

**A randomised controlled trial to assess the pain associated
with the debond of orthodontic fixed appliances**

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Abstract

Objectives:

To determine patients' experiences of pain during treatment with fixed appliances, expectations of pain during debond and whether biting on a soft acrylic wafer during debond decreases the pain experienced.

Method:

Ethical approval was gained. Subjects were randomly allocated to the control or wafer group. A visual analogue scale (VAS) based questionnaire was completed pre-debond to determine their pain experience during treatment and expectations of pain during the debond. The appliances were debonded and those in the wafer group bit on a soft acrylic wafer. A second questionnaire was completed post-debond to assess the pain experienced

Results:

90 subjects participated. Biting on an acrylic wafer significantly reduced the pain experienced when debonding the posterior teeth ($P < .05$). 39% found the lower anterior teeth the most painful. The expected pain was significantly greater than that actually experienced ($P < .001$). Greater pain during treatment correlated with increased expectations and increased actually experienced pain ($P < .001$).

Conclusions:

Biting on a soft acrylic wafer during debond of the posterior teeth reduces the pain experienced. The lower anterior teeth are the most painful. The pain expected is significantly greater than the actual experience. Patients who had greater pain during treatment expected and experienced greater pain at debond.

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Chapter 1

Literature Review

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1.1 Introduction

Pain is defined by the International Association of the Study of Pain (IASP) as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or is described in terms of such damage. Oliver and Knapman (1985) reported that the fear of pain was a major factor in preventing patients from seeking orthodontic treatment and that 39% of patients thought the worst aspect of treatment was the pain. Orthodontists reportedly tend to underestimate the level of pain experienced by their patients (Krukemeyer et al., 2009) despite the fact that there is evidence to show that up to 95% of patients experience some level of pain or discomfort during orthodontic treatment and the fact that pain has been cited as a reason for discontinuing treatment (Oliver and Knapman, 1985; Brown and Moerenhout, 1991).

Pain is very subjective, with great individual variation. Numerous studies (Ngan et al., 1989; Brown and Moerenhout, 1991; Firestone et al., 1996; Bergius et al., 2000; Kluemper et al., 2002) have shown that pain is dependent upon a number of factors such as age, sex, emotional state, culture and previous pain experience.

Generally the pain threshold appears to increase with age. Tucker et al. (1989) measured the cutaneous pain threshold in subjects aged 5 to 105 years and showed there to be an increase to 25 years of age, followed by a plateau, with a very gradual rise to 75 years. This relationship is not so clear when looking at the pain related to orthodontic treatment. A number of studies have shown that younger patients experience less pain than older patients

(Fernandes et al., 1988; Brown et al., 1991; Jones et al., 1992). By contrast others found there to be no difference with age (Ngan et al., 1989; Bergius, 2002).

With regard to the effect of gender the literature is again divided. Several studies report that females experience greater pain than males during orthodontic treatment (Scheurer et al., 1996; Bergius et al., 2002) whilst others show there to be no difference in the pain experienced during orthodontic treatment between the sexes (Ngan et al., 1989; Erdinc and Dincer, 2004). In a study by Kvam et al. (1989) females with fixed appliances reported more ulceration (23.1%) than males (9.6%). This may be a reflection of the slight female predilection of recurrent aphthous ulceration.

Pain experience is modulated by higher centres of the central nervous system and therefore is affected by emotional and cognitive factors. Increased anxiety levels correlate with increased pain experienced. Likewise expectations of the results of treatment and the motivation to wear appliances may serve to reduce the pain experienced by filtering painful stimuli or by increasing the pain threshold (Bergius et al., 2000; Krishnan, 2007). Sergl et al. (1998) suggested that the level of discomfort following fitting of orthodontic appliances might be an indicator of the acceptance of orthodontic treatment, with those who have less discomfort being more accepting of treatment.

Cultural variations in the level of pain experienced have been documented and are probably learned responses. Some ethnic groups encourage pain expression and respond with sympathy and attention, whereas others expect stoical behaviour. People of Jewish and Italian origin are more likely to report

pain than northern Europeans (Bergius et al., 2000), reflecting cultural variations in the verbalisation of the pain experience.

1.2 Neuroanatomy of orthodontic pain

Pain is caused by tissue damage that results in cell death and subsequent release of intracellular factors such as histamine, substance P, bradykinin, prostaglandins and serotonin (5-HT) that stimulate nociceptors and cause depolarisation of the local pain nerve fibres. The majority of the sensory nerve cell bodies are located in the dorsal horn of the spinal cord and from here impulses are transmitted upwards to the thalamus, via the spinothalamic tract, and then up to the primary sensory cortex.

Sensory innervation of the jaws, teeth and oral mucosa is supplied by the maxillary and mandibular branches of the trigeminal nerve (cranial nerve V). The cell bodies of these nerve fibres are located in the trigeminal nucleus (as opposed to the dorsal horn of the spinal cord). From the trigeminal nucleus impulses are transmitted up to the thalamus, via the trigeminothalamic tract, and then on to the primary sensory cortex.

Myelinated A- δ fibres and or unmyelinated C fibres transmit nociceptive information. Both these fibre types are found in the dental pulp and periodontium. A- δ fibres are activated by mechanical and thermal stimulation and transmit information at up to 30 metres/second, whilst C fibres are stimulated by high intensity chemical, mechanical and thermal stimuli and transmit signals at approximately 0.5-2.5 metres/second. Myelinated A- β

fibres transmit touch and pressure sensations and transmit signals at 30-70 metres/second.

As the impulses ascend the central nervous system and progress to higher centres they are subject to modulation, which can either increase or reduce the impulse and thus the pain experienced. Melzack and Wall (1965) proposed the gate-control theory of pain modulation. Activity in the large diameter nerve fibres tends to inhibit transmission of pain signals from the dorsal horn (or trigeminal nucleus) to the thalamus (closes the gate), for example rubbing an injured area helps to relieve pain by stimulating large diameter A- β fibres that prevent onward transmission of impulses from the small diameter C fibres. Similarly emotions can also control the 'gate' as descending signals from the thalamus (descending inhibition). Emotions such as anger and excitement tend to increase the descending inhibition (close the gate) and reduce the pain experienced. Anxiety and depression reduce the descending inhibition (open the gate) and result in increased pain perception. Central neurotransmitters include opioid peptides such as endorphins and enkephalins and non-opioid peptides such as substance P and amino-acids. Generally the endogenous opioid peptides suppress pain by inhibiting transmission of nociceptive information whilst substance P promotes pain. Pain is normally categorised as acute or chronic. Acute 'nociceptive' pain is usually well localised and resolves once the irritant is removed and the inflammation subsides. Chronic pain is defined as pain that is present for greater than three months or that persists once the irritant has been removed. Given these definitions, orthodontic pain must therefore be considered as acute pain, which is of more rapid onset and shorter duration.

Orthodontic forces create zones of pressure and tension in the periodontal ligament space, and result in an inflammatory reaction within the periodontium and pulp along with the release of inflammatory mediators. Ischaemic necrosis can occur if the force is excessive. It is thought that the perception of pain is influenced by changes in blood flow and is correlated with the release of mediators such as prostaglandins, leukotrienes, histamine, serotonin and substance P, which elicit a hyperalgesic response. The increase of these mediators following the application of force is well documented in the dental and orthodontic literature (Davidovitch et al., 1991 and 1988).

Burstone (1962) described an immediate and a delayed pain response to orthodontic forces. The immediate response was due to compression of the periodontal ligament and the delayed response due to hyperalgesia of the periodontal ligament.

1.3 Causes of orthodontic pain

The orthodontic literature reports that many orthodontic procedures have the capacity to cause pain. Potentially painful procedures include:

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

It is important to have knowledge of the causes of pain during orthodontic treatment so that we can understand how pain might be minimised and also so the patient can be warned of the risk of pain occurring during their treatment.

1.3.1 Removable and fixed appliances

Removable and fixed appliances may both cause pain. In contemporary orthodontics there has been a shift towards the use of fixed appliances due to the 3-dimensional control they offer the operator. Fixed appliances produce more sustained forces between activations, although the force levels can be variable. Force levels are dependant on many factors, principally governed by bracket and archwire interactions. Removable appliances mainly tip teeth and tend to produce intermittent forces the level of which are determined by the amount and frequency of the activation placed on the active components.

Oliver et al. (1985) in their survey of attitudes towards orthodontic treatment reported no statistically significant difference in the pain experienced by fixed appliance wearers compared to removable appliance wearers. However more recent research (Stewart et al., 1997; Sergl et al., 1998) found fixed appliances to be significantly more painful than removable appliances and functional appliances to be similar to fixed appliances.

It may appear logical that the greater the orthodontic force the greater the pain experienced and indeed this was suggested as a theory by Burstone (1962). Similarly, it might be expected that the worse the degree of crowding the greater the pain due to increased deflection of the archwires as they are tied into the brackets. However there appears to be little correlation between the force levels and the pain experienced (Andreasen et al., 1980; Jones et al., 1985) and there is no statistically significant correlation between initial tooth positions and the pain experienced.

1.3.2 Rapid maxillary expansion

Rapid maxillary expansion (RME) causes separation of the midpalatal suture of the maxilla over a period of 2-3 weeks. An RME appliance with a Hyrax screw provides 0.25mm of expansion per turn of the screw and the screw is usually turned 2-3 times per day. The expansion is then retained for 3 months. Needleman et al. (2000) found 98% of patients reported pain during rapid maxillary expansion and the highest pain levels were during the first 10 turns of the screw of the expansion device. Pain during the initial expansion would be expected due to the initial separation of the suture and stretching of the

palatal mucosa. Scheuster et al. (2005) also listed pain as a complication of rapid maxillary expansion.

1.3.3 Headgear

Headgear is used to provide extra-oral anchorage or traction and pain is cited as the main reason for non-compliance with headgear (Cureton, 1994). Force levels of up to 500g per side are applied to the posterior teeth via an extra-oral bow and heavily elasticated connector. These forces are intermittent as the headgear is only worn part-time and as such it may be more difficult for the patient to get used to.

1.3.4 Temporary anchorage devices

More recently temporary anchorage devices (TADs) have been used to provide additional anchorage. These are usually placed chairside using a small amount of local anaesthetic to provide soft-tissue analgesia. Lee et al. (2008) compared the placement of TADs to other orthodontic procedures, such as initial alignment, and 78% of patients anticipated experiencing greater pain with TADs than they actually experienced. The level of post-operative pain was also significantly less than that of initial tooth alignment. TADs placed without an incision or raising a mucoperiosteal flap are significantly more comfortable for patients (Kuroda et al., 2007). This would be expected as there is less soft tissue damage if the TADs are placed directly through the mucosa.

1.3.5 Orthodontic separators

Separators are used to open up space between the contact points, usually over a period of seven days, to facilitate the placement of orthodontic bands. Ngan et al. (1989, 1994) in 2 controlled trials concluded that pain started within 4 hours of placement and increased over the next 24 hours before diminishing to pre-placement levels by day 7. This pattern was supported by Bondemark et al. (2004) who found that pain was at its peak by 2 days and had diminished by 5 days. Placement of separators is generally perceived, by orthodontists, to be the most painful aspect of orthodontic treatment however in the study by Ngan et al. (1989) there was no difference in the pain experienced following the placement of separators or the initial aligning archwire.

1.3.6 Archwire placement and activation

After initial archwire placement pain begins within 4 hours, increases over the next 24 hours and then declines gradually over a period of 2-4 days (Kvam et al., 1989; Jones et al., 1992; Ngan et al., 1994; Scheurer et al., 1996; Erdinc et al., 2004; Polat et al., 2005). Pain is reported more in the anterior teeth compared to the posterior teeth (Scheurer et al., 1996; Firestone et al., 1999; Erdinc et al., 2004), probably due to the smaller root surface area of the anterior teeth and greater movements of the anterior teeth in the initial levelling and aligning stages.

Several studies have investigated the effect of different archwires on the level of pain experienced. Erdinc et al. (2004) found no difference between 0.014" and 0.016" nickel titanium (NiTi) archwires and Fernandes et al. (1998) found

no difference between superelastic NiTi and conventional NiTi archwires or conventional NiTi and stainless steel archwires.

Goldreich et al. (1994) reported a reduction in masseter muscle activity (as recorded by electromyographic activity) following activation of an orthodontic archwire. They hypothesised that this reduction in muscle activity was due to noxious stimulation of the periodontal membrane and paradental receptors, which triggered a reflex mechanism inhibiting the jaw closing muscles.

1.3.7 Debonding fixed appliances

The process of debonding removes the brackets and residual adhesive from the teeth. The brackets are debonded and then any remaining composite is removed. Ideally the debonding process should cause minimal iatrogenic harm.

Brackets can be removed using several techniques. Purpose made debonding pliers are used by placing the beaks of the pliers as close as possible to the base of the bracket and applying a peel force which breaks the adhesive bond (see figure 1.3). The 'lift-off debracketing instrument' (LODI) uses a wire loop hooked over the bracket tie wings that pulls the wings of the bracket directly away from the tooth surface. This transmits a tensile force which breaks the adhesive bond. Ligature cutters can be used to debond brackets but this tends to damage the beaks rendering them useless for their intended purpose. Weingart pliers use a shear force to remove the brackets when placed either side of the bracket wings and squeezed. With this

technique the bond is most likely to fail at the interface between the bracket and adhesive leaving excess residual composite on the tooth (Turner, 1996).

