blinded to the participant's group allocation (and therefore surgical intervention received).

All participants were treated using a pre-adjusted Edgewise appliance (0.022" x 0.028", MBT prescription). There was some variation in the method of traction applied to the impacted canine, as shown in figure 3.3.1. Examples of the NiTi auxiliary and Ballista spring used are shown in figures 3.3.2 and 3.3.3.

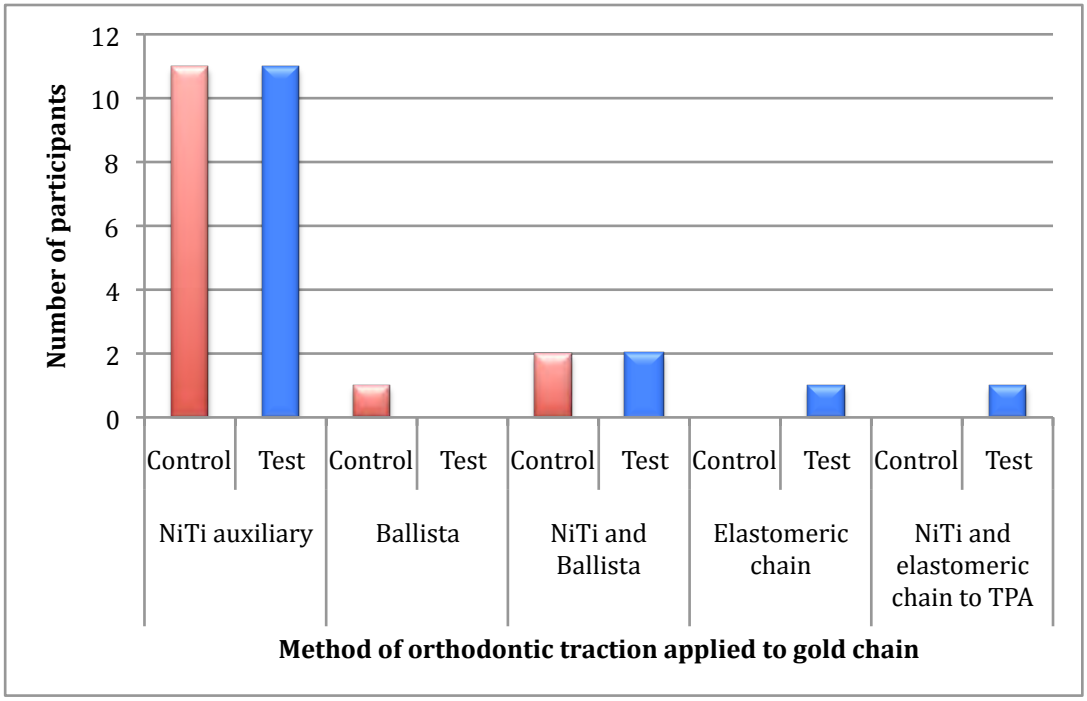


Figure 3.3.1 A graph to show how the method of orthodontic traction applied to the gold chain varied amongst participants, and also the distribution between the control and test groups

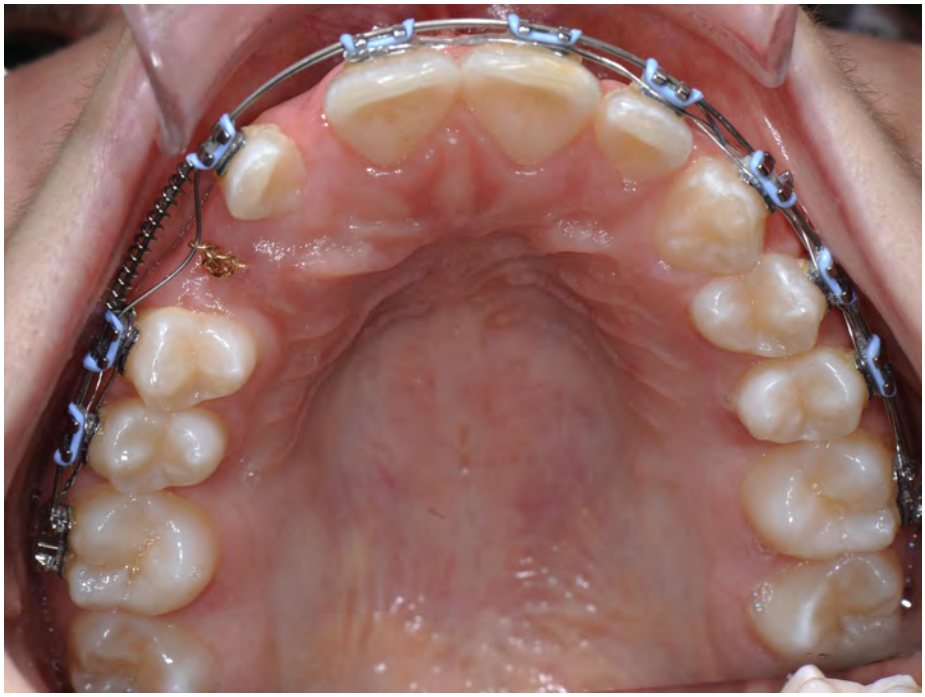

Figure 3.3.2 NiTi auxiliary used to apply traction to the gold chain. Fifteen year old patient, 12 weeks after surgical exposure

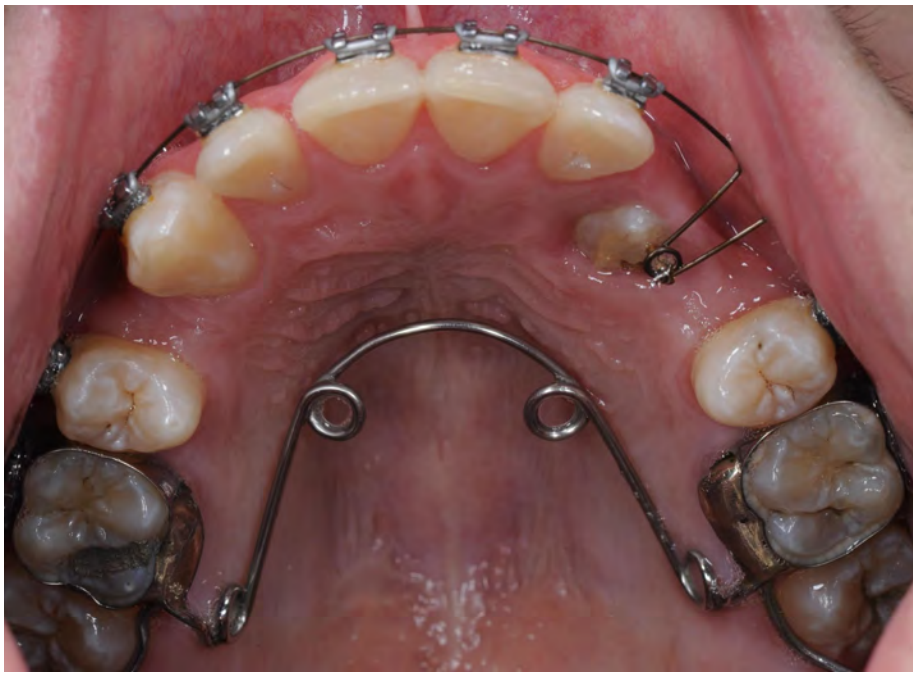

Figure 3.3.3 Ballista spring used to apply traction to the gold chain. Fourteen year old patient, 41 weeks after surgical exposure

The period of time between surgery and activation of the fixed appliance varied between 1 and 93 days, with a median of 13 days. The median time for activation in the control group was 10 days, and in the test group was 15 days, as shown in table 3.3.1 and figure 3.3.4.

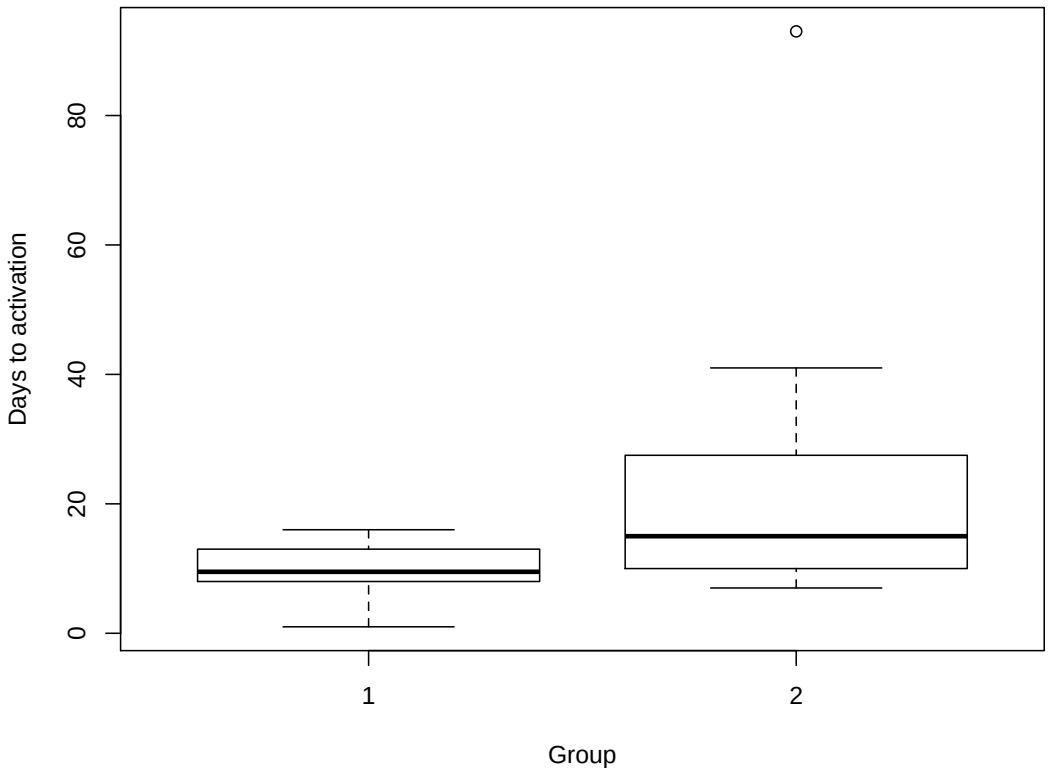


Figure 3.3.4 A box and whisker plot of the time between the surgical procedure and activation of the fixed appliance

### 3.3.1 TIME TAKEN TO VARIOUS ENDPOINTS

Table 3.3.1 shows the data for time to activation of the fixed appliance, the time to eruption, and the time to the tip of the canine being in the line of the upper arch (when viewed from the occlusal plane).

When considering the duration of time from surgery to eruption, this period was shorter in the test group. The mean time to eruption was 34 weeks in the control group, compared to 21 weeks in the test group. This difference would be clinically significant, however, it was not statistically significant according to the Wilcoxon rank-sum analysis (p=0.1109). This difference was less when considering the mean time from surgery to the tip of the canine being in the line of the upper arch (when viewed from the occlusal plane), at 39 and 33 weeks respectively (see table 3.3.1 and figure 3.3.5). There was no statistically significant difference according to the Wilcoxon rank-sum analysis (p=0.5348).

| | | **Control group (group 1) n=14** | **Test group (group 2) n=15** | **Total n=29** |
|---|---|---|---|---|
| **Time to activation (days)** | Mean (SD) | 10 (4.03) | 23 (22.13) | 17 (17.29) |
| | Median | 10 | 15 | 13 |
| | Minimum | 1 | 7 | 1 |
| | Maximum | 16 | 93 | 93 |
| | | **n=13** | **n=11** | **n=24** |
| **Time to eruption (weeks)** | Mean (SD) | 34 (21.16) | 21 (19.31) | 28 (20.95) |
| | Median | 27 | 14 | 25 |
| | Minimum | 8 | 2 | 2 |
| | Maximum | 84 | 55 | 84 |
| | | **n=13** | **n=10** | **n=23** |
| **Time to line of arch (weeks) *primary endpoint** | Mean (SD) | 39 (19.92) | 33 (16.69) | 36 (18.46) |
| | Median | 31 | 31 | 31 |
| | Minimum | 8 | 9 | 8 |
| | Maximum | 84 | 55 | 84 |

Table 3.3.1 Time recorded from surgery to various study endpoints

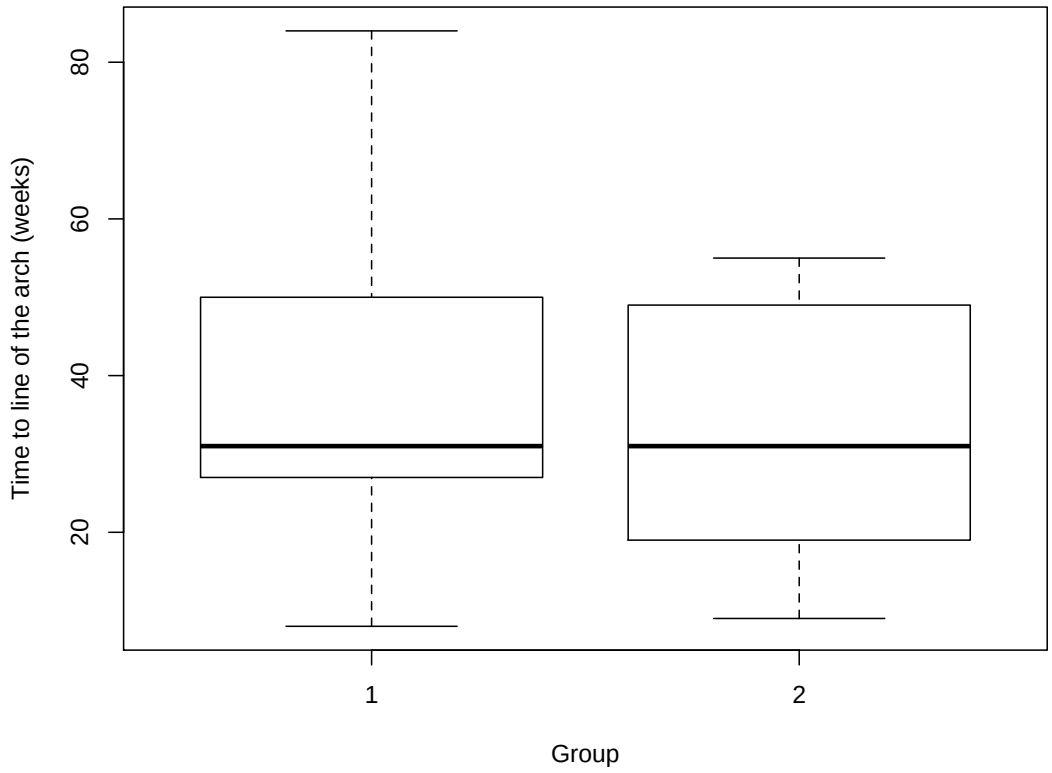


Figure 3.3.5 A box and whisker plot of the time between surgical exposure and the tip of the canine being in the line of the upper arch (when viewed from the occlusal plane)

### 3.3.2 STUDY MODEL MEASUREMENTS

The model cast from the impression taken during surgery was used to measure the distance from impaction to desired position in the upper arch. The direct distance measured at the time of surgery from the tip of the impacted canine to the desired position of the tip of the canine in the line of the upper arch was repeated on the

study models (DD). This distance was measured with callipers, and repeated 3 times over a period of 3 months, and the mean value determined (see Appendix 4).

