A MULTI-CENTRE PILOT CLINICAL TRIAL TO ASSESS PATIENT'S EXPECTATIONS AND EXPERIENCE OF PAIN WITH TEMPORARY ANCHORAGE DEVICES

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Abstract

Objectives:

To determine whether placement of an O-Cap reduces discomfort after temporary anchorage device (TAD) placement and to assess the expectations and discomfort experienced after TAD placement.

Method:

Ethical approval and research and development (R & D) permission was obtained from the different hospital sites. 30 patients (14 female, 16 male; mean age 14 years 6 months) requiring bilateral TAD (3M Unitek) placement for maxillary anchorage reinforcement, completed short answer and 100mm visual analogue scale (VAS) questionnaires at different time-points prior to and 6 weeks following TAD placement. One of the TADs on each patient was randomly allocated to placement of an O-Cap (3M Unitek).

Results:

VAS scores were higher on the control side compared to the O-Cap side for all time-points. Wilcoxon signed-rank test showed statistically significant levels at 4 hour post-placement ($p<0.05$), 24hour ($p<0.05$) and 1 week ($p<0.0005$) for cheek discomfort and at 1 week ($p<0.05$) and 2 weeks ($P<0.05$) for gingival discomfort. Median VAS for cheek discomfort with O-Cap and control scored highest at 24 hours and 4 hours with 23 mm (0-100 mm) and 42.1 mm (0-94.9 mm) respectively. Median VAS for gingival discomfort with O-Cap and control scored highest at 1 hour post placement with 36.8 mm (0-100mm) and 48.4 mm (0-100 mm) respectively. Null

hypothesis rejected. 80% of subjects reported extractions to be more painful than TAD placement.

Conclusions:

Discomfort levels of the overall TAD experience were greatest during the first hour following placement. During the first 6 weeks the discomfort associated with an Imtec TAD was gradually reduced by placement of an O-Cap particularly as the local anaesthetic starts to wear off.

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Page

Contents

Chapter 1: Literature review 16

Chapter 2: Materials and methods 38

Chapter 3: Results 51

Chapter 4: Discussion 75

Chapter 5: Conclusions 84

Appendix 1 88

Appendix 2 96

References 103

Page

Chapter 1: Literature review 16

1.1 Introduction 19

1.2 Terminology 19

1.3 Method of review 20

1.4 History of implants 21

1.5 Clinical applications 22

1.6 Classification of miniscrews 23

1.7 Clinical success 24

1.8 Efficacy 25

1.8.1 Failures of miniscrews 26

1.8.2 Operative factors 28

1.9 Safety 29

1.10 Pain 29

1.10.1 Causes of orthodontic pain 31

1.10.2 Pain associated with placement of TADs 32

1.10.3 Patient experience with TAD placement 32

1.11 Assessment of pain 32

1.11.1 Visual analogue scale 33

1.11.2 Verbal rating scale 33

1.11.3 Numerical rating scale 34

1.11.4 The McGill pain questionnaire 34

1.11.5 Clinically significant difference in pain scores with VAS scores 34

1.12 Pain control during orthodontics 35

1.12.1 Pharmacological control **35**

1.12.2 Non-pharmacological control **36**

Page

Chapter 2: Materials and methods 38

2.1 Study aims 40

2.2 Null hypothesis 40

2.3 Study design 40

2.4 Ethical approval and Research and Development approval 41

2.5 Randomisation process 41

2.6 Sample size 42

2.7 Subjects 42

2.7.1 Inclusion criteria 42

2.7.2 Exclusion criteria 43

2.8 Method 43

2.8.1 Placement method 44

2.8.2 TAD and O-Cap 45

2.8.3 Questionnaires 48

2.8.4 Outcome measurements 49

2.8.5 Statistical analysis 50

Page

Chapter 3: Results 51

3.1 Baseline results 54

3.1.1. Descriptive data 54

3.1.2. Expectations of overall experience of placement of TADs 55

3.1.3. Expectations of pain during placement of TADs 56

3.2 Results 57

3.2.1 Actual pain experienced during the placement of TADs 57

3.2.2. Discomfort experienced in the cheeks after placement of TADs without the O-Cap 61

3.2.3 Discomfort experienced in the cheeks after placement of TADs with the O-Cap 62

3.2.4 Discomfort experienced in the gingivae after placement of TADs 70 without the O-Cap 63

3.2.5 Discomfort experienced in the gingivae after placement of TADs with the O-Cap 64

3.2.6 Discomfort experienced with placement of TADs with and without O-Cap 65

3.2.7 Pain relief 69

3.2.8 Extractions versus placement of TADs 70

3.3 Analysis of the results 71

3.3.1 Wilcoxon Signed Rank analysis of cheek discomfort levels of TADs with and without O-Caps 71

3.3.2 Wilcoxon Signed Rank analysis of gingival discomfort levels of TADs with and without O-Caps 71

3.3.3 Spearman's Rank Correlations 72

3.4 Intra-examiner reliability 73

Page

Chapter 4: Discussion 75

4.1 Baseline results 77

4.2 Effect of the O-Cap 82

Page

Chapter 5: Conclusions 84

5.1 Conclusions 86

5.2 Null hypotheses 86

5.3 Recommendations for clinical practice 87

5.4 Further research 87

Page

List of figures

Figure 1 The visual analogue scale 33

Figure 2.8 TAD insertion site 46

Figure 2.8.3 3M Unitek Imtec TAD and O-cap (courtesy of 3M Unitek) 47

Figure 2.8.4 Self-threading driver 47

Figure 3.1.1 A box and whisker plot for the feeling experienced prior to and the expectations of pain during the placement of TADs 56

Figure 3.2.1 A box and whisker plot for the actual pain experienced during the placement of TADs and the following 6 weeks 58

Figure 3.2.2 A box and whisker plot for the comparison between the patients' expectations and actual pain experienced during the placement of TADs 60

Figure 3.2.3 A box and whisker plot illustrating the levels of discomfort experienced in the cheeks after placement of TADS without O-Caps 62

Figure 3.2.4. A box and whisker plot illustrating the levels of discomfort experienced in the cheeks after placement of TADS with O-Caps 63

Figure 3.2.5. A box and whisker plot illustrating the levels of discomfort experienced in the gums after placement of TADS without O-Caps 64

Figure 3.2.6. A box and whisker plot illustrating the levels of discomfort experienced in the gums after placement of TADS with O-Caps 65

Figure 3.2.7. A box and whisker plot for the discomfort experienced in the cheeks after placement of the TADs with and without O-Caps over 6 weeks 66

Page

Figure 3.2.8. A box and whisker plot for the discomfort experienced in the gingivae after placement of the TADs with and without O-Caps over 6 weeks 67

Figure 3.2.9. Bar graph illustrating the frequency of pain relief during the 6 weeks following the placement of TADs. 70

Page

List of tables

Table 3.1.1 Descriptive data 55

Table 3.1.2 Baseline results – VAS scores prior to placement of TADs 57

Table 3.2.1 Results – VAS scores for actual pain during the placement of TADs and the subsequent 6 weeks after the placement of TADs 59

Figure 3.2.2 Results- VAS score data for the level of discomfort of the cheeks and gums experienced following placement of TADs with and without O-Cap 68

Table 3.2.3. The percentage rating of the more uncomfortable side immediately after and over the subsequent 6 weeks following the placement of the TADs 69

Table 3.2.4 The Wilcoxon Signed Ranks Test to compare the cheek pain scores for TADs with and without O-Caps at different time-points after placement 71

Table 3.2.5 The Wilcoxon Signed Ranks Test to compare the gingival pain scores for TADs with and without O-Caps at different time-points after placement 72

Table 3.2.7. Spearman rank correlations between expected pain VAS scores and cheek VAS scores for TADs without O-Caps 73

Table 3.4.1 The intraclass correlation coefficient analysis for the intra-examiner reliability of the measurement of the visual analogue scale pain scores 74

CHAPTER 1

LITERATURE REVIEW

Page

Chapter 1: Literature review 16

1.1 Introduction 19

1.2 Terminology 19

1.3 Method of review 20

1.4 History of implants 21

1.5 Clinical applications 22

1.6 Classification of miniscrews 23

1.7 Clinical success 24

1.8 Efficacy 25

1.8.1 Failures of miniscrews 26

1.8.2 Operative factors 28

1.9 Safety 29

1.10 Pain 29

1.10.1 Causes of orthodontic pain 31

1.10.2 Pain associated with placement of TADs 32

1.10.3 Patient experience with TAD placement 32

1.11 Assessment of pain 32

1.11.1 Visual analogue scale 33

1.11.2 Verbal rating scale 33

1.11.3 Numerical rating scale 34

1.11.4 The McGill pain questionnaire 34

1.11.5 Clinically significant difference in pain scores with VAS scores 34

1.12 Pain control during orthodontics 35

1.12.1 Pharmacological control **35**

1.12.2 Non-pharmacological control **36**

1.1 Introduction

Anchorage in orthodontics can be defined as the resistance to unwanted tooth movement during treatment. This can be provided by intra-oral anchor sites like the teeth and palate, or alternatively extra oral devices such as headgear. Unfortunately these conventional methods have a major drawback: they all rely on patient compliance in order to be successful (Liou *et al.,* 2004). Recent literature has suggested that the introduction of miniscrews or temporary anchorage devices (TADs), a term of American origin (Mizrahi and Mizrahi 2007), has created a potential to achieve the goals of ideal anchorage control.

1.2 Terminology

Successful *skeletal anchorage* is the main biological concept behind these devices and this involves 2 categories. *Indirect anchorage* use of such devices is defined as provision of immovable connections to the teeth, which serve as the actual anchorage units. On the other hand *direct anchorage* means utilisation of direct forces originating from the actual device itself, in this case the screws inserted into the bone.

Osseointegrated dental implants, which include palatal implants and retromolar implants, fall into the former category. One commonly used mid palatal implant has a diameter of 3.75 mm and osseointegrated implants vary in length from 7 to 20 mm.

Intra oral implants continued to develop into another category, the miniplates and miniscrews. Miniplates are attached to cortical bone by miniscrews and are

commonly inserted into the mandibular buccal bone or maxillary zygomatic buttress (Wahl, 2008). Osseointegration is not a desired feature in this particular category, as it would complicate removal, nor has it been found to be necessary for successful clinical use.

Onplants are another completely different category from implants, they are placed sub-periosteally and are meant to integrate to the outer surface of cortical bone. These are manufactured as flat, titanium discs, sometimes with hydroxyapatite-coated surfaces to encourage bone integration. Onplants have been reported to withstand orthodontic forces of up to 311g (Hong, 2005).

1.3 Method of review:

A Medline, PubMed and Cochrane Clinical Trials Register (CCTR) search was conducted using the following keyword search:

- Orthodontic miniscrews OR mini implants OR microscrews
- Success of miniscrews OR mini implants OR microscrews
- Temporary anchorage devices

The total number of 105 papers found, were manually sifted to exclude any, which involved in-vitro or animal studies. The final collection of 72 papers included in this search was divided into the following groups:

- Clinical trials
- Case reports

- Comparison reports between TADs and other anchorage devices
- Relevant papers about history, surveys and types of miniscrews
- One paper about ongoing national audit processes has also been included.

1.4 History of implants

The first reported attempt of intra oral anchorage with metal screws was carried out on dogs, by Gainsforth and Higley (Gainsforth and Higley, 1945). After the introduction of osseointegrated implants in restorative dentistry and oral surgery in the 1960s, it became widely accepted that this new armamentarium could be a useful source of anchorage in orthodontic practice (Mizrahi and Mizrahi, 2007). It was at this time that Bränemark published a series of experimental studies demonstrating the successful stability of titanium implants to bony interface.

One of the earliest successful results with miniscrews was in 1983 when a report was published about incisor elevation using a screw placed in the anterior nasal spine region (Creekmore and Eklund, 1983). It was not until the 1990s that further experiments with non-osseointegrated titanium microscrew implants were published by Kanomi and Melsen consecutively (Kanomi, 1997; Melsen *et al.,* 1998). Roberts first published studies about successful closure of first molar extraction sites utilising mini-implants in the retromolar region as anchorage (Roberts *et al.*, 1990).

The mid-palatal implant was first described in 1992 by Triaca and colleagues (Triaca *et al.,* 1992). Straumann Limited later developed the Orthosystem where a short cylindrical implant is placed into the palatal vault for a period of 12 weeks before it is

loaded. Experiments involving onplants, an indirect method of anchorage, were reported by Block and Hoffman in 1995 (Block and Hoffman, 1995). This evidence was however based on a dog and monkey study, both samples were of not more than 7 subjects. Following this successful period, it was Kanomi, in 1997, who described a mini implant exclusive for orthodontic use (Kanomi, 1997). Costa *et al* then described a 2mm diameter titanium miniscrew that could be used for direct or indirect anchorage in a preliminary report published the year after. This looked particularly at anchorage problems and relative solutions associated with deficient dentitions by evaluating the evidence on bone quality in dry skulls (Costa *et al.,* 1998).

1.5 Clinical application

Titanium has long been established as the material of choice for implants but new clinical applications for these anchorage devices are still in early stages of development. The burgeoning numbers of case reports in peer-reviewed journals are continuing to illustrate the versatility of TADs and their use in any clinical situation where anchorage is of concern.

DeVincenzo published a series of papers in 2006, showing how the use of TADs successfully corrected potentially surgical, high-angle cases (DeVincenzo 2006). In the same year Prabhu and Cousley also reported on a couple of commercial mini-implant systems available providing various anchorage solutions (Prabhu and Cousley, 2006).

The main indications for TADs to date have been:

- Reinforcement of anchorage
- Movement of buccal teeth in a mesial or distal direction
- Movement of anterior teeth in a lingual or labial direction
- Correction of crossbite or scissor bite (Young 2007)
- Movement of buccal or anterior teeth in a vertical intrusive direction (Mizrahi and Mizrahi, 2007; Baumgartel *et al.,* 2008; Cacciafesta, 2009)

1.6 Classification of miniscrews

Mini implants or mini screws have been classified in various ways:

- Position: the site of anchorage is dictated by the type and severity of the malocclusion. The most common insertion site is the endosseous position but others may include subperiosteal or transosseous.
- Implant surface may be rough or smooth.
- Screw design: determines the extent of support it attracts from its surrounding bone. The smooth, cylindrical design is thought to increase such support (Wahl, 2008). Self-drilling or self-tapping (thread-forming) miniscrews eliminate the necessity of drilling pilot holes. Various miniscrew head designs are also available; namely the bracket head or button head design as well as the through hole design. The main purpose for these differing designs is to

meet various skeletal anchorage needs by enabling the miniscrew to accept wires, hooks and elastics or even act as a slightly unconventional bracket. TADs are also produced in various lengths between 5 mm and 12 mm, and with diameters of 1.2 to 2.0 mm.

Examples of current systems include self-tapping screws such as the Tomas, Imtec and the Orthoimplant. The Aarhus Mini-implant, originating from Denmark provided the possibility of immediate loading of such screws (Sherwood *et al.,* 2002). The Spider Screw, which has been popularised in Italy has a similar cylindrical design. Another popular self-drilling screw is the AbsoAnchor system developed in Korea by Dr Park and colleagues (Block and Hoffman, 1995).

1.7 Clinical Success:

Though the use of miniscrews has become widely popular and is one of the hot topics in current orthodontic discussions, there is still a lack of sound scientific evaluation in the form of clinical randomized controlled trials. The number of case reports on this subject is enormous with over 3300 at last count (Reynders *et al.,* 2009) and continues to expand, but unfortunately these tend to merely illustrate different techniques and versatility of applications.

Buschang et al. recently published the results of an electronic survey on the worldwide use of miniscrews amongst members of the American Association of orthodontics. 42.6% of the respondents had placed over 10 screws and interestingly more than half were now placing their own screws rather than referring this

procedure to their surgical colleagues. It also seemed popular to use a combination of topical and local anaesthetic for placement of screws (Buschang *et al.,* 2008; Cacciafesta, 2009). The majority of clinicians had not received any specific training prior to their first screw placement, and this was reflected in lower failure rates in the more experienced and satisfied operators (Buschang *et al.,* 2008).

1.8 Efficacy

Osseointegrated dental implants such as the mid-palatal implants have been reported to have a success rate ranging from 85% to 100% from human studies. Success rate in such cases was defined by National Institute for Health and Care Excellence (Ni(H)CE) as stable anchorage for 1 year or until completion of orthdontic treatment (Moon *et al.,* 2008). Animal studies in non-osseointegrated miniscrews have reported a success rate of 91% to 100%, however these types of studies do not portray a realistic clinical situation. A few human studies published in recent years have revealed a success rate of more than 75% when orthodontic forces of 100g-400g are applied to such devices (Janssen, 2008; Reynders *et al.,* 2009; Cheng 2004; Kim *et al.,* 2010; Kuroda *et al.,* 2007; Asscherickx *et al.,* 2010; Park *et al.,* 2006). Comparative trials between mini-implant anchorage and conventional anchorage such as headgear showed that the former provide faster and effective anchorage reinforcement in cases of absolute anchorage (Upadhyay *et al.,* 2008; Thiruvenkatachari *et al.,* 2008; Skeggs *et al.,* 2009; Yao *et al.,* 2008; Deguchi *et al.,* 2008; Benson *et al.,* 2007). 1.2mm diameter and 8mm length miniscrews have been reported to be the most popular and successful. Crismani et al concluded that flap

versus flapless and immediate versus delayed miniscrew loading resulted in similar successful outcomes (Crismani *et al.,* 2010).