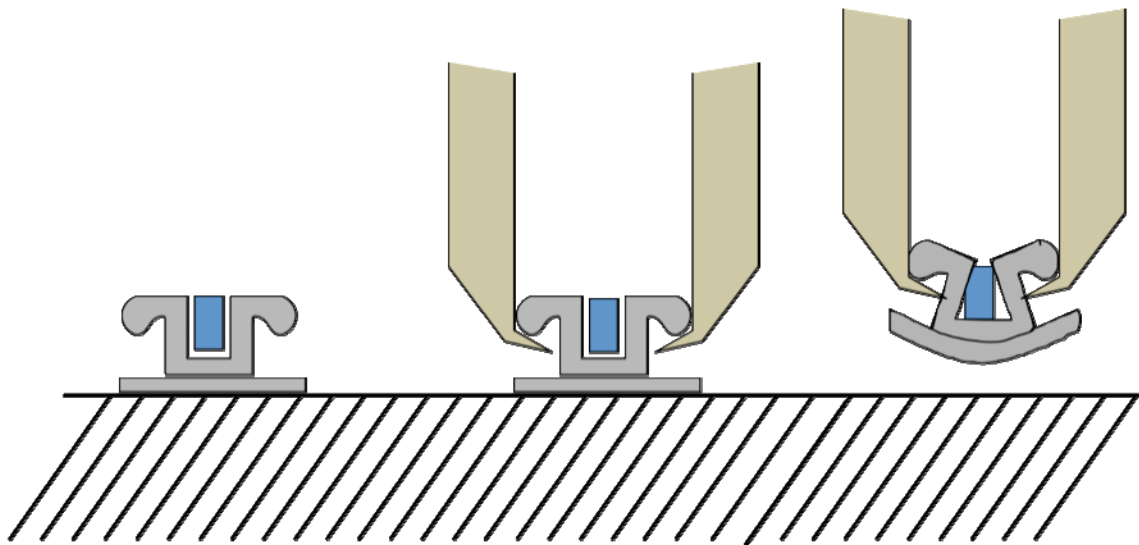


Figure 1.3 Debonding brackets using a peel force

Rotary instruments are most commonly used for composite removal as they leave the most acceptable enamel finish. Ireland et al. (2005) conducted an in-vitro study to compare the enamel loss at bond-up, debonding and enamel clean-up. Tungsten carbide burs (plain or spiral fluted) in a contra-angled slow handpiece allow good accessibility and cause the least enamel damage

compared with an ultrasonic scaler, high speed tungsten carbide bur or hand instruments, which tend to gouge or scar the enamel.

Williams and Bishara (1992) in a pilot study of 15 patients investigated the threshold for the level of force that could be tolerated at debond. The threshold level was influenced by the direction of force, the mobility of the tooth, the tooth type and the gender of the patient. Intrusive forces were tolerated best (mean average of 934g) and extrusive forces were least tolerated (mean average 827g.) Torsional forces, applied using a long lever arm, were very poorly tolerated and an accurate result was not obtained as the threshold level was below that registered by the force gauge used (<100g.) Tooth mobility significantly lowered the discomfort threshold, incisor teeth had the lowest threshold and it was suggested that females had lower discomfort thresholds than males. They concluded that discomfort could be reduced by placing an intrusive force on the tooth, such as finger pressure or biting on a cotton wool roll. However, as this was a pilot study the number of subjects was small. There were uneven numbers of males and females and the gender differences reported may be biased. Molar teeth were not included in the study and tooth mobility was not recorded for all teeth. The level of torsional force was not fully evaluated and when debonding brackets there is usually an element of torsional force. The tolerated force levels are much lower than the forces required to debond brackets in vitro.

Rinchuse (1994) described a method for pain-free debonding using an occlusal wax rim trimmed from soft bite-block wax but the claim that this was pain-free was unsubstantiated as no evidence was included to support this.

The shear force required to debond metal brackets in vitro has been reported to range from 7.91 MPa to 22.08 MPa depending upon the adhesive used (Rix et al., 2001; Sfondrini et al., 2001; Summers et al., 2004; Al., Shamsi et al., 2006; Arhun et al., 2006; Habibi et al., 2007). Composite resin adhesives containing resins such as BisGMA and BisEMA, fillers and curatives produce higher bond strengths than resin modified glass ionomer cements (RMGIC). The force needed to debond brackets varies depending upon the composition of the adhesive. Filled adhesives produce a stronger bond than those which are lightly filled or contain no filler (Turner, 1996). They are also more likely to fail at the enamel/adhesive interface which may lead to fractures in the enamel.

The bond strength of self-etching primer (Transbond plus) and Transbond in vitro has been shown to be 11.9 MPa, with air-dispersion of the self-etching primer (Dorminey et al., 2003). Vicente and Bravo (2007) reported the mean bond strength of self-etch prime (Transbond plus) and APC plus adhesive (3M Unitek) to be 14.28 MPa.

Reynolds (1975), in a review of orthodontic bonding reported 5.9-7.8 MPa to be adequate for clinical use. The bond strengths actually achieved in-vitro are greater than this. Accurate measurement of bond strength in-vivo is not practical and instead bond failure rate is measured.

The bond failure rate of brackets bonded with self-etching primer ranges from 1.6% to 6.88% (Alijubouri et al., 2004; Pasquale et al., 2007; Banks et al., 2007; Cal-Neto et al., 2009) whilst that of conventional etch and bond ranges from 3.1% to 5.3% (Alijubouri et al., 2004; Banks et al., 2007; House et al., 2006).

Assuming a bracket base of 11mm^2 a force of 7.9 MPa is equivalent to 87.01 N which in turn is equivalent to 8872.55g. This is much greater than the level of force that can be tolerated, as demonstrated by Williams and Bishara (1992), which implies that the debonding procedure is likely to induce pain.

Methods to reduce the force needed for debonding, such as thermal and chemical debonding have been investigated. Ruggenberg and Lockwood (1990) demonstrated that the application of heat to the bracket/adhesive interface reduced the force needed to debond by approximately 50%.

However this study was performed using chemically cured adhesives rather than light cured adhesives, which are more commonly used today and this may have influenced the bond strength.

Depending upon the adhesive used the temperature required to enable debonding using a force of 22.2 N (still enough to generate pain) ranged from 44°C to 228°C . This technique has an obvious risk of thermal damage to the pulp as well as the risk of damage to local soft tissue with less than careful handling. As increasing the temperature of the pulp above 50°C causes necrosis in 60% of teeth (Zach et al., 1965) electrothermal debonding has not been universally adopted by the orthodontic profession.

Laser energy has been used, with success, for the debonding of ceramic brackets. Unlike metal brackets, ceramic brackets have a significantly lower fracture toughness and are more prone to shattering during debonding, which in turn increases the risk of enamel damage. Laser energy degrades the adhesive resin reducing the force required to debond. In a review of laser debonding of ceramic brackets, Azzeh and Feldon (2003) concluded that although there is an increase in temperature of the dental pulp it is considered to be within the acceptable physiological limit and this temperature rise can be reduced using a super-pulse CO₂ laser. Unfortunately super-pulse CO₂ lasers are very expensive and are not routinely used.

Chemical debonding using a viscous gel containing a peppermint oil derivative (available as a commercial product) has been investigated. Waldron and Causton (1991) reported that application of peppermint oil aided the removal of ceramic brackets and they suggested that the oil functioned as a crazing agent which facilitated crack propagation through the composite bond. In contrast, Larmour et al. (1995 and 1998) found that peppermint oil had little effect on the force required to debond ceramic brackets. Peppermint oil can cause allergic or hypersensitivity reactions and dermatitis and as such has not been adopted for routine use.

1.4 Assessment of pain

Pain is a very subjective experience that can only be assessed indirectly. Several methods have been described that try to assess pain. Acute pain is commonly assessed using self-administered questionnaires, incorporating unidimensional scales that measure pain intensity, such as the visual analogue scale, the verbal rating scale and the numerical rating scale. Chronic pain is more difficult to assess and the questionnaires used for chronic pain, such as the McGill pain questionnaire and the brief pain inventory are usually more complex because they aim to measure the pain intensity and take into account the other factors that influence its perception. Orthodontic pain has been most commonly evaluated using the visual analogue scale, the numerical rating scale or a shortened form of the McGill pain questionnaire.

1.4.1 Visual analogue scale

The visual analogue scale consists of a line, usually 100 mm long, which denotes the extremes of pain at its ends e.g. 'no pain' at one end and 'worst pain imaginable' at the other (see figure 1.4). The patient marks the severity of their pain at a particular point along the line. The distance of the mark along the scale is taken as the pain score. This scale gives the freedom to choose the exact intensity of the pain and it is a reliable and sensitive method of measuring pain and the effect of pain reducing methods (Huskisson, 1974; Seymour et al., 1982 and 1985). It is possible to standardise pain ratings to compare pain between different populations (Kane et al., 2005) and generally

individuals over the age of 5 years are capable of understanding and completing visual analogue scales (Bergius et al., 2002).



Figure 1.4 The visual analogue scale

1.4.2 Verbal rating scale

Verbal rating scales consist of a ranked list of adjectives that describe different intensities of pain. The patient selects the word that describes best their level of pain. The scale should include the extremes of pain at either end. Verbal rating scales are easy to use but are the least sensitive to changes in pain intensity when compared with other scales (Searle et al., 2008). They also assume equal intervals between the adjectives and it is very unlikely that this is actually the case.

1.4.3 Numerical rating scale

Numerical rating scales are less sensitive than visual analogue scales (Searle et al., 2008). The patient gives their pain level a score, usually from one to ten, with no pain at one end and worst pain imaginable at the other.

1.4.4 The McGill pain questionnaire

The McGill pain questionnaire (Melzack, 1975) has three sections. A descriptive scale to record present pain intensity, a diagram of the human form on which the pain location is marked and a pain-rating index based on the selection of adjectives from 20 categories. The development of this questionnaire provided a major advance in clinical research regarding pain but completion of the questionnaire is very time consuming, even in its shortened form and the visual analogue scale has been shown to be as valuable clinically (Sokka, 2003).

1.4.5 The brief pain inventory

The brief pain inventory assesses the effect of pain on daily life, using numerical rating scales, as well as assessing the pain intensity and the relief gained from current pain treatments (Searle et al., 2008). It is not suitable for patients with cognitive impairment.

Orthodontic pain has been most commonly evaluated using the visual analogue scale, the numerical rating scale or a shortened form of the McGill pain questionnaire.

1.4.6 Clinically significant difference in pain scores with visual analogue scales

Clinical management of pain is performed using either pharmacological or non-pharmacological methods. In order to determine whether pain management is successful it is necessary to know what is a "clinically significant reduction in pain score". Using visual analogue scales to assess the pain severity, several studies have determined the clinically significant pain score reduction in young people. The majority of these studies have been carried out in Accident and Emergency departments on children and adolescents in acute pain, from a variety of causes. The clinically significant reduction in pain score on a 100 mm VAS ranged from 10 mm (Powell et al., 2001) to 13 mm (Todd et al., 1996). The mean clinically significant pain score reduction does not differ with the severity of the pain experienced (Kelly, 2001).

To the best of my knowledge no studies have determined the clinically significant reduction in pain scores for orthodontic patients.

1.5 Pain control during orthodontics

Pain control can be broadly divided into pharmacological and non-pharmacological methods. Within orthodontics the following methods have been used to reduce pain:

- The use of non-steroidal anti-inflammatories (NSAIDs)
- Bite wafers
- Vibration devices
- Transcutaneous electrical nerve stimulation (TENS)
- Low level laser use.

1.5.1 Pharmacological control

Numerous studies have investigated the pain relieving effect of various analgesics and found them to be successful in reducing orthodontic pain (Ngan et al., 1994; Steen Law et al., 2000; Bernhardt et al., 2001; Polat et al., 2005; Arias et al., 2006; Bradley et al., 2007; Bird et al., 2007; De Carlos et al., 2007).

Analgesics are the most commonly recommended method of pain control during orthodontic treatment and it is generally agreed that non-steroidal anti-inflammatories (NSAIDs) reduce the discomfort accompanying orthodontic treatment by reducing or inhibiting the inflammatory response caused by the orthodontic force. Ibuprofen and other NSAIDs act peripherally by inhibiting the synthesis of prostaglandins at the site of injury through inhibition of the

cyclo-oxygenase enzymes (COX-1 and COX-2). Phospholipase A₂ cleaves arachidonic acid from the phospholipid cell membrane and the COX enzymes act on the arachidonic acid to produce prostaglandins. Prostaglandins are important promoters of bone resorption and deposition and are therefore necessary for orthodontic tooth movement. A major concern is that the long-term use of NSAIDs will inhibit tooth movement. Arias et al. (2006) found less bone resorption following administration of ibuprofen in a rat model however the clinical significance of this in humans is still unclear.

Paracetamol in contrast to NSAIDs is thought to act centrally by inhibiting COX-3 enzymes in the brain and spinal cord. Bradley et al. (2007) compared the effectiveness of ibuprofen with paracetamol and concluded that ibuprofen was more effective in the control of orthodontic pain. However Bird et al. (2007) found no significant difference between ibuprofen and paracetamol in the reduction of pain from separators.

Aspirin (acetylsalicylic acid), like ibuprofen, acts on COX-1 and COX-2 enzymes and irreversibly inhibits COX-1 enzymes. It is contra-indicated in children under 12 years of age due to the risk of Reyes syndrome. Ngan et al. (1994) carried out a randomised double-blind trial of ibuprofen and aspirin and concluded that ibuprofen was more effective than aspirin in preventing orthodontic pain.

The use of ibuprofen prior to bond-up of fixed appliances or archwire adjustment has been shown to significantly reduce the pain experienced

(Ngan et al., 1994; Bernhardt et al., 2001; Polat et al., 2005; Bird et al., 2007) and it has been suggested that ibuprofen should be taken both before and after orthodontic appointments to maximise pain reduction (Bernhardt et al., 2001; Polat et al., 2005).

1.5.2 Non-pharmacological control

Low-level laser therapy theoretically reduces pain by either a direct effect on the nerve fibres that stabilises the depolarizing potential or by an inhibitory effect on the inflammatory response. Due to the low energy output and intensity of the lasers the effects are mainly non-thermal and biostimulatory. Clinically it has been used to reduce the pain associated with wound healing, oedema and inflammation. Applications within dentistry include the management of neuropathy (paraesthesia and trigeminal neuralgia), dentine hypersensitivity and oral mucositis following radiotherapy. Turhani et al. (2006) reported the low level laser to be beneficial in reducing pain following placement of a fixed appliance, however Hwang et al. (1994) found no statistically significant difference between the effect of the low level laser and a placebo on the reduction of pain caused by orthodontic separators. Unfortunately this is an expensive piece of equipment and is unlikely to be routinely available for everyday use in orthodontics.

Transcutaneous electrical nerve stimulation (TENS) acts to block the unmyelinated C-fibres in the spinal cord and thus prevent the transmission of painful stimuli by stimulating A- β fibres (the gate control theory). TENS has been reported as being effective in the reduction of pain following orthodontic

separation (Roth et al., 1986), however it is not routinely offered to patients as a method of pain relief.