The mean study model distance (DD) was 12.3mm in the control group and 13.0mm in the test group, as shown in table 3.3.2. According to the Mann-Whitney U test ($p=0.5971$) there was no statistically significant difference in this measurement, and so the groups were considered evenly matched with regards to distance from impaction to desired position in the upper arch.

Figure 3.3.6 allows comparison between the clinical measurement (taken during surgery) and the equivalent measurement on the study model (DD).

The Spearman's rank correlation coefficient was used to calculate the correlation between the clinical and equivalent study model measurements. The Spearman's rho value of 0.79 indicated a good correlation.

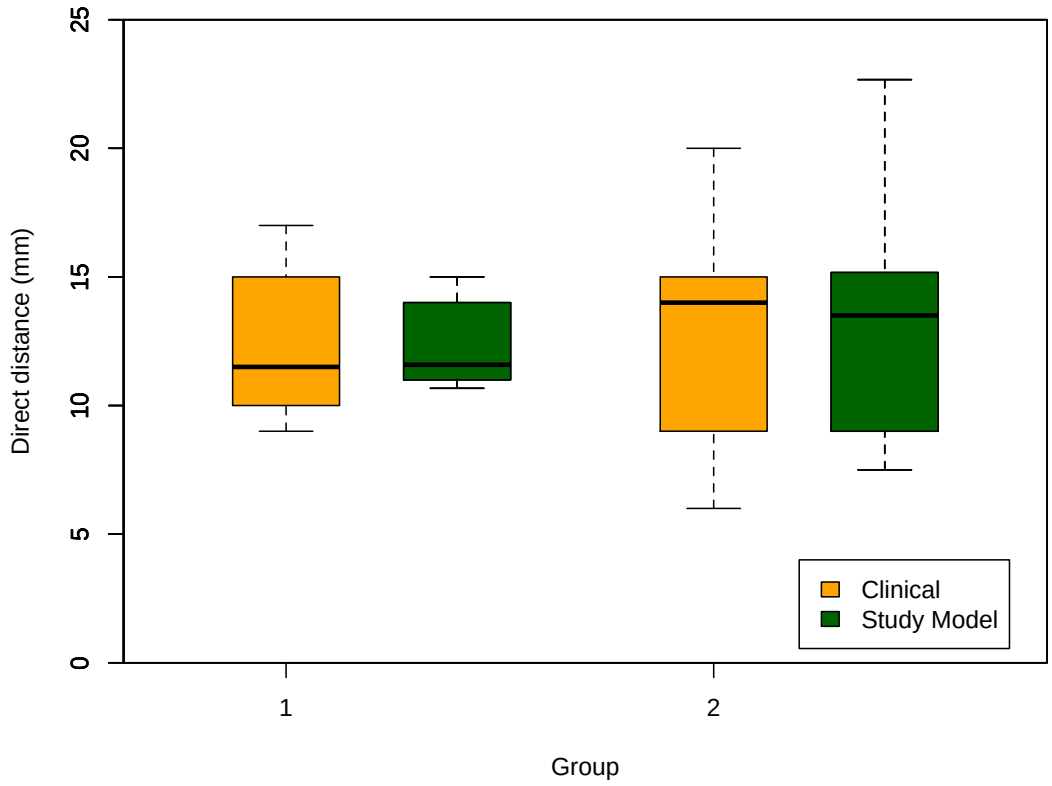


Figure 3.3.6 A box and whisker plot of the direct distance from the tip of the impacted canine to the desired position of the tip of the canine in the line of the upper arch measured clinically (orange boxes) and on the study models (green boxes)

In addition to this, the following measurements were made and repeated on 3 separate occasions:

- Horizontal distance, parallel to the occlusal plane, from the tip of the impacted canine to its desired position in the upper arch (HD) (figure 2.6.5)
- Vertical distance from the tip of the impacted canine to the overlying mucosa (VD)

The mean horizontal distance (HD) was 10.2mm. The mean horizontal distance was 10.0mm in the control group and 10.3mm in the test group. The mean vertical distance (VD) was 2.9mm. The mean vertical distance was 2.5mm in the control group and 3.3mm in the test group, as shown in table 3.3.2.

| | | **Control group (group 1) n=10*** | **Test group (group 2) n=14*** | **Total n=24*** |
|---|---|---|---|---|
| **Mean direct distance (DD) (mm)** | Mean (SD) | 12.33 (1.69) | 12.97 (4.08) | 12.70 (3.26) |
| | Median | 11.58 | 13.5 | 12.34 |
| | Minimum | 10.67 | 7.5 | 7.5 |
| | Maximum | 15 | 22.67 | 22.67 |
| **Mean horizontal distance (HD) (mm)** | Mean (SD) | 10.03 (2.19) | 10.32 (3.96) | 10.20 (3.28) |
| | Median | 9.67 | 9.67 | 9.67 |
| | Minimum | 7.33 | 3.67 | 3.67 |
| | Maximum | 15 | 18.17 | 18.17 |
| **Mean vertical distance (VD) (mm)** | Mean (SD) | 2.47 (1.02) | 3.33 (2.28) | 2.97 (1.88) |
| | Median | 2.59 | 2.92 | 2.59 |
| | Minimum | 1 | 1 | 1 |
| | Maximum | 4.17 | 8.17 | 8.17 |

Table 3.3.2 Distances measured on the study models

* For 5 participants (4 in the control group, and 1 in the test group) a study model was not available to measure the distances for data analysis. Four participants did not have an impression taken during surgery, and for 1 participant the quality of the study model was not suitable for data collection.

## 3.4 VELOCITY OF TOOTH MOVEMENT

The vertical distance (VD) and time to eruption were used to calculate the velocity from site of impaction to eruption through the palatal mucosa. The mean velocity was 0.19mm/wk. The mean velocity was greater in the test group, at 0.29mm/wk compared to 0.10mm/wk in the control group, as shown in table 3.4.1.

The horizontal distance (HD) and time taken were used to calculate the velocity from site of impaction to desired position in the line of the upper arch (when viewed from the occlusal plane). The mean velocity was 0.37mm/wk. There was a smaller difference in velocities in the control and test groups, which were 0.39mm/wk and 0.35mm/wk respectively.

When considering the clinical measurement, the mean velocity of canine movement from its impacted position to the tip being in its desired position in the upper arch was 0.43mm/wk and 0.44mm/wk for the control and test groups respectively.
When the equivalent measurement from the study model was used to calculate the velocity; the mean velocity was 0.48mm/wk and 0.44mm/wk for the control and test groups respectively.

| **Velocity (mm/wk)** | | **Control group (group 1) n=10** | **Test group (group 2) n=10** | **Total n=20** |
|---|---|---|---|---|
| **To eruption using study model measurement (VD)** | Mean (SD) | 0.10 (0.04) | 0.29 (0.36) | 0.19 (0.26) |
| | Median | 0.1 | 0.16 | 0.11 |
| | Minimum | 0.03 | 0.06 | 0.03 |
| | Maximum | 0.17 | 1.25 | 1.25 |
| **To line of arch using study model measurement (HD)** | Mean (SD) | 0.39 (0.28) | 0.35 (0.19) | 0.37 (0.23) |
| | Median | 0.31 | 0.29 | 0.30 |
| | Minimum | 0.1 | 0.08 | 0.08 |
| | Maximum | 1.08 | 0.67 | 1.08 |
| | | **n=13** | **n=9** | **n=22** |
| **To line of the arch using the clinical measurement** | Mean (SD) | 0.43 (0.36) | 0.44 (0.18) | 0.43 (0.29) |
| | Median | 0.32 | 0.34 | 0.33 |
| | Minimum | 0.14 | 0.29 | 0.14 |
| | Maximum | 1.5 | 0.71 | 1.5 |
| | | **n=10** | **n=10** | **n=20** |
| **To line of the arch using study model measurements (DD)** | Mean (SD) | 0.48 (0.34) | 0.44 (0.22) | 0.46 (0.28) |
| | Median | 0.38 | 0.34 | 0.35 |
| | Minimum | 0.13 | 0.27 | 0.13 |
| | Maximum | 1.33 | 0.83 | 1.33 |

Table 3.4.1 Velocity of tooth movement

### 3.5 PAIN EXPERIENCED FOLLOWING THE SURGICAL PROCEDURE

Participants recorded any pain experienced in the week following surgery. The pain scores recorded for the control and test groups are shown in table 3.5.1 and figure 3.5.1. There was considerable variation in the pain scores recorded, with a range of 0 (no pain) to 10 (worst pain). Overall the pain experienced by patients in the control and test groups was similar, with an overall median score of 2 for each group. Participants experienced the most pain on the first day following surgery, the pain decreased from a median score of 7 on day 1 to a score of 0 on day 7.

There was a marked difference in the pain scores of 1 participant (subject number 18 in the test group; see adverse event in section 3.2.4). This participant was the only participant who required an additional appointment and course of antibiotics following surgery.

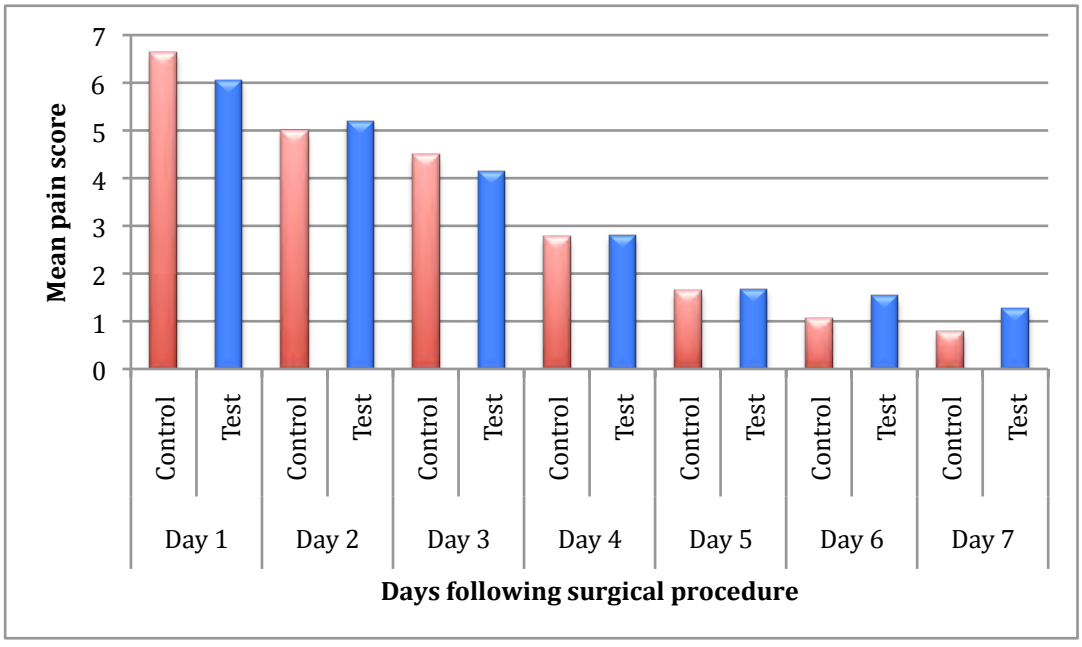


Figure 3.5.1 A graph to show the mean pain scores recorded in the week following surgery

| **Pain experienced in week following surgery** | | **Control group (group 1)** **n=14** | **Test group (group 2)** **n=15** | **Total** **n=29** |
|---|---|---|---|---|
| **Day 1** | Mean (SD) | 6.64 (2.31) | 6.06 (2.96) | 6.34 (2.66) |
| | Median | 7 | 7 | 7 |
| | Range | 3-10 | 1-10 | 1-10 |
| **Day 2** | Mean (SD) | 5 (2.39) | 5.2 (2.88) | 5.10 (2.61) |
| | Median | 5.5 | 6 | 6 |
| | Range | 2-9 | 0-10 | 0-10 |
| **Day 3** | Mean (SD) | 4.5 (2.68) | 4.13 (3.29) | 4.31 (2.97) |
| | Median | 4.5 | 4 | 4 |
| | Range | 0-8 | 0-10 | 0-10 |
| **Day 4** | Mean (SD) | 2.78 (2.39) | 2.8 (2.98) | 2.79 (2.66) |
| | Median | 3.5 | 2 | 3 |
| | Range | 0-8 | 0-10 | 0-10 |
| **Day 5** | Mean (SD) | 1.64 (2.13) | 1.66 (2.92) | 1.66 (2.53) |
| | Median | 1 | 0 | 1 |
| | Range | 0-8 | 0-10 | 0-10 |
| **Day 6** | Mean (SD) | 1.07 (1.38) | 1.53 (2.83) | 1.31 (2.22) |
| | Median | 1 | 0 | 1 |
| | Range | 0-5 | 0-10 | 0-10 |
| **Day 7** | Mean (SD) | 0.78 (1.37) | 1.27 (2.89) | 1.03 (2.26) |
| | Median | 0 | 0 | 0 |
| | Range | 0-5 | 0-10 | 0-10 |