Failure of miniscrews has been reported to vary from 10% to 18% in recent years, and is the most common reported complication in the literature (Mizrahi and Mizrahi, 2007; Baumgartel *et al.,* 2008; Miyawaki *et al.,* 2003; Tsaousidis and Bauss, 2008). Breakages of miniscrews are rare because bone is not able to offer sufficiently high resistance. It is usually advised to remove the miniscrew if resistance is encountered. The clinician should also ensure that the mini-implant is not directed into a root (Cacciafesta, 2009).

1.8.1 Failures of miniscrews

Contraindications for TADs are minimal and may include any systemic disease that results in poor bone quality. Locally it is contraindicated to place a miniscrew in a young child, especially in an area of a permanent successor or insufficient interradicular space.

The main reported factors to contribute to miniscrew failures are:

- Improper surgical technique/ loading protocol
- Placement site
- Host factors – smoking, management factors, parafunctional habits, bone quality, high mandibular angle that is thin cortical bone
- Implant structural elements

- Soft tissue response
- Excessive force application

Chen et al reported in their systematic review, that choice of implant size should depend on the quality and quantity of bone available. Immediate implant loading showed high success rates with direct forces of up to 200g and resulted in shorter treatment time, but this evidence was regarded as secondary quality (Crismani *et al.,* 2010; Chen *et al.,* 2009). Luzi et al also reported on the effectiveness of immediately loaded mini-implants, suggesting that the overall failure rate is not altered, especially when light forces are employed (Luzi *et al.,* 2007).

Patients who smoke or are currently on bisphosphanates predispose to higher failure rates and should only be treated on case to case basis. Bayat reported a significantly higher failure rate of orthodontic miniscrews in heavy smokers than light or non-smokers (Bayat and Bauss, 2010).

The main factors influencing the clinical success rate of mid-palatal miniscrews are the patient's age, with patients younger than 15 years increasing the failure risk; operator's skill (Garfinkle *et al.,* 2008); placement of miniscrew in the palatal suture (Kim *et al.,* 2010).

Despite the implication of these factors in miniscrew failures, stability or loosening of the screw is difficult to predict, therefore each patient should be warned of the possibility of failure during the consent process.

1.8.2 Operative factors

Several clinical guidelines on the placement have been proposed. Miniscrews are typically placed under topical or minimal local infiltration anaesthesia. They can be drilled or screwed into the bone cortex using a screw-driver or a contra-angled driver, either with or without prior pilot hole placement. Procedure time ranges from 5 to 15 minutes depending on the operator and the patient (Gelgor *et al.,* 2004; Chen *et al.,* 2006). Lee et al described the premolar and subapical areas in the anterior region as being the most reliable for orthodontic miniscrew placement. A depth of more than 4mm of alveolar bone is easily available in intermolar regions and between the second premolar and the first molar in both arches (Tsaousidis & Bauss, 2008; Lee *et al.,* 2009). Adequate bone depth and miniscrew orientation will affect the resistance to failure on the implant-bone interface. It was suggested that the long axis of the miniscrew should be closely approximated to the line of applied force giving greater stability in all dimensions (Pickard *et al.,* 2010). Miniscrew placement in 2 stage surgery, at a high level, in non-keratinised mucosa has been reported to promote an unwelcome inflammatory hypertrophic tissue response, a significant predictor for failure especially in the mandible (Park *et al.,* 2006; Viwattanatipa *et al.,* 2009).

1.9 Safety

Despite all the possible insertion sites discussed, probably the most common would be in the keratinised gingivae of the interradicular space between upper second premolar and first molar. This choice of site would invariably raise the possibility of root damage during insertion of the device or during tooth movement. Clinical and histological observations of this have shown that the respective root areas react by initiating resorptive processes. However, reports have demonstrated that elimination of contact, will swiftly lead to cementum deposition and full root recovery within a few weeks (Kadioglu *et al.,* 2008; Maino *et al.,* 2007).

Poggio et al suggested 1mm safety margin between a miniscrew and a root for both periodontal health and miniscrew stability. It could be also therefore recommended that miniscrews with a diameter of 1.5mm or less are adequate for insertion into an interradicular bone of at least 3.5mm (Poggio *et al.,* 2006).

Unfortunately the conclusions from these studies on safety are based on small patient samples and further work in this field is required.

1.10 Pain

The International Association of the Study of Pain (IASP, 1994) defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or is described in terms of such damage. Patients have been found to avoid seeking orthodontic treatment due to fear of pain and for 95% of these patients pain has also been the main reason for discontinuing treatment (Oliver and

Knapman, 1985). Orthodontists, however tend to underestimate the pain thresholds experienced by their patients (Krukemeyer *et al*, 2009).

There is great individual variation in levels of pain experienced and this can prove to be very subjective. The literature (Ngan *et al*, 1989; Brown and Moerenhout, 1991; Firestone *et al*, 1996; Bergius *et al*, 2000; Kluemper *et al*, 2002) suggests that pain is dependent upon various factors such as age, sex, emotional state and previous pain experience.

Tucker *et al.* (1989) measured the cutaneous pain threshold in ages 5 to 105 years and showed that pain levels increase up to 25 years of age, than plateau off to then increase again gradually by age 75. In the orthodontic context, the published literature has on the contrary shown that younger patients experience less pain than older patients (Fernandes *et al.*, 1988; Brown *et al.*, 1991; Jones *et al.*, 1992). Despite these claims Ngan *et al.,* (1989) and Bergius (2002) have found no difference with age.

The gender factor in relation to pain experience also presents divided thought in reported studies. Scheurer *et al* (1996) and Bergius *et al* (2002) reported that females tend to experience greater pain than males during orthodontic treatment but Ngan *et al* (1989) and Erdinc and Dincer (2004) showed no difference in the pain experienced during orthodontic treatment between genders. Soft tissue complaints and ulceration have been found more commonly in females than males (Kvam *et al* 1989) but this could be attributed to the fact that there is a higher female predilection for recurrent aphthous ulceration.

In humans higher centres of the central nervous system modulate pain levels, which are therefore highly affected by emotional and cognitive factors. An increase in

anxiety is often correlated with higher pain levels. Similarly positive motivation towards treatment and its results may lead to a reduction in anxiety and subsequent pain levels. This could be explained by filtration of painful stimuli and favourable alteration of pain thresholds (Bergius *et al.*, 2000; Krishnan, 2007). Sergl *et al.* (1998) suggested that the level of acceptance of orthodontic treatment is related to the level of discomfort experienced after fitting of orthodontic appliances.

There are different cultural variations in the level of pain experienced where some ethnic groups believe that pain expression should be sympathised whereas others behave oppositely. Northern Europeans are lass likely to report pain as other people of Italian or Jewish origin (Bergius *et al.,* 2000).

1.10.2 Causes of orthodontic pain

Potentially painful procedures as described by the orthodontic literature include:

- Placement of separators
- Placement and activation of archwires
- Functional appliances
- Removable appliances
- Headgear
- Placement of temporary anchorage devices
- Debonding

In order to improve patient experience it is important to recognise which procedures cause pain during orthodontic treatment so the same patient can be warned of the risk of pain occurring during their treatment.

1.10.3 Pain associated with placement of Temporary anchorage devices

Temporary anchorage devices (TADs) are usually placed chairside using minimal local anaesthetic to provide soft-tissue analgesia. The placement of TADs has been compared to other orthodontic procedures (Lee *et al*., 2008) and 78% of patients believed that they would experience greater pain than they actually experienced. Kuroda *et al*., 2007 also established that TADs, which are placed without any incisions or mucoperiosteal flaps, are significantly more comfortable. This could be explained by the potentially less soft tissue damage when TADs are placed transmucosally.

1.10.4 Patient's experience of TAD placement

Patient compliance is very important for successful orthodontic treatment and is usually quite dependent on their pain experience. The literature is quite scarce on evidence for toleration of TADs by patients (Cornelis *et al.,* 2008). Asscherickx *et al.,* (2010) and Lee *et al.,* (2008) have rated placement of TADs less painful to other orthodontic procedures or even tooth extractions, even though patients usually expect otherwise.

1.11 Assessment of pain

Pain is a very subjective experience and there is a lot of individual variation hence the need to assess it in an indirect manner. The visual analogue scale, the verbal rating scale and the numerical rating scale are examples of unidimensional scales that measure intensity of pain. These are incorporated in self-administered questionnaires often in turn used to assess acute pain. On the other hand the McGill

pain questionnaire is an example used to measure chronic pain. From published studies it can be determined that orthodontic pain is often assessed using the visual analogue scale, the numerical rating scale or a modified form of the McGill pain questionnaire.

1.11.1 Visual analogue scale

The visual analogue scale consists of a line, usually 100 mm long, which denotes the extremes of pain at its ends (see figure 1.11). The patient is asked to mark the level of his or her pain at a particular point along the line. The pain score is determined from the measured distance of the mark along the scale. This scale is a reliable and sensitive method of measuring pain and the effect of pain reducing methods. It also allows the patient to choose the exact intensity of the pain experienced without bias (Huskisson, 1974; Seymour *et al*., 1982 and 1985). Patients of age 5 and over are able to understand and fully complete a given visual analogue scale (Bergius *et al*., 2002).

Figure 1.11 The visual analogue scale

1.11.2 Verbal rating scale

Verbal rating scales are made up of a ranked list of words that describe pain rather than a measurable scale. The patient needs to choose the word that describes best

his or her level of pain. These scales are quite easy to use but tend to be less sensitive to differences between levels of pain than other scales (Searle *et al.,* 2008).

1.11.3 Numerical rating scale

Numerical rating scales give an indication of pain level by the patient giving a score usually from one to ten with no pain at one end and worst pain at the other end.

1.11.4 The McGill pain questionnaire

The McGill pain questionnaire (Melzack, 1975) is more versatile but classically consists of three sections. A descriptive scale to record the current pain intensity, a diagram of a human where the pain location gets marked and a pain-rating index based on the selection of words from 20 different categories. This scale tends to be time consuming even though it has been found very useful in pain studies (Sokka, 2003).

1.11.5 Clinically significant difference in pain scores with visual analogue scales

Clinical management of pain is performed using either pharmacological or non-pharmacological methods. Most studies that have set out to determine the clinically significant pain score reduction in young people have been carried out in Accident and Emergency departments on children and adolescents in acute pain. The range of clinically significant reduction in pain scores on a 100 mm VAS has been reported to be from 10 mm (Powell *et al*., 2001) to 13 mm (Todd *et al.,* 1996). There have not

been any further studies to determine clinically significant reduction in pain levels for orthodontic patients to the best of the author's knowledge.

1.12 Pain control during orthodontics

There is a wide variation of pharmacological and non-pharmacological methods that have been used to reduce pain caused by orthodontic intervention:

- Non-steroidal anti-inflammatories (NSAIDs)
- Bite wafers
- Transcutaneous electrical nerve stimulation (TENS)
- Low level laser use.

1.12.1 Pharmacological control

The literature includes several studies that have investigated the effect of different analgesics successful in reducing orthodontic pain (Ngan *et al*., 1994; Steen Law *et al*., 2000; Arias *et al*., 2006; Bradley *et al*., 2007; De Carlos *et al*., 2007).

Non-steroidal anti-inflammatories (NSAIDs) reduce orthodontic pain by inhibiting the inflammation caused by orthodontic force. The mian mode of action is by peripherally stopping the synthesis of prostaglandins at the site of injury through inhibition of the cyclo-oxygenase enzymes (COX-1 and COX-2). Phospholipase A_2 cleaves arachidonic acid from the phospholipid cell membrane and the COX enzymes act on the arachidonic acid to produce prostaglandins. There is a major concern though that long-term use of NSAIDs might inhibit tooth movement.

Paracetamol acts centrally by inhibiting COX-3 enzymes in the brain and spinal cord. Bradley *et al*. (2007) compared the effects of ibuprofen with paracetamol and concluded that ibuprofen was more successful in the controlling orthodontic pain. In contrast a study by Bird *et al*. (2007) compared the reduction of pain from separators between the same mentioned anagesics and found no significant difference.

1.12.2 Non-pharmacological control

Low-level laser therapy theoretically is able to reduce pain by a non-thermal and a biostimulatory effect. There is either a direct effect on the nerve fibres that stabilises the depolarizing potential or by an inhibitory effect on inflammation. Dental applications of low-level laser therapy management of trigeminal neuralgia, dentine hypersensitivity and oral mucositis.

Transcutaneous electrical nerve stimulation (TENS) inhibits the unmyelinated C-fibres in the spinal cord and stimulates the A-β fibres (the gate control theory). Roth *et al.* (1986) found TENS effective in the reduction of pain when using separators.

Chewing on a bite wafer to reduce pain has been a concept of split thought. Mangnall (2011) found that the pain experienced in the posterior during debond is significantly reduced by biting on an acrylic wafer. Other studies have found that bite wafers may increase the pain or made no difference at all (Hwang *et al*. 1994, Otasevic *et al.* 2006, Bhogal *et al.* 2008).

The Tooth Masseuse™ is commercially designed to be used after bond-up and activation of fixed appliances to block the ischaemic response that results in pain. It produces vibratory effects to the teeth. This device may not always be tolerated well especially if used after the onset of pain (Marie *et al.,* 2003).

CHAPTER 2

MATERIALS AND METHODS

Page

Chapter 2: Materials and methods 38

2.1 Study aims 40

2.2 Null hypothesis 40

2.3 Study design 40

2.4 Ethical approval and Research and Development approval 41

2.5 Randomisation process 41

2.6 Sample size 42

2.7 Subjects 42

- 2.7.1 Inclusion criteria 42
- 2.7.2 Exclusion criteria 43

2.8 Method 43

- 2.8.1 Placement method 44
- 2.8.2 TAD and O-Cap 45
- 2.8.3 Questionnaires 48
- 2.8.4 Outcome measurements 49
- 2.8.5 Statistical analysis 50

2.1 Study aims

The aims of the study are:

- To determine whether the placement of an O-Cap (described to the patients as the different version of TAD) reduces the discomfort experienced after TAD placement
- To determine the expectations of pain during placement of TADs
- To determine the discomfort during placement of 3M Unitek TAD

2.2 Null Hypothesis

Placement of an O-Cap does not affect discomfort experienced in the first 6 weeks of treatment.

2.3. Study design

The study was designed as a pilot, multicentre split mouth randomised controlled trial of patients who need fixed orthodontic appliances supplemented with bilateral TAD placement for extra anchorage. The recruiting orthodontic departments included Mid-Staffordshire NHS Foundation Trust, University Hospital of North Staffordshire, Birmingham Dental Hospital and Countess of Chester Hospital NHS Trust.

All subjects who met the inclusion criteria were invited to take part and subsequently provided with an information leaflet together with the standard BOS leaflet on TADs. Once informed consent was obtained from the patient, the left and right halves of the mouth were randomly assigned to having a TAD or a TAD with an O-Cap placed. The subjects were asked to complete a set of questionnaires to determine their pain

experience prior to and following TAD placement at different time-points, 1 hour, 4 hours, 1 week, 2 weeks and 6 weeks later at recall outpatient appointment. Patients participating in the study were also included in the national BOS Audit on miniscrews.

The local collaborators in the trial were not aware of which side was assigned to receive the O-Cap until the time of TAD placement. The principal investigator (AP) who analysed the questionnaires was blind to the side allocations throughout the whole process.

2.4 Ethical Approval and Research and Development approval

Ethical approval was gained from the East Midlands and Derby Research Ethics Committee. Reference number: 11/EM/0394. Local NHS Research and Development approval was gained for the four research sites and site-specific approval was also obtained from the respective local Research and Ethics Committees.

2.5 Randomisation process

30 sealed brown envelopes were used to conceal the side of the mouth to receive the O-Cap at the time of TAD placement. They carried equal numbers of left and right side assignment papers and were shuffled by an independent individual. The envelopes were kept in a locked office at one of the research sites and subsequently opened by an independent staff member at the time of TAD placement.

2.6 Sample size

This is the first study to evaluate the effect of O-Cap placement on discomfort associated with TADs. Therefore, no formal sample size calculation is presented for this pilot study. We planned to recruit 25 patients and permission was gained for further recruitment in case of dropouts or TAD failures.

2.7 Subjects

30 subjects were recruited from April 2012 to March 2013 from the Orthodontic Departments at Mid-Staffordshire NHS Foundation Trust, University Hospital of North Staffordshire, and Birmingham Dental Hospital. All potential participants had been referred for orthodontic treatment and were approached at their first consultation outpatient appointment. They were invited to participate following full explanation about the purpose of the trial and provision of a letter of invitation along with an information sheet. For those under 16 years of age, their parent or guardian also received an information sheet.