Chewing on a bite wafer immediately following activation of an orthodontic appliance has been suggested to reduce pain by temporarily displacing the teeth and allowing blood flow to increase, preventing or relieving inflammation and oedema. Furstman (1972) thought this effect was due to loosening of tightly grouped fibres around nerves and blood vessels. Chewing must be instigated before the pain begins for it to be beneficial. The results of studies on the use of bite wafers has however been split. Hwang et al. (1994) reported just over 50% found the bite wafers beneficial whilst the remainder found the wafers to increase their pain and Otasevic et al. (2006) also found the bite wafers increased pain. Bhogal et al. (2008) investigated the effect of chewing a bite wafer immediately following bond-up of fixed appliances and found no statistically significant reduction in the pain experienced.

The Tooth Masseur™ is a commercially available product that provides vibratory stimulation of the teeth. It is designed to be used following bond-up and adjustment of fixed appliances and in a similar way to chewing, aims to re-establish the blood supply and prevent the ischaemic response that leads to pain. Marie et al. (2003) found that use of a vibratory device before the initial onset of pain significantly reduced the discomfort but if used once pain had begun it was poorly tolerated.

The intensity and episodic nature of pain experienced during orthodontic treatment is usually discussed with the patient as part of the informed consent process at the start of treatment. This information is normally supplemented with written guidance but frequently further mention is only made in response to concerns from patients.

Orthodontists should be aware of the potential causes of pain at all stages of treatment and the most effective methods of minimising pain experience.

The pain experienced during the process of debonding brackets is currently poorly quantified in the published literature and requires further investigation to provide adequate information for consent and to review potential methods of minimising discomfort.

Chapter 2

Materials and Methods

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2.1 Study aims

The aims of this study were:

1. To determine the pain experience during orthodontic fixed appliance treatment
2. To determine the expectations of pain during the debonding of orthodontic fixed appliances
3. To determine whether biting on a soft acrylic wafer reduces the pain experienced when debonding orthodontic fixed appliances

2.2 Null Hypotheses

- There is no difference between expected and perceived levels of pain during debonding of fixed appliances
- Biting on an acrylic wafer during debonding of fixed appliances does not reduce the pain experienced

2.3 Study design

The study was designed as a prospective randomised controlled trial. Patients being treated with fixed orthodontic appliances in the orthodontic departments of Mid-Staffordshire NHS Foundation Trust, Birmingham Dental Hospital and

University Hospital of North Staffordshire, who were ready for debond were invited to take part.

Subjects were randomly assigned to either the control or wafer group. They were asked to complete a questionnaire to determine their pain experience during fixed appliance treatment and their expectations of pain during the debond process. Their fixed appliances were then debonded using debond pliers in a standardised method. Those in the wafer group were asked to bite on a soft acrylic wafer as the brackets were debonded and those in the control group were asked to leave their teeth out of occlusion. Immediately following debond and composite removal the subjects completed a questionnaire to determine their pain experience during the debond.

The investigator performing the debond was aware of the group allocation for the participant but the individual (LM) who analysed the questionnaires did not know the group allocation.

2.4 Ethical approval and Research and Development approval

Ethical approval was gained from the Northern and Yorkshire Research Ethics Committee. Reference number: 09/H0903/6

Local NHS Research and Development approval was gained for the three research sites and site specific approval was also obtained from the respective local Research and Ethics Committees.

2.5 Randomisation process

The randomisation process was performed using Minitab computer software by the statistician, Dr AP White, from the University of Birmingham's Statistical Advisory Service. A runs test confirmed that there was no significant tendency to have runs of identical values in the data.

Sealed opaque envelopes were used to conceal the group to which the participant had been assigned. The envelopes were kept in a locked filing cabinet and opened by an independent individual when each participant was recruited to the study and had signed the consent, immediately prior to the debond process. Duplicate envelopes were available at each of the three sites and their use was co-ordinated via direct contact with the principle investigator.

2.6 Sample Size

A sample size calculation was performed by Dr AP White, University of Birmingham Statistical Advisory Service, using the following parameters:

- Power of study = 80%
- Significance level = 0.05
- To detect a difference of 13 mm on a visual analogue scale (100 mm long) with a standard deviation of 20 mm

The required sample size was calculated to be 39 subjects per group (78 subjects)

A difference of 13 mm on a VAS was taken to be a clinically significant difference in pain score based on research conducted by Todd et al. (1996) on children aged 5-16 years in acute pain in Accident and Emergency Departments. To the best of my knowledge no studies have determined the clinically significant reduction in pain score for orthodontic patients. A standard deviation of 20 mm was determined using data from an MPhil thesis investigating the discomfort associated with fixed appliances, in a similar cohort of patients (Bhogal et al., 2008).

2.7 Subjects

90 subjects were recruited from March 2009 to December 2009 from the Orthodontic Departments at Birmingham Dental Hospital, Mid-Staffordshire NHS Foundation Trust and University Hospital of North Staffordshire. All potential participants were approached at their routine appointment prior to the debond and invited to participate. The purpose of the trial was fully explained and they were given a letter inviting them to participate 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
- Full orthodontic fixed appliances in both arches, which were ready for debond.
 - Brackets either MBT prescription Victory series or MBT prescription SmartClip (both 3M Unitek). Both these brackets have bases of the same shape, size and morphology.
 - Precoated with APC adhesive (3M Unitek)
- Aged 12-18 years, as this is the most commonly treated age group.

2.7.2 Exclusion criteria

The following exclusion criteria were applied:

- Patients who had completed a previous course of orthodontic treatment as prior experience of treatment and discomfort may bias the results
- Patients unable to comprehend or complete the questionnaire
- Patients unwilling to sign the required consent form
- Patients with craniofacial syndromes or cleft lip and palate

2.8 Method

Informed consent was obtained and the subjects were randomly allocated to one of two groups, the control group (group 1) or the wafer group (group 2). Both groups completed the first visual analogue scale based questionnaire investigating their pain experience during their fixed appliance treatment and their expectations of pain during the removal of their appliances. The investigator was present whilst the questionnaires were answered to supervise and provide further information if required. The questionnaire used is shown in appendix 1.

Following completion of the first questionnaire the fixed appliances were debonded using a standardised procedure. Debonding pliers were used (see figures 2.8.3 and 2.8.4), beginning with the upper right quadrant and working around to the upper left quadrant, followed by the lower right quadrant around to the lower left quadrant. The archwire was left in-situ during the debond.

A fluted tungsten carbide bur in a contra-angled slow handpiece was then used to remove any residual composite (see figure 2.8.5), again following the same pattern of quadrants and moving back and forth from tooth to tooth to prevent overheating.

Immediately following removal of the brackets and the residual composite, the subjects completed a second series of questions related to the pain experienced during the debonding process, marking the level of pain once again on a visual analogue scale.

2.8.1 Group 1 (control)

This group of subjects had their appliances debonded using the standardised method described above. They were asked to keep their teeth out of occlusion during the debond.

2.8.2 Group 2 (wafer)

This cohort of subjects were asked to bite into a soft acrylic wafer as their fixed appliances were debonded using the standardised method. If molar bands were present on the molars they were removed without the subject biting into the wafer.

2.8.3 Soft acrylic bite wafer

The soft acrylic wafers were manufactured "in house" by the orthodontic laboratory at Birmingham Dental Hospital. They were constructed from 3 mm transparent Drufosoft® material (Dreve, GmbH) which is ethylene-

vinylacetate, a form of silicone (see figures 2.8.2 and 2.8.3) This material is commonly used in orthodontics for the manufacture of:

- Orthodontic retainers
- Positioners
- Sports mouthguards

Routinely our clinical practice would involve the use of a cotton wool roll to bite down onto, however this was considered too variable as the packing and softness of the cotton wool rolls varies considerably from batch to batch. The use of the fabricated wafers provided a standardised, single use material which could be used to provide an intrusive force onto the teeth when bitten into.

The Medicines and Healthcare Products Regulatory Agency (MHRA) was contacted prior to beginning the study regarding the use of the soft acrylic wafer, which is classified as a medical device. Registration with the MHRA was not required because the wafers were manufactured "in-house" and there were no plans to market them following completion of the study.

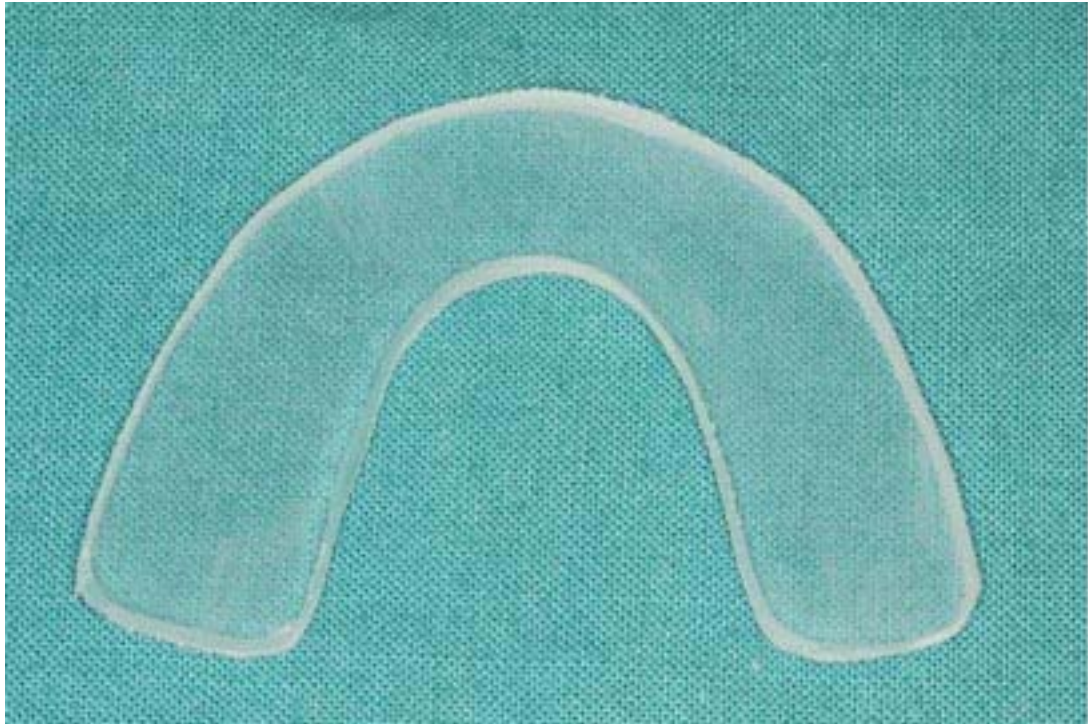


Figure 2.8.1 The soft acrylic bite wafer



Figure 2.8.2 The soft acrylic bite wafer in situ

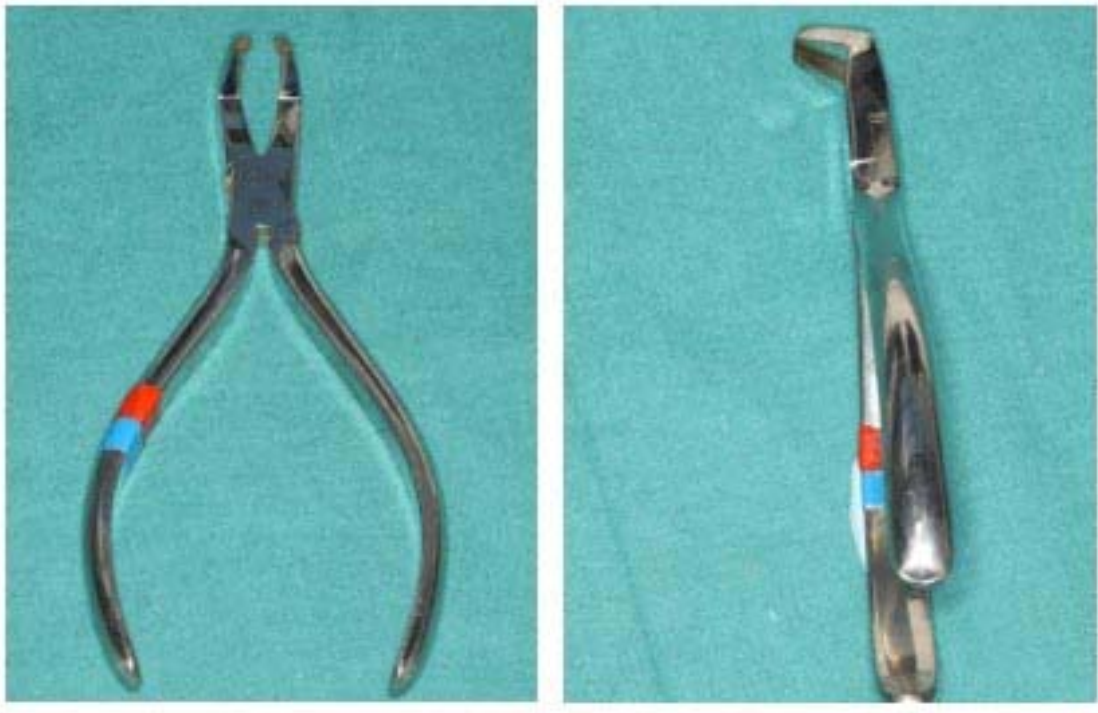


Figure 2.8.3 The debond pliers

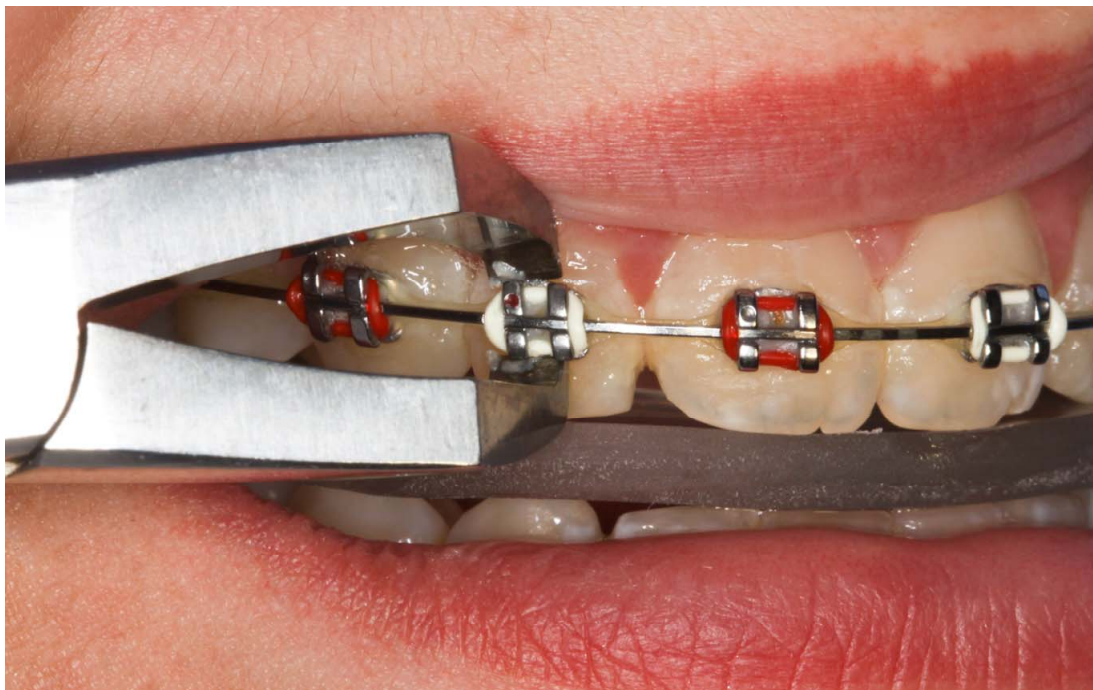


Figure 2.8.4 The debond pliers in use



Figure 2.8.5 Removal of the composite using a fluted tungsten carbide bur

2.9 The questionnaires

Each subject was asked to complete the 2 questionnaires and rate the severity of their pain 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. The subjects placed a vertical line on the scale to mark the point corresponding to their level of pain.