Table 3.5.1 Pain scores during the week following surgery

There was no statistically significant difference in the pain scores between the control and test groups. The Mann-Whitney U test was used to determine any statistical difference, as shown in table 3.5.2.

| **Data** | **Median** | **p-value** | **Statistical significance? (p=0.05)** |
|---|---|---|---|
| Pain scores on day 1 (P1) | 7 | 0.6916 | No |
| Pain scores on day 2 (P2) | 6 | 0.8428 | No |
| Pain scores on day 3 (P3) | 4 | 0.709 | No |
| Pain scores on day 4 (P4) | 3 | 0.8066 | No |
| Pain scores on day 5 (P5) | 1 | 0.4428 | No |
| Pain scores on day 6 (P6) | 1 | 0.7968 | No |
| Pain scores on day 7 (P7) | 0 | 0.6055 | No |
| Analgesics taken on day 1 (A1) | 1 | 1 | No |
| Analgesics taken on day 2 (A2) | 1 | 0.2733 | No |
| Analgesics taken on day 3 (A3) | 1 | 0.5738 | No |
| Analgesics taken on day 4 (A4) | 0 | 0.8983 | No |
| Analgesics taken on day 5 (A5) | 0 | 0.9504 | No |
| Analgesics taken on day 6 (A6) | 0 | 0.7686 | No |
| Analgesics taken on day 7 (A7) | 0 | 0.9504 | No |

Table 3.5.2 The Mann-Whitney U test for the effect of the intervention on pain scores and need for analgesics in the week following surgery

Participants were also asked to record the type and dose of analgesics taken in the week following surgery. There was a large variation between participants. The majority of participants took Paracetamol and Ibuprofen, with a standard dose of 500mg and 200mg respectively, see figure 3.5.2. One participant took Aspirin, and 1 participant (subject number 18 in the test group; see adverse event in section 3.2.4) took Diclofenac, Codeine and Tramadol in addition to Paracetamol and Ibuprofen. There was no statistically significant difference in the need for analgesics between the control and test groups. The Mann-Whitney U test was used to determine any statistical difference, as shown in table 3.5.2.

The Spearman's rank correlation coefficient was used to calculate the correlation between the pain scores and need for analgesics in the week following surgery. The correlation varied from poor to fair, as shown in table 3.5.3.

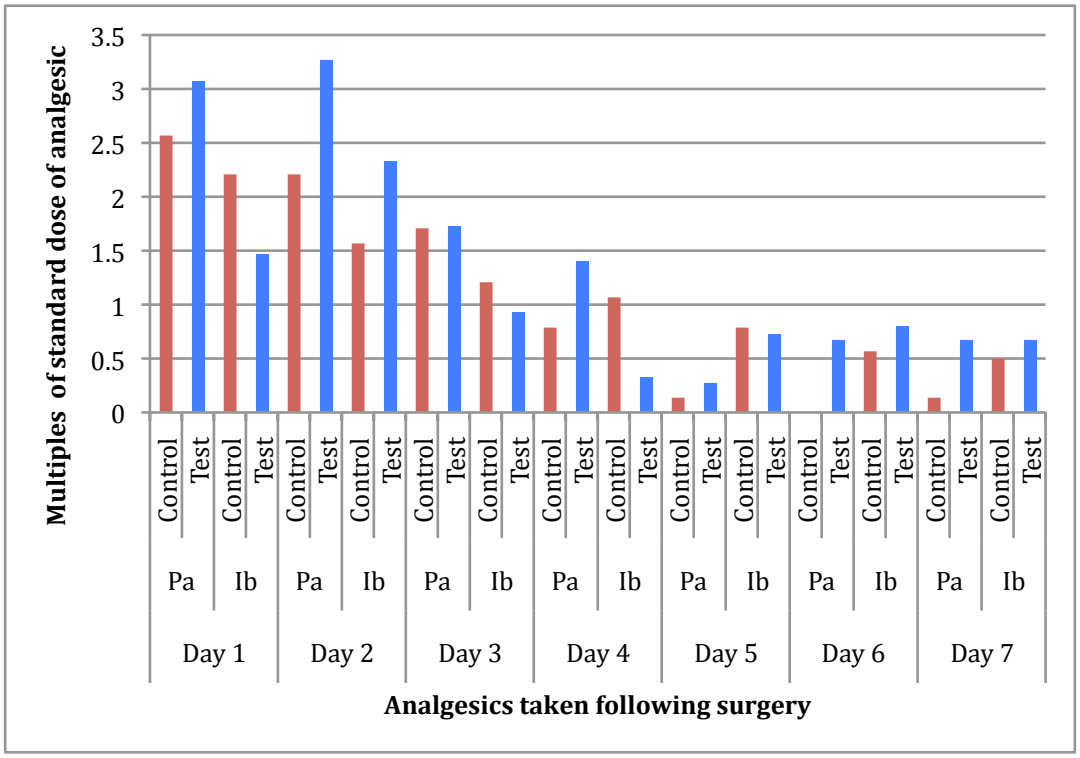


Figure 3.5.2 A graph to show the mean multiples of the standard dose of Paracetamol (Pa) and Ibuprofen (Ib) taken by the control and test groups in the week following surgery

| | S | p-value | Spearman's rho |
|---|---|---|---|
| P1 and A1 | 3026.338 | 0.1826 | 0.25 |
| P2 and A2 | 2639.022 | 0.0627 | 0.35 |
| P3 and A3 | 2299.622 | 0.0188 | 0.43 |
| P4 and A4 | 1496.424 | 0.0002 | 0.63 |
| P5 and A5 | 1528.424 | 0.0003 | 0.62 |
| P6 and A6 | 1669.28 | 0.0008 | 0.59 |
| P7 and A7 | 1713.516 | 0.0010 | 0.58 |

Table 3.5.3 Spearman rank correlation coefficient to determine the correlation between pain score and need for analgesics in the week following surgery

## 3.6 ANALYSIS OF DATA

### 3.6.1 SHAPIRO-WILK NORMALITY TEST

A Shapiro-Wilk normality test was used to determine the normality of distribution of the data, as shown in table 3.6.1.

| Data | Median | p-value | Parametric/Non-parametric |
|---|---|---|---|
| Age (years) | 17 | 0.0001 | Non-parametric |
| Clinical distance (mm) | 12 | 0.3245 | Parametric |
| Surgical time (mins) | 40 | 0.0028 | Non-parametric |
| Activation (days) | 13 | 1.153e-07 | Non-parametric |
| Time to eruption (weeks) | 25 | 0.0521 | Parametric |
| Time to line of the arch (weeks) | 31 | 0.3586 | Parametric |
| Horizontal distance on study models [SM-HD] (mm) | 9.7 | 0.8492 | Parametric |
| Direct distance on study models [SM-DD] (mm) | 12.3 | 0.0824 | Non-parametric |
| Velocity to line of the arch, using the clinical measurement (mm/wk) | 0.33 | 2.133e-05 | Non-parametric |
| Velocity to line of the arch, using the horizontal measurement [SM-HD] (mm/wk) | 0.3 | 0.0136 | Non-parametric |
| Velocity to line of the arch, using the direct measurement [SM-DD] (mm/wk) | 0.35 | 0.0011 | Non-parametric |
| Velocity to eruption, using the vertical measurement [SM-VD] (mm/wk) | 0.11 | 3.644e-07 | Non-parametric |

Table 3.6.1 The Shapiro-Wilk normality test

### 3.6.2 WILCOXON RANK-SUM ANALYSIS

A Wilcoxon rank-sum analysis was used on the non-parametric data to determine whether the effect of the intervention was statistically significant (see tables 3.6.1 and 3.6.2).

The mean surgical time was 40 minutes and 44 minutes in the control and test groups respectively; this difference was not statistically significant (p=0.2961).

The period of time between surgery and activation of the fixed appliance varied considerably, and the median time for activation in the control group was 10 days, and in the test group was 15 days. There was an outlier in the test group of 93 days, and the difference between the 2 groups was statistically significant (p=0.01422). One participant in the test group (the outlier) failed to attend several orthodontic appointments after surgery, and so there was a delay in activation of their fixed appliance.

The mean velocity of canine movement from its impacted position to the tip being in its desired position in the upper arch was 0.43mm/wk and 0.44mm/wk for the control and test groups respectively (when considering the clinical measurement). There was little difference in these values, which was not statistically significant (p=0.5251). When the equivalent measurement from the study model was used to calculate the velocity, the mean velocity was 0.48mm/wk and 0.44mm/wk for the control and test groups respectively; again this was not statistically significant (p=0.9698).

There was a small difference in the velocity of tooth movement to the line of the arch, when considering the horizontal measurement on the study models; which was 0.39mm/wk and 0.35mm/wk in the control and test groups respectively. This difference was not statistically significant (p=1).

The mean velocity to eruption was greater in the test group, at 0.29mm/wk compared to 0.10mm/wk in the control group. This difference in velocity would be clinically significant, however, it does not reach a level of statistical significance (p=0.1969).

| | **Median** | **p-value** | **Statistical significance? (P=0.05)** |
|---|---|---|---|
| Age (years) | 17 | 0.2416 | No |
| Surgical time (mins) | 40 | 0.2961 | No |
| Activation (days) | 13 | 0.01422 | Yes |
| Velocity to line of the arch, using the clinical measurement (mm/wk) | 0.33 | 0.5251 | No |
| Velocity to line of the arch, using the horizontal measurement [SM-HD] (mm/wk) | 0.30 | 1 | No |
| Velocity to line of the arch, using the direct measurement [SM-DD] (mm/wk) | 0.35 | 0.9698 | No |
| Velocity to eruption, using the vertical measurement [SM-VD] (mm/wk) | 0.11 | 0.1969 | No |
| Clinical distance (mm) | 12 | 0.7633 | No |
| Time to eruption (weeks) | 25 | 0.1109 | No |
| Time to line of the arch (weeks) | 31 | 0.5348 | No |
| Horizontal distance on study models [SM-HD] (mm) | 9.7 | 0.8374 | No |
| Comparison of clinical distance and direct distance on study model [SM-DD] | 12.3 | 0.9706 | No |

Table 3.6.2 The Wilcoxon rank-sum analysis for the effect of the intervention

### 3.6.3 INDEPENDENT SAMPLES T-TEST

The independent samples t-test was used on the parametric data to determine whether the effect of the intervention was statistically significant (see tables 3.6.1 and 3.6.3).

The mean clinical distance was 12.1mm in the control group and 12.8mm in the test group, there was no statistically significant difference in these measurements (p=0.6312).

The mean horizontal distance (HD) was 10.03mm in the control group and 10.32mm in the test group. There was no significant difference between the groups (p=0.8209), and so the groups were evenly matched.

The duration of time from surgery to eruption was shorter in the test group. The mean time to eruption was 34 weeks in the control group, compared to 21 weeks in the test group. This difference would be clinically significant, however, it was not statistically significant (p=0.1338). This difference was less when considering the mean time from surgery to the tip of the canine being in the line of the upper arch (when viewed from the occlusal plane), at 39 and 33 weeks respectively, again this was not statistically significant (p=0.4101).

| | **Median** | **p-value** | **Statistical significance? (P=0.05, CI=95%)** |
|---|---|---|---|
| Clinical distance (mm) | 12 | 0.6312 | No |
| Time to eruption (weeks) | 25 | 0.1338 | No |
| Time to line of the arch (weeks) | 31 | 0.4101 | No |
| Horizontal distance on study models [SM-HD] (mm) | 9.7 | 0.8209 | No |
| Comparison of clinical distance and direct distance on study model [SM-DD] | 12.3 | 0.7996 | No |

Table 3.6.3 Independent samples t-test for the effect of the intervention on clinical distance; time to eruption; time to line of the arch; horizontal distance on study model; and direct distance on study model vs. clinical distance

### 3.6.4 SPEARMAN'S RANK CORRELATION COEFFICIENT

The Spearman's rank correlation coefficient was used to determine the correlation between pain score and need for analgesics, and clinical distance and equivalent distance on the study models (see tables 3.5.3 and 3.6.4).

The clinical distance measured during surgery, was repeated on the study models (DD). The Spearman's rho value of 0.79 indicated a good correlation (table 3.6.4).

| | **p-value** | **Spearman's rho** |
|---|---|---|
| Clinical distance and direct distance on study model [SM-DD] | 6.742e-06 | 0.79 |

Table 3.6.4 Spearman's rank correlation coefficient calculation to determine the correlation between clinical measurements and equivalent (direct distance) study model measurement

## 3.7 INTRA-EXAMINER RELIABILITY

The intraclass correlation coefficient values (ICC) for the horizontal and direct distances measured on the study models were 0.94 and 0.96 respectively, indicating good intra-examiner reliability for the study model measurements (see table 3.7.1).

| | **Horizontal distance** | **Direct distance** |
|---|---|---|
| **Intraclass correlation** | 0.94 | 0.96 |

Table 3.7.1 Intraclass correlation coefficient for the intra-examiner reliability of the horizontal distance (HD) and direct distance (DD) measured on the study models.

# Chapter 4

# DISCUSSION

# CHAPTER 4: DISCUSSION

## 4.1 STUDY DESIGN

The period of recruitment for this study was much longer than anticipated. Despite, palatally impacted canines presenting fairly frequently, the current set-up of patients being placed on a waiting list, increased the period for identifying potential participants. Consultants have varied approaches to managing palatally impacted canines, and so it was a matter of waiting for patients who were planned in such a way, that the fixed appliance could be fitted prior to surgical exposure. In many cases, consultants chose to open space and monitor eruption of the canine. When successful, this approach saves the patient from a surgical procedure.

Increasing the sites for recruitment of patients may have reduced the recruitment period; the disadvantages of this would have been an increase in the number of clinicians and therefore variety in surgical and orthodontic techniques used.

In this study, we chose to include only palatally impacted canines, this was to limit study variables, and to reduce variation in the distance from position of impaction to desired position in the upper arch. It is accepted that treatment time for dis-impaction and alignment of palatally impacted canines is lengthily, and so any reduction in treatment duration would be welcome by orthodontic clinicians and patients alike. There is no reason why alveolar-decortication could not be used whilst exposing a buccally impacted canine.