2.7.1 Inclusion criteria

- Informed consent gained
- Male/females under 18 years of age
- Fully erupted upper second premolar and upper first permanent molar and sufficient space to allow TAD placement
- Treatment plan of extraction of both upper first premolars

- Requirement for anchorage reinforcement which could be achieved with placement of two maxillary TADs between the upper second premolar and the upper first permanent molar to reinforce anchorage

2.7.2 Exclusion criteria

- Patients who had completed a previous course of orthodontic treatment as prior experience of treatment and discomfort could bias the results
- Patients unable to comprehend or complete the questionnaire
- Patients with cleft lip or palate or any other dentofacial deformity
- Patients with previous surgery to the insertion site or planned orthognathic surgery

2.8 Method

Informed consent was obtained for each participant. All patients underwent thorough oral prophylaxis and pre-orthodontic restorative procedures prior to starting treatment. TADs were placed prior to any planned extractions and appliance placement to minimise confounding pain variables resulting from these procedures. At the time of TAD placement a sealed envelope was assigned for each patient according to the order in which he or she were recruited. Placement of TADs was carried out by 4 clinicians involved in the trial – JS, JS, LM, AP. All participants completed a questionnaire to determine their experience of TAD placement at different time-points. The first section of the questionnaire (A) investigated the expectations of discomfort during TAD placement, immediately prior to the procedure. There was a similar section (B) immediately post placement to find out

the exact nature of the patient's experience of the actual procedure. Further sections followed at time points 1 hour (C), 4 hours (D) and 24 hours (E) after placement in order to investigate any changes in discomfort taking place as the analgesia wore off. The patient was then asked to complete the final sections of the questionnaires 1 week (F), 2 weeks (G) at home and finally 6-8 weeks (H) later at the recall outpatient appointment.

The questionnaire (please refer to Appendix 1) consisted of simple questions or completion of a visual analogue scale to determine discomfort. One of the local collaborators was always present whilst the questionnaires were answered to supervise and provide further information if required.

2.8.1 Placement method

The following placement method was agreed upon by all clinicians involved in this study in order to standardise the procedure. Prior to insertion, the interdental space between the maxillary second premolar and maxillary first molar was assessed for bone quality and quantity utilising the orthopantamogram taken previously as part of the initial orthodontic records. The TAD required a clear margin of at least 2.5mm between the roots of the teeth. The patient was asked to complete questionnaire A. Topical anesthetic gel (20% Benzocaine) was applied for 3 to 5 minutes on the attached gingivae where the TAD was designated followed by buccal infiltration of 0.3ml of Lidocaine (2% Lignocaine 1:80,000 adrenaline) local anaesthetic in the adjacent free gingivae. This application was repeated for both the left and the right side. The planned site of insertion was clearly marked in between the distal and the

mesial root eminences of the maxillary second premolar and maxillary first permanent molar respectively using a Williams periodontal probe (Figure 1). The patient was asked to rinse for a minute with 15ml of 0.12% Chlorhexidine Gluconate mouthwash. This was followed with placement of self-threading TADS bilaterally at 45^0 to 90^0 just below the junction between the attached and free gingivae. Each TAD was inserted until half the cuff was buried. An O-Cap was then placed only on the TAD, indicated by the random allocation. The patient was asked to complete Questionnaire B immediately after placement of TADs and O-Cap and the remaining questionnaires C to G were given to the patient to take home for completion at the respective time-points as specified on them. Permission was granted to the principal investigator by each participant and or parents to send text reminders at the appropriate time to ensure completion of questionnaires. The final questionnaire H was completed at the recall outpatient appointment. At this point the TAD was engaged with the bracket of the maxillary second premolar using a 0.010" stainless steel ligature wire, which was passed through the hole of the head of the implant. An extraction letter for removal of both upper first premolars was also given and bonding of upper and lower fixed appliances was planned for the subsequent visit.

2.8.2 TAD and O-Cap

Titanium self-threading TADs of 1.8mm diameter and 6mm tapered length were used in this trial. The design is composed of a 2.4mm head with holes attached to a 1.5mm squared cuff (Figure 2). The TAD used in the trial is a product manufactured by 3M Unitek and was particularly chosen because it is one of the few products of its

type to come available with an adjunctive O-Cap designed to protect soft tissues and as a means of attachment for auxilliaries. The O-Cap, which is supported by a rubber O-ring, is designed to fit tightly over the head of the TAD and also has a retentive groove at the neck.

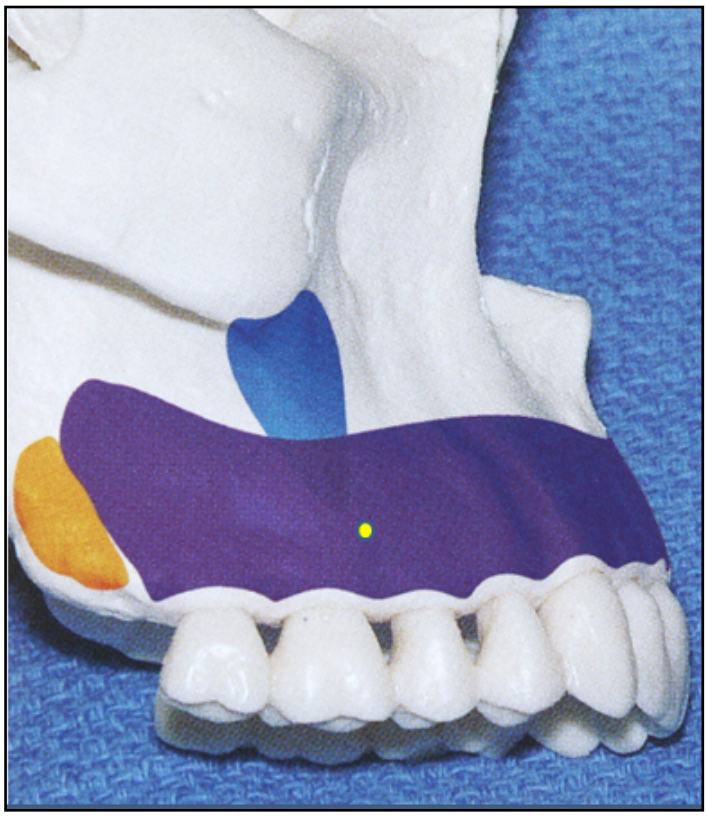
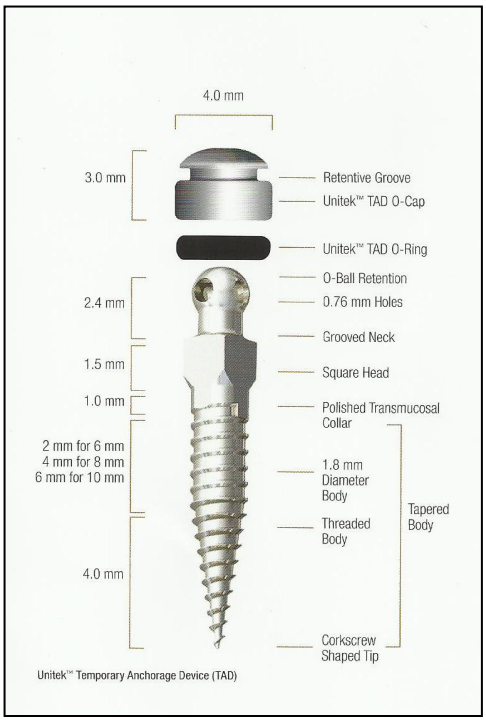


Figure 2.8.1 TAD insertion site



O-Cap
MH-4

O-Ring
IM0351-01

Figure 2.8.2. Imtec TAD and O-Cap (courtesy of 3M Unitek)

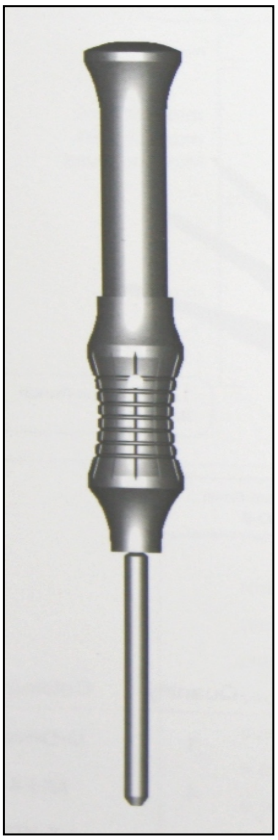


Figure 2.8.4 Self-threading O- driver

2.8.3 Questionnaires

Each patient was asked to complete an anonymised questionnaire (see appendix 1) with 8 short sections labelled A to H according to different time-points and rate the severity of their discomfort using a visual analogue scale (VAS). The 100 mm line was labelled at the extremes with "no pain" and a happy face and "worst pain imaginable" and a sad face. Similar faces were also placed at 20 mm intervals along the same line. The subjects placed a vertical line on the scale to mark the point corresponding to their level of pain. Comment boxes were also added to give the participants an opportunity to express any added concerns or remarks.

The first section (A) completed immediately prior to TAD placement enquired about the perceived expectations and discomfort that the patient would experience during the intervention. A comment box enquired about any specific concerns that the patient might have at that point. The second questionnaire (B) recorded the amount of pain experienced during the intervention. The patient was asked to compare the discomfort experienced immediately after placement between the cheeks of each side. A comment was also included here to allow the patient to comment on their worst perceived aspect of the intervention. Similarly the following questionnaire (C), which was completed an hour after the TADs placement, included visual analogue scales for the patient to score the amount of pain experienced for the soft tissues of the cheeks and gingivae on each side together with a comment box on any pain relief that was required to control the pain. Questionnaires D to G followed the same pattern of questions applied to different time-points 4 hours as the local anaesthetic started to wear off, 2 hours, 1 week, 2 weeks and 6 weeks later. The final questionnaire (H) completed at recall outpatient appointment, also asked the patient

to identify which intervention was the most uncomfortable from having TADs placed or teeth extracted. This was completed at the bond-up appointment once the extractions had been carried out by the general dental practitioner.

The visual analogue scale scores were measured using digital callipers by one operator (AP). The operator was blinded to the group. Intra-examiner reliability for the measurement of the VAS was tested by re-measuring 15 questionnaires one month later.

2.8.4. Outcome measurements

The completed questionnaires represented the severity of discomfort experienced by the patient on visual analogue scales at different time-points.

Primary endpoint:

The primary endpoint is the difference in soft tissue discomfort levels as measured on the VAS between sides with O-Cap and sides without O-Cap.

Secondary endpoints:

- Anticipated level of discomfort with TAD placement
- Perceived level of discomfort with TAD placement
- Perceived level of discomfort associated with TADs at different time points
- Perceived level of discomfort associated with soft tissues around TADs at different time points
- Any adverse events
- Retention rates
- Proportion of patients who completed study

2.8.5 Statistical analysis

All statistical analysis were performed with STATA 11.2 (Statacorp., College Station, TX, U.S.A).

The resultant data was not normally distributed and so the effect of placing an O-Cap on the TAD was assessed using Wilcoxon signed rank test, a non-parametric statistical test.

Spearman's Rank correlations were determined between the overall pain experienced during the placement of TADs, the level of anxiety prior to placement and the overall pain expected during the placement.

Descriptive statistics were used to determine the most painful time-point for gums and cheeks following the placement of TADs.

The intra-examiner reliability for the measurement of the VAS was assessed using intraclass correlation coefficient following re-measurement of 15 VAS, 3 months apart.

CHAPTER 3

RESULTS

Page

Chapter 3: Results 51

3.1 Baseline results 54

3.1.1. Descriptive data 54

3.1.2. Expectations of overall experience of placement of TADs 55

3.1.3. Expectations of pain during placement of TADs 56

3.2 Results 57

3.2.1 Actual pain experienced during the placement of TADs 57

3.2.2. Discomfort experienced in the cheeks after placement of TADs without the O-Cap 61

3.2.3 Discomfort experienced in the cheeks after placement of TADs with the O-Cap 62

3.2.4 Discomfort experienced in the gingivae after placement of TADs 70 without the O-Cap 63

3.2.5 Discomfort experienced in the gingivae after placement of TADs with the O-Cap 64

3.2.6 Discomfort experienced with placement of TADs with and without O-Cap 65

3.2.7 Pain relief 69

3.2.8 Extractions versus placement of TADs 70

3.3 Analysis of the results 71

3.3.1 Wilcoxon Signed Rank analysis of cheek discomfort levels of TADs with and without O-Caps 71

3.3.2 Wilcoxon Signed Rank analysis of gum discomfort levels of TADs with and without O-Caps 71

3.3.3 Spearman's Rank Correlations 72

3.4 Intra-examiner reliability 73

3.1 Baseline results

3.1.1. Descriptive data

A favourable ethical opinion was granted in January 2012 by Derby Research Ethics Committee (Reference number 11/EM/0394). The recruitment of participants commenced on April 2012 and was completed in May 2013. The sample consisted of 30 subjects all of whom agreed to participate in the trial when approached during their outpatient new patient appointment. 18 subjects were recruited from Mid-Staffordshire District General Hospital, 10 from University Hospital of North Staffordshire and 2 from Birmingham Dental Hospital. Overall there were more males than females (16 males, 14 females). The age of the patients ranged from 10 years 11 months to 18 years with a mean age of 14.64 years, see table 3.1.1.

All the patients accepted for orthodontic treatment in all hospital sites involved underwent a course of oral health education to standardise oral hygiene and avoid any complications from gingival inflammation. There were 60 TADs placed under local anaesthetic for this trial with 30 O-Caps randomly placed on one TAD in the allocated side. Equal numbers of O-Caps were allocated to left as to the right hand sides of subjects in the sample. Hundred percent response rate was achieved for the questionnaire provided but section H was not completed for three patients due to failure of four anchorage devices. Out of these subjects, one lost the TADs bilaterally and two subjects lost a TAD unilaterally. There was no specific cause determined for the failure of the TADs and an alternative anchorage solution was sought for the case with bilateral failure whilst the TAD was replaced for the cases with unilateral failure. In total four TADs failed during the trial period of 6 weeks giving an overall failure rate of 6.7%.

		Control	O-Cap		Total
			Left	Right	
TADs	Number	30	15	15	60
	Males (%)	16 (26.7)	11 (18.3)	5 (8.3)	32 (53.3)
	Females (%)	14 (23.3)	4 (6.7)	10 (16.7)	28 (46.7)
Age (years)	Mean (SD)	14.6 (1.6)			
	Median	14.5			
	Minimum	10.9			
	Maximum	18.1			

Table 3.1.1 Descriptive data

3.1.2. Expectations of overall experience of placement of TADs

The subjects marked their level of anxiety prior to having the TADs placed under local anaesthetic, see table 3.1.2. Overall the VAS pain scores varied considerably and ranged from 0 to 79.2 with a median score of 20.2.

Fifty percent of the completed comment boxes expressed concerns about having the local anaesthetic as part of the TAD placement. 33.7% of the subjects were concerned over the pain that the placement of TADs or the local anaesthetic injection could involve whilst 17% were worried about the feeling of having the “TADs inside the gums”. The remainder of the comments expressed no concerns or left the box vacant.

3.1.3. Expectations of pain during the placement of TADs

VAS scored in section A of the questionnaire illustrated the level of anxiety about pain of the subjects during the placement of the TADs under local anaesthetic. The range extended from 10.3 to 80.5 with a median of 39.9.

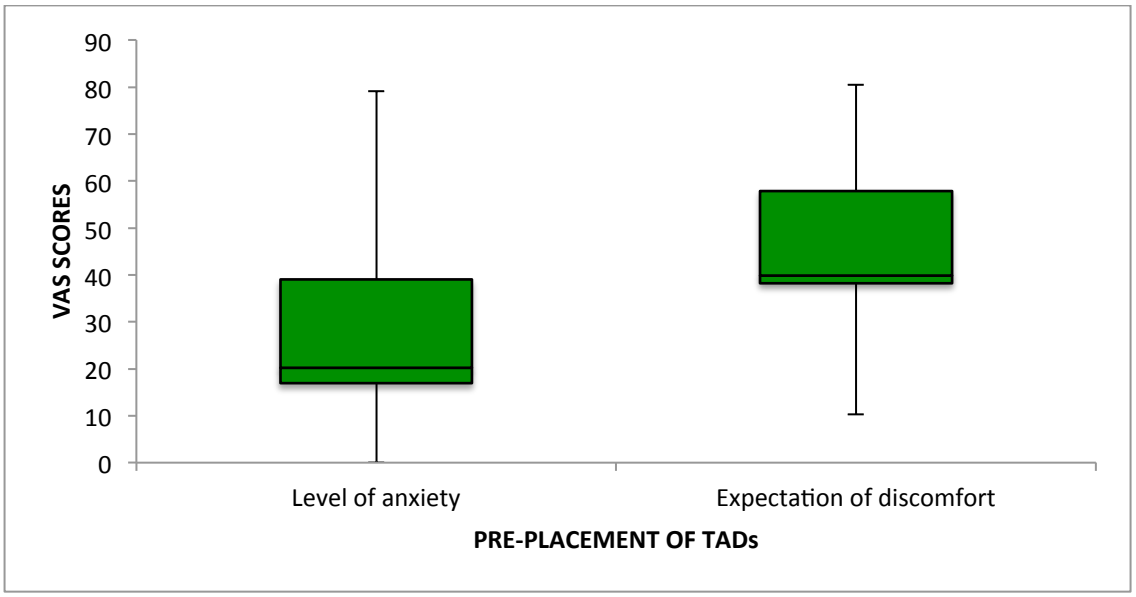


Figure 3.1.1 A box and whisker plots for the overall level of anxiety prior to and the actual expectations of discomfort experienced by the patient during the placement of TADs.