The first questionnaire, completed prior to debond, investigated the pain experienced overall during their fixed appliance treatment, the anxiety levels of the subjects before the debond and their expectations of the amount of discomfort they would experience during the debond. The questionnaire divided the teeth into the upper back teeth (molars and premolars), upper front teeth (canines and incisors), the lower back teeth (molars and premolars) and the lower front teeth (canines and incisors).

The second questionnaire recorded the actual amount of pain experienced as the brackets were debonded and when the residual composite was removed. The subjects were also asked to identify which sextant was the most painful, circling one answer only. The sextants comprised: upper right back teeth (molars and premolars), upper front teeth (canines and incisors), upper left back teeth (molars and premolars), lower right back teeth, lower front teeth and lower left back teeth. Finally subjects scored their satisfaction with the final treatment result.

Whilst the questionnaires were being completed the operator was present to answer any queries arising from the questions.

The questionnaire also recorded some basic demographic information about the subject and information about the type of fixed appliance including:

- Age
- Gender
- Bracket type - Victory series (3M Unitek) or SmartClip (3M Unitek)
- Attachments on the first molars - molar bands or molar bonds
- Duration of the fixed appliance treatment

The questionnaires used are shown in appendix 1.

The visual analogue scale scores were measured using digital callipers by one operator (LM). 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.

2.10 Statistical analysis

Statistical advice was given by Professor Dietrich, Professor of Oral Surgery, Birmingham Dental School.

PASW (Predictive Analytics SoftWare) 18.0 statistical program was used for the statistical analysis of the data.

The results were not normally distributed and so a logarithmic transformation was applied to all the VAS pain scores, of the form: $y = \log(\chi+1)$ prior to

carrying out the analyses. Using logarithmically transformed data enabled the use of parametric statistical tests.

The effect of the intervention (control or wafer group) was assessed using multiple regression analysis and the model was adjusted for age, gender, type of molar attachment and the expected pain at debond. Age and gender were adjusted for to account for any differences in pain scores between the males and females and any possible age differences. The type of molar attachment was included because due to the technique required to remove bands from the molars it is not possible for the wafer to be bitten on whilst the bands are removed. The overall pain expected during the debond was included in the regression analysis because it was baseline data and the expectations had the potential to influence the pain actually experienced.

The multiple regression analysis was carried out using logarithmically transformed data and so the percentage difference in pain scores between the control and the wafer groups was calculated, to give the log-transformed data a meaningful value.

The difference between the expected and actual pain scores was determined using Wilcoxon signed rank analysis.

Spearman's Rank correlations were determined between the overall pain experienced during the fixed appliance treatment, the level of anxiety about the debond, the overall pain expected during the debond and the actual pain experienced at debond.

Descriptive statistics were used to determine the most painful sextant during the debond.

The intra-examiner reliability for the measurement of the VAS was performed using intraclass correlation following re-measurement of 15 subject questionnaires.

Chapter 3

Results

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3.1 Baseline results

3.1.1 Baseline data

90 subjects participated, with 45 in each group. Overall there were more females than males (51 females and 39 males). The control group (group 1) had 23 females and 22 males whilst the wafer group (group 2) had 28 females and 17 males. The patients ranged from 13 to 18 years of age with a mean age of 15.96 years. The control and wafer groups were evenly matched for age, with mean ages of 15.89 years and 16.02 years respectively.

There was some variation in the type of molar attachment of the fixed appliances. Subjects were divided into those with molar bands on all 4 molars, those with molar tubes on all 4 molars and those with a combination of bands and tubes on the 4 molars. There were various combinations of bands and tubes however they were all incorporated into a single group due to the small numbers involved. Within the control group, 17.8% had all bands, 55.5% had all tubes and 26.7% had a combination of bands and tubes. In the wafer group, 15.6% had all bands, 46.6% had all tubes and 37.8% had a combination of tubes and bands.

The duration of the fixed appliance treatment ranged from 12-48 months with a mean duration of 26.92 months. The mean treatment for the control group was slightly less than the wafer group, 26.13 months and 27.71 months respectively.

Satisfaction with the overall treatment result was generally high, with a median VAS score of 98.32 (see table 3.1.1).

		Group 1 - Control	Group 2 - Wafer	Total
Subjects	Number	45	45	90
	Males (%)	22 (48.89)	17 (37.78)	39 (43.33)
	Females (%)	23 (51.11)	28 (62.22)	51 (56.67)
Age (years)	Mean (SD)	15.89 (1.465)	16.02 (1.588)	15.96 (1.521)
	Median	16.00	16.00	16.00
	Minimum	13	13	13
	Maximum	18	18	18
Molar attachment	Bands (%)	8 (17.8)	7 (15.6)	15 (16.7)
	Tubes (%)	25 (55.5)	21 (46.6)	46 (51.1)
	Bands+tubes (%)	12 (26.7)	17 (37.8)	29 (32.2)
Treatment duration (months)	Mean (SD)	26.13 (7.273)	27.71 (9.781)	26.92 (8.607)
	Median	25.00	25.00	25.00
	Minimum	12	12	12 - 48
	Maximum	41	48	48
Satisfaction with treatment result	Mean (SD)	91.55 (14.02)	94.79 (8.75)	93.19 (11.73)
	Median	98.51	98.20	98.32
	Minimum	48.79	49.18	48.79
	Maximum	100	100	100

Table 3.1.1 Baseline data

3.1.2 Pain experienced during the fixed appliance treatment

Subjects marked their pain during the fixed appliance treatment, see table

3.1.2. Overall the VAS pain scores varied considerably with a range of 0 - 90.4. The median score was 27.10.

Whilst the subjects were having their appliances adjusted there was again a large range of scores given, from 0 - 86.6. The median VAS pain score was 17.09.

24 hours post-adjustment of the fixed appliances the VAS pain scores were greater with a median of 35.46 and a range of 0 - 99.4.

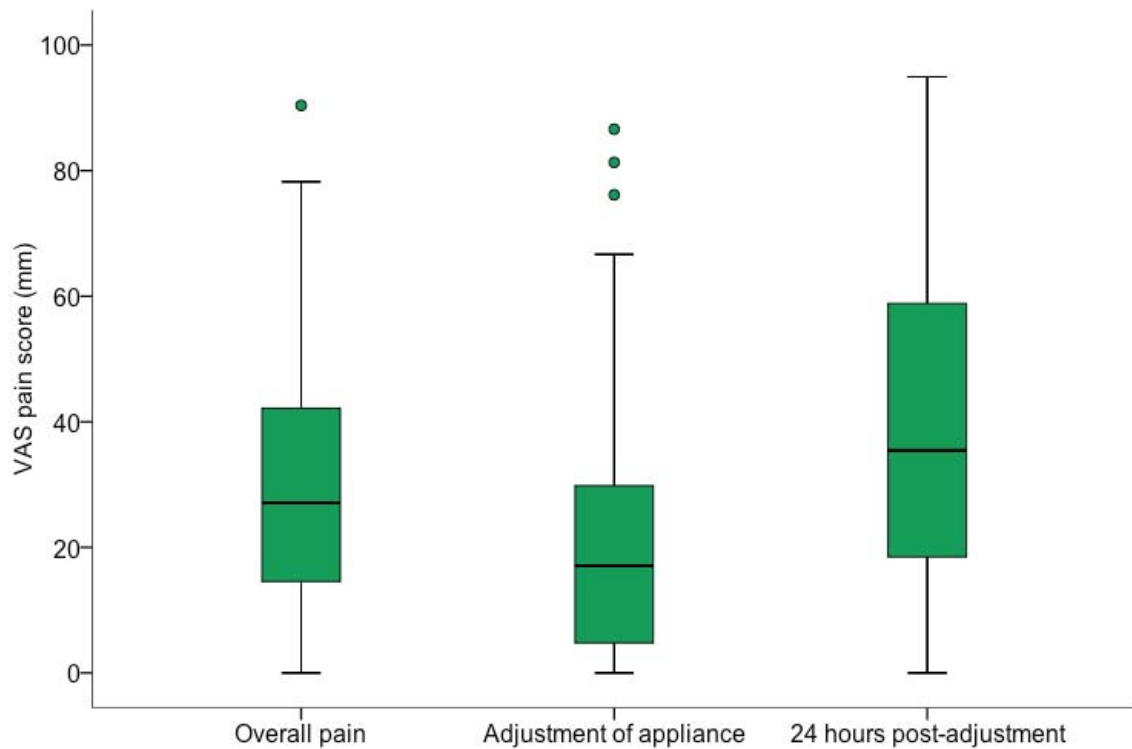


Figure 3.1.2 A box and whisker plot for the pain experienced during the fixed appliance treatment

The box represents the 25th to 75th percentiles with the 50th percentile (median) indicated by the black line. The whiskers indicate the range, up to 1.5 times the interquartile range and any values 1.5-3 times the interquartile range are classed as outliers and shown by the dots.

Pain during fixed appliance treatment		Group 1 control	Group 2 wafer	Total
Overall during FA	Mean (SD)	29.86 (19.05)	29.78 (20.99)	29.82 (19.93)
	Median	26.77	27.20	27.10
	Range	0 - 71.2	0 - 90.4	0 - 90.4
During adjustment	Mean (SD)	22.23 (18.44)	21.23 (22.72)	21.73 (20.58)
	Median	17.80	15.83	17.09
	Range	0 - 86.6	0 - 81.3	0 - 86.6
24 hours post adjustment	Mean (SD)	36.55 (26.08)	40.33 (25.29)	38.44 (25.62)
	Median	32.16	37.86	35.46
	Range	0 - 91.4	0 - 94.9	0 - 94.9

Table 3.1.2 Baseline data - the VAS scores for the pain experienced during fixed appliance treatment

3.1.3 Expectations of pain during the debond process

Levels of anxiety about the debond varied, see table 3.1.3. A full range of VAS scores (0 - 100) were given in response to how anxious the subjects were about the debond process. The median score for the level of anxiety was 11.43.

A large range of scores were given for the expectations of pain during the debond. The median VAS score for the overall levels of pain was 33.13. The wafer group expected slightly more pain overall than the control group, with VAS scores of 33.64 and 25.93 respectively.

Debond of the upper anterior teeth was expected to be the most painful, with a median VAS score of 33.69. The median expected VAS pain score when debonding the upper posterior teeth was 30.16. The lower anterior teeth were expected to be the third most painful with median VAS pain scores of 27.82 followed by the lower posterior teeth with median VAS score of 23.04. For all quadrants the wafer group expected slightly more pain than the control group. Expectations of the pain from the removal of the residual composite gave a median VAS pain score of 23.80. In contrast to the bracket removal, the control group expected more pain than the wafer group during composite removal with median VAS pain scores of 29.56 and 21.46 respectively.