Two participants included in this study, had a buccally impacted canine, which was only revealed during surgery. Since these participants had been randomised, they

were included in accordance with the intention-to-treat analysis. This highlights errors with identification of the position of an impacted canine. This error is more likely to occur with use of vertical compared to horizontal parallax (Armstrong et al., 2003).

### 4.1.1 TREATMENT VARIATION

Approaches to treatment of palatally impacted canines vary in many ways with regards to surgery and orthodontic treatment. In this study patients had a closed exposure of their palatally impacted canine/s. This is currently the favoured approach at Birmingham Dental Hospital, due to preference of the clinicians. Alveolar-decortication can be used with both open and closed surgical techniques.

All participants had their fixed appliance fitted prior to surgery; this was to ensure that traction could be applied as soon as possible following the surgical procedure. Prior to the study, the standard approach was for patients to have their canine exposed and then return to the orthodontic department for fitting of their fixed appliance. Placement of the fixed appliance first, increases the overall efficiency of treatment. Whilst the patient awaits surgery, levelling and alignment can be completed, allowing placement of a rigid archwire for immediate traction to the gold chain. This approach of fitting the fixed appliance first will be used more frequently in the future.

### 4.1.2 MULTIPLE OPERATORS

Multiple operators (6 oral surgeons and 9 orthodontists) increased the number of variables, with regards to treatment techniques used in this study. Due to the number of variables, it is difficult to assess the true outcome of this study. There was a variation in the number of surgical cuts and perforations made, due to operator judgement and anatomical variation. The amount of decortication required for maximising the rate of tooth movement remains unknown.
Cuts/perforations were made in both the surrounding palatal and buccal bone. The buccal area of bone may have healed without any benefit to the canine. Further research is required to determine whether alveolar-decortication should be carried out in the bone surrounding the tooth, or in the bone into which the tooth will move following application of traction.

There was also a variation in the method of traction applied to the gold chain; this was influenced by operator preference, position of the canine, and direction of traction required. Participant factors including attendance, co-operation and any breakages may also influence the operator's choice of mechanics. To the best of my knowledge, there is no evidence in the literature to suggest that one method of traction is superior to another. Each case should be judged on its own merits, and different methods of traction will remain appropriate for different clinical situations.

Reducing the number of operators would have minimised inter-operator variability, as achieved by Fischer (2007) where a single surgeon and orthodontic clinician were

used. Multiple operators reduce the purity of the results, but at the same time allow the reader to consider the effects of surgery in their own setting.

## 4.2 BASELINE DATA

Thirty participants were recruited into the study, and within the sample no sexual dimorphism was seen. This differed from the literature, which reports that palatally impacted canines are twice as common in females (Dachi and Howell, 1961).
The incidence of bilateral occurrence was 17% of the total sample, which also differed from that reported in the literature. Bishara (1992) reported an incidence of 8% for bilateral occurrence of palatally impacted canines. The findings of this study may be due to the small sample size or a reflection of the local population.

The mean age of participant in the study was 17 years. This is quite high, given that a canine may be considered late if it has not erupted by 12.3 years in girls and 13.1 years in boys (Hurme, 1949; Husain et al., 2010). Becker and Chaushu (2003) reported that the prognosis for alignment worsens with age, and also that the duration of treatment increases. The age range in the Fischer (2007) study was 11.1 to 12.9 years; the older patients seen in this study may highlight a delayed referral of patients to the hospital department, or the waiting list prior to treatment.
An upper age limit was not set in the exclusion criteria. This had the advantage of increasing potential participants for the study; however, older patients will have a

slower bone turnover and have a higher risk of associated complications, such as ankylosis.

In this study, only the chronological age of the participant was recorded. The addition of the cervical vertebral maturation stage would have allowed consideration of the developmental age of the participant.

## 4.3 PRIMARY ENDPOINT (VELOCITY OF TOOTH MOVEMENT)

The results suggest that there is no difference in the velocity of tooth movement from impaction, to the tip of the canine being in the line of the upper arch (when viewed from the occlusal plane). The overall mean velocity was 0.37mm/wk (calculation using the horizontal distance (HD) on the study models) and the mean velocity was slightly greater in the control group at 0.39mm/wk compared to 0.35mm/wk in the test group.

There was a difference in the velocity to eruption between the control and test groups (see section 4.4.2), although this difference was not statistically significant. This may suggest that the alveolar-decortication accelerated tooth movement initially, but that the RAP diminished following eruption of the canine.

The duration of the RAP and desired changes allowing accelerated tooth movement following surgery remains unknown. Lee et al. (2008) suggested a three to four-month window of opportunity to move teeth rapidly through the demineralised bone. The results of this study support the theory that the additional trauma is unlikely to facilitate tooth movement for a prolonged period of time. The methodology lacked the

degree of sensitivity required to determine the duration of RAP and any associated acceleration in tooth movement.

An impression was taken at the time of surgery to record the start position of the impacted canine. The use of sterile impression material allowed a more accurate measurement of distance compared to Fischer (2007) where the impression was taken at the first orthodontic appointment following surgery.

However, there were limitations in the data used to calculate the velocity of tooth movement. Participants attended orthodontic appointments at the standard appointment interval of 6-8 weeks. Therefore, data collection was limited to appointments only, and time to eruption was recorded as the first orthodontic appointment following eruption.

The method of measuring the distance from impaction to desired position in the upper arch at the time of surgery was subjective, and open to variation between operators. The equivalent distance was measured on the study models (DD), and a good correlation between the 2 methods of measuring the same distance was seen (Spearman's rho value = 0.79).

Fischer (2007) measured the horizontal distance parallel to the occlusal plane to determine the velocity of tooth movement; this does not take account of any vertical discrepancy between the position of impaction and desired position in the arch. In this study, attempts were made to account for this vertical distance by measuring the vertical distance to eruption and also the direct distance from impaction to desired position in the upper arch.

The use of cone-beam computed tomography (CBCT) would allow an accurate assessment of distance to calculate the velocity of tooth movement. The images would also allow clear assessment of any long-term bone loss. However, the additional exposure to radiation makes this inappropriate for clinical studies, along with the practicality and cost implications.

## 4.4 SECONDARY ENDPOINTS

### 4.4.1 SURGICAL TIME

There was no significant difference in the duration of surgical procedure between the control and test groups. The mean surgical time was 42 minutes; this is longer than a standard time slot used for routine expose and bond surgery. Surgeons felt that the duration was increased due to the additional sterile impression and clinical photographs taken. As long as a small surgical bur is available, there is no reason why the addition of alveolar-decortication will increase the duration of a surgical procedure.

### 4.4.2 ERUPTION TIME

Extraction of the retained deciduous canine alone would result in trauma to the bone surrounding the exposed tooth. Frost (1994) and Buchanan et al. (1988) have

suggested that extracting a tooth may stimulate the RAP, but whether this may express a sufficient level of RAP to have an affect on the velocity of tooth movement remains unknown.

An extraction in close proximity of the exposure may augment any effects of alveolar-decortication. Such extraction would also have the effect of creating a void in the bone prior to healing, thereby facilitating a reduced path of resistance, and accelerated tooth movement.

The sample size in this study was too small, to determine whether extraction of the retained deciduous canine had a significant effect on the velocity of tooth movement.

The mean time to eruption was less in the test group compared to the control group, at 21 weeks and 34 weeks respectively. Both of these values had significant standard deviations, which highlights the large variation in eruption times in both groups.

The vertical distance to eruption (VD) was measured on the study models, this distance was fairly difficult to measure, and therefore these values should be interpreted with caution. The mean distance was greater in the test group, than the control group, with values of 3.3mm and 2.5mm respectively. However, this difference was not statistically significant.

The velocity to eruption was 0.10mm/wk in the control group, and 0.29mm/wk in the test group, suggesting that eruption of the impacted canine was quicker in the test group. Again, there was no statistical significance between these values.

### 4.4.3 TIME TO PLACEMENT OF WORKING ARCHWIRE

At the time of writing up, only 9 participants had a working archwire *in situ*. This sample size is too small to determine whether the addition of alveolar-decortication reduces the time for complete alignment of a palatally impacted canine.

There are other factors, which contribute to the time of placing a working archwire, including patient attendance and compliance.

### 4.4.4 TOTAL TREATMENT DURATION

At the time of writing up, only 4 participants had completed their course of orthodontic treatment. This highlights the lengthily duration of treatment involving alignment of an impacted canine.

This sample size was too small to conclude whether the addition of alveolar-decortication can reduce the overall treatment duration. Further to placement of the working archwire, root alignment, torque and finishing details to the position of the canine are required. In addition, correction of the presenting malocclusion will add to the overall treatment duration.

Long-term follow-up of the participants in this study, will hopefully provide further information regarding whether a significant reduction in treatment time, as suggested by Wilcko et al. (2001, 2008, 2009) and Fischer (2007) is possible.

### 4.4.5 PAIN FOLLOWING THE SURGICAL PROCEDURE

There was a large variation in the pain experienced, and also the need for analgesics amongst participants following surgery. The range of pain score from 0 to 10 highlights the subjective nature of pain and also great individual variation.

Pain experienced was greatest on the first day, and diminished over the week following surgery. Patients are usually advised of some discomfort for a few days following surgery. These results indicate that the majority of patients will experience some pain and discomfort, but can expect little pain after the fourth day following surgery.

In this study participants were asked to mark the point corresponding to their level of pain on a line labelled with the numbers 0 – 10. The placement of numbers along the line assumes that there are set intervals between the levels of pain recorded, but this may not be the case. A visual analogue scale with extremes of pain marked at each end e.g. ‘no pain’ and ‘worst pain’ would have allowed a greater degree of freedom for the participant to mark their point. Visual analogue scales have been shown to be a reliable and sensitive method of measuring pain (Huskisson, 1974; Seymour et al., 1982 and 1985).

There was no significant difference in the pain scores, or need for analgesics between the control and test groups, indicating that alveolar-decortication does not increase the level of pain or discomfort experienced following surgery.

The majority of participants took Paracetamol and/or Ibuprofen for pain relief. It has been suggested that non-steroidal anti-inflammatory drugs (NSAIDs) e.g. Ibuprofen may decrease the rate of tooth movement. A recent systemic review of the literature

reported that NSAIDs have an inhibitory effect on tooth movement, whereas Paracetamol has no effect (Bartzela et al., 2009). Bartzela et al (2009) concluded that due to the high proportion of animal studies in this field, the clinical significance of medication on the rate of orthodontic tooth movement remains unknown, and that further research is required.

### 4.4.6 ADVERSE EVENTS

Only 2 adverse events have been recorded to date. One participant in the control group required a repeat surgical procedure. Pearson et al. (1997) reported that reasons for a second surgical intervention include failure of eruption, failure of exposure, and bond or attachment failure. A second surgical intervention is more common following closed (30.7%) compared to open (15.3%) surgical exposures (Pearson et al., 1997). In this example, following traction to the palatally impacted canine, the canine became palpable on the buccal aspect. Continuation of traction did not result in eruption, and so, an apically repositioned flap was carried out to allow placement of an attachment on the buccal aspect of the canine.

The second adverse event was an unusual episode of flap necrosis and wound infection of the palatal mucosa following surgery. This resulted in increased pain and discomfort, the need for analgesics and also antibiotics. This adverse event occurred in the oldest participant in the study, and it is reported in the literature that complications are far more likely to arise in older patients (Becker and Chaushu,

2003). It remains unknown whether this episode of infection was linked to the surgical intervention.

## 4.5 ADDITIONAL INFORMATION

### 4.5.1 APPOINTMENT INTERVALS

The interval between orthodontic appointments in this study was not controlled in an ideal manner, due to multiple orthodontic clinicians and heavily booked clinic diaries. The time to activation of traction following surgery may be considered as an example, and there was great variation (1-93 days). Patients attended regular orthodontic appointments at the standard interval of 6-8 weeks, however, individual clinic diaries and patient compliance may have led to an increase in time between appointments. Other studies have restricted the time between appointments, including a 4-5 week appointment interval (Fischer, 2007) and even a 2-week appointment interval (Wilcko et al., 2008).

The force applied to the gold chain was not standardised, whereas Fischer (2007) standardised the force at 60g. The forces used were judged appropriate by the orthodontic clinicians, and therefore may be considered within a standard clinical range.

A shorter duration between appointments would allow improved maintenance of the level of force applied to the gold chain. However, the level of force can never be kept constant due to constant movement of the impacted canine. Ren et al. (2004)

suggested that as long as an optimal range of force is delivered continuously, then the maximum rate of tooth movement would be achieved.

### 4.5.2 LONG-TERM FOLLOW-UP

There are no arrangements for long-term follow-up, further to completion of orthodontic treatment, for the participants in this study. Ideally, patients should be kept under review for 3-5 years to determine any long-term changes in gingival health and surrounding alveolar bone. At present, there are no well-controlled clinical trials, which have established the long-term gingival health following corticotomy and alveolar-decortication.

A successful outcome of any treatment should include long-term periodontal health. Baseline measurements including plaque index, gingival index, pocket depth, and attached gingiva, and regular follow-up would have allowed the long-term periodontal health to be ascertained. The type of orthodontic tooth movement, e.g. tipping, and torque may also have an affect on the long-term bony support (Kohavi et al., 1984).

# Chapter 5

# CONCLUSIONS

# CHAPTER 5: CONCLUSIONS

## 5.1 CONCLUSIONS

- The use of alveolar-decortication in addition to conventional surgical exposure does not reduce the time taken for eruption and alignment of a palatally impacted canine

- The use of alveolar-decortication in addition to conventional surgical exposure does not lead to a reduction in the overall treatment duration, when carrying out dis-impaction and alignment of a palatally impacted canine

- The addition of alveolar-decortication does not increase the duration of the surgical procedure when exposing an impacted tooth

- There is no additional pain or discomfort when alveolar-decortication is used in conjunction with conventional surgical exposure of an impacted tooth

## 5.2 NULL HYPOTHESIS

There is no difference in the velocity of tooth movement whilst aligning an impacted canine, following conventional surgical exposure or the use of alveolar-decortication in addition to surgical exposure.