The box represents the 25th to 75th percentiles with the 50th percentile, also representing the median, indicated by the black line. The whiskers indicate the range, the minimum and maximum of the ranked values of the VAS scores.

TIME-POINT	VAS SCORES	
Level of anxiety prior to placement of TADs	Mean (SD)	27.8(18.8)
	Median	20.2
	Range	0 – 79.2
Expectations of pain during placement of TADs	Mean (SD)	45.7(18.3)
	Median	39.9
	Range	10.3 – 80.5

Table 3.1.2 Baseline results – VAS scores prior to placement of TADs

3.2 Results

3.2.1 Actual pain experienced during the placement of TADs

The subjects rated the level of pain they experienced during the placement of TADs after local anaesthetic administration. The range of VAS scores varied from 0 to 68.5 with a median of 13.7.

There highest VAS scores were recorded 1 hour following the placement of TADs, following which the subjects reduced their scorings throughout the subsequent 6 weeks, as assessed by the different time-points in the different sections of the questionnaire, see table 3.2.1.

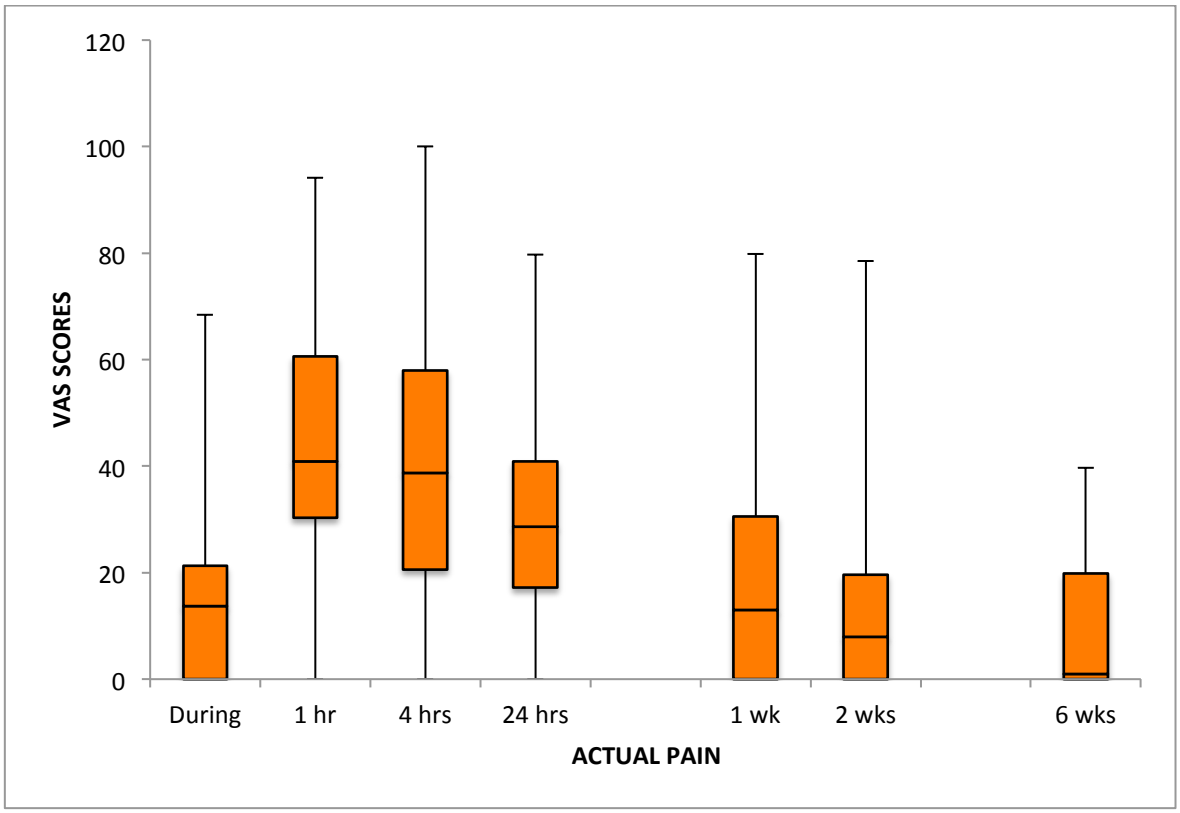


Figure 3.2.1 A box and whisker plot for the actual pain experienced during the placement of TADs and the following 6 weeks

Pain with placement of TADs at different time-points	VAS SCORES	
During placement of TADs	Mean (SD)	17.4(19.4)
	Median	13.7
	Range	0 – 68.5
1 hour	Mean (SD)	47.7 (24)
	Median	40.9
	Range	0 – 94.2
4 hours	Mean (SD)	41.1 (23.3)
	Median	38.8
	Range	0 - 100
24 hours	Mean (SD)	31.2 (23.6)
	Median	28.6
	Range	0 – 79.8
1 week	Mean (SD)	19.5 (22.6)
	Median	13
	Range	0 – 79.9
2 weeks	Mean (SD)	14.4 (19.7)
	Median	8
	Range	0 – 78.5
6 weeks	Mean (SD)	9.1 (11.7)
	Median	1
	Range	0 – 39.7

Table 3.2.1 Results – VAS scores for actual pain during the placement of TADs and the subsequent 6 weeks after the placement of TADs

Overall, the VAS scores rated prior to the placement of the TADs were higher than the VAS scores rating the actual pain experienced during the procedure, see figure 3.2.2. However, the VAS scores for the pain expectations were comparable to the high scores rated for the pain experienced 1 hour following the placement of the TADs.

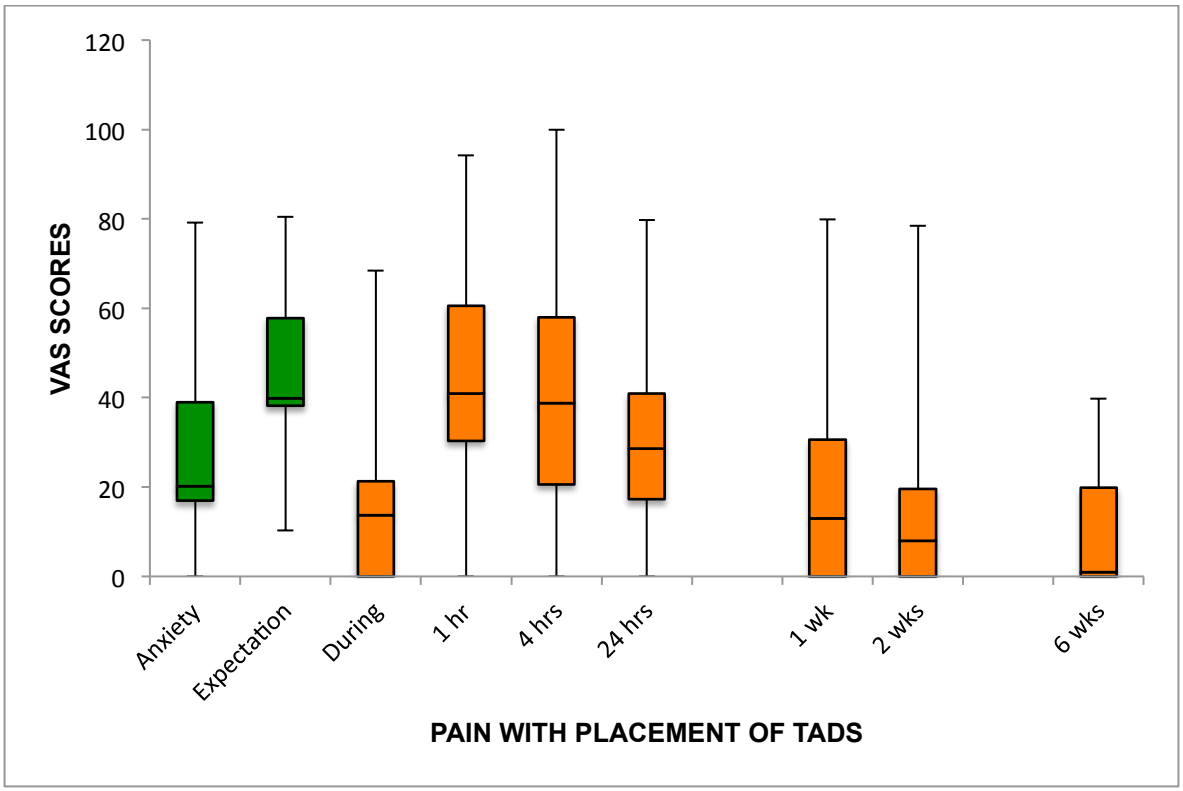


Figure 3.2.2 A box and whisker plot for the comparison between the patients' expectations and actual pain experienced during the placement of TADs

When the subjects were asked:

"What was the worst part of having the TAD placed?"

in Section B of the questionnaire, 33% felt that the local anaesthetic injection and the numbness were most uncomfortable. 23% of the subjects did not like the sensation of the TADs being inserted and 23 % did not feel that there was an uncomfortable instant at all during the procedure. The remainder of the subjects commented on slight pressure felt on insertion of the TADs and the stretch of the cheeks.

3.2.2. Discomfort experienced in the cheeks after placement of TADs without the O-Cap

Each subject scored the VAS in each section from B to H in the questionnaire to rate their level of discomfort of the cheeks bilaterally following placement of the TADs under local anaesthetic. The sections B to H covered the time period of immediately after, 1 hour, 4 hours, 24 hours, 1 week, 2 weeks and 6 weeks after the placement of the TADs, see table 3.2.2. The subjects could not be blinded as to which side received the TAD with the O-Cap but were told that the TADs inserted were different to each other in order to reduce bias.

The levels of discomfort of the cheeks were highest at 4 hours following placement of the TADs, with VAS scores ranging from 0 to 83.7 having a median of 42.1. The scores reduced consistently following the first day reaching the lowest level of discomfort at 6 weeks with VAS scores ranging from 0 to 40.4 with a median of 9.1.

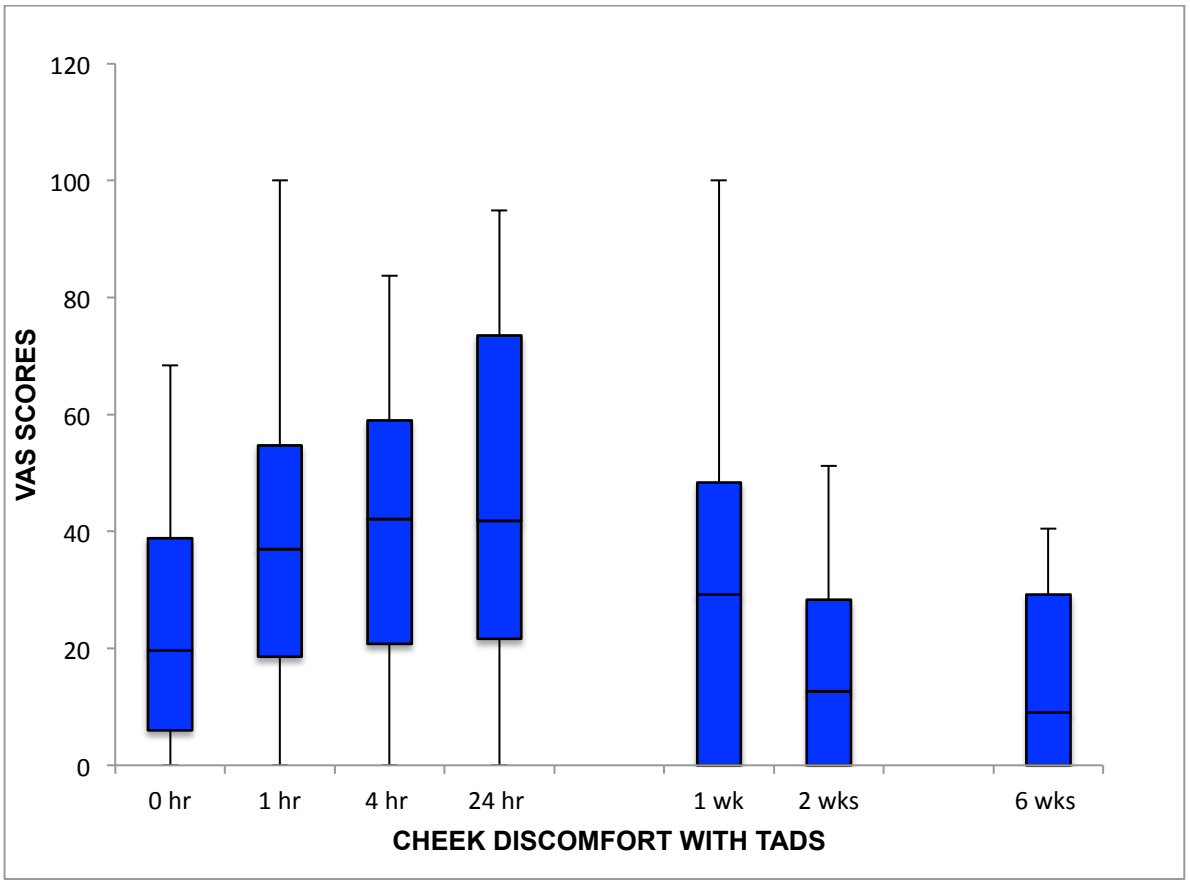


Figure 3.2.3 A box and whisker plot illustrating the levels of discomfort experienced in the cheeks after placement of TADS without O-Caps

3.2.3 Discomfort experienced in the cheeks after placement of TADs with the O-Cap

The VAS scores for the side with the TAD that received an O-Cap were higher than the VAS scores for the side without the O-Cap initially at the time of placement but reduced consistently following this time-point to a reach the lowest VAS scores recorded for cheek discomfort at 6 weeks. The scores at this time-point ranged from 0 to 53.6, with a median of 0.

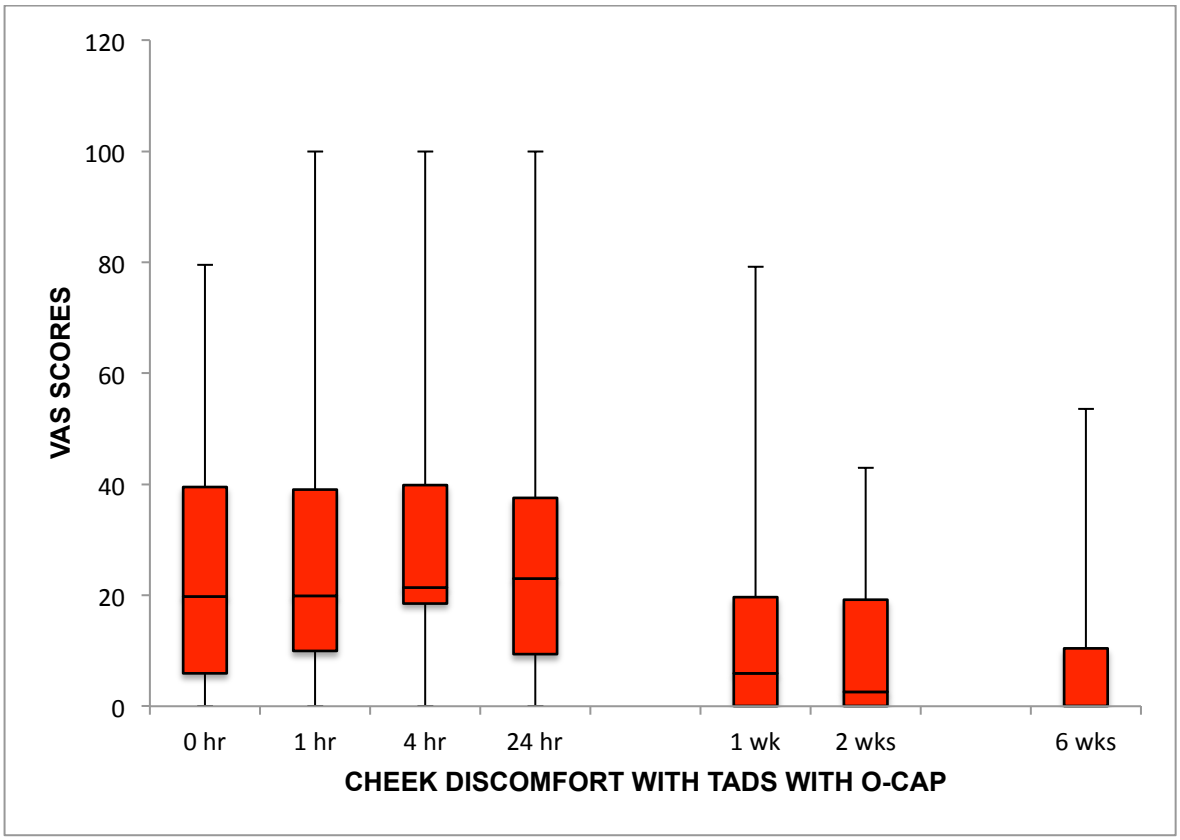


Figure 3.2.4. A box and whisker plot illustrating the levels of discomfort experienced in the cheeks after placement of TADS with O-Caps

3.2.4 Discomfort experienced in the gingivae after placement of TADs without the O-Cap

Similarly to cheek discomfort, the subjects scored their level of pain experienced for the gingivae at different time-points on the questionnaire. These time-points included 1 hour, 4 hours, 24 hours, 1 week, 2 weeks and 6 weeks after the placement of the TADs, see table 3.2.2.