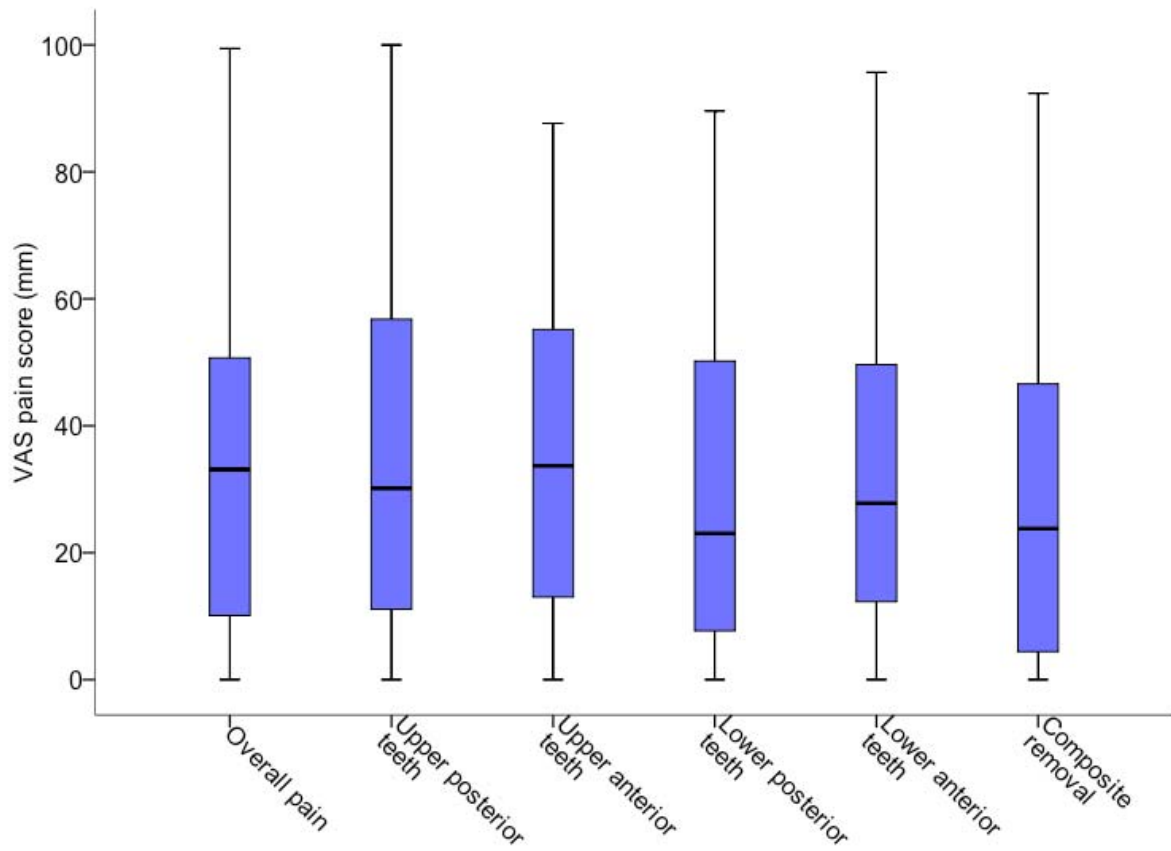


Figure 3.1.3 A box and whisker plot of the expectations of pain during the debond process for all subjects

Expectations of the debond process		Group 1 control	Group 2 wafer	Total
Anxiety about debond	Mean (SD)	22.24 (25.70)	24.34 (29.70)	23.29 (27.63)
	Median	13.19	11.40	11.43
	Range	0 - 89.9	0 - 100	0 - 100
Pain overall	Mean (SD)	30.20 (24.17)	35.94 (24.85)	33.07 (24.54)
	Median	25.93	33.64	33.13
	Range	0 - 76.0	0 - 99.4	0 - 99.4
Upper posterior teeth	Mean (SD)	32.37 (26.45)	36.94 (26.34)	34.66 (26.34)
	Median	29.35	30.41	30.16
	Range	0 - 88.1	0 - 100	0 - 100
Upper anterior teeth	Mean (SD)	32.87 (23.98)	37.44 (25.87)	35.15 (24.91)
	Median	33.23	34.77	33.69
	Range	0 - 85.7	0 - 87.7	0 - 87.7
Lower posterior teeth	Mean (SD)	29.79 (25.89)	31.47 (24.68)	30.63 (25.16)
	Median	22.30	23.55	23.04
	Range	0 - 83.8	0 - 89.6	0 89.6
Lower anterior teeth	Mean (SD)	29.62 (21.56)	35.49 (26.49)	32.55 (24.20)
	Median	25.99	27.85	27.82
	Range	0 - 75.7	0 - 95.7	0 - 95.7
Composite removal	Mean (SD)	30.72 (28.38)	27.73 (24.57)	29.44 (26.44)
	Median	29.56	21.46	23.80
	Range	0 - 92.4	0 - 88.4	0 - 92.4

Table 3.1.3 Baseline data - the VAS scores for the expectations of pain during the debond

3.2 Results

3.2.1 The actual pain experienced at debond

The VAS pain scores recorded for the debond, for the control and the wafer groups, are shown in table 3.2.1 and figure 3.2.1

Once again a large range of scores was obtained, in both the control and the wafer groups. Overall the pain experienced by the wafer group was less than that experienced by the control group, with median VAS scores of 14.88 for the wafer group and 20.65 for the control group.

The lower anterior teeth were reported to be the most painful by both the control and the wafer group, however the wafer group reported more pain than the control group. The median pain score for the wafer group was 20.55 whilst that of the control group was 16.36. For all other quadrants and the composite removal, the median VAS pain scores for the wafer group were lower than those of the control group. Debond of the lower posterior teeth and the upper anterior teeth gave the next highest scores and debond of the upper posterior teeth gave the lowest scores for both the wafer and the control groups when measured on the VAS.

The wafer was removed during removal of the residual composite and the total median VAS pain score was 10.26.

		Group 1 control	Group 2 wafer	Total
Overall pain	Mean (SD)	22.00 (18.15)	19.44 (19.45)	20.72 (18.30)
	Median	20.65	14.88	18.31
	Range	0 - 72.8	0 - 84.0	0 - 84.0
Upper posterior teeth	Mean (SD)	23.65 (25.20)	17.03 (20.80)	20.34 (23.21)
	Median	11.84	6.78	9.69
	Range	0 - 100	0 - 83.9	0 - 100
Upper anterior teeth	Mean (SD)	20.38 (21.35)	21.96 (20.46)	18.81 (22.33)
	Median	14.86	9.4	12.01
	Range	0 - 78.9	0 - 70.7	0 - 78.9
Lower posterior teeth	Mean (SD)	24.51 (24.86)	15.59 (17.84)	20.05 (21.98)
	Median	16.07	9.4	12.25
	Range	0 - 100	0 - 61.5	0 - 100
Lower anterior teeth	Mean (SD)	21.64 (19.30)	24.76 (25.02)	23.20 (22.27)
	Median	16.36	20.55	18.37
	Range	0 - 65.4	0 - 92.5	0 - 92.5
Composite removal	Mean (SD)	19.78 (21.93)	17.97 (23.62)	18.88 (22.68)
	Median	11.00	9.68	10.26
	Range	0 - 74.1	0 - 83.7	0 - 83.7

Table 3.2.1 The VAS scores for the pain experienced during the debond

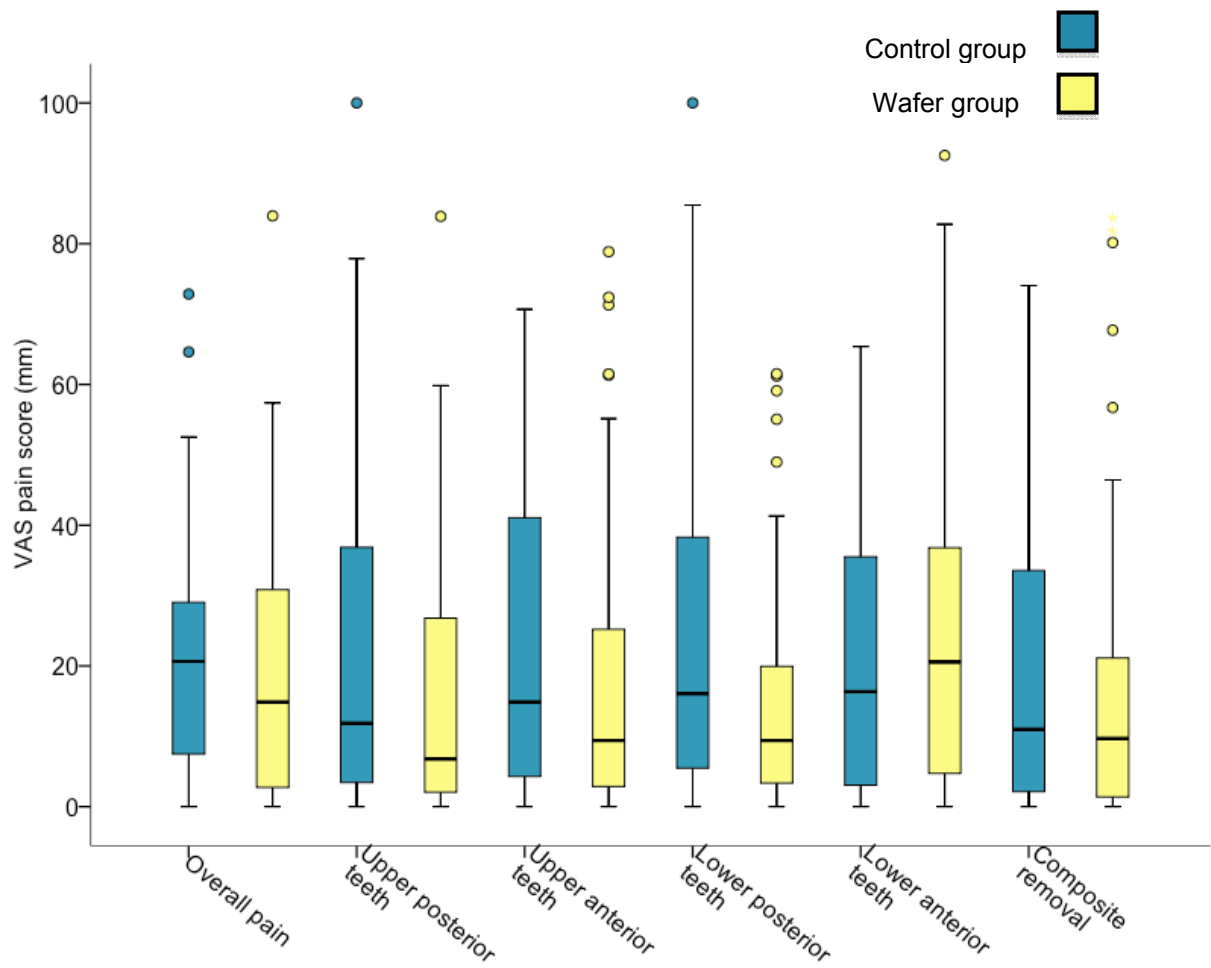


Figure 3.2.1 A box and whisker plot of the pain experienced during the debond for the control and wafer groups

3.2.2 The most painful sextant

The subjects separately selected the sextant that they felt was the most painful during the debond, see table 3.2.2 and figure 3.2.2. The lower anterior teeth were considered to be the most painful by 39% of the subjects. 18% thought the upper right posterior teeth were the most painful and this was followed by the upper anterior teeth, from 14%, and the lower right posterior teeth from 13% of the participants. The posterior teeth on the left side were the least frequently reported sextants, with only 6% considering the upper posterior sextant and 6% the lower posterior sextant the most painful. 4% of subjects were unable to choose only one sextant and marked more than one.

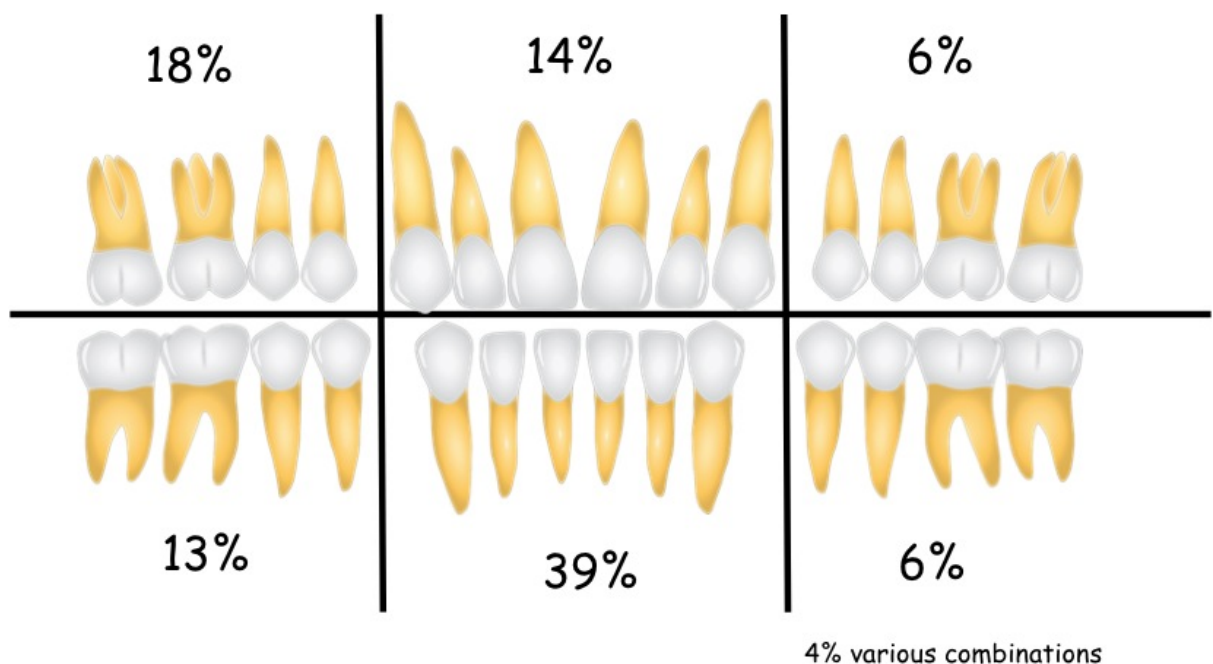


Figure 3.2.2 The most painful sextant during the debond

3.3 Analysis of the results

3.3.1 Multiple regression analysis of the control group compared with the wafer group

Multiple regression analysis was used to examine the effect of the intervention (see table 3.3.1). The wafer group had lower pain scores overall, for the posterior teeth and the upper anterior teeth, with up to a 55% difference in the pain scores (from the lower posterior teeth) however this did not reach statistical significance ($P = .107$, 95% confidence interval (C.I.) = -1.0, 0.1). The debond of the lower anterior teeth was more painful in the wafer group and the difference in pain was 11%, although again this was not statistically significant ($P = .742$, C.I. = -0.5, 0.7).

Once the multiple regression model had been adjusted for age, gender, type of molar attachment and the expected pain at debond, the wafer group had significantly less pain during debond of the upper posterior teeth ($P = .037$, C.I. = -1.1, 0) and the lower posterior teeth ($P = .031$, C.I. = -1.1, -0.1). For the posterior teeth the wafer resulted in a 79% reduction in the VAS pain scores. There was a 57% reduction in the pain scores for the upper anterior teeth, but this was not statistically significant ($P = .078$, C.I. = -1.0, 0.1). Similarly for the overall pain score, there was a 55% reduction with the wafer and again this was not statistically significant ($P = .079$, C.I. -0.9, 0.1).