- Accepted

## 5.3 RECOMMENDATIONS FOR CLINICAL PRACTICE

Further research is required before recommendations can be made regarding the clinical use of alveolar-decortication as an adjunct to orthodontic treatment.

The use of alveolar-decortication may be considered in addition to conventional surgical exposure of a tooth, as in these cases the patient is already committed to a surgical intervention. However, the results of this study do not support an acceleration of tooth movement, or reduction in overall treatment time.

Patients should be warned of pain and discomfort following surgical exposure of an impacted canine, and can expect little pain following the fourth day post-surgery.

This study confirms the lengthily course of treatment that patients undergo to dis-impact and align a palatally impacted canine. Patients should be given a realistic estimation of treatment duration during the consenting process. Initial alignment of a palatally impacted canine (to placement of a working archwire) may take from 33 weeks (8 months) to over 72 weeks (18 months).

## 5.4 FURTHER RESEARCH

Further research is indicated within this subject area. The results of this preliminary study could be used to determine the sample size required for a larger, multi-centre randomised controlled clinical trial.

In order to improve on this study, further studies should consider a restriction of the age of participants, number of clinicians, method of traction and appointment intervals. A larger sample size will increase the accuracy of the results, as would a more thorough and accurate measurement of time and distance.
In order to address the questions raised in section 1.6 and to determine the precise duration of RAP further laboratory investigations are also required. Unfortunately the results of such studies are limited, when considering the clinical implications.

A local study of the mean duration and success of treatment for alignment of palatally impacted canines would allow accurate and relevant information to be given to patients during the consenting process.

# Chapter 6

# APPENDICES

# CHAPTER 6: APPENDICES

**1. PATIENT INFORMATION SHEETS AND CONSENT FORMS**

# Participant Information Sheet

Movement of an impacted tooth
Version 4.0 (7th June, 2009)

**The efficacy of surgical exposure with alveolar-decortication vs. conventional surgical exposure to reduce treatment time for orthodontic alignment of palatally impacted canines.**

You are being invited to take part in a research study, because you are about to have treatment to uncover one of your teeth, which is not going to grow properly. However, before you decide whether you would like to take part, it is important that you understand why this research is being carried out, and what it will involve. Thank you for taking the time to consider participating in this research study.

**What is the purpose of this research study?**
The purpose of the study is to investigate if a change in the treatment to uncover your tooth will reduce the time taken to complete the treatment.
Sometimes, as in your case, canine teeth remain unerupted. As part of orthodontic treatment, buried canine teeth are surgically exposed. Once the buried tooth has been uncovered, an orthodontic bracket can be attached to the tooth, and a brace used to pull this tooth into line with the other teeth. This course of treatment is fairly slow, and can take up to 2.5 years.
During this study we plan to investigate an alternative method of surgically exposing a buried tooth. Previous research has suggested that using an alternative surgical method, may allow the tooth to move more quickly through the bone.
We will measure the speed of tooth movement, following the conventional surgical exposure, and also following exposure using an alternative technique.
If we find that the alternative technique, speeds up the movement of the tooth; this technique may become the routine treatment in the future. This will allow a reduction in treatment time, which results in a shorter time wearing braces and also less hospital appointments (time off school or work).

**What is the alternative surgical technique?**
The alternative surgical technique involves a process known as alveolar-decortication. The biological principle of this surgical method is well established.

During the routine exposure of a buried tooth; the surgeon uncovers the buried tooth by making an incision and lifting a flap of soft tissue (your gum), and then removing bone if necessary in order to expose the buried tooth. An orthodontic bracket is attached to the uncovered tooth, and stitches are placed to close the area with the flap of soft tissue. This is the method normally used by Oral Surgeons.
During the alternative technique all of the above will be carried out, as per normal; however an additional procedure will be carried out – whilst the tooth is exposed, additional holes will be drilled in the bone surrounding your tooth. This is known to lead to changes in the bone that may allow the tooth to move more quickly. This may require a slight extension of the flap of soft tissue (gum) raised by the Oral Surgeon. These additional holes will be prepared, so that we can study this alternative technique.

**Why would we like you to take part in this study?**
You have been asked to take part in this research study, because you are over 10 years of age, and have a palatally impacted canine tooth (tooth buried in the roof of your mouth), which you require uncovering as part of your orthodontic treatment.

<u>You will be unable to take part if;</u>
You have a history of gum disease (periodontal disease).
You have evidence of any abnormality (e.g. infection) around your buried tooth.
You are already participating in a research study.

**Do I have to take part in the study?**
We would like you to take part in the study, but it is up to you to decide whether or not to participate. If you do decide to take part, you will be given this information sheet to keep, and will be asked to sign a consent form. However, if you then decide that you no longer wish to take part, you are free to withdraw from the study at any time, and you will not be required to give a reason for leaving the study.
A decision to leave the study will not affect your course of orthodontic treatment, or the standard of care you receive at Birmingham Dental Hospital.

**What will happen if I do take part in the study?**
If you decide to participate in the study, you will be treated in exactly the same manner as all of our patients and will receive the course of treatment chosen for you – as per normal.
Photographs and impressions will be taken of your upper teeth, and we will use these to calculate the speed at which your buried tooth moves into line with your other teeth.

Clinical photographs and impressions are routinely taken as part of treatment at Birmingham Dental Hospital, so you will not be required to attend any extra appointments.

As with all surgical procedures at the Birmingham Dental Hospital, you will receive an Oral Surgery consultation appointment. At this appointment, the surgeon will discuss the surgical procedure, gain consent and arrange an appointment for the surgery to be carried out.
Whether you will receive the normal surgical procedure or the alternative technique (additional holes prepared in the bone for research purposes) will be determined randomly (similar to the toss of a coin) at the time of surgery. Only the surgeon will know which group you have been selected for. This increases the accuracy of the research study.
At the time of surgery, photographs and an impression of your upper teeth will be taken. Following this, your treatment will be carried out in the normal way- just as if you weren't participating in the study.
At routine appointments we will take photographs and an impression of your upper teeth, to assess the speed of tooth movement.

We will ask to you to record any discomfort, need for painkillers, or any other comments of your experiences following the surgery in a 'pain diary'. We will contact you by telephone at a convenient time, 1 week following the surgical procedure to make note of your 'pain diary'.

**What will I have to do?**
Once you have agreed to participate in the study, you will be required to sign a consent form, and attend your routine appointments as part of your orthodontic treatment.

**Will my details be kept confidential?**
You will be allocated a study number, so that your name and personal details will not be disclosed to anyone outside of the Birmingham Dental Hospital. Only the members of the study team [employee's at Birmingham Dental Hospital] will have access to your dental hospital notes. Your details will not be identified with the data collected other than by your allocated study number.
If you wish to know the results of the study, or which treatment you have received, this information will be available by request after the study has been completed.

**Are there any side effects to the alternative surgical technique?**
Side effects of the standard surgery, which can be experienced for up to 2 weeks, include post-operative pain, swelling, bleeding, infection, and damage to adjacent teeth. If you experience any of these side effects, appropriate care will be provided by the Birmingham Dental Hospital.
The above side effects also apply, if the alternative surgical technique is carried out; risks may be slightly increased.

However, there are no reported adverse effects of using alveolar-decortication to assist with the surgical exposure of palatally impacted canines.

**What are the disadvantages of taking part?**
You will not be required to attend any additional appointments; however, some of your routine appointments may take a little longer, as we would like to take regular photographs and impressions in order to calculate the speed at which your tooth moves.

**What are the benefits of taking part?**
Your course of treatment may be shortened, reducing the overall period for wearing your brace and the number of visits to Birmingham Dental Hospital.
Due to the extra photographs taken, the progress of your treatment and the health of your exposed tooth will be closely monitored.

**What if new information becomes available?**
If additional information becomes available, you will be informed of this at your next appointment.

**What happens when the research study comes to an end?**
At the end of the study, if your orthodontic treatment has not been finished, arrangements will be made to continue your treatment as per normal. You will then enter the normal review process at the Birmingham Dental Hospital, and following this you will be discharged to your General Dental Practitioner for routine dental care.

**What if something goes wrong during the study?**
There is no reason to believe, that there will be any complications during the treatment you will receive as part of this study. However, if you have any concerns or questions, at any time, a member of the research team will be available to discuss these with you.
If you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for this.

If you wish to make a complaint about, or during the study; you should contact Professor P Lumley, The School of Dentistry, University of Birmingham, St Chad's Queensway, Birmingham, B4 6NN. Telephone, 0121 236 8611

If you have any additional concerns; you may contact PALS [Patient Advice and Liaison Services] who can provide confidential advice and support on NHS and health related matters. PALS, Moseley Hall Hospital, Alcester Road, Moseley, Birmingham, B13 8JL. Telephone, 0800 917 2855. Email, PALS@sbpct.nhs.uk

**Who is organising and funding this research?**
This research study is one that has been designed at the School of Dentistry, and is being sponsored by the University of Birmingham.

**Who has reviewed this study?**
This study has been reviewed at Birmingham Dental School, and has been ethically approved by South Birmingham Research Ethics Committee.

**Further information.**
If you have any further questions, or require any additional information; please phone 0121 237 2817 and ask to speak to Miss Mary Bussell, who is managing this study.

# Parent Information Sheet

Movement of an impacted tooth
Version 4.0 (7th June, 2009)

**The efficacy of surgical exposure with alveolar-decortication vs. conventional surgical exposure to reduce treatment time for orthodontic alignment of palatally impacted canines.**

Your child is being invited to take part in a research study, because they are about to have treatment to uncover one of their teeth, which is not going to grow properly. However, before you decide whether you would like your child to take part, it is important that you understand why this research is being carried out, and what it will involve. Thank you for taking the time to consider participating in this research study.

**What is the purpose of this research study?**
The purpose of the study is to investigate if a change in the treatment to uncover your child's tooth will reduce the time taken to complete your child's treatment. Sometimes, as in your child's case, canine teeth remain unerupted. As part of orthodontic treatment, buried canine teeth are surgically exposed. Once the buried tooth has been uncovered, an orthodontic bracket can be attached to the tooth, and a brace used to pull this tooth into line with the other teeth. This course of treatment is fairly slow, and can take up to 2.5 years.
During this study we plan to investigate an alternative method of surgically exposing a buried tooth. Previous research has suggested that using an alternative surgical method, may allow the tooth to move more quickly through the bone.
We will measure the speed of tooth movement, following the conventional surgical exposure, and also following exposure using an alternative technique.
If we find that the alternative technique, speeds up the movement of the tooth; this technique may become the routine treatment in the future. This will allow a reduction in treatment time, which results in a shorter time wearing braces and also less hospital appointments (time off school or work).

**What is the alternative surgical technique?**
The alternative surgical technique involves a process known as alveolar-decortication. The biological principle of this surgical method is well established.

During the routine exposure of a buried tooth; the surgeon uncovers the buried tooth by making an incision and lifting a flap of soft tissue (gum), and then removing bone if necessary in order to expose the buried tooth. An orthodontic bracket is attached to the uncovered tooth, and stitches are placed to close the area with the flap of soft tissue. This is the method normally used by Oral Surgeons.
During the alternative technique all of the above will be carried out, as per normal; however an additional procedure will be carried out – whilst the tooth is exposed, additional holes will be drilled in the bone surrounding the tooth. This is known to lead to changes in the bone that may allow the tooth to move more quickly. This may require a slight extension of the flap of soft tissue (gum) raised by the Oral Surgeon. These additional holes will be prepared, so that we can study this alternative technique.

**Why would we like your child to take part in this study?**
Your child has been asked to take part in this research study, because they are over 10 years of age, and have a palatally impacted canine tooth (tooth buried in the roof of their mouth), which they require uncovering as part of their orthodontic treatment.

<u>Your child will be unable to take part if;</u>
They have a history of gum disease (periodontal disease).
They have evidence of any abnormality (e.g. infection) around the buried tooth.
They are already participating in a research study.

**Does your child have to take part in the study?**
We would like your child to take part in the study, but it is up to you to decide whether or not you are happy for them to participate. If you do decide for your child to take part, you will be given this information sheet to keep, and will be asked to sign a consent form. However, if you then decide that you no longer wish for your child to take part, you are free to withdraw from the study at any time, and you will not be required to give a reason for leaving the study.
A decision to leave the study will not affect your child's course of orthodontic treatment, or the standard of care you receive at Birmingham Dental Hospital.

**What will happen if my child does take part in the study?**
If your child decides to participate in the study, they will be treated in exactly the same manner as all of our patients and will receive the course of treatment chosen for them – as per normal.
Photographs and impressions will be taken of your child's upper teeth, and we will use these to calculate the speed at which their buried tooth moves into line with the other teeth.

Clinical photographs and impressions are routinely taken as part of treatment at Birmingham Dental Hospital, so your child will not be required to attend any extra appointments.

As with all surgical procedures at the Birmingham Dental Hospital, your child will receive an Oral Surgery consultation appointment. At this appointment, the surgeon will discuss the surgical procedure, gain consent and arrange an appointment for the surgery to be carried out.
Whether they will receive the normal surgical procedure or the alternative technique (additional holes prepared in the bone for research purposes) will be determined randomly (similar to the toss of a coin) at the time of surgery. Only the surgeon will know which group your child has been selected for. This increases the accuracy of the research study.
At the time of surgery, photographs and an impression of your child's upper teeth will be taken. Following this, your child's treatment will be carried out in the normal way- just as if they weren't participating in the study.
At routine appointments we will take photographs and an impression of your child's upper teeth, to assess the speed of tooth movement.

We will ask you and your child to record any discomfort, need for painkillers, or any other comments of their experiences following the surgery in a 'pain diary'. We will contact you by telephone at a convenient time, 1 week following the surgical procedure to make note of your child's 'pain diary'.

**What will they have to do?**
Once you and your child have agreed to participate in the study, you will be required to sign a consent form, and attend routine appointments as part of you child's orthodontic treatment.