The levels of discomfort for the gingivae of sides with TADs without O-Cap were highest at 1 hour following placement and then reduced throughout the period of 6 weeks. The lowest scores were achieved at 6 weeks following placement once again and ranged from 0 to 59.5, with a median of 1.8.

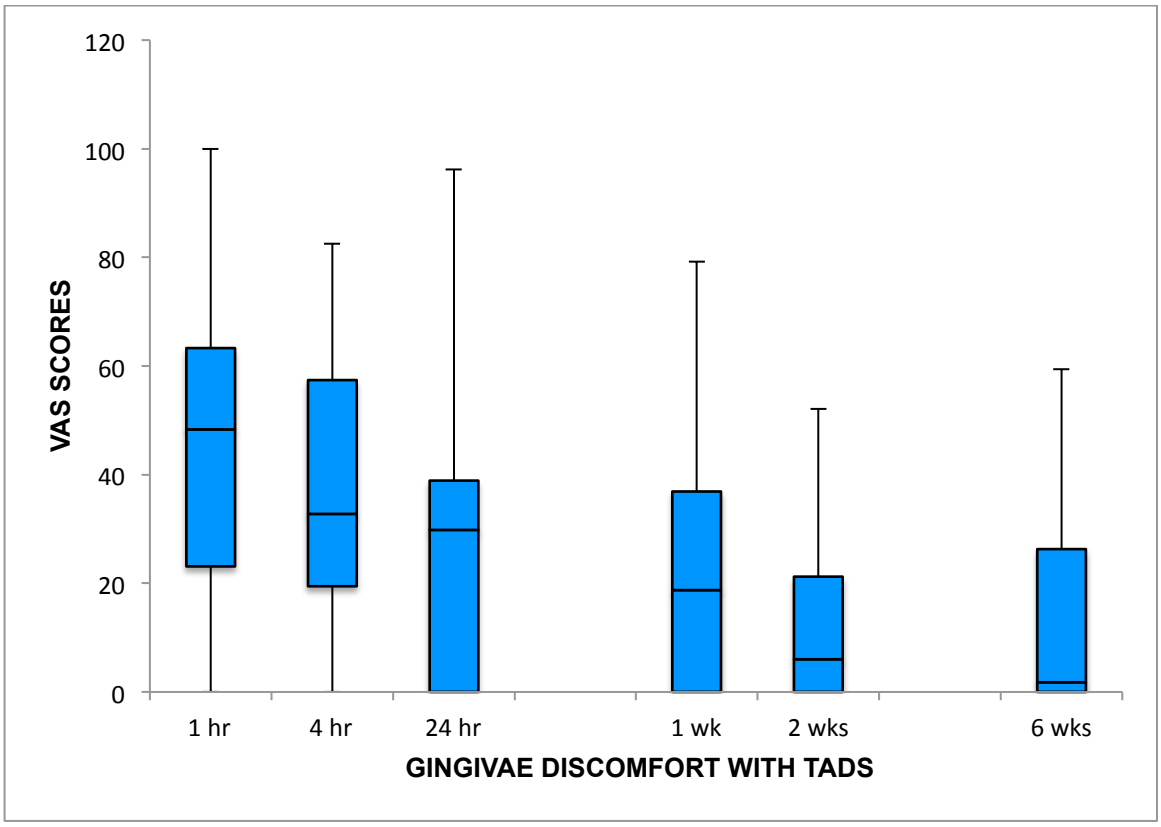


Figure 3.2.5. A box and whisker plot illustrating the levels of discomfort experienced in the gingivae after placement of TADS without O-Caps

3.2.5 Discomfort experienced in the gingivae after placement of TADs with the O-Cap

The VAS scores for the levels of gingival discomfort associated with TADs, which received an O-Cap, followed a similar pattern to the ones for the TADs without the O-Caps but were lower at every time-point.

The levels of discomfort for the gingivae of sides with TADs with the O-Cap were highest at 1 hour following placement and then reduced throughout the period of 6 weeks. The range of VAS scores at 1 hour following placement was from 0 to 100 and the median was 36.6. The lowest scores were achieved at 6 weeks following placement once again and ranged from 0 to 50.6, with a median of 0.

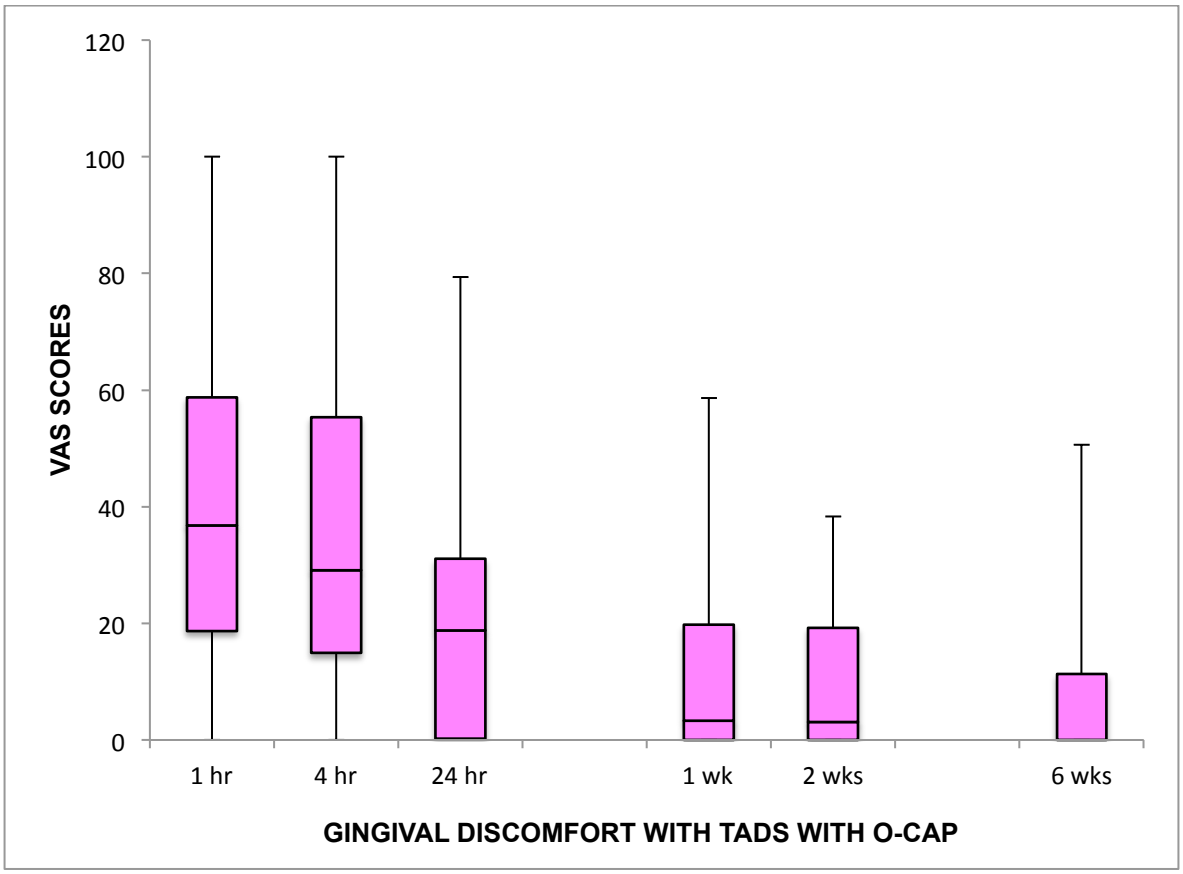


Figure 3.2.6. A box and whisker plot illustrating the levels of discomfort experienced in the gingivae after placement of TADS with O-Caps

3.2.6 Discomfort experienced with placement of TADs with and without O-Cap

The VAS scores rated showed a large variation. The subjects rated their pain experience higher in the control group (without the O-Caps) over all the time-points from immediately after to 6 weeks after the placement of TADs see table 3.2.2. Overall, the VAS scores reduced over the 6 weeks following placement of the TADs for both discomfort in the cheeks and the gingivae, see figures 3.2.7.and 3.2.8.

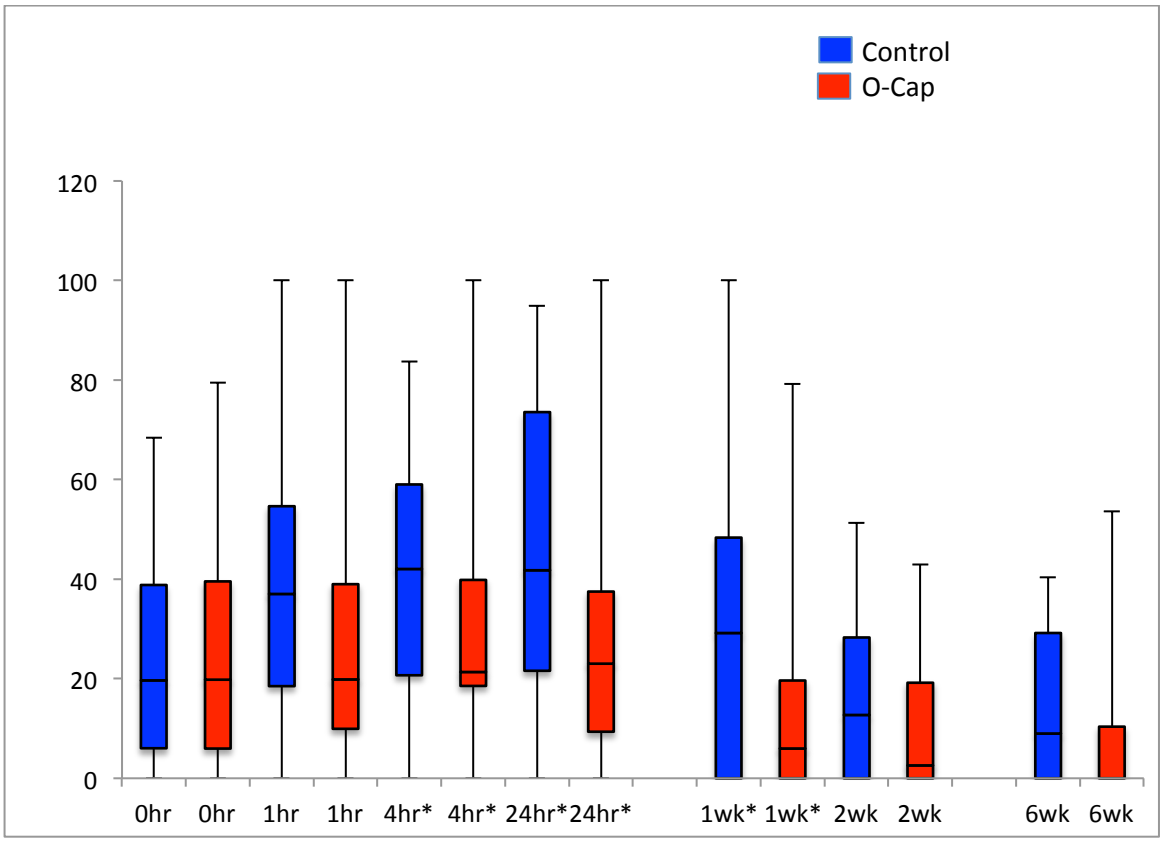


Figure 3.2.7. A box and whisker plot for the discomfort experienced in the cheeks after placement of the TADs with and without O-Caps over 6 weeks

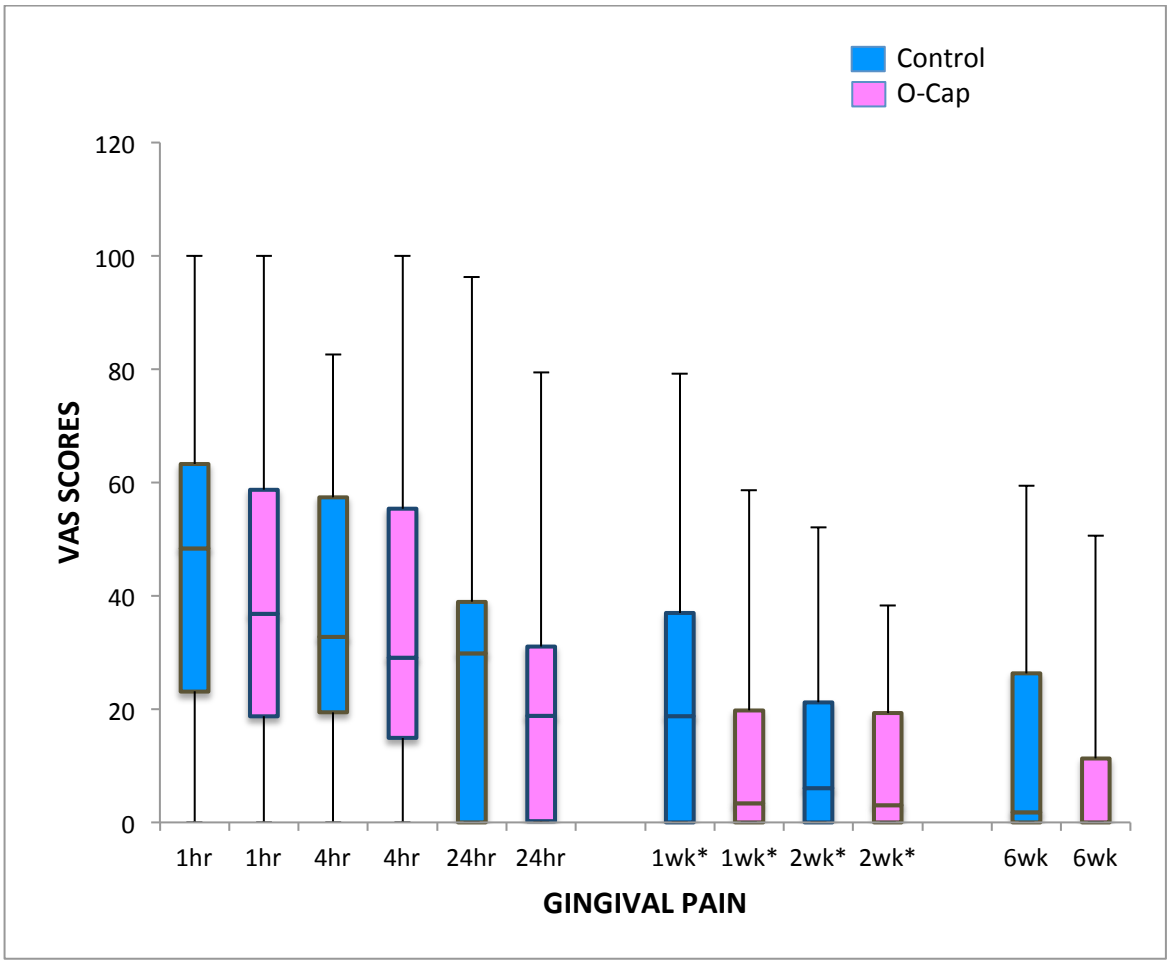


Figure 3.2.8. A box and whisker plot for the discomfort experienced in the gingivae after placement of the TADs with and without O-Caps over 6 weeks

Time-point after placement of TADs		VAS scores for discomfort experienced			
		Cheek		Gingivae	
		Control	O-Cap	Control	O-Cap
Immediately	Mean (SD)	22 (18.6)	24.4 (21.4)		
	Median	19.8	19.8		
	Range	0 – 68.4	0 – 79.5		
1 hour	Mean (SD)	38.4 (26.4)	28.2 (25)	47.6 (26.4)	37.6 (25.4)
	Median	37	19.9	48.4	36.8
	Range	0 – 100	0 – 100	0 – 100	0 - 100
4 hours	Mean (SD)	43.4 (23.7)	32.4 (25.1)	36.6 (27.3)	35.6 (27.9)
	Median	42.1	21.4	32.8	29.1
	Range	0 – 83.7	0 - 100	0 – 82.6	0 - 100
24 hours	Mean (SD)	45.2 (30.4)	27.9 (25)	26.5 (26.5)	20.8 (20.7)
	Median	41.8	23	29.9	18.8
	Range	0 – 94.9	0 - 100	0 – 96.2	0 – 79.4
1 week	Mean (SD)	31.4 (28.9)	12 (17)	21.3 (23.6)	12.2 (15.8)
	Median	29.2	6	18.8	3.3
	Range	0 – 100	0 – 79.2	0 – 79.2	0 – 58.6
2 weeks	Mean (SD)	14.7 (15.1)	9.5 (12.6)	13.7 (16.5)	8.9 (10.9)
	Median	12.7	2.6	6.1	3.1
	Range	0 – 51.2	0 – 43	0 – 52.1	0 – 38.3
6 weeks	Mean (SD)	14.1 (15.3)	7.8 (12.9)	13.2 (17.9)	8.4 (12.7)
	Median	9.1	0	1.8	0
	Range	0 – 40.4	0 – 53.6	0 – 59.5	0 – 50.6

Figure 3.2.2 Results- VAS score data for the level of discomfort of the cheeks and gingival experienced following placement of TADs with and without O-Cap

When asked which side was more uncomfortable immediately after and over the 6 weeks following placement of the TADs, more subjects rated the TAD with the O-Cap more uncomfortable during time-points 1 hour and 4 hours after placement. However, over the subsequent 24 hour to 6-week time-points, the TAD without the O-Cap was more uncomfortable. The subjects experiencing no difference in discomfort between

the left and the right sides increased as time passed following the placement of the TADs.