In the fully adjusted model, the debond of the lower anterior teeth was more painful in the wafer group than in the control group and the difference in the pain scores was 20%. However there was no statistically significant difference between the two groups ($P = .496$, C.I. = -0.7, 0.3).

		Overall	Upper posterior teeth	Upper anterior teeth	Lower posterior teeth	Lower anterior teeth
Control / wafer	B	-0.31	-0.4	-0.22	-0.44	0.095
	% difference in pain	36%	49%	25%	55%	11%
	95% confidence interval	-0.81, 0.20	-1.0, 0.2	-0.8, 0.3	-1.0, 0.1	-0.5, 0.7
	Significance P-value	.236	.161	.427	.107	.742
Age / Gender adjusted	B	-0.35	-0.46	-0.29	-0.49	0.03
	% difference in pain	42%	58%	34%	63%	3%
	95% confidence interval	-0.9, 0.2	-1.0, 0.1	-0.8, 0.3	-1.0, 0.4	-0.5, 0.6
	Significance P-value	.183	.107	.292	.70	.912
Age, Gender, molar attachment adjusted	B	-0.33	-0.45	-0.28	-0.47	0.03
	% difference in pain	39%	57%	32%	60%	3%
	95% confidence interval	-0.8, 0.2	-1.0, 0.1	-0.8, 0.3	-1.0, 0.7	-0.6, 0.6
	Significance P-value	.204	.118	.319	.086	.933

		Overall	Upper posterior teeth	Upper anterior teeth	Lower posterior teeth	Lower anterior teeth
Age, gender, molar attachment, expected pain adjusted	B	-0.44	-0.58	-0.45	-0.58	-0.18
	% difference in pain	55%	79%	57%	79%	20%
	95% confidence interval	-0.9, 0.1	-1.1, -0.0	-1.0, 0.1	-1.1, -0.1	-0.7, 0.3
	Significance P-value	.079	.037	.078	.031	.496

Table 3.3.1 The multiple regression analysis for the effect of the intervention, adjusted for age, gender, type of molar attachment and the expected level of pain at debond, carried out on logarithmically transformed data.

B is the regression coefficient along with the 95% confidence interval. The percentage difference in pain is a calculated to give a meaningful value to the log-transformed values.

3.3.2 Wilcoxon Signed Rank analysis of the expected and actual pain scores at debond

Comparison of the expected pain scores and the actually experienced pain scores using Wilcoxon signed rank analysis showed the expected pain scores to be significantly greater than the experienced scores overall, for all quadrants and for the composite removal ($P = < .001$). See table 3.3.2 and figure 3.3.2

	Overall pain	Upper posterior teeth	Upper anterior teeth	Lower posterior teeth	Lower anterior teeth	Composite removal
Z	-4.194	-4.053	-5.349	-3.569	-4.159	-3.274
Significance P-value	.000	.000	.000	.000	.000	.001

Table 3.3.2 The Wilcoxon Signed Ranks Test to compare the expected pain scores with the actually experienced pain scores

Z is the Wilcoxon Signed Ranks test result.

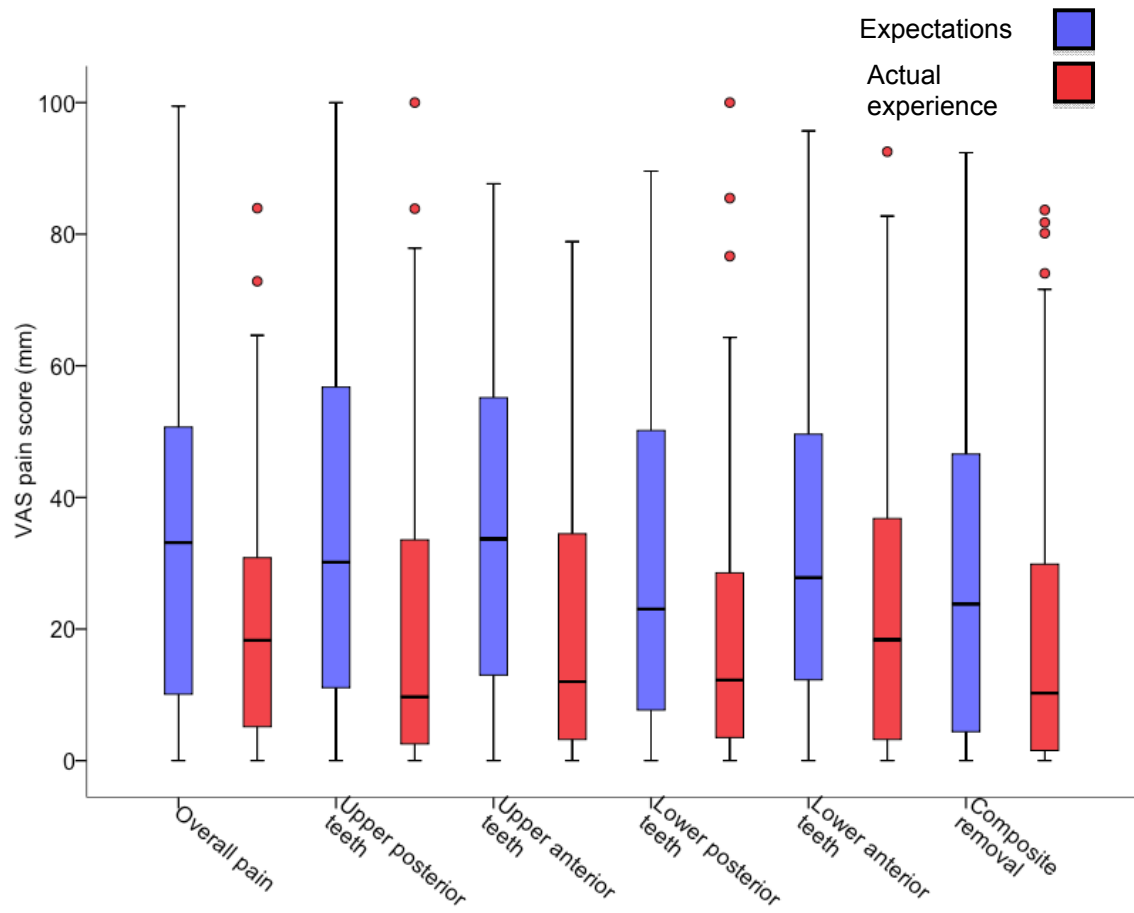


Figure 3.3.2 A box and whisker plot of the expected pain scores and the actual pain scores during the debond

3.3.3 Spearman's Rank Correlations

Correlations between the pain experienced during the fixed appliance treatment, the level of anxiety about the debond, the overall pain expected during the debond and the overall pain experienced were examined using Spearman's Rank correlations (see table 3.3.3).

There were significant correlations between the level of pain experienced during the course of fixed appliance treatment and the anxiety about the debond (correlation coefficient (r) = 0.215, P = .041), the expected level of pain at debond (r = 0.373, P = <.001) and the pain experienced during the debond (r = 0.408, P = <.001). The level of anxiety about the debond correlated with the expected pain (r = 0.617, P = <.001) and with the actually experienced pain (r = 0.249, P = .018). The expected pain scores correlated with the actually experienced pain scores (r = 0.340, P = .001). Subjects who experienced higher levels of pain during their fixed appliance treatment were more anxious about the debond, expected more pain and actually experienced more pain during the debond.

		Overall pain during fixed appliances	Anxiety about the debond	Overall pain expected	Overall pain experienced
Overall pain during fixed appliances	Correlation Coefficient <i>r</i>	1.000			
	Significance P-value	.			
Anxiety about the debond	Correlation Coefficient <i>r</i>	.215	1.000		
	Significance P-value	.041	.		
Overall pain expected	Correlation Coefficient <i>r</i>	.373	.617	1.000	
	Significance P-value	.000	.000	.	
Overall pain experienced	Correlation Coefficient <i>r</i>	.408	.249	.340	1.000
	Significance P-value	.000	.018	.001	.

Table 3.3.3 Spearman's rank correlations between the overall pain experienced during the fixed appliance treatment, the level of anxiety about the debond, the overall pain expected during the debond and the actual pain experienced at debond.

3.4 Intra-examiner reliability

Intraclass correlation coefficient for the measurement of the visual analogue scales was 0.984 indicating good intra-examiner reliability for the measurement of the visual analogue scale (see table 3.4).

Intraclass correlation	95% confidence interval of the difference	
	Upper	Lower
0.984	0.979	0.987

Table 3.4 The intraclass correlation coefficient for the intra-examiner reliability of the measurement of the visual analogue scale pain scores

Chapter 4

Discussion

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4.1 Baseline results

90 subjects participated in the study, with 45 per group. There were more females than males and this is a reflection of the female predilection in the orthodontic population at the sites included in the trial. Gender differences in the amount of pain experienced during orthodontic treatment have been reported by several studies, with females reporting more pain than males (Scheurer et al., 1996; Bergius et al., 2002). However other studies found no statistically significant differences in the pain scores of males and females (Ngan et al., 1989; Erdinc and Dincer 2004). In this study the wafer group consisted of more females than males and the potential difference in the reporting of pain was accounted for in the multiple regression analysis used.

The mean age of the subjects, 15.96 years, reflects the typical age of the patients treated at the three hospitals participating in the study. Patients over the age of 18 years were excluded, to minimise any effect of age on the results and to exclude patients who had undergone orthognathic surgery.

Routine orthodontic patients are commonly quoted an average treatment time of 18 to 24 months. The fixed appliance treatment duration for this study ranged from 12 to 48 months with a mean average of 26.92 months. This increased treatment duration may be a reflection of the complexity of the cases treated in hospital or it could possibly be due to the level of experience of the treating clinician, with Specialist Registrars providing the treatment for over half of the subjects.

Contemporary fixed appliances usually consist of brackets bonded to the enamel surface of the incisors, canines and premolars. The molars can either be banded or bonded with tubes. The type of attachment used on the molars is usually down to operator preference, but may be dictated by large buccal amalgam restorations or the need for additional tubes such as headgear tubes. A combination of attachments could be used, with bands on one or more of the molars and tubes on the remaining molars. At two of the hospitals (Mid-Staffordshire Foundation Trust and University Hospital of North Staffordshire) tubes are used preferentially for the molars whenever possible, unless the type of treatment, or the restorations present necessitates band placement. At the third site (Birmingham Dental Hospital) the use of bands is more common, again due to operator preference. The debonding procedure for bands is different to tubes and it is not possible for the subjects to occlude during removal of the bands. In this study, just over half of the subjects (51.1%) had tubes on all first molars and there were slightly more in the control group than the wafer group, 15 subjects (16.7%) had bands on all first molars and they were evenly distributed between the groups. Almost one third (32.2%) had a combination of bands and tubes on their first molars and there were slightly more in the wafer group than the control group.

Although the two groups were well matched for age there were differences in the number of males and females and the type of molar attachment. Ideally the two groups would have been matched for both gender and the type of molar attachments. Matched groups would have made the statistical analysis

more straightforward, however the number of subjects required per group would have been considerably greater.

The level of pain experienced during fixed appliance treatment was included to give background information on the pain of orthodontic treatment. The large range of pain scores given (0 - 94.9) indicates the subjective nature of pain and the great individual variation. This mirrors previous descriptions in the literature.

In keeping with previous research the pain experienced 24 hours post-adjustment of the fixed appliances was greater than that experienced during the adjustment or the overall pain experienced. Pain is expected to begin within 4 hours of archwire placement, to increase over the next 24 hours and then be followed by a gradual decrease over the next 2 to 4 days (Kvam et al., 1989; Jones et al., 1992; Ngan et al., 1994; Scheurer et al., 1996; Erdinc et al., 2004; Polat et al., 2005).

Patients are frequently advised to expect discomfort following adjustment of their appliances, but not usually during the actual adjustment. The results indicate that patients do experience pain during the adjustment of their appliances, with a median VAS score of 17.09 (range = 0 - 86.6) and perhaps patients should also be warned about this at the start of treatment.

Patient's expectations regarding the debond were investigated to give information about their specific concerns and to allow comparison with the actual debond process.

A full range of anxiety levels about the debond were reported with some subjects being extremely anxious whilst others were not at all concerned. The

median score was 11.43, which suggests a relatively low level of anxiety overall. 46 subjects listed particular concerns regarding the debond, the most common of which was, "having white marks" (decalcification) or, "discoloured teeth" (47.8%), followed by pain (41.3%). 4% were worried about both pain and staining of the teeth. Unfortunately decalcification is a common risk of orthodontic treatment and patients are informed of this at the beginning of treatment. The need for good oral hygiene and a low sugar diet is continuously reinforced throughout treatment to try and prevent decalcification and therefore it is not surprising that the most commonly listed concern was, "having marks on the teeth". Subjects were also worried about the possibility of pain during the debond and given that orthodontic procedures do have the propensity to cause pain, either immediately or after a few hours, this is also not surprising. Other comments made by individual subjects included concerns about, "bleeding gums", "the impressions", "having the bands removed" and their teeth "going out of shape".

Subjects expect to experience pain when their appliances are debonded and the overall median expected pain score was 33.13. This is greater than the reported overall pain during the fixed appliance treatment (median VAS score = 27.10). The upper teeth were expected to be more painful than the lower teeth, and the upper anteriors were expected to be the most painful (median VAS score = 33.69). Potentially this could be because the upper anterior teeth had been felt to be the most painful during the course of treatment, which might be expected if the upper anterior teeth had been retracted during treatment. However neither the type of presenting malocclusion nor the most

painful sextant during the fixed appliance treatment were recorded during the data collection.

Removal of the residual composite was expected to cause some pain, the median VAS score was 23.80, however this was one of the lowest expected pain scores given. This is perhaps somewhat surprising as anecdotal accounts describe the composite removal as uncomfortable and disliked by patients and many will have experienced composite removal due to bracket repositions and breakages.

4.2 Debond results

Williams and Bishara (1992), in their pilot study of the force that could be tolerated at debond, found that the lower incisors had the lowest threshold for the tolerated force and that mobility of the teeth reduced the threshold further. The threshold for discomfort varied depending upon the type of force applied, with intrusive forces tolerated best and torsional forces very poorly tolerated. They concluded that providing an intrusional force on the teeth during debond may reduce the discomfort experienced.