**Will my child's details be kept confidential?**
Your child will be allocated a study number, so that his or her name and personal details will not be disclosed to anyone outside of the Birmingham Dental Hospital. Only the members of the study team [employee's at Birmingham Dental Hospital] will have access to your child's dental hospital notes. His or her details will not be identified with the data collected other than by an allocated study number.
If you wish to know the results of the study, or which treatment your child has received, this information will be available by request after the study has been completed.

**Are there any side effects to the alternative surgical technique?**
Side effects of the standard surgery, which can be experienced for up to 2 weeks, include post-operative pain, swelling, bleeding, infection, and damage to adjacent teeth. If your child experiences any of these side effects, appropriate care will be provided by the Birmingham Dental Hospital.

The above side effects also apply, if the alternative surgical technique is carried out; risks may be slightly increased.

However, there are no reported adverse effects of using alveolar-decortication to assist with the surgical exposure of palatally impacted canines.

**What are the disadvantages of taking part?**
Your child will not be required to attend any additional appointments; however, some of the routine appointments may take a little longer, as we would like to take regular photographs and impressions in order to calculate the speed at which the tooth moves.

**What are the benefits of taking part?**
Your child's course of treatment may be shortened, reducing the overall period for wearing the brace and the number of visits to Birmingham Dental Hospital.
Due to the extra photographs taken, the progress of your child's treatment and the health of the exposed tooth will be closely monitored.

**What if new information becomes available?**
If additional information becomes available, you will be informed of this at your next appointment.

**What happens when the research study comes to an end?**
At the end of the study, if your child's orthodontic treatment has not been finished, arrangements will be made to continue your child's treatment as per normal. Your child will then enter the normal review process at the Birmingham Dental Hospital, and following this your child will be discharged to your General Dental Practitioner for routine dental care.

**What if something goes wrong during the study?**
There is no reason to believe; that there will be any complications during the treatment your child will receive as part of this study. However, if you have any concerns or questions, at any time, a member of the research team will be available to discuss these with you.
If your child is harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for this.

If you wish to make a complaint about, or during the study; you should contact Professor P Lumley, The School of Dentistry, University of Birmingham, St Chad's Queensway, Birmingham, B4 6NN. Telephone, 0121 236 8611

If you have any additional concerns; you may contact PALS [Patient Advice and Liaison Services] who can provide confidential advice and support on NHS and

health related matters. PALS, Moseley Hall Hospital, Alcester Road, Moseley, Birmingham, B13 8JL. Telephone, 0800 917 2855. Email, PALS@sbpct.nhs.uk

**Who is organising and funding this research?**
This research study is one that has been designed at the School of Dentistry, and is being sponsored by the University of Birmingham.

**Who has reviewed this study?**
This study has been reviewed at Birmingham Dental School, and has been ethically approved by South Birmingham Research Ethics Committee.

**Further information.**
If you have any further questions, or require any additional information; please phone [redacted] and ask to speak to Miss Mary Bussell, who is managing this study.

# Information Sheet for 13-17 year olds

Movement of an impacted tooth
Version 1.0 (10th June, 2009)

## Will uncovering your tooth using a different surgical technique allow your tooth to move more quickly?

We would like to invite you to take part in a research study to find out whether uncovering your tooth in a different way will allow it to move more quickly through the bone. If the tooth can move more quickly, this will speed up your orthodontic treatment (time wearing braces).
Before you decide whether you want to join in, it is important that you understand why this research is being carried out, and what it will involve for you.
**Please read the following information carefully.** You may talk to your family and friends about it, and ask the your Orthodontist and Oral Surgeon questions about the study.

**What is the study about?**
Some teeth may remain buried in the bone. If we decide to bring this tooth into line with your other teeth, it requires uncovering by an Oral Surgeon. Once the tooth is uncovered, a brace can be attached to the tooth.
Treatment for uncovering and pulling these teeth into line with your other teeth is slow.
Other research studies have shown that there is a technique to expose teeth, which may allow teeth to move more quickly. We would like to investigate this further; therefore, we are asking patients with buried teeth if they would like to take part.

**What is the new technique for uncovering a tooth?**
Whenever a buried tooth is uncovered, the Oral Surgeon lifts up a flap of gum and drills away a little bit of bone to uncover your tooth. Patients do not feel this, as the Oral Surgeon makes the area numb. Once the tooth is uncovered, a gold chain is attached to your tooth, and the flap of gum stitched back into place. The Orthodontist attaches your brace to the gold chain.

During the new technique, after the Oral Surgeon has uncovered your tooth, they make some extra cuts in the bone; this creates small holes in the bone. It is believed

that these holes make it easier for the tooth to move through the bone. The holes also change the bones reaction to the surgery, allowing the tooth to move more quickly. Again, the Oral Surgeon will attach a gold chain to the tooth, and the flap of gum is stitched back into place.

**How will my tooth be uncovered?**
We will decide whether your tooth is uncovered using the standard or new technique. This decision will be determined randomly (similar to the toss of a coin) at the time of surgery.
Only the Oral Surgeon will know which group you have been selected for. This increases the accuracy of the research study.

**Why have I been chosen?**
You have been chosen to take part because you have a tooth buried in the roof of your mouth, which you require uncovering as part of your orthodontic treatment.

**What will happen if I do agree to take part in the study?**
We will talk more about the study to you and your parents, and you will be able to ask as many questions as you like. If you are happy to take part, you will be asked to sign a form. This form will be kept in your hospital notes.

**What will I have to do?**
You will attend the hospital as part of your normal orthodontic treatment. Some of your appointments may take a little longer, as we will take photographs of your tooth and small impressions. This will allow us to record the speed at which your buried tooth is moving.
After the appointment during which your tooth is uncovered, we will give you a diary and ask you to record any discomfort you may experience for 1 week.

**Do I have to take part?**
You are free to choose whether or not you take part in the study. If you agree to take part, and then change your mind, you are free to do so at any time. You do not have to give us a reason, and it will not affect the care you receive at the hospital.

**What are the benefits of taking part?**
Your tooth may move more quickly, which would reduce the overall time you have to wear braces and the number of visits to the hospital.
The extra photographs, will allow us to watch the progress of your treatment and health of your uncovered tooth.

**What are the possible risks of taking part?**
There are side effects to any surgical procedure. The uncovering of your tooth will be a surgical procedure. The side effects of uncovering a tooth include pain, swelling, bleeding, infection and damage to nearby teeth. If you experience any of these, care will be provided by the hospital.
If your tooth is uncovered using the new technique, (with the extra holes placed in the bone around your tooth) the same side effects also apply. The risks may be slightly increased.

Other studies have looked at the new technique, so it has been tried before. These studies have not found any unwanted or extra side effects.

**What will happen at the end of the study?**
At the end of the study, you and your parents can see the results; we will also tell you which technique was used to uncover your tooth if you would like to know.

**What if there is a problem?**
If you have any concerns or questions during the study, you should tell your parents, or someone at the dental hospital. We will be able to answer your questions, and remember you can change your mind about the study at any time.

**Will anyone else know I'm doing this?**
Only the people at the hospital involved with the study will see the information we collect. Any information that leaves the hospital will have your name, address and personal details removed, so that you cannot be recognised from it.

We will share the results with other Dentists, Orthodontists and Oral Surgeons, and they may be published in a dental journal. However, there will be no names and no details that could identify you.

We will also tell your general Dentist that you are taking part, if that is okay by you.

**Who has reviewed the study?**
Before any research is allowed to happen it has to be checked by a group of people to make sure it is safe. This study has been checked by people at the Birmingham Dental School, and also by South Birmingham Research Ethics Committee.

If you or your parents have any other questions, or there is something that you don't understand, please speak to Mary Bussell.

## Information Sheet for 10-13 year olds

Movement of an impacted tooth
Version 1.0 (10th June, 2009)

# Can we make your buried tooth move more quickly, into line with your other teeth?

We would like to invite you to take part in a research study to find out whether uncovering your tooth in a different way will allow it to move more quickly through the bone.

Before you decide whether you want to join in, it is important that you understand why this research is being carried out, and what it involves.
**Please read the following information carefully.** You may talk to your family and friends about it, and ask people at the dental hospital lots of questions.

### What is the study about?

Some teeth may remain buried in the bone, and do not grow down into line with the other teeth. Sometimes we decide to bring this tooth into line with your other teeth, it requires uncovering by an Oral Surgeon. Once the tooth is uncovered, a brace can be attached to the tooth.
Treatment for uncovering and pulling these teeth into line with your other teeth is slow.
Other research studies have shown that there is a technique to uncover teeth, which may allow teeth to move more quickly.

**What is the new technique for uncovering a tooth?**
Whenever a buried tooth is uncovered, the Oral Surgeon lifts up a flap of gum and takes away a little bit of bone, so that we can see your tooth. You will not feel this, as the Oral Surgeon makes the area numb. Once we can see your tooth, a gold chain is attached to your tooth, and the flap of gum stitched back into place. The Orthodontist attaches your brace to the gold chain.

During the new technique, after the Oral Surgeon has uncovered your tooth, they will make some extra cuts in the bone; this makes some small holes in the bone around your tooth. It is believed that these holes make it easier for the tooth to move through the bone. Again, the Oral Surgeon will attach a gold chain to the tooth, and the flap of gum is stitched back into place.

**How will my tooth be uncovered?**
We will decide whether your tooth is uncovered using the normal or new technique. There is a chance we will choose the normal technique, or a chance we will choose the new technique. We will decide at the time of surgery, and will decide in a way, which is similar to the toss of a coin.
Only the Oral Surgeon will know how your tooth has been uncovered. You and the Orthodontist will not know until the end of the study.

**What will I have to do?**
You will attend the hospital as part of your normal orthodontic treatment. Some of your appointments may take a little longer, as we will take photographs and impressions of your tooth. This will allow us to record the speed at which your buried tooth is moving.

After the appointment during which your tooth is uncovered, we will give you a diary and ask you and your parents to record any discomfort you may experience for 1 week.

**Do I have to take part?**
If you do not want to take part in the study, or if you change your mind, this is okay. You do not have to give us a reason, and it will not affect the care you receive at the hospital.
If you do decide to join in, we will ask you to sign a form to say that you are happy to take part.

**What are the possible risks of taking part?**
There are side effects to any surgical procedure. The uncovering of your tooth will be a surgical procedure. The side effects of uncovering a tooth include pain, swelling, bleeding, infection and damage to nearby teeth. We will give you and your parents information, so that if you experience any of these, help will be provided by the hospital.
If your tooth is uncovered using the new technique, (with the extra holes placed in the bone around your tooth) the same side effects will apply. The risks may be slightly higher.

Other studies have looked at the new technique, so it has been tried before. These studies have not found any extra side effects.

**Will joining in help me?**
Your tooth may move more quickly, which would reduce the overall time you have to wear braces, and the number of visits to the hospital.

**What will happen at the end of the study?**
At the end of the study, you and your parents can see the results; we will also tell you which technique was used to uncover your tooth if you would like to know.

**What if there is a problem?**
If you have any questions or become unhappy about the study, you should tell your parents, or someone at the dental hospital.

**Will anyone else know I'm doing this?**
Only a few people at the hospital will see the information we collect. Any information that leaves the hospital will not have your name on it. We will also tell your dentist that you are taking part.

If you or your parents have any other questions, or there is something that you don't understand, please speak to Mary Bussell.

# Participant Consent Form

**The efficacy of surgical exposure with alveolar-decortication vs. conventional surgical exposure to reduce treatment time for orthodontic alignment of palatally impacted canines.**

Version 2.0 (12th March, 2009)

Patient's Name:_____
Hospital Number:_____

**Consent Statement:**
I have read the information sheet, and have been given the opportunity to ask questions regarding my involvement in this study. I understand what is involved, and hereby agree to my participation in the study. I understand that the study team will need access to my dental hospital notes, and that all data collected will be anonymous.

I understand that my identity will be kept confidential to the members of the study team [employee's at Birmingham Dental Hospital], and that I may withdraw from the study at any time, and that this will not affect my orthodontic treatment.

_____
Patient's name (Please PRINT).

_____
Patient's signature, and date.

……..

Name of clinician taking consent:_____

Signature/Date:_____

# Parent Consent Form

**The efficacy of surgical exposure with alveolar-decortication vs. conventional surgical exposure to reduce treatment time for orthodontic alignment of palatally impacted canines.**

Version 2.0 (12th March, 2009)

Patient's Name:_____
Hospital Number:_____

**Consent Statement:**
I have read the information sheet, and have been given the opportunity to ask questions regarding my child's involvement in this study. I understand what is involved, and hereby agree for my child to take part in the study. I understand that the study team will need access to my child's dental hospital notes, and that all data collected will be anonymous.

I understand that my child's identity will be kept confidential to the members of the study team [employee's at Birmingham Dental Hospital], and that we may withdraw from the study at any time, and that this will not affect my child's orthodontic treatment.

_____
Parent/Guardian's name (Please PRINT).

_____
Parent/Guardian's signature, and date.

……..

Name of clinician taking consent:_____

Signature/Date:_____

# Consent Form

Movement of an impacted tooth

**Will uncovering your tooth using a different surgical technique allow your tooth to move more quickly?**

| **Please check,** | **✓ Tick,** |
|---|---|
| I have read the information sheet | ☐ |
| I was able to ask questions about the study | ☐ |
| My questions have been answered | ☐ |
| I have been told, all I need to know | ☐ |
| I understand that I can stop doing the study at any time and I'll still receive the best possible care | ☐ |
| People in the hospital, involved in the study can see my hospital notes | ☐ |

| **To be completed by the patient** | **To be completed by the investigator** |
|---|---|
| I agree to take part in the above study. | |
| Patient's signature | Investigator's signature |
| Date | Date |
| Name in BLOCK CAPITALS | Name in BLOCK CAPITALS |

# Assent Form

Movement of an impacted tooth

## Can we make your buried tooth move more quickly, into line with your other teeth?

| **Please check,** | **✓ Tick,** |
|---|---|
| I have read the information sheet | ☐ |
| I was able to ask questions about the study | ☐ |
| My questions have been answered | ☐ |
| I have been told, all I need to know | ☐ |
| I understand that I can stop doing the study at any time and I'll still receive the best possible care | ☐ |
| People in the hospital, involved in the study can see my hospital notes | ☐ |

| **To be completed by the patient** | **To be completed by the investigator** |
|---|---|
| I agree to take part in the above study. | |
| Patient's signature | Investigator's signature |
| Date | Date |
| Name in BLOCK CAPITALS | Name in BLOCK CAPITALS |

**2. CASE REPORT FORMS**

**Case Report Form – Oral Surgery**

Participant number ☐

Participant sticker

☐

Date of Surgery: _____
Surgeon: _____
Length of procedure (from raising flap to closure): ____minutes
Number of cuts/perforations: _____

| | Please tick, ✓ |
|---|---|
| Alveolar-decortication/test group | ☐ |
| Conventional surgery/control group | ☐ |
| Intra-oral photographs taken | ☐ |
| Impression taken | ☐ |

Any comments/complications during procedure?