Time-point after placement of TADs	More uncomfortable side (% ratings)			
	Control	O-Cap	Same	Not rated
Immediately after	30	37	33	-
1 hour	30	47	23	-
4 hours	37	33	27	3
24 hours	47	26	27	-
1 week	47	10	43	-
2 weeks	27	13	57	3
6 weeks	33	7	50	10

Table 3.2.3. The percentage rating of the more uncomfortable side immediately after and over the subsequent 6 weeks following the placement of the TADs.

3.2.7 Pain relief

Sections C to H in the questionnaires (time-points 1 hour, 4 hours, 1 week, 2 weeks and 6 weeks after placement of TADs) asked the subjects whether any pain relief has been taken and which type was taken.

47% of the subjects felt the need to take pain relief, which varied from paracetamol, ibuprofen, Beechams©, co-codamol and Bonjela©. The number of subjects taking pain relief reduced as more time passed following the placement of TADs until none of them were making any use of pain relief at 6 weeks following placement.

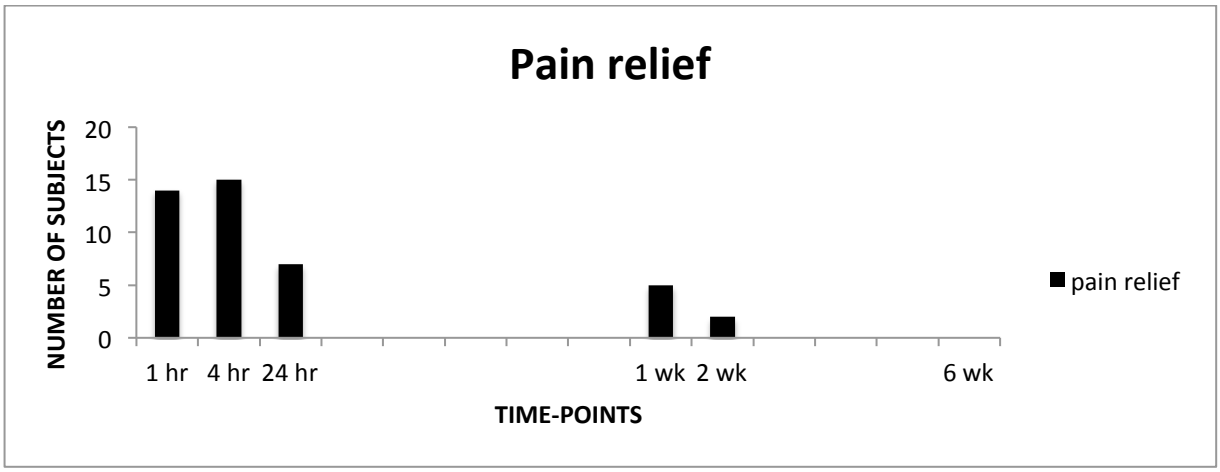


Figure 3.2.9. Bar graph illustrating the frequency of pain relief during the 6 weeks following the placement of TADs.

3.2.8 Extractions versus placement of TADs

Once the questionnaire was fully completed, at the recall outpatient appointment 6 weeks following the placement of TADs, the subjects were given a subsequent appointment for bonding up of the fixed appliances, by which time both upper first premolars been extracted. At this appointment the subjects were each asked which of the two procedures, having the teeth extracted or the TADs placed, did they find most uncomfortable.

80% reported that extraction of teeth was more uncomfortable, whilst 3% were unsure leaving the remainder percentage to subjects who felt that having TADs placed was more uncomfortable. 3 out of the latter 5 subjects commented that placement of TADs turned out to be worse than extractions of teeth because they had never experienced administration of local anaesthetic prior to having the TADs placed.

3.3 Analysis of the results

3.3.1 Wilcoxon Signed Rank analysis of cheek discomfort levels of TADs with and without O-Caps

Wilcoxon signed rank analysis was used to examine the effect of the O-Cap on the discomfort levels between the sides having the TADs with and without the O-Caps.

The results showed the pain scores for the control group to be higher than those for the O-Cap group for all time-points. Wilcoxon signed-rank test showed statistically significant differences at time-points 4 hour post-placement ($p<0.05$), 24hour ($p<0.05$) and 1 week ($p<0.0005$) for cheek discomfort.

Wilcoxon sign rank analysis	**Cheek discomfort: control versus O-Cap scores**						
	Immediately after	**1 hour**	**4 hours**	**24 hours**	**1 week**	**2 weeks**	**6 weeks**
z	- 0.743	-1.674	-2.30	- 2.107	- 3.508	-1.775	- 1.390
Significance P value	0.4577	0.094	***0.0215***	***0.0351***	***0.0005***	0.0759	0.1645

Table 3.2.4 The Wilcoxon Signed Ranks Test to compare the cheek pain scores for TADs with and without O-Caps at different time-points after placement.

3.3.2 Wilcoxon Signed Rank analysis of gingival discomfort levels of TADs with and without O-Caps

The results for gingival discomfort showed that the pain scores for the control group were also higher than those for the O-Cap group for all time-points. Wilcoxon signed-

rank test showed statistically significant levels at time-points 1 week ($p<0.05$) and 2 weeks ($P<0.05$) for gingival discomfort.

Wilcoxon sign rank analysis	**Gingival discomfort: control versus O-Cap scores**					
	1 hour	**4 hours**	**24 hours**	**1 week**	**2 weeks**	**6 weeks**
z	- 1.742	-1.026	- 1.315	- 2.473	-2.403	- 0.627
Significance P value	0.0815	0.3051	0.1883	***0.0134***	***0.0162***	0.5306

Table 3.2.5 The Wilcoxon Signed Ranks Test to compare the gingival pain scores for TADs with and without O-Caps at different time-points after placement.

3.3.3 Spearman's Rank Correlations

The Spearman Rank correlation test was used to analyse the correlations between the rated VAS scores for the expected levels of discomfort prior to placement of TADs and those for cheek discomfort for TADs without O-Caps (control group). There were weak positive correlations, however none of them were statistically significant.

		Cheek discomfort for control group					
		1 hour	**4 hours**	**24 hours**	**1 week**	**2 weeks**	**6 weeks**
Expected pain scores	**Correlation Coefficient *r***	0.2178	0.3286	0.0169	0.2054	0.1389	0.2424
	Significance P value	0.2476	0.0762	0.9292	0.2763	0.4643	0.2051
		Gingival discomfort for control group					
		1 hour	**4 hours**	**24 hours**	**1 week**	**2 weeks**	**6 weeks**
Expected pain scores	**Correlation Coefficient *r***	0.2231	0.1738	0.1855	0.1221	0.1652	0.1406
	Significance P value	0.2359	0.3585	0.3265	0.5205	0.3830	0.4669

Table 3.2.7. Spearman's rank correlations between expected pain VAS scores and cheek VAS scores for TADs without O-Caps.

3.4 Intra-examiner reliability

Intraclass correlation coefficient test was used for the measurement of the visual analogue scales was 0.99 indicating good intra-examiner reliability for the measurement of the visual analogue scale (see table 3.4.1).

Intraclass correlation	95% confidence interval of the difference
	Number of observations
0.9994	15

Table 3.4.1 The intraclass correlation coefficient analysis for the intra-examiner reliability of the measurement of the visual analogue scale pain scores

CHAPTER 4

DISCUSSION

Page

Chapter 4: Discussion 75

4.1 Baseline results 77

4.2 Effect of the O-Cap 82

4.1 Baseline results

Anchorage has been defined as resistance to unwanted tooth movement. Over the past 60 years several methods have been developed to prevent anchorage loss with minimal patient compliance possible. Some of the variables for anchorage control are linked to diagnosis, treatment planning and treatment mechanics and are more dependent on the orthodontist. Others such as elastic wear and use of headgear are very dependent on patient compliance. The increased popularity and use of temporary anchorage devices has developed to reduce the risks of poor patient compliance in the hope of providing more predictable outcomes. They also offer increased versatility in supporting tooth movements, such intrusion of teeth, hitherto very difficult to achieve with conventional appliance mechanics.

As new systems are continuously being introduced into the orthodontic market, there is a strong focus on improving the patient experience. This has been found to be strongly dependent on their experience of pain (Oliver and Knapman, 1985; Krukemeyer *et al,* 2009). However there is limited evidence on this aspect of skeletal anchorage. This trial investigated the effect an O-Cap has on the discomfort experienced by the patient following the placement of the temporary anchorage device. It also provided baseline data on patient expectations and pain experience in the early stages of Tad use.

STUDY DESIGN

The purpose of an O-Cap has been marketed by 3M Unitek as means of attachment of auxiliaries, preventing and soft tissue overgrowth and protecting adjacent soft tissue from trauma or irritation. Whilst practical experience suggests that the latter

benefit is helpful in clinical practice, there is no evidence to prove this. Hence the sample for this pilot trial could not based on a power of calculation from previous data and was carried out as a pilot study. A split mouth design was chosen to eliminate inter-individual variability from the treatment effect. Despite the commonly claimed disadvantage of carry-across effects, it was felt a crucial benefit to avoid problems caused by the subjectivity of pain. Pain has also been found to be dependent on other factors such as age, cultural differences and previous pain experience (Ngan *et al.*, 1989; Bergius *et al.,* 2000; Kluemper *et al.,* 2002). The mean age of this sample was 14 years 6 months, reflecting the greater majority of the orthodontic patient population. Adults over age 18 years were excluded from the trial to minimise orthognathic cases and effects of age on results especially since pain threshold has been found to increase with older age (Woodrow *et al.,* 1972). There was a slightly greater predilection for males in this sample. Most studies report no statistically significant differences in pain ratings between subjects of different gender (Ngan *et al*., 1989; Erdinç and Dinçer, 2004), but others have claimed that females may report more pain than males (Scheurer *et al*., 1996; Bergius *et al*., 2002). Ideally the gender number would have been completely balanced in the sample.

The TADs placed were not loaded immediately, nor were fixed appliances placed. This was in order to avoid confounding factors from tooth pain and soft tissue discomfort which are typical during the early stages of treatment caused by inflammation due to tooth movement and from abrasion of fixed appliances against the soft tissues.

Despite the increased popularity of temporary anchorage devices, the choice of an anchorage method may be down to clinician preference. Unless dictated by patient

circumstances, skeletal anchorage is used preferentially to other intraoral or extraoral anchorage methods at two of the hospital sites involved in this trial (Mid-Staffordshire Foundation Trust and University Hospital of North Staffordshire). At the third site (Birmingham Dental Hospital), the use of temporary anchorage devices is less common, hence the resultant reduced number of patients recruited compared to the Staffordshire sites. The fourth site Countess of Chester at this time were having issues with TAD failure and so although included in the original site planning had changed their preference for a different type of TAD and so no patients were recruited from this unit.

TAD FAILURE

The overall failure rate for the TADs in this trial was 6.7%. However favourable this may be, it is not necessarily comparable to the most recently published failure rate of 13.5% from a meta-analysis (Papageorgiou *et al.,* 2012). Success data is based on either having achieved the desired anchorage at the time of failure or removal. As this investigation dealt with the first six weeks of treatment only prior to engagement for anchorage these figures cannot be extrapolated as the true failure rate. It is however consistent with published data which show that unloaded TADs, if they fail at all, are likely to show reduced stability within the first three weeks of placement (Ure *et al.,* 2011).

EXPECTATIONS OF TAD PLACEMENT

The general feeling about having the TADs placed and the level of pain expected by each subject was recorded to give a baseline comparison for the pain scores that

followed and to assess the relationship between expectations of pain and actual pain experience. Some of these patients had never had any dental work carried out under local anaesthetic before and this could have been assessed during recruitment in order to reduce bias on pain scores. There was a considerable variation in the pain scores throughout the trial reflecting the individual subjectivity of pain.

The levels of expected pain were found to be higher than the actual pain experienced during the placement of TADs. The median VAS score varied from 39.87 for the expected levels to 13.72 for the actual pain. This correlates with previous literature, which shows that heightened anxiety about a procedure can lead to a greater pain experience. In a study in the same population group that looked at pain during debond Mangnall *et al* (2011) found that those patients who expected to have more pain did indeed record the procedure as more painful than those who did not expect the procedure to be painful. This relationship may be due to fear of the unknown or inaccurate information given for example by peer groups. It was clear from the written responses that many patients specifically cited fear of the injection and for many patients this will have been their first experience of an intra-oral injection. As needles are synonymous with a painful stimulus it is not surprising that these responses have been recorded.

PAIN EXPERIENCE

The level of pain after the placement of TADs peaked at 1 hour following the procedure reaching a median of 40.90 after which it progressively reduced throughout the subsequent 6 weeks to a median of 0.97. A study evaluating factors influencing the clinical usefulness of miniscrews examined the postoperative

discomfort experienced by patients having different types of miniscrews placed (Kuroda *et al.,* 2007). The results of our study followed a similar progression of pain levels after the placement of miniscrews.

The VAS levels reported by the patients were lower for the TADs placed with an overlying O-Cap than without, in all time-points for cheek and gingival discomfort. The Imtec O-Cap has been designed as an optional alternative means of auxiliary attachment to the TAD as well as for protection of adjacent tissues. There have been no similar studies looking into the benefits of the O-Cap after TAD placement to the author's knowledge but this study shows that an overlying healing cap improves the overall patient's pain experience. This reduction in pain levels could be brought about by the suppression of soft tissues especially immediately after the time of placement when the adjacent soft tissues may be tender or erythematous (Herman and Cope, 2005).

Gingival discomfort levels peaked at 1 hour after TAD placement whilst cheek discomfort levels peaked at 24 hours after the procedure reaching medians of 48.4 and 42.1 respectively. Such high ratings of pain levels occurring in the first few hours following placement reflect the time when the patient is getting used the sensation of the presence of the TAD in place and the local anaesthetic starts to wear off. The overall actual pain scores reduced consistently throughout the six weeks until recall appointment reaching a median of 1 with a range of values from 0 to 39.7. This pattern of pain level rating has been reported to follow a similar course in most orthodontic interventions (Erdinç and Dinçer 2004; Leavitt *et al.,* 2002)

ANALGESIA

Patients are usually advised to take pain relief shortly after orthodontic intervention. Despite this only half the subjects in the sample reported any intake of such medication. The type of pain relief taken by the subjects varied from Paracetamol, Ibuprofen, Co-codamol to Gengigel and Beechams sachets. Relief wax was also included in the comments at two time-points for one of the patients. The frequency of pain relief intake was higher at the immediate post-operative time period but progressively reduced by the end of the six-week study. This correlates to the course of pain level ratings reported by the same patients.

4.2 Effect of the O-Cap

Cheek discomfort resulted in a different pattern of VAS scores to gingival discomfort despite the similar large variation illustrated by the range of VAS values for each of the time-points. The pain levels for cheek discomfort built up during the first 24 hours after placement whilst those for gingival discomfort peaked immediately 1 hour after placement. Both slowly reduced during the rest of the assessed time period to a similar low level at 6 weeks. The TADs *in situ* following insertion clearly have a stronger influence on the overall patient's pain experience than the actual intervention.