Theoretically biting on a soft acrylic wafer, or in the normal clinical environment, a cotton wool roll, reduces the pain associated with debonding by applying an intrusive force to the teeth. Provision of an intrusive force helps to stabilise the teeth and counteract the sheer/peel and torsional forces applied during the debond. Occluding during debond also helps to protect the

airway because if a bracket becomes detached from the archwire it will drop into the buccal sulcus, from where it can be easily retrieved, rather than dropping lingually and potentially down the airway.

Multiple regression analysis of the effect using the wafer, compared with the control group, indicates that providing an intrusional force during debond of the posterior teeth causes a statistically significant reduction in the pain experienced ($P = <.05$). There was no statistically significant reduction in pain for the anterior teeth. This difference may be because it is possible to provide a greater biting force with the posterior teeth, which is distributed along the long-axis of the tooth. When debonding the upper anterior teeth the wafer was repositioned to ensure that all of the anterior teeth were contacting the wafer, but due to the small differences in the level of the incisal edges (with the lateral incisor edges positioned just above those of the central incisors and canines, to achieve optimum aesthetics) perhaps the intrusive force may have been reduced on these teeth, and because of the inclination of the upper anterior teeth the intrusive force is not distributed along the long-axis.

In order to debond the lower anterior teeth it was necessary to ask the patient to bite into the wafer in an edge-to-edge incisor position. This was required to ensure that there was sufficient space between the incisal edge of the bracket and the upper incisors to accommodate the beaks of the debond pliers. It is conceivable that the biting force would be reduced by the forward positioning of the mandible to achieve the edge-to-edge position.

The use of a graduated wafer, which is thicker anteriorly and made of a slightly softer material may allow an even biting force to be applied to all of the

teeth.

The null hypothesis that biting on a soft acrylic wafer during debond does not reduce the pain experienced is rejected for the posterior teeth and accepted for the anterior teeth. Asking the patient to bite onto either a wafer or a cotton wool roll, whilst debonding, will also help to protect the airway and for these reasons it is recommended.

Subjects were also asked to choose the most painful sextant during debond. 39% reported the lower incisors to be the most painful. Clinical experience also suggests that the lower incisors are the most painful and this would be expected because of the small root surface area of these teeth. Pressure is equal to force per unit area and if a given force is dissipated over a smaller root surface area the pressure (and potential pain) will be increased.

The second most painful sextant was the upper right posterior teeth (18%), however explanation of this is more difficult. The standardised debond process began with the upper right molars. It could be that this was reported as the most painful by 18% because it was the first sextant to be debonded and as such was the most memorable. Additionally the two clinicians who carried out the debonds are both right-handed and operating on the right side requires a more twisted hand position and there is limited direct vision.

Because of this it could be that the posterior teeth on the right side are subjected to greater torsional forces, which are poorly tolerated. 14% thought the upper anterior teeth the most painful, followed by the lower right posteriors (13%) and the left posteriors, both upper and lower, were the most painful for

6%. Despite being asked to choose the one most painful sextant, 4% of subjects chose multiple sextants, with one subject selecting all of the sextants.

The expected pain was significantly greater than the actually experienced pain ($P = <.001$) so those patients who are concerned can be advised that the debond is unlikely to be as painful as they expect.

Thus the null hypothesis that there is no difference between the expected and actual pain scores is rejected.

Subjects who experienced more pain during their fixed appliance treatment expected and experienced more pain during the debond. They were also more anxious about the debond procedure.

Pain experience can be modulated by the emotional state of the patient and increased anxiety can act to lower the pain threshold. Similarly excitement, about the often long awaited debond, may raise the pain threshold or act to filter the painful stimuli and thus reduce the pain experienced.

Due to the relatively long duration of orthodontic treatment and the regular appointments, orthodontists are able to gain insight into the personality of the patient, their general response to treatment and therefore the likely response to the debond, with regard to the pain experience.

4.3 Additional information

Subjects were also given the opportunity to make additional comments, if they wished. Only 7 subjects (2 from the control group and 5 from the wafer group) responded. 3 subjects commented that they felt no pain (2 of whom were in the control group). One thought that the worst aspect was the noise of the handpieces and another that it was the removal of the glue (composite) from the back teeth. The final respondent commented, "biting on something made the pain less" which is positive for the study, although they had nothing to compare it to.

Chapter 5

Conclusions

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5.1 Conclusions

Patients experience pain during their fixed appliance treatment, including during appliance adjustment.

Biting on a soft acrylic wafer during debond of the posterior teeth reduces the pain experienced.

The lower anterior teeth are the most painful during the debond.

The levels of pain expected during the debond are significantly greater than the actually experienced pain.

Patients who experience greater pain during their fixed appliances expect and actually experience greater pain during the debond of their appliances

5.2 Null hypotheses

There is no difference between the expected and experienced levels of pain during debonding of fixed appliances.

- Rejected

Biting on a soft acrylic wafer during debonding of fixed appliances does not reduce the pain experienced.

- Rejected for the posterior teeth

5.3 Recommendations for clinical practice

Orthodontic procedures can be painful and patients should be fully informed of this as part of the initial consent. As clinicians we should strive to make treatment as comfortable as possible for our patients. As part of this, providing an intrusive force on the teeth during debond, particularly for the posterior teeth can reduce the discomfort. It will also help to protect the airway if a bracket becomes detached from the archwire. This intrusive force can be applied using a custom made soft acrylic bite-wafer, or more simply by using a cotton wool roll which is routinely available. Patients can be anxious about the debond and when necessary should be reassured that it is unlikely to be as bad as they are expecting.

5.4 Further research

Further research into the pain associated with the debond of orthodontic fixed appliances could include the debond of ceramic brackets compared to metal brackets and the debond of adult patients.

Consideration should be given to the use of a graduated bite wafer, which is thicker in the anterior section to provide a more uniform biting force around the arch. If a slightly softer material was used for construction of the bite wafer it would ensure all of the anterior teeth occluded firmly into the wafer.

Information of the presenting malocclusion and the extraction pattern should be recorded as this would provide information on whether the teeth that had been moved the furthest were the most uncomfortable.

Appendix 1: The questionnaire

PATIENT ID NUMBER:

AGE:

SEX:

APPLIANCE: MBT Victory Smartclip
 Bonds Bonds+Bands

DURATION OF TREATMENT:

PAIN EXPERIENCE DURING TREATMENT

Please make a small vertical line on each horizontal line below e.g. (-----
|-----)

1. How much pain have you had overall during your fixed brace treatment?

No pain

Worst pain
imaginable





2. How much pain did you experience during each appointment?

No pain

Worst pain
imaginable





3. How much pain did you experience the day following each appointment?

No pain

Worst pain
imaginable





EXPECTATIONS OF REMOVAL OF YOUR FIXED BRACES

Please make a small vertical line on each horizontal line below e.g. (----
|-----)

1. How worried are you about the removal of your fixed braces?

No worries

Extremely
worried





**2. Is there anything particular you are worried about e.g. pain, what will your teeth feel like, will I have white marks?
(please write below)**

3. Do you think removal of your fixed braces will be painful?

No pain

Worst pain
imaginable





4. Do you think the top back teeth will be painful?

No pain

Worst pain
imaginable





5. Do you think the top front teeth will be painful?

No pain

Worst pain
imaginable





6. Do you think the bottom back teeth will be painful?

No pain

Worst pain
imaginable





7. Do you think the bottom front teeth will be painful?

No pain

Worst pain
imaginable





8. Do you expect the removal of the glue to be painful?

No pain

Worst pain
imaginable





REMOVAL OF YOUR FIXED BRACES

Please make a small vertical line on each horizontal line below e.g. (----
|-----)

1. Overall how did you find the removal of your braces?

No pain

Worst pain
imaginable





2. How was the removal of the top back teeth brackets?

No pain

Worst pain
imaginable





3. How was the removal of the top front teeth brackets?

No pain

Worst pain
imaginable





4. How was the removal of the bottom back teeth brackets?

No pain

Worst pain
imaginable





5. How was the removal of the bottom front teeth brackets?

No pain

Worst pain
imaginable





6. How was the removal of the glue?

No pain

Worst pain
imaginable





7. Circle the teeth that were the most uncomfortable.

Right top back teeth	Front top teeth	Left top back teeth
Right bottom back teeth	Front bottom teeth	Left bottom back teeth

8. How happy are you with the result?

Very happy

Not very
happy





ADDITIONAL COMMENTS AND SUGGESTIONS

Please make any additional comments/suggestions that you feel would be helpful to our study. For example, you may describe the worst feature of any pain that you may have experienced.

Appendix 2: Raw data

Subject number	Age	Gender	Appliance	Tubes /bands	Treatment duration	Control /wafer	Satisfaction with result
1	18	0	1	3	30	0	70.52
2	13	0	1	3	24	0	100.00
3	13	0	1	1	18	0	50.36
4	15	1	1	2	30	1	98.20
5	15	0	2	2	19	0	95.77
6	15	1	1	2	23	0	100.00
7	17	0	1	2	18	0	100.00
8	15	1	1	2	19	1	95.08
9	17	1	1	3	41	1	98.81
10	17	1	1	2	33	1	84.20
11	15	0	1	3	25	1	100.00
12	15	1	1	3	41	0	95.67
13	17	0	1	2	32	1	97.37
14	15	0	1	2	25	1	100.00
15	18	0	1	2	22	1	98.80
16	16	0	1	2	24	0	85.18
17	18	1	1	2	21	1	84.94
18	16	0	1	2	22	0	100.00
19	18	1	1	2	38	1	99.33
20	18	0	1	9	37	0	91.82
21	15	1	1	2	12	0	86.09
22	16	1	1	3	23	1	99.29
23	15	1	1	2	30	0	100.00
24	16	0	1	2	16	1	49.18
25	13	0	1	1	12	1	100.00
26	15	1	1	2	26	0	100.00
27	17	0	1	1	34	1	100.00
28	18	0	1	2	28	1	99.74
29	18	0	1	3	24	0	100.00
30	16	0	1	2	19	1	85.83
31	18	1	1	5	16	1	96.53
32	16	1	1	3	12	0	100.00
33	16	0	1	1	37	0	99.11
34	15	1	1	1	21	1	100.00
35	18	1	1	2	39	0	100.00
36	18	1	1	2	39	0	100.00
37	15	1	1	2	15	1	100.00
38	18	0	2	2	38	1	96.92
39	18	0	1	1	42	1	100.00
40	16	1	2	2	25	0	92.64
41	16	0	1	3	40	1	96.79
42	16	0	1	1	24	1	97.29
43	14	1	1	3	27	1	100.00
44	15	0	1	1	31	0	97.87
45	18	0	1	4	26	0	78.32
46	18	1	1	2	24	1	81.18
47	18	0	1	6	48	1	100.00
48	15	1	1	8	38	0	91.30
49	17	0	1	2	13	1	100.00
50	14	0	1	3	20	1	95.10
51	14	0	1	3	32	0	96.99
52	17	0	1	3	24	1	98.48
53	18	1	1	1	24	0	100.00
54	14	1	1	2	18	0	100.00

55	18	0	1	1	19	1	91.07
56	16	1	1	2	29	0	100.00
57	16	1	1	3	24	0	98.51
58	16	0	1	3	29	0	100.00
59	16	1	1	2	30	1	98.45
60	14	1	1	2	18	1	100.00
61	16	0	1	2	27	0	100.00
62	14	0	1	8	22	1	93.94
63	14	1	1	2	23	0	63.83
64	15	0	1	1	33	0	76.08
65	18	1	1	2	37	0	52.46
66	15	1	1	2	23	1	100.00
67	15	0	1	2	41	1	92.81
68	16	1	1	3	31	1	90.26
69	17	1	1	1	24	0	100.00
70	15	1	1	2	17	0	93.11
71	15	0	1	2	22	0	95.91
72	16	0	1	2	27	0	99.49
73	16	0	1	3	28	1	96.23
74	17	0	1	2	28	0	100.00
75	13	0	1	3	21	1	84.67
76	15	0	1	3	37	1	100.00
77	18	0	1	1	30	0	48.79
78	16	0	1	3	32	0	81.75
79	18	0	1	1	41	1	87.97
80	14	0	1	2	14	1	99.69
81	15	0	1	3	35	1	92.01
82	17	1	1	2	18	0	94.48
83	18	0	1	1	25	0	86.02
84	15	1	1	2	25	0	97.64
85	15	0	1	2	24	0	100.00
86	18	0	1	3	44	1	88.27
87	14	1	2	2	17	0	100.00
88	16	0	1	7	48	1	97.00
89	14	1	1	2	16	0	100.00
90	13	1	1	2	25	1	100.00

Subject number	Overall FA pain	Pain during adjustment	Pain at 24 hours
1	18.46	12.43	24.65
2	4.63	3.07	15.42
3	29.60	54.48	66.74
4	16.14	15.89	26.46
5	54.50	.94	.83
6	.0	.0	13.40
7	30.89	26.08	33.24
8	20.68	25.38	61.56
9	28.71	10.33	56.78
10	5.73	2.27	10.91
11	78.22	14.27	87.04
12	21.59	39.42	.0
13	26.18	22.66	36.52
14	59.62	.0	81.18
15	17.67	4.30	38.36
16	32.55	23.73	32.16
17	12.50	5.95	38.30
18	12.42	13.51	32.11
19	7.34	.0	18.49
20	54.97	22.19	73.82
21	14.58	13.49	20.62
22	29.40	.0	33.99
23	44.42	6.16	21.03
24	.0	.61	.0
25	26.99	47.41	60.46
26	29.45	40.17	27.49
27	27.28	56.35	33.07
28	58.22	66.68	68.67
29	27.49	14.13	.0
30	33.51	22.43	61.82
31	13.87	18.55	49.40
32	20.71	.0	.0
33	16.91	36.93	56.51
34	27.23	24.83	23.96
35	64.04	27.51	49.20
36	21.74	21.53	43.40
37	.0	.0	18.87
38	23.45	4.37	41.24
39	43.05	53.92	67.35
40	22.42	17.80	50.89
41	21.74	26.69	34.39
42	48.19	15.83	67.99
43	.0	25.79	47.21
44	38.25	27.30	45.65
45	21.93	29.82	43.58
46	30.01	43.67	90.05
47	20.90	6.15	47.57
48	48.55	86.60	79.94
49	30.72	7.78	31.19
50	21.07	3.82	37.86
51	13.10	20.40	28.95
52	10.54	2.79	1.53
53	54.90	8.54	79.20
54	.0	.0	.0
55	49.12	9.06	31.38
56	9.14	5.59	15.12
57	64.56	66.44	86.48
58	35.87	30.67	61.17