……
……

**Case Report Form – Orthodontics**

**<u>This patient is participating in a research study, please do not remove this from the patient's notes. If further information is required regarding the patient's participation in the study, please contact Mary Bussell, SpR, Department of Orthodontics, 3E.</u>**

Participant number ☐

Participant sticker

Orthodontic clinician: _____

Date seen post-surgery: _____

Date of appointment, when canine first visible through the mucosa: _____

Date of appointment, when canine tip in the line of arch (when viewed from the occlusal plane): _____

Any complications: _____

**3. PAIN DIARY**

# Pain Diary

Movement of an impacted tooth
Version 2.0 (24th April 2009)

**The efficacy of surgical exposure with alveolar-decortication vs. conventional surgical exposure to reduce treatment time for orthodontic alignment of palatally impacted canines.**

We would like you to record any pain you experience in the week following the surgical procedure to uncover your buried tooth.
We would like you to do this, by scoring any pain you experience on a scale of 0-10 below. We would also like you to record any painkillers you may take, how many you take and also the name of the medicine.
We will contact you by telephone in one week, at a time convenient to you, to collect this information.

**DIARY PAIN SCORES**

***NO PAIN*** ***WORST PAIN***

0 1 2 3 4 5 6 7 8 9 10

*Example*----------*X*----------

Day 1 ----------

Day 2 ----------

Day 3 ----------

Day 4 ----------

Day 5 ----------

Day 6 ----------

Day 7 ----------

***How often did you take painkillers?***

**Day 1** Yes [ ] No [ ]

If yes, ---------- time(s) per day Name of Painkiller & Dose _____

**Day 2** Yes [ ] No [ ]

If yes, --------- time(s) per day Name of Painkiller & Dose _____

**Day 3** Yes [ ] No [ ]

If yes, ---------- time(s) per day Name of Painkiller & Dose _____

**Day 4** Yes [ ] No [ ]

If yes, ---------- time(s) per day Name of Painkiller & Dose _____

**Day 5** Yes [ ] No [ ]

If yes, ---------- time(s) per day Name of Painkiller & Dose _____

**Day 6** Yes [ ] No [ ]

If yes, ---------- time(s) per day Name of Painkiller & Dose _____

**Day 7** Yes [ ] No [ ]

If yes, ---------- time(s) per day Name of Painkiller & Dose _____

## 4. RAW DATA

| Control/Test | Subject number | Gender | Age (years) | UR3 | UL3 | Bilateral |
|---|---|---|---|---|---|---|
| 1 | 1 | Female | 15 | 0 | 1 | 0 |
| 2 | 2 | Female | 16 | 0 | 1 | 0 |
| 2 | 3 | Female | 15 | 0 | 1 | 0 |
| 1 | 4 | Female | 18 | 0 | 1 | 0 |
| 1 | 5 | Female | 22 | 1 | 0 | 0 |
| 1 | 6 | Male | 14 | 0 | 0 | 1 |
| 2 | 7 | Female | 14 | 0 | 0 | 1 |
| 2 | 8 | Male | 14 | 1 | 0 | 0 |
| 2 | 9 | Male | 22 | 1 | 0 | 0 |
| 1 | 10 | Female | 18 | 0 | 1 | 0 |
| 1 | 11 | Male | 15 | 1 | 0 | 0 |
| 1 | 12 | Male | 18 | 0 | 1 | 0 |
| 2 | 13 | Female | 16 | 0 | 1 | 0 |
| 1 | 14 | Male | 17 | 0 | 0 | 1 |
| 1 | 15 | Male | 19 | 0 | 1 | 0 |
| 1 | 16 | Male | 18 | 1 | 0 | 0 |
| 2 | 17 | Female | 17 | 0 | 1 | 0 |
| 2 | 18 | Female | 30 | 0 | 0 | 1 |
| 2 | 19 | Male | 14 | 1 | 0 | 0 |
| 1 | 20 | Male | 18 | 1 | 0 | 0 |
| 2 | 21 | Male | 19 | 1 | 0 | 0 |
| 2 | 22 | Female | 19 | 0 | 1 | 0 |
| 1 | 23 | Male | 15 | 0 | 1 | 0 |
| 2 | 24 | Female | 16 | 0 | 1 | 0 |
| 2 | 25 | Female | 15 | 1 | 0 | 0 |
| 1 | 26 | Male | 17 | 0 | 1 | 0 |
| 2 | 27 | Male | 15 | 1 | 0 | 0 |
| 1 | 28 | Female | 24 | 0 | 1 | 0 |
| 2 | 29 | Female | 15 | 1 | 0 | 0 |
| 1 | 30 | Male | ND | 0 | 0 | 1 |

ND = No data

| Subject number | Surgeon ID | GA | LA | LA+Ivsed | Sx time (mins) | No of cuts | Clinical (mm) |
|---|---|---|---|---|---|---|---|
| 1 | 1 | 1 | 0 | 0 | 29 | ND | 10 |
| 2 | 4 | 1 | 0 | 0 | 60 | 13 | 15 |
| 3 | 5 | 1 | 0 | 0 | 55 | 9 | 20 |
| 4 | 2 | 0 | 1 | 0 | 40 | ND | 11 |
| 5 | 3 | 0 | 0 | 1 | 45 | ND | 12 |
| 6 | 1 | 1 | 0 | 0 | 30 | ND | 9 |
| 7 | 5 | 1 | 0 | 0 | 60 | 9 | 10 |
| 8 | 5 | 1 | 0 | 0 | 30 | 6 | 15 |
| 9 | 3 | 0 | 1 | 0 | 30 | 6 | 15 |
| 10 | 2 | 0 | 1 | 0 | 35 | ND | 9 |
| 11 | 4 | 0 | 1 | 0 | 55 | ND | 17 |
| 12 | 4 | 0 | 0 | 1 | 42 | ND | 15 |
| 13 | 2 | 0 | 1 | 0 | 50 | 9 | ND |
| 14 | 3 | 0 | 1 | 0 | 90 | ND | 10 |
| 15 | 3 | 0 | 1 | 0 | 45 | ND | 10 |
| 16 | 2 | 0 | 1 | 0 | 20 | ND | 17 |
| 17 | 2 | 0 | 1 | 0 | 40 | 8 | 16 |
| 18 | 4 | 0 | 0 | 1 | 55 | 6 | 13 |
| 19 | 6 | 1 | 0 | 0 | 40 | 8 | 9 |
| 20 | 2 | 0 | 1 | 0 | 30 | ND | 12 |
| 21 | 4 | 0 | 0 | 1 | 30 | 6 | 6 |
| 22 | 2 | 0 | 1 | 0 | 30 | 7 | 7 |
| 23 | 2 | 0 | 1 | 0 | 45 | ND | 12 |
| 24 | 3 | 0 | 1 | 0 | 60 | 7 | 16 |
| 25 | 3 | 0 | 1 | 0 | 40 | 6 | 9 |
| 26 | 2 | 0 | 1 | 0 | 30 | ND | 16 |
| 27 | 3 | 0 | 1 | 0 | 45 | 6 | 13 |
| 28 | 3 | 0 | 1 | 0 | 30 | ND | 10 |
| 29 | 3 | 0 | 1 | 0 | 30 | 7 | 15 |
| 30 | ND | ND | ND | ND | ND | ND | ND |

Clinical = clinical distance measured during surgery

ND = No data

| Subject number | Clinician ID | Activation (days) | Eruption (wks) | Arch (wks) | Final AW (wks) | Debond (mths) | Tx (mths) |
|---|---|---|---|---|---|---|---|
| 1 | 7 | 13 | 13 | 31 | 37 | 29 | 29 |
| 2 | 8 | 7 | 24 | 44 | 44 | 19 | 19 |
| 3 | 9 | 10 | ND | ND | ND | ND | ND |
| 4 | 7 | 8 | 33 | 41 | 53 | ND | ND |
| 5 | 7 | 13 | 84 | 84 | ND | ND | ND |
| 6 | 10 | 9 | 41 | 50 | 60 | ND | ND |
| 7 | 8 | 10 | 4 | 32 | 33 | 16 | 16 |
| 8 | 7 | 16 | 2 | 21 | 41 | 13 | 13 |
| 9 | 7 | 9 | 31 | 49 | 72 | ND | ND |
| 10 | 11 | 6 | 19 | 30 | 58 | ND | ND |
| 11 | 10 | 7 | 25 | 47 | ND | ND | ND |
| 12 | 7 | 8 | 59 | 59 | ND | ND | ND |
| 13 | 9 | 12 | 52 | 52 | ND | ND | ND |
| 14 | 9 | 1 | 28 | 28 | ND | ND | ND |
| 15 | 12 | 10 | 25 | 25 | ND | ND | ND |
| 16 | 7 | 9 | 55 | 55 | ND | ND | ND |
| 17 | 9 | 22 | 55 | 55 | ND | ND | ND |
| 18 | 10 | 41 | ND | ND | ND | ND | ND |
| 19 | 7 | 10 | 30 | 30 | 52 | ND | ND |
| 20 | 7 | 13 | 8 | 8 | ND | ND | ND |
| 21 | 10 | 21 | 3 | 9 | ND | ND | ND |
| 22 | 13 | 33 | 5 | 19 | ND | ND | ND |
| 23 | 7 | 16 | 27 | 27 | ND | ND | ND |
| 24 | 13 | 39 | ND | ND | ND | ND | ND |
| 25 | 14 | 93 | 14 | 14 | ND | ND | ND |
| 26 | 15 | 14 | 21 | 21 | ND | ND | ND |
| 27 | 7 | 15 | 9 | ND | ND | ND | ND |
| 28 | 7 | 14 | ND | ND | ND | ND | ND |
| 29 | 14 | 14 | ND | ND | ND | ND | ND |
| 30 | ND | ND | ND | ND | ND | ND | ND |

ND = No data

| Subject number | NiTi auxiliary | Ballista spring | NiTi and ballista | Powerchain | NiTi auxiliary and elastomeric chain |
|---|---|---|---|---|---|
| 1 | 1 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | 1 | 0 | 0 |
| 3 | 0 | 0 | 0 | 0 | 1 |
| 4 | 1 | 0 | 0 | 0 | 0 |
| 5 | 1 | 0 | 0 | 0 | 0 |
| 6 | 1 | 0 | 0 | 0 | 0 |
| 7 | 1 | 0 | 0 | 0 | 0 |
| 8 | 1 | 0 | 0 | 0 | 0 |
| 9 | 1 | 0 | 0 | 0 | 0 |
| 10 | 1 | 0 | 0 | 0 | 0 |
| 11 | 0 | 1 | 0 | 0 | 0 |
| 12 | 1 | 0 | 0 | 0 | 0 |
| 13 | 1 | 0 | 0 | 0 | 0 |
| 14 | 1 | 0 | 0 | 0 | 0 |
| 15 | 1 | 0 | 0 | 0 | 0 |
| 16 | 0 | 0 | 1 | 0 | 0 |
| 17 | 1 | 0 | 0 | 0 | 0 |
| 18 | 0 | 0 | 1 | 0 | 0 |
| 19 | 1 | 0 | 0 | 0 | 0 |
| 20 | 1 | 0 | 0 | 0 | 0 |
| 21 | 1 | 0 | 0 | 0 | 0 |
| 22 | 1 | 0 | 0 | 0 | 0 |
| 23 | 1 | 0 | 0 | 0 | 0 |
| 24 | 0 | 0 | 0 | 1 | 0 |
| 25 | 1 | 0 | 0 | 0 | 0 |
| 26 | 0 | 0 | 1 | 0 | 0 |
| 27 | 1 | 0 | 0 | 0 | 0 |
| 28 | 1 | 0 | 0 | 0 | 0 |
| 29 | 1 | 0 | 0 | 0 | 0 |
| 30 | ND | ND | ND | ND | ND |

ND = No data

| Subject number | SM-DD (mm) | SM-HD (mm) | SM-VD (mm) | VelA (clinical) mm/wk | VelA (DD) mm/wk | VelA (HD) mm/wk | VelE (VD) mm/wk |
|---|---|---|---|---|---|---|---|
| 1 | 11 | 9 | 1.33 | 0.32 | 0.35 | 0.29 | 0.1 |
| 2 | 14 | 3.67 | 7.67 | 0.34 | 0.32 | 0.08 | 0.32 |
| 3 | 22.67 | 18.17 | 8.17 | ND | ND | ND | ND |
| 4 | 11 | 7.33 | 2.83 | 0.27 | 0.27 | 0.18 | 0.09 |
| 5 | 11 | 8 | 2.5 | 0.14 | 0.13 | 0.1 | 0.03 |
| 6 | 12.67 | 10.67 | 3.67 | 0.18 | 0.25 | 0.21 | 0.09 |
| 7 | 8.67 | 6.67 | 1.33 | 0.31 | 0.27 | 0.21 | 0.33 |
| 8 | 11.67 | 9.33 | 2.5 | 0.71 | 0.56 | 0.44 | 1.25 |
| 9 | 17 | 12.67 | 3.33 | 0.31 | 0.35 | 0.26 | 0.11 |
| 10 | ND | ND | ND | 0.3 | ND | ND | ND |
| 11 | 14.83 | 10.33 | 4.17 | 0.36 | 0.32 | 0.22 | 0.17 |
| 12 | ND | ND | ND | 0.25 | ND | ND | ND |
| 13 | 15.17 | 12 | 4 | ND | 0.29 | 0.23 | 0.08 |
| 14 | 11.17 | 15 | 3 | 0.36 | 0.4 | 0.55 | 0.11 |
| 15 | 14 | 11.33 | 2.67 | 0.4 | 0.56 | 0.45 | 0.11 |
| 16 | ND | ND | ND | 0.31 | ND | ND | ND |
| 17 | 15.33 | 14.67 | 4 | 0.29 | 0.28 | 0.27 | 0.07 |
| 18 | 14 | 11.67 | 4.67 | ND | ND | ND | ND |
| 19 | 9 | 9 | 1.83 | 0.3 | 0.3 | 0.3 | 0.06 |
| 20 | 10.67 | 8.67 | 1 | 1.5 | 1.33 | 1.08 | 0.13 |
| 21 | 7.5 | 5.67 | 1 | 0.67 | 0.83 | 0.63 | 0.33 |
| 22 | 8 | 7 | 1 | 0.37 | 0.42 | 0.37 | 0.2 |
| 23 | 12 | 9 | 1.5 | 0.44 | 0.44 | 0.33 | 0.06 |
| 24 | 13 | 14.67 | 2.33 | ND | ND | ND | ND |
| 25 | 11.5 | 9.33 | 1.33 | 0.64 | 0.82 | 0.67 | 0.1 |
| 26 | 15 | 11 | 2 | 0.76 | 0.71 | 0.52 | 0.1 |
| 27 | ND | ND | ND | ND | ND | ND | ND |
| 28 | ND | ND | ND | ND | ND | ND | ND |
| 29 | 14 | 10 | 3.5 | ND | ND | ND | ND |
| 30 | ND | ND | ND | ND | ND | ND | ND |