There was a higher pain level scored with the TAD having no O-cap at all time-points with statistically significant difference in VAS scores at 4 hours ($p<0.05$), 24 hour ($p<0.05$) and 1 week ($p<0.0005$) for cheek discomfort. The higher pain levels for gingival discomfort were statistically significant at 1 week ($p<0.05$) and 2 weeks

($p<0.05$). The resultant comments in the questionnaires indicate that whilst the percentage of patients rating the control side remained constant, the percentage of patients rating the O-Cap side as more uncomfortable reduced drastically. Therefore, the null hypothesis that placing an O-Cap has no effect on the discomfort experienced in the first six weeks following placement can be rejected.

The statistical tests for possible correlations between expected and actual pain levels showed mild correlations, which were not statistically significant for any of the time-points. This should be considered with caution since the size of the sample is small.

Patients have different pain thresholds. Placing TADs at the very beginning of treatment does not give enough opportunity to assess the patient's anxiety levels and general response to treatment. Alternatively, reinforcing anchorage following alignment, might offer the benefit of being able to control the patient's increased anxiety during the first phase of treatment, thus reducing the actual pain experienced.

Patients are usually warned about the possible discomfort experienced during the placement of TADs along with that of the administered local anaesthetic that always accompanies this procedure. In view of these results patients should also be informed about the discomfort throughout the first few weeks as well as the need for pain relief during this period at the consent process.

CHAPTER 5

CONCLUSIONS

Page

Chapter 5: Conclusions 84

5.1 Conclusions 86

5.2 Null hypotheses 86

5.3 Recommendations for clinical practice 87

5.4 Further research 87

5.1 Conclusions

Discomfort is experienced in the cheeks and gums during and following the placement of TADs.

The levels of discomfort expected during the placement of TADs are significantly greater than the actually experienced discomfort.

Placement of an O-Cap over the TADs reduces the level of discomfort during the first 6 weeks especially as the local anaesthetic wears off.

The highest level of cheek discomfort experienced peaks at 4 hours following placement whilst for gum discomfort at 1 hour following placement.

Patients find extractions of teeth more painful than having TADs placed.

5.2 Null hypotheses

Placement of an ‘o’ cap does not affect discomfort experienced in the first 6 weeks of treatment

- Rejected

5.3 Recommendations for clinical practice

There are many procedures in orthodontics, which may prove to be of discomfort for our patients, but as clinicians we have a duty to inform them during the consent process and to make the experience as comfortable as possible. Placement of TADs will be more comfortable if local anesthesia is administered in the gentlest way and O-Caps are used during the first 6 weeks following placement. It is beneficial to reassure anxious patients that the experience of placing TADs will not be as bad as could be expected, and is less uncomfortable than a tooth extraction.

5.4 Further research

Further research is required into the patient experience related to placement and use of TADs. The main trial expected to follow-up this pilot trial will be designed to assess the effect of different types of TADs on the discomfort levels experienced by the patients.

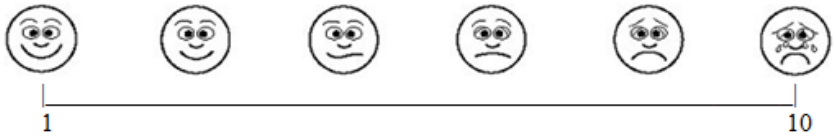
APPENDIX 1: QUESTIONNAIRE

Envelope No: _____

We would like to thank you for taking part in our study. Here are some questionnaires that we would like you to complete. These consist of short simple questions just before and after having your TADs placed, then 1 hour, 4 hours, 24hours, 1 week, 2 weeks and finally at your recall outpatient appointment. Please mark the line below the cartoon faces. Someone will be present to ask the questions and answer any queries.

Questionnaire A: pre-placement **DATE:** **Env:**

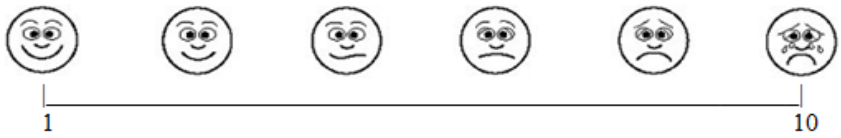
1. How do you feel about having TADs placed?



2. Is there anything in particular that you are concerned about?

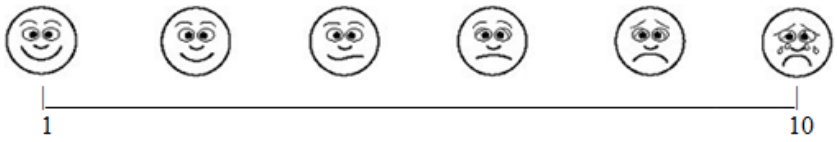
_____

3. How uncomfortable do you expect placing the TADs will be?



Questionnaire B: post-placement **DATE:** **Env:**

1. How uncomfortable was the placement of the TAD?



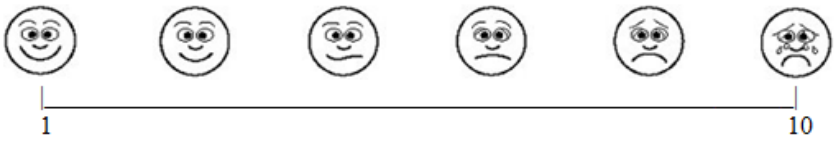
2. Was one side more uncomfortable than the other? Please circle.

YOUR RIGHT / YOUR LEFT / SAME

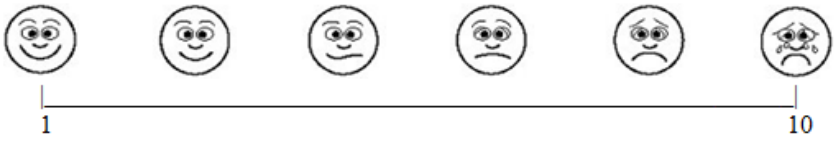
3. What was the worst part of having the TAD placed?

_____

4. How uncomfortable does your cheek feel against the TAD on your RIGHT side?

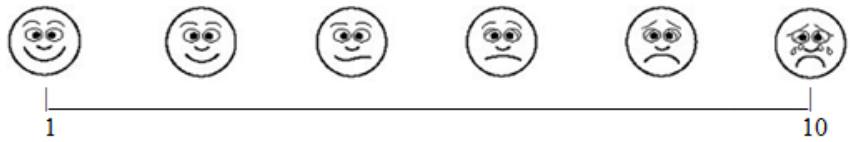


5. How uncomfortable does your cheek feel against the TAD on your LEFT side?



Questionnaire C: 1 hour post placement **DATE:** **Env:**

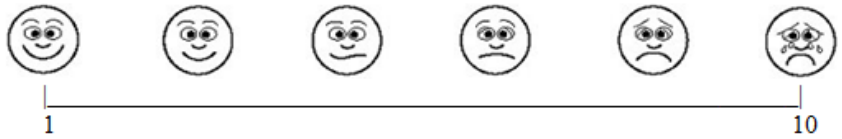
1. How uncomfortable are the TADs?



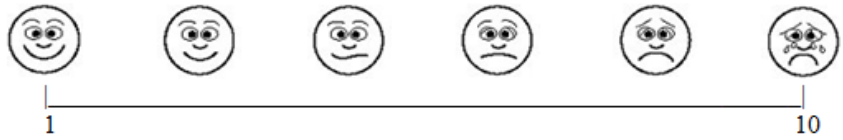
2. Is one side more uncomfortable than the other? Please circle.

YOUR RIGHT / YOUR LEFT / SAME

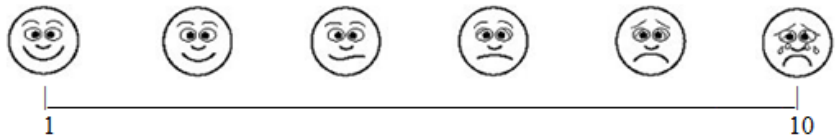
3. How uncomfortable is the gum around the TAD on the RIGHT side?



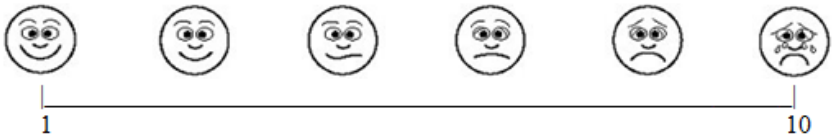
4. How uncomfortable is the gum around the TAD on the LEFT side?



5. How uncomfortable does your cheek feel against the TAD on the RIGHT hand side?



6. How uncomfortable does your cheek feel against the TAD on the LEFT hand side?

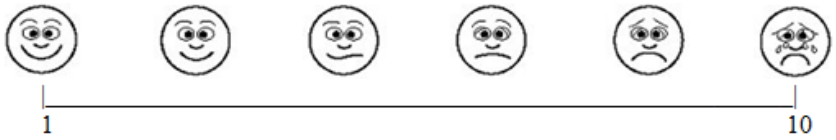


7. Have you taken any pain relief eg. tablets? Yes / No

   If yes, which type? _____

Questionnaire D: 4 hours post placement **DATE:** **Env:**

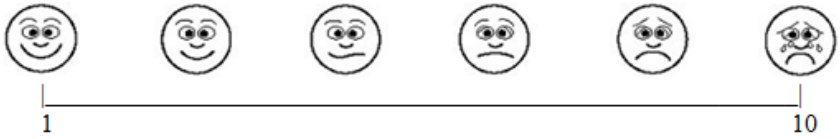
1. How uncomfortable are the TADs?



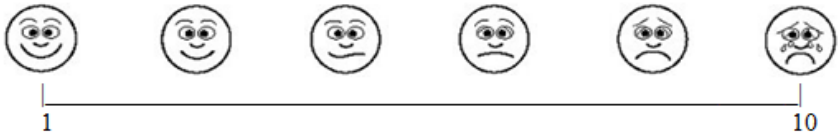
2. Is one side more uncomfortable than the other? Please circle.

YOUR RIGHT / YOUR LEFT / SAME

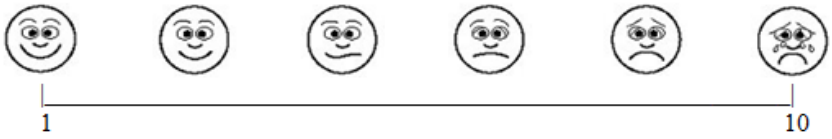
3. How uncomfortable is the gum around the TAD on the RIGHT side?



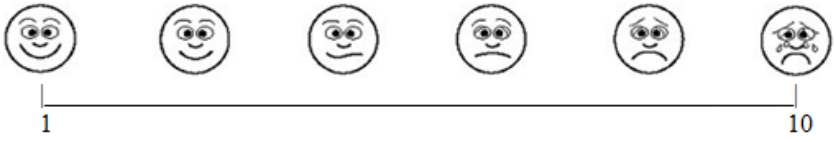
4. How uncomfortable is the gum around the TAD on the LEFT side?



5. How uncomfortable does your cheek feel against the TAD on the RIGHT hand side?



6. How uncomfortable does your cheek feel against the TAD on the LEFT hand side?

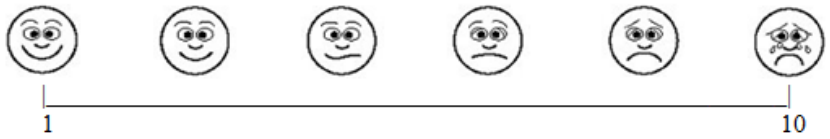


7. Have you taken any pain relief eg. tablets? Yes / No

If yes, which type? _____

Questionnaire E: 24 hours post placement **DATE:** **Env:**

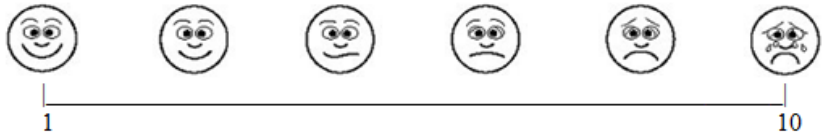
1. How uncomfortable are the TADs?



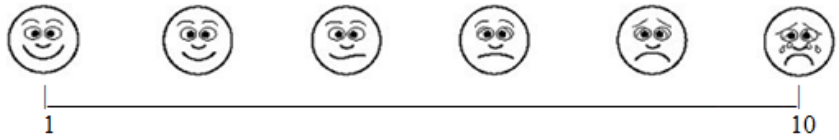
2. Is one side more uncomfortable than the other? Please circle.

YOUR RIGHT / YOUR LEFT / SAME

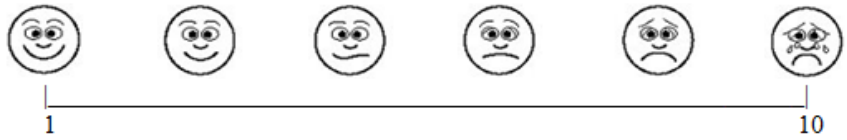
3. How uncomfortable is the gum around the TAD on the RIGHT side?



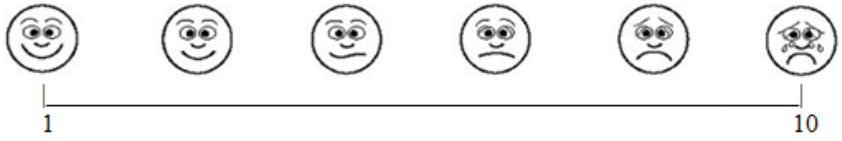
4. How uncomfortable is the gum around the TAD on the LEFT side?



5. How uncomfortable does your cheek feel against the TAD on the RIGHT hand side?



6. How uncomfortable does your cheek feel against the TAD on the LEFT hand side?

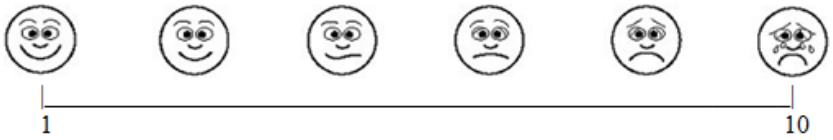


7. Have you taken any pain relief eg. tablets? Yes / No

If yes, which type? _____

Questionnaire F: 1 week post placement **DATE:** **Env:**

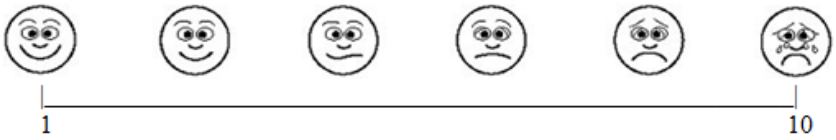
1. How uncomfortable are the TADs?



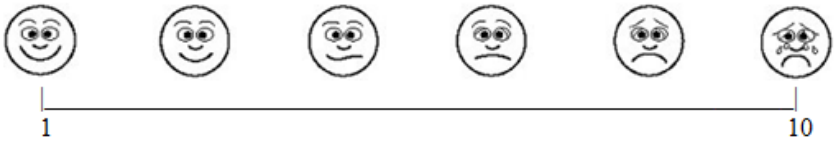
2. Is one side more uncomfortable than the other? Please circle.

YOUR RIGHT / YOUR LEFT / SAME

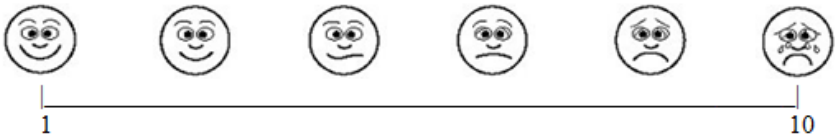
3. How uncomfortable is the gum around the TAD on the RIGHT side?



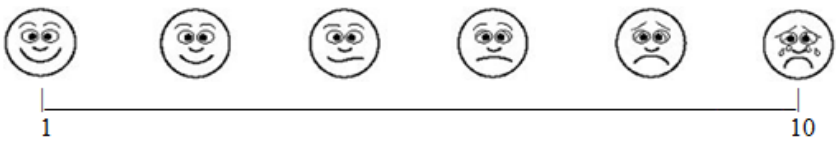
4. How uncomfortable is the gum around the TAD on the LEFT side?



5. How uncomfortable does your cheek feel against the TAD on the RIGHT hand side?



6. How uncomfortable does your cheek feel against the TAD on the LEFT hand side?

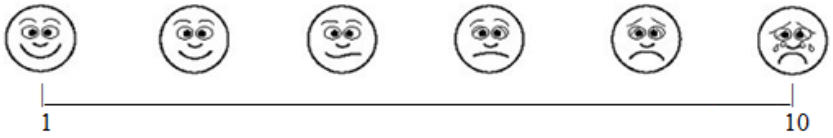


7. Have you taken any pain relief eg. tablets? Yes / No

If yes, which type? _____

Questionnaire G: 2 weeks post placement **DATE:** **Env:**

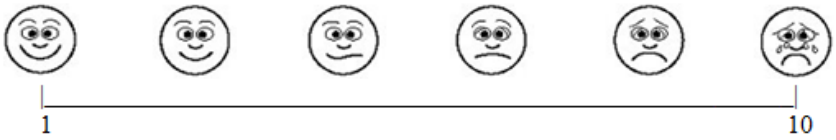
1. How uncomfortable are the TADs?