SM = study model
DD = direct distance
HD = horizontal distance
VD = vertical distance
VelA (clinical) = velocity to line of arch using clinical measurement
VelA (DD) = velocity to line of arch using direct distance from study model
VelA (HD) = velocity to line of arch using horizontal distance from study model
VelE (VD) = velocity to eruption using vertical distance from study model

ND = No data

| Subject number | P1 | P2 | P3 | P4 | P5 | P6 | P7 | GDP | Antibiotics |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 5 | 7 | 6 | 3 | 1 | 1 | 0 | 0 | 0 |
| 2 | 3 | 2 | 1 | 0 | 0 | 2 | 1 | 0 | 0 |
| 3 | 8 | 6 | 6 | 2 | 2 | 2 | 2 | 0 | 0 |
| 4 | 8 | 6 | 8 | 2 | 2 | 2 | 2 | 0 | 0 |
| 5 | 4 | 5 | 7 | 4 | 2 | 1 | 1 | 0 | 0 |
| 6 | 5 | 6 | 5 | 4 | 3 | 2 | 0 | 0 | 0 |
| 7 | 1 | 4 | 2 | 1 | 0 | 0 | 0 | 0 | 0 |
| 8 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 9 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 10 | 8 | 7 | 5 | 4 | 2 | 0 | 0 | 0 | 0 |
| 11 | 7 | 2 | 4 | 4 | 0 | 0 | 0 | 0 | 0 |
| 12 | 7 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 13 | 10 | 10 | 9 | 7 | 6 | 6 | 6 | 0 | 0 |
| 14 | 10 | 9 | 8 | 8 | 8 | 5 | 5 | 0 | 0 |
| 15 | 10 | 4 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| 16 | 8 | 6 | 4 | 4 | 3 | 2 | 1 | 0 | 0 |
| 17 | 5 | 3 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| 18 | 6 | 7 | 10 | 10 | 10 | 10 | 10 | 1 | 1 |
| 19 | 10 | 9 | 9 | 6 | 4 | 1 | 0 | 0 | 0 |
| 20 | 3 | 2 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| 21 | 7 | 6 | 2 | 1 | 0 | 0 | 0 | 0 | 0 |
| 22 | 8 | 6 | 4 | 0 | 0 | 0 | 0 | 0 | 0 |
| 23 | 4 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| 24 | 8 | 8 | 5 | 4 | 0 | 0 | 0 | 0 | 0 |
| 25 | 7 | 7 | 5 | 4 | 2 | 1 | 0 | 0 | 0 |
| 26 | 9 | 8 | 8 | 5 | 1 | 1 | 1 | 0 | 0 |
| 27 | 5 | 4 | 3 | 3 | 1 | 1 | 0 | 0 | 0 |
| 28 | 5 | 2 | 3 | 1 | 1 | 1 | 1 | 0 | 0 |
| 29 | 9 | 5 | 5 | 3 | 0 | 0 | 0 | 0 | 0 |
| 30 | ND | ND | ND | ND | ND | ND | ND | ND | ND |

Pain scores recorded in the week following surgery, and need to see a GDP, and antibiotics
P1 = pain score on day 1

ND = No data

| Subject number | A1 | A2 | A3 | A4 | A5 | A6 | A7 |
|---|---|---|---|---|---|---|---|
| 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 2 | 1 | 1 | 1 | 0 | 0 | 1 | 1 |
| 3 | 1 | 1 | 1 | 1 | 0 | 0 | 0 |
| 4 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| 5 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 6 | 1 | 1 | 1 | 1 | 0 | 0 | 0 |
| 7 | 1 | 1 | 1 | 1 | 0 | 0 | 0 |
| 8 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| 9 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| 10 | 1 | 1 | 1 | 0 | 0 | 0 | 0 |
| 11 | 1 | 1 | 1 | 1 | 0 | 0 | 0 |
| 12 | 1 | 1 | 1 | 0 | 0 | 0 | 0 |
| 13 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 14 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 15 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| 16 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| 17 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| 18 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 19 | 1 | 1 | 1 | 1 | 1 | 1 | 0 |
| 20 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 21 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| 22 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| 23 | 1 | 1 | 1 | 0 | 0 | 0 | 0 |
| 24 | 1 | 1 | 1 | 0 | 0 | 0 | 0 |
| 25 | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| 26 | 1 | 1 | 1 | 1 | 0 | 0 | 0 |
| 27 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 28 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| 29 | 1 | 1 | 1 | 1 | 0 | 0 | 0 |
| 30 | ND | ND | ND | ND | ND | ND | ND |

The need for analgesics in the week following surgery
A1 = analgesics on day 1

ND = No data

| Subject number | Pa_1 | Pa_2 | Pa_3 | Pa_4 | Pa_5 | Pa_6 | Pa_7 |
|---|---|---|---|---|---|---|---|
| 1 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | 8 | 8 | 4 | 4 | 0 | 0 | 0 |
| 4 | 2 | 4 | 2 | 0 | 0 | 0 | 0 |
| 5 | 8 | 8 | 8 | 2 | 2 | 0 | 2 |
| 6 | 2 | 2 | 0 | 0 | 0 | 0 | 0 |
| 7 | 2 | 6 | 4 | 4 | 0 | 0 | 0 |
| 8 | 2 | 1 | 0 | 0 | 0 | 0 | 0 |
| 9 | 2 | 1 | 0 | 0 | 0 | 0 | 0 |
| 10 | 2 | 2 | 1 | 0 | 0 | 0 | 0 |
| 11 | 2 | 1 | 2 | 1 | 0 | 0 | 0 |
| 12 | 0 | 2 | 2 | 0 | 0 | 0 | 0 |
| 13 | 4 | 4 | 4 | 3 | 2 | 2 | 2 |
| 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 16 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 17 | 4 | 0 | 0 | 0 | 0 | 0 | 0 |
| 18 | 8 | 8 | 8 | 8 | 2 | 8 | 8 |
| 19 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 20 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 21 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 22 | 2 | 1 | 0 | 0 | 0 | 0 | 0 |
| 23 | 8 | 4 | 1 | 0 | 0 | 0 | 0 |
| 24 | 8 | 16 | 4 | 0 | 0 | 0 | 0 |
| 25 | 2 | 2 | 0 | 0 | 0 | 0 | 0 |
| 26 | 8 | 8 | 8 | 8 | 0 | 0 | 0 |
| 27 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 28 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| 29 | 2 | 2 | 2 | 2 | 0 | 0 | 0 |
| 30 | ND | ND | ND | ND | ND | ND | ND |

Multiples of standard dose of Paracetamol (Pa) taken in the week following surgery
Standard dose = 500mg
Pa_1 = Paracetamol day 1

ND = No data

| Subject number | Ib_1 | Ib_2 | Ib_3 | Ib_4 | Ib_5 | Ib_6 | Ib_7 |
|---|---|---|---|---|---|---|---|
| 1 | 3 | 5 | 4 | 4 | 3 | 2 | 1 |
| 2 | 1 | 3 | 2 | 0 | 0 | 1 | 1 |
| 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5 | 8 | 8 | 8 | 6 | 4 | 2 | 2 |
| 6 | 2 | 2 | 1 | 1 | 0 | 0 | 0 |
| 7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 10 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| 11 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 12 | 4 | 0 | 0 | 0 | 0 | 0 | 0 |
| 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 14 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| 15 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| 16 | 3 | 3 | 0 | 0 | 0 | 0 | 0 |
| 17 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| 18 | 0 | 0 | 0 | 0 | 7 | 9 | 9 |
| 19 | 8 | 8 | 8 | 4 | 4 | 2 | 0 |
| 20 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 21 | 2 | 8 | 0 | 0 | 0 | 0 | 0 |
| 22 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 23 | 4 | 0 | 0 | 0 | 0 | 0 | 0 |
| 24 | 8 | 16 | 4 | 0 | 0 | 0 | 0 |
| 25 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 26 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 27 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 28 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 29 | 2 | 0 | 0 | 1 | 0 | 0 | 0 |
| 30 | ND | ND | ND | ND | ND | ND | ND |

Multiples of standard dose of Ibuprofen (Ib) taken in the week following surgery
Standard dose = 200mg
Ib_1 = Ibuprofen day 1

ND = No data

| Subject number | As_1 | As_2 | As_3 | As_4 | As_5 | As_6 | As_7 |
|---|---|---|---|---|---|---|---|
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 11 | 2 | 1 | 2 | 1 | 0 | 0 | 0 |
| 12 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 16 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 17 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 18 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 19 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 20 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 21 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 22 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 23 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 24 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 25 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 26 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 27 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 28 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 29 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 30 | ND | ND | ND | ND | ND | ND | ND |

Multiples of standard dose of Aspirin (As) taken in the week following surgery
Standard dose = 300mg
As_1 = Aspirin day 1

ND = No data

| Subject number | Di_1 | Di_2 | Di_3 | Di_4 | Di_5 | Di_6 | Di_7 |
|---|---|---|---|---|---|---|---|
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 11 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 12 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 16 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 17 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 18 | 3 | 3 | 3 | 4 | 1 | 0 | 0 |
| 19 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 20 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 21 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 22 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 23 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 24 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 25 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 26 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 27 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 28 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 29 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 30 | ND | ND | ND | ND | ND | ND | ND |

Multiples of standard dose of Diclofenac (Di) taken in the week following surgery
Standard dose = 50mg
Di_1 = Diclofenac day 1

ND = No data

| Subject number | Co_1 | Co_2 | Co_3 | Co_4 | Co_5 | Co_6 | Co_7 |
|---|---|---|---|---|---|---|---|
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 11 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 12 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 16 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 17 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 18 | 4 | 4 | 5 | 4 | 1 | 0 | 0 |
| 19 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 20 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 21 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 22 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 23 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 24 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 25 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 26 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 27 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 28 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 29 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 30 | ND | ND | ND | ND | ND | ND | ND |

Multiples of standard dose of Codeine (Co) taken in the week following surgery
Standard dose = 60mg
Co_1 = Codeine day 1

ND = No data

| Subject number | Tr_1 | Tr_2 | Tr_3 | Tr_4 | Tr_5 | Tr_6 | Tr_7 |
|---|---|---|---|---|---|---|---|
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 11 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 12 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 16 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 17 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 18 | 0 | 0 | 0 | 0 | 3 | 4 | 3 |
| 19 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 20 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 21 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 22 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 23 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 24 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 25 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 26 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 27 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 28 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 29 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 30 | ND | ND | ND | ND | ND | ND | ND |

Multiples of standard dose of Tramadol (Tr) taken in the week following surgery
Standard dose = 100mg
Tr_1 = Tramadol day 1

ND = No data

Reliability

| Subject number | SM-HD(mm) [1] | SM-HD(mm)[2] | SM-HD(mm)[3] | SM-HD (mm) |
|---|---|---|---|---|
| 1 | 9 | 9 | 9 | 9 |
| 2 | 5 | 3 | 3 | 3.67 |
| 3 | 17 | 19 | 18.5 | 18.17 |
| 4 | 9 | 6 | 7 | 7.33 |
| 5 | 8 | 8 | 8 | 8 |
| 6 | 9 | 11 | 12 | 10.67 |
| 7 | 7 | 6 | 7 | 6.67 |
| 8 | 8 | 10 | 10 | 9.33 |
| 9 | 12 | 13 | 13 | 12.67 |
| 10 | ND | ND | ND | ND |
| 11 | 11 | 10 | 10 | 10.33 |
| 12 | ND | ND | ND | ND |
| 13 | 11 | 12 | 13 | 12 |
| 14 | 15 | 14 | 16 | 15 |
| 15 | 11 | 11 | 12 | 11.33 |
| 16 | ND | ND | ND | ND |
| 17 | 15 | 15 | 14 | 14.67 |
| 18 | 13 | 11 | 11 | 11.67 |
| 19 | 9 | 9 | 9 | 9 |
| 20 | 8 | 9 | 9 | 8.67 |
| 21 | 5 | 6 | 6 | 5.67 |
| 22 | 7 | 7 | 7 | 7 |
| 23 | 9 | 8.5 | 9.5 | 9 |
| 24 | 15 | 14 | 15 | 14.67 |
| 25 | 10 | 9 | 9 | 9.33 |
| 26 | 12 | 11 | 10 | 11 |
| 27 | ND | ND | ND | ND |
| 28 | ND | ND | ND | ND |
| 29 | 10 | 10 | 10 | 10 |
| 30 | ND | ND | ND | ND |

Average of 3 repeat readings of the horizontal distance (HD) measured on the study models

ND = No data

Chapter 7

# LIST OF REFERENCES

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