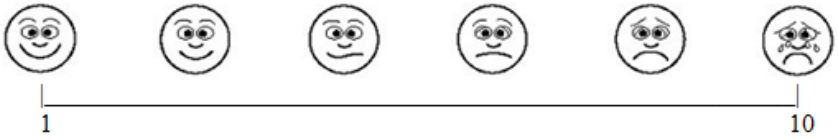
2. Is one side more uncomfortable than the other? Please circle.

YOUR RIGHT / YOUR LEFT / SAME

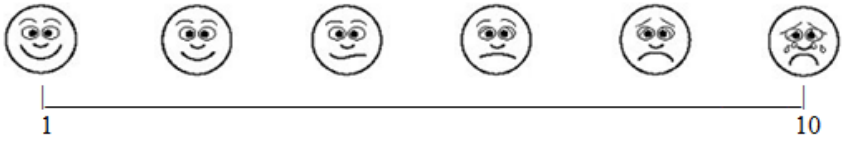
3. How uncomfortable is the gum around the TAD on the RIGHT side?



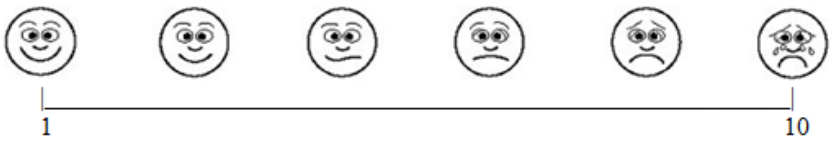
4. How uncomfortable is the gum around the TAD on the LEFT side?



5. How uncomfortable does your cheek feel against the TAD on the RIGHT hand side?



6. How uncomfortable does your cheek feel against the TAD on the LEFT hand side?

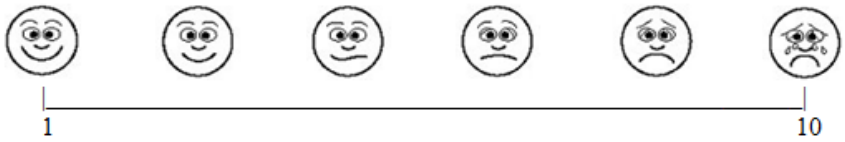


7. Have you taken any pain relief eg. tablets? Yes / No

   If yes, which type? _____

Questionnaire H: 6-8 weeks post placement (recall appt) **DATE:** **Env:**

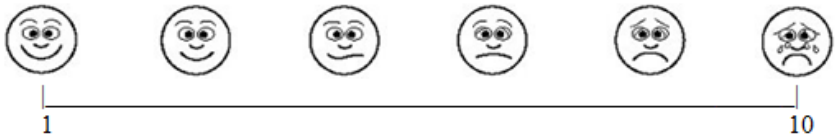
1. How uncomfortable are the TADs?



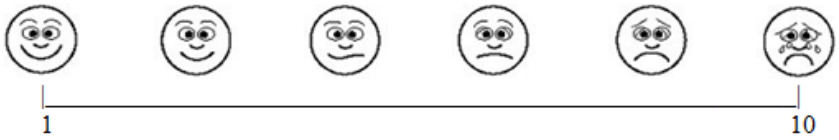
2. Is one side more uncomfortable than the other? Please circle.

   YOUR RIGHT / YOUR LEFT / SAME

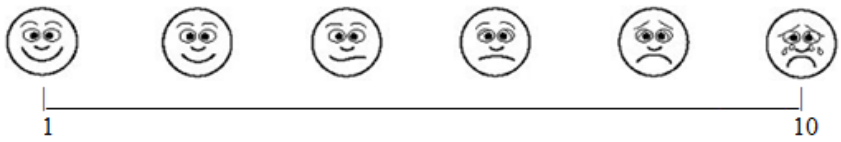
3. How uncomfortable is the gum around the TAD on the RIGHT side?



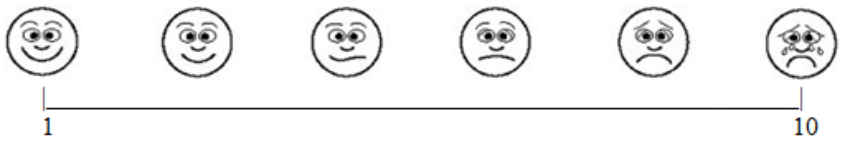
4. How uncomfortable is the gum around the TAD on the LEFT side?



5. How uncomfortable does your cheek feel against the TAD on the RIGHT hand side?



6. How uncomfortable does your cheek feel against the TAD on the LEFT hand side?



7. Have you taken any pain relief eg. tablets? Yes / No

   If yes, which type? _____

8. What was most uncomfortable having the teeth removed or the TADs placed?

   _____

APPENDIX 2: RAW DATA

ID No	AGE	Gender
1	15.33	F
2	14.17	M
3	10.92	F
4	12.33	M
5	13.33	M
6	14.08	M
7	13.25	M
8	14.67	M
9	12.5	M
10	14.33	M
11	15.5	M
12	17.33	M
13	13.58	F
14	14.83	M
15	14.67	F
16	14	M
17	18.08	F
18	15.5	M
19	14.42	F
20	16.5	F
21	15.58	F
22	15.58	F
23	14.25	M
24	18.08	F
25	15.67	F
26	14.75	F
27	16.08	F
28	13.42	F
29	12.33	M
30	14.08	M

ID	VAS scores								
	Pre placement		Post placement						
	Feeling	Exp	Dur	1 hr	4 hr	24 hr	1 wk	2 wk	6 wk
1	29.87	30.07	11.36	10.83	29.14	29.25	27.87	9.62	10.1
2	38.37	59.06	19.53	60.17	39.84	0	0	0	0
3	19.6	39.12	0	20.6	78.65	2.07	0	0	0.97
4	53.83	34.69	16.08	76.27	34.4	16.46	0	0	15.22
5	38.71	79.93	58.25	20.67	58.28	39.24	0	0	0
6	8.83	57.58	6.34	0	56.83	2.67	3.08	6.77	
7	0	28.58	19.44	39.4	59.67	27.95	6.23	0	0
8	48.66	78.74	4.64	40.65	48.36	68.51	18.3	10.87	0
9	37.82	48.93	68.45	94.18	50.73	41.72	31.53	24.04	13.56
10	20.33	58.12	21.45	42.08	19.46	40.97	58.44	18.94	20.6
11	19.46	39.11	19.75	59.7	39.01	19.49	0	0	0
12	39.88	40.59	20.37	20.7	20.11	40.54	79.86	20.96	0
13	12.02	19.64	0	30.63	6.14	31.64	0	0	0
14	38.88	39.48	0	39.83	40.06	20.46	0	0	0
15	16.29	39.16	4.89	81.81	39.25	0	0	0	0
16	12.31	25.17	1.7	30.2	38.57	39.78	20.62	2.98	1.51
17	0	40.07	0	60.64	79.14	79.76	19.22	69.03	7.35
18	0	19.86	0	81.83	19.29	40.15	19.82	0	0
19	39.01	39.05	58.51	40.48	19.67	79.08	58.96	39.37	20.48
20	67.65	72.65	32.53	32.09	38.36	46.36	27.19	18.93	26.97
21	79.15	80.47	39.3	80.61	59.41	20.84	38.7	19.75	19.81
22	30.81	48.21	0	28.4	81.63	34.48	20.11	25.25	24.32
23	20.06	38.94	18.82	39.78	20.14	0	0	18.15	0
24	18.99	48.95	48.32	47.21	28.67	26.48	49.43	39.15	34.03
25	19.53	37.96	0	81.36	20.62	59.58	38.91	19.27	20.63
26	39.05	79.01	20.6	81.47	0	20.66	0	0	0
27	7.25	10.29	8.46	27.33	28.09	8.56	7.59	9.19	7.59
28	39.79	39.66	23.07	60.16	59.45	20.04	0	0	0
29	19.06	40.56	0	41.14	20.63	0	0	0	0
30	19.03	57.87	0	60.33	100	78.58	58.8	78.53	39.71

ID	VAS scores for cheek discomfort: Control						
	0 hr	1 hr	4 hr	24 hr	1 wk	2 wks	6 wks
1	18.2	68.51	83.71	94.92	30.88	34.73	30.16
2	39.12	54.33	82.89	93.86	48.47	31.34	20.62
3	39.01	80.08	80.12	85.1	52.52	28.41	20.17
4	0	80.29	79.48	82.09	40.04	0	0
5	0	60.23	78.82	81.76	79.12	21.45	39.92
6	5.49	44.1	65.02	80.51	100	20.12	39.2
7	68.37	74.86	62.33	79.29	59.24	0	19.09
8	20.14	41.02	59.06	75.04	30.34	27.95	29.24
9	20.52	39.27	58.7	68.91	28.13	29.87	9.88
10	19.69	39.16	58.65	63.1	27.38	28.43	8.31
11	19.72	20.1	56	59.62	39.43	19.2	19.35
12	51.78	4.98	51.92	59.08	78.87	40.08	39.15
13	55.05	54.81	51	58.96	39.23	20.85	38.56
14	7.65	7.41	46.43	43.94	47.87	34.9	32.07
15	30.99	14.97	45	42.86	59.69	51.24	10.96
16	39.6	79.53	39.19	40.78	79.5	19.63	40.43
17	38.72	100	38	40.78	0	0	0
18	16.35	35.42	34.06	39.54	0	0	0
19	10.58	28.2	30.08	31.22	21.31	2.86	1.58
20	45.79	43.29	29.06	29.1	0	0	0
21	0	0	27.81	28.39	27.15	9.43	9.05
22	0	0	21.45	26.62	0	0	0
23	20.37	21.48	20.5	19.94	0	0	0
24	38.88	19.67	20.14	19.78	0	0	0
25	0	38.59	19.64	10.7	8.39	4.82	0
26	19.8	18.28	19.63	0	0	0	0
27	18.45	18.03	17.17	0	44.41	15.99	
28	15.73	34.72	16.24	0	0	0	0
29	0	10.75	8.46	0	0	0	0
30	0	19.33	0	0	0	0	0

ID	VAS scores for cheek discomfort: O-Cap						
	0 hr	1 hr	4 hr	24 hr	1 wk	2 wks	6 wks
1	9.81	8.94	10.47	12.03	9.35	8.95	8.56
2	39.32	0	19.96	0	0	0	0
3	50.65	4.6	11.84	8.46	8.93	9.04	0
4	15.41	34.53	75.24	14.15	15.36	0	0
5	79.48	59.35	58.58	79.4	0	0	0
6	4.73	3.66	15.23	27.18	5.75	2.16	
7	0	28.4	29.44	38.15	0	0	0
8	17.31	12.94	28.83	0	0	0	0
9	33.55	15.48	49.25	6.19	6.21	11.21	37.98
10	43.16	59.77	21.24	19.55	20.84	20.6	3.62
11	58.89	18.95	20.11	18.98	0	20.57	19.59
12	40.08	0	21.46	0	0	0	0
13	0	38.86	34.87	35.56	0	0	0
14	0	39.03	79.18	19.57	0	0	0
15	5.8	27.4	13.2	28.14	0	0	0
16	9.45	6.66	20.2	83.99	25.37	3.69	1.95
17	20.07	39.55	60.53	28	0	3.01	8.83
18	20.92	19.54	18.85	21.29	20.3	0	0
19	39.09	19.35	0	19.15	19.78	0	0
20	24.35	26.24	24.51	24.75	24	17.85	10.29
21	40.65	78.51	40.02	40.12	19.21	40.21	21.05
22	26.4	26.44	84.17	29.06	18.15	35.04	17.19
23	19.54	18.61	19.45	0	0	20.63	
24	68.72	12.92	30.52	44.2	38.1	42.98	53.61
25	19.44	100	18.45	59.76	38.58	19.64	17.83
26	0	0	20.27	40.8	0	0	0
27	6.47	8.05	7.78	7.58	10.73	9.01	10.45
28	39.62	39.06	39.31	30.27	0	0	0
29	0	20.18	0	0	0	0	0
30	0	80.06	100	100	79.15	19.79	

ID	VAS scores for gingival discomfort: Control					
	1 hr	4 hr	24 hr	1 wk	2 wks	6 wks
1	28.89	30.32	28.79	9.75	9.94	8.29
2	79.15	79.17	0	0	0	0
3	62.26	28.11	0	0	8.42	0
4	74.98	35.17	0	0	0	14.46
5	58.73	78.6	18.91	0	0	0
6	61.66	55.08	46.79	27.52	9.13	
7	39.25	38.34	19.32	18.86	0	0
8	63.59	0	0	0	0	0
9	83.66	53.45	96.22	31.2	50.29	59.45
10	19.96	20.16	37.53	20.85	19.48	3.65
11	20.41	0	0	18.64	0	0
12	21.16	20.64	39.31	79.23	21.52	39.89
13	1.4	19.62	30.88	0	0	0
14	0	0	0	0	0	0
15	86.11	66.29	0	0	0	0
16	34.6	29.88	34.56	19.71	3.67	1.78
17	60.05	80.03	91.37	48.16	34.62	8.6
18	80.68	79.9	0	20.51	0	0
19	19.35	0	39.14	59.02	39.23	38.69
20	49.43	48.57	34.53	38.35	20.16	26.31
21	39.08	58.14	58.7	38.99	38.31	20.39
22	49.56	82.56	49.83	32.82	34.83	28.71
23	18.21	19.38	0	0	0	0
24	47.29	29.52	31.11	50.65	52.09	50.62
25	100	38.95	58.43	39.44	19.64	36.24
26	59.29	0	0	0	0	0
27	10.15	8.04	9.05	6.68	29.29	7.25
28	79.74	59.97	31.78	0	0	0
29	40.66	0	0	0	0	0
30	39.69	39	38.25	79.03	19.5	38.56

ID	VAS scores for gingival discomfort: O-Cap					
	1 hr	4 hr	24 hr	1 wk	2 wks	6 wks
1	10.15	10.12	9.53	10.07	8.91	8.59
2	0	79.77	0	0	0	0
3	6.83	28.69	0	0	0	0
4	74.52	34.94	0	0	15.07	0
5	39.36	78.51	57.22	0	0	0
6	7.11	44.94	58.07	15.08	4.1	
7	58.15	68.32	17.48	0	0	0
8	18.84	0	0.87	0	0	0
9	67.21	10.59	0.95	9.67	7.98	11.98
10	40.07	38.67	21.21	19.96	21.21	5.52
11	19.94	58.85	0	0	0	18.7
12	0	21.97	18.84	0	0	0
13	12.56	24.15	33.99	0	0	0
14	57.87	79.36	20.27	19.01	0	0
15	65.5	13.38	0	0	0	0
16	16.04	27.83	34.56	30.59	2.05	1.78
17	20.22	59.49	29.65	8.06	7.93	9.68
18	19.76	19.66	0	0	0	0
19	39.51	0	18.91	39	20.06	20.48
20	31.19	31.03	28.78	27.62	20.16	10.65
21	59.02	39.15	38.25	39.71	18.38	20.39
22	25.19	82.89	18.78	19.32	23.18	24.16
23	18.69	20.15	0	0	38.32	
24	34.27	29.45	31.5	22.86	32.27	50.63
25	100	19.54	56.23	38.9	19.55	37.95
26	59.82	0	20	0	0	0
27	46.6	7.36	10.23	6.68	7.28	6.78
28	79.46	39.69	18.07	0	0	0
29	40.07	0	0	0	0	0
30	58.89	100	79.44	58.64	20.12	

Pain relief : 1 = yes 2 = no										
1 hr	**Type**	**4 hrs**	**Type**	**24 hrs**	**Type**	**1wk**	**Type**	**2 wk**	**Type**	**6 wk**
2		2		1	P	2		2		2
1	P	1	P	2		2		2		2
1	C	2		2		2		2		2
1	C	2		2		2		2		2
1		1	P	1	P	2		2		2
2		2		2		2		2		
1	I	2		2		2		2		2
2		2		2		2		2		2
1	P	2		2		2	W	2	W	2
2		2		2		1	I	2		2
1	P	1	P	2		2		2		2
2		2		2		2		2		2
1	P	1	P	1	P	2		2		2
2		2		2		2		2		2
2		1	B	2		2		2		2
1	P	2		2		2		2		2
2		1	P	1	G	1	B	1	G	2
2		1	I	2		2		2		2
1	P	2		1	P	1	P	2		2
2		1	I	1	I	1	I	2		2
2		1	P	2		2		2		2
2		1	P	2		2		2		2
2		2		2		2		2		2
1	P	2		2		2		2		2
1	I	1	I	2		2		2		2
2		1	N	2		2		2		2
1	I	1	I	2		2		2		2
2		1	C	2		2		2		2
1		2		2		2		2		2
2		1	CO	1	CO	1	B	1	CO	2

B = Bonjela

C = Calpol

CO = CO-Codamol

G = Gengigel

I = Ibuprofen

N = Neurofen

P = Paracetamol

W= Wax

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