59	41.94	17.09	11.99
60	13.21	.78	18.02
61	4.31	15.15	3.77
62	72.42	24.90	7.31
63	17.86	.0	3.74
64	36.38	10.08	37.80
65	36.74	23.52	58.86
66	10.59	.0	2.58
67	16.15	1.52	33.51
68	55.96	57.36	73.06
69	10.23	35.01	.20
70	55.23	49.02	61.00
71	51.14	4.78	63.77
72	46.64	11.20	40.75
73	90.39	60.49	94.94
74	3.60	2.79	19.24
75	59.40	45.19	51.61
76	29.43	3.58	15.70
77	61.71	11.24	49.19
78	71.22	43.71	91.38
79	27.20	76.15	51.30
80	42.17	.0	43.26
81	9.35	10.13	.0
82	26.77	17.55	30.55
83	25.33	17.14	66.80
84	20.43	26.26	26.82
85	23.51	30.67	54.53
86	12.47	17.08	65.46
87	36.85	38.56	24.52
88	29.16	22.12	33.21
89	8.12	14.68	10.29
90	41.97	81.32	9.45

Subject number	Anxiety	Expected pain overall	Expected upper posteriors	Expected upper anteriors	Expected lower posterior	Expected lower anteriors	Expected composite removal
1	19.32	58.93	58.93	62.03	55.44	66.12	77.15
2	.87	1.61	1.61	2.29	5.09	5.73	6.35
3	.65	50.75	50.75	16.09	83.82	12.04	76.91
4	.97	30.53	30.53	.0	.85	.37	.0
5	.0	.0	.0	.0	.0	.0	.42
6	.0	.0	.0	.0	.0	.0	.0
7	.0	.20	.20	.0	.14	.28	.49
8	.73	59.61	59.61	68.09	61.77	58.92	20.13
9	92.79	76.72	76.72	78.20	77.87	80.72	16.26
10	1.02	3.86	3.86	4.33	3.67	3.52	12.12
11	5.56	45.09	45.09	31.90	30.81	5.76	4.40
12	19.44	43.07	43.07	16.16	47.93	11.08	46.20
13	44.23	35.39	35.39	41.89	16.70	34.40	37.60
14	62.35	32.99	32.99	30.31	55.55	46.92	18.56
15	3.68	3.48	3.48	5.93	16.29	9.13	3.69
16	86.01	76.02	76.02	43.23	46.82	49.62	49.16
17	1.73	47.31	47.31	72.54	27.62	69.70	1.70
18	38.98	26.66	26.66	19.48	20.53	20.04	30.88
19	.0	6.84	6.84	.84	1.35	1.35	1.77
20	3.37	43.78	43.78	51.44	7.72	13.06	41.59
21	3.20	36.13	36.13	41.03	28.93	42.44	36.01
22	16.67	32.82	32.82	63.19	66.49	18.73	76.24
23	3.93	10.36	10.36	11.29	14.58	14.12	43.04
24	.0	.0	.0	12.67	11.40	6.82	.0
25	89.16	85.47	85.47	82.73	83.45	95.69	55.64
26	.85	.59	.59	26.67	1.14	37.72	14.35
27	.0	66.78	66.78	63.75	6.93	64.23	.0
28	1.27	33.64	33.64	34.77	36.58	44.21	34.33
29	59.99	64.43	64.43	54.51	83.59	52.21	30.26
30	65.45	48.17	48.17	50.72	22.79	64.62	47.49
31	6.34	17.34	17.34	14.94	16.11	14.19	13.51
32	.0	.0	.0	.0	.54	.0	.72
33	89.86	49.48	49.48	59.81	61.55	62.33	31.01
34	.28	16.57	16.57	18.45	20.29	20.28	19.52
35	.0	.0	.0	11.12	59.26	10.10	57.34
36	39.48	46.58	46.58	47.10	45.58	44.59	13.96
37	31.37	10.11	10.11	4.19	20.34	49.17	64.03
38	20.25	22.95	22.95	27.78	15.63	15.81	22.51
39	100.00	99.44	99.44	83.08	76.08	74.97	88.35
40	13.19	50.61	50.61	55.17	21.56	19.16	29.56
41	59.50	53.30	53.30	26.80	32.38	24.90	13.54
42	4.79	34.03	34.03	42.60	23.55	27.85	36.02
43	.0	43.55	43.55	65.84	65.56	63.74	.0
44	18.78	25.93	25.93	42.47	28.66	47.22	40.41
45	.0	16.18	16.18	11.28	4.85	13.25	32.82
46	11.46	70.24	70.24	18.33	14.93	14.41	31.06
47	13.41	23.01	23.01	22.84	23.58	23.61	36.53
48	76.07	60.62	60.62	66.75	66.74	67.31	92.38
49	10.77	15.31	15.31	35.92	16.37	29.32	16.93
50	3.18	21.57	21.57	28.32	10.67	12.38	28.60
51	.70	6.01	6.01	4.08	6.62	5.19	5.74
52	7.66	11.59	11.59	6.64	5.08	5.28	3.85
53	22.40	41.66	41.66	76.74	5.29	25.59	3.30
54	.0	8.52	8.52	6.07	7.48	7.66	10.82
55	.64	33.27	33.27	36.19	43.90	27.22	1.69
56	43.32	19.41	19.41	22.80	1.17	19.85	2.01
57	4.10	1.73	1.73	34.32	3.77	32.75	5.48
58	61.88	47.56	47.56	44.42	55.38	50.97	82.78

59	1.88	1.76	1.76	5.11	3.49	4.14	3.65
60	.89	21.87	21.87	15.02	10.54	12.29	25.08
61	10.60	16.58	16.58	11.43	12.72	12.38	12.38
62	40.43	36.42	36.42	16.58	28.01	7.62	74.34
63	36.79	24.59	24.59	34.15	38.46	31.46	46.60
64	.0	33.83	33.83	33.23	22.30	29.06	15.49
65	41.12	62.83	62.83	49.27	47.96	47.65	84.09
66	.0	.93	.93	2.91	2.01	1.88	.63
67	2.56	25.64	25.64	22.61	6.76	27.78	29.54
68	28.35	59.44	59.44	57.25	59.86	58.33	50.24
69	.0	62.61	62.61	85.78	3.33	41.87	.16
70	38.56	57.67	57.67	61.40	58.88	58.32	10.42
71	.0	3.24	3.24	6.29	7.70	7.93	.0
72	69.26	60.12	60.12	64.98	69.84	75.69	70.73
73	11.40	3.97	3.97	87.66	89.59	40.79	36.67
74	47.20	56.25	56.25	45.98	62.44	49.41	.80
75	44.72	43.91	43.91	55.88	39.23	57.89	47.27
76	48.16	50.48	50.48	48.59	16.27	58.50	5.55
77	34.35	53.32	53.32	47.14	56.20	44.66	52.91
78	37.34	68.05	68.05	76.29	23.29	68.67	91.36
79	100.00	79.25	79.25	57.45	45.27	69.10	47.01
80	30.76	38.47	38.47	35.34	37.58	39.37	21.46
81	40.37	64.96	64.96	70.24	65.08	76.02	67.89
82	13.27	6.12	6.12	16.29	20.20	18.53	20.70
83	32.35	23.16	23.16	43.40	68.46	24.35	47.02
84	5.49	14.38	14.38	12.09	35.55	34.38	41.59
85	3.11	7.61	7.61	13.02	17.97	25.99	1.04
86	11.68	49.45	49.45	49.63	50.18	48.18	16.57
87	15.62	15.62	15.62	26.73	2.96	3.28	1.06
88	50.53	50.68	50.68	68.89	41.82	70.27	78.99
89	9.56	6.41	6.41	25.24	28.32	28.78	25.63
90	28.17	9.31	9.31	17.87	15.99	16.70	36.87

Subject number	Overall pain	Pain upper posteriors	Pain upper anteriors	Pain lower posteriors	Pain lower anteriors	Pain composite removal	Most painful sextant
1	48.13	65.90	70.68	40.41	35.50	15.60	1
2	19.86	6.97	17.95	13.12	23.53	11.00	5
3	38.60	35.61	3.21	41.10	2.30	.09	1
4	.09	.02	.88	.0	.0	.0	6
5	25.64	.77	1.60	62.79	22.48	.0	6
6	8.50	29.20	.26	26.74	.0	.0	1
7	12.60	1.66	.46	11.07	.0	3.34	6
8	57.38	59.82	55.13	61.19	59.49	29.88	5
9	5.84	5.39	5.10	4.30	4.88	.0	5
10	5.15	5.66	7.19	3.61	5.05	.0	1
11	9.64	20.12	3.47	13.86	11.71	25.56	6
12	29.04	64.45	18.25	64.32	19.78	.67	1
13	18.52	26.78	22.25	22.02	20.55	29.95	1
14	14.88	.0	25.19	55.06	27.83	.55	6
15	38.71	10.58	18.15	11.69	11.66	8.27	1
16	28.51	33.57	33.98	62.24	59.04	60.05	5
17	45.15	46.47	71.29	28.62	69.44	46.41	5
18	7.49	14.63	7.02	15.56	9.95	28.46	1,3,4,6
19	.0	.0	1.05	.34	1.12	.0	1,2,3,4,5,6
20	26.18	72.84	31.24	27.04	47.25	15.81	3
21	2.29	1.42	5.14	1.58	2.65	5.49	5
22	4.58	5.78	5.73	5.06	4.72	11.88	5
23	.0	.0	.0	.0	.0	.0	1
24	.0	6.82	6.90	6.90	6.60	15.42	2
25	12.16	2.66	1.56	.0	.86	11.29	5
26	.0	.0	.0	.0	.0	.0	5
27	20.79	83.87	2.86	4.02	24.04	1.39	1
28	42.78	47.90	72.39	41.29	68.86	41.14	5
29	36.79	23.87	25.10	28.55	33.11	56.11	5
30	34.16	58.25	26.65	59.10	20.60	56.72	6
31	6.80	15.41	15.09	13.76	16.95	13.08	2
32	.0	.0	.0	.0	.0	.0	3
33	24.73	60.25	61.96	23.79	34.08	31.75	1
34	24.66	21.35	9.62	28.51	22.50	.48	4
35	52.53	100.00	12.00	100.00	.0	14.32	4
36	3.47	2.32	1.80	2.35	3.23	2.15	2
37	83.95	.0	7.51	3.36	25.67	83.67	6
38	1.94	1.08	1.09	1.86	1.32	6.60	5
39	18.88	5.30	78.86	16.19	74.92	.0	2
40	8.54	1.42	11.28	3.39	26.11	15.14	5
41	18.09	50.64	9.40	13.78	13.25	1.83	1
42	4.56	5.00	5.00	6.59	8.47	14.79	5
43	46.16	.0	.31	12.13	40.84	.0	5
44	17.89	9.15	20.88	18.70	11.76	2.76	2
45	6.89	3.44	12.49	.80	29.66	4.02	5
46	34.13	24.85	61.30	19.84	82.75	80.16	5
47	1.05	.0	.57	.47	.65	.0	5
48	28.73	11.07	31.02	11.35	37.87	1.56	2
49	23.72	13.02	12.01	19.95	31.59	13.21	5
50	2.10	1.94	1.75	1.52	12.58	10.12	5
51	1.22	1.57	.92	1.23	.0	3.94	3
52	.0	.0	.0	.44	.0	3.11	5
53	12.47	7.03	34.48	19.59	3.05	1.35	4
54	3.96	9.06	.0	.0	1.95	1.46	1,3
55	32.49	27.87	14.88	23.29	21.10	1.68	6
56	5.57	6.39	14.86	9.24	12.27	.99	2
57	20.65	2.54	1.75	2.27	1.50	74.05	5
58	5.70	23.40	8.91	11.54	12.32	11.26	1

59	2.55	5.68	4.02	2.35	2.32	4.45	4
60	1.04	.0	.0	.97	.61	4.26	5
61	10.81	10.30	9.30	8.70	9.55	9.56	6
62	30.85	6.78	10.35	6.88	30.86	46.44	5
63	47.03	48.29	45.39	46.77	51.63	51.51	3
64	23.31	17.54	15.13	9.84	11.31	35.33	1
65	21.47	36.85	35.05	32.65	31.54	47.10	4
66	.60	2.07	.0	.0	.0	.0	2
67	2.74	5.51	3.95	3.74	3.43	6.98	5
68	19.96	27.32	33.15	34.41	37.18	15.90	3
69	2.84	5.30	6.92	5.49	27.22	21.33	5
70	72.84	77.88	65.34	85.48	65.40	4.27	6
71	20.65	1.04	5.28	3.52	12.15	6.43	5
72	30.93	49.22	44.47	50.05	64.31	33.56	5
73	19.16	4.89	61.48	3.78	43.31	81.78	2
74	26.03	11.84	41.15	16.07	37.49	25.62	5
75	56.74	55.77	35.64	61.50	30.10	67.71	1,3,4,6
76	12.94	47.20	37.03	16.94	36.79	.43	1
77	39.03	38.63	41.05	38.28	38.55	35.26	6
78	64.62	47.03	44.92	76.66	48.40	71.63	2
79	28.99	11.50	21.55	14.50	55.03	15.03	5
80	.30	1.39	1.42	.88	1.27	4.99	1
81	25.76	5.01	18.51	6.41	55.11	14.41	5
82	9.33	6.85	4.31	5.73	7.01	10.40	2
83	20.65	19.65	48.33	25.18	27.59	53.35	2
84	46.63	47.60	53.48	40.19	39.08	14.93	1
85	16.97	34.52	43.45	28.90	16.36	5.35	2
86	8.93	8.27	8.74	9.40	6.76	9.68	6
87	51.59	13.66	42.46	12.36	45.37	47.12	5
88	6.40	9.88	17.96	11.95	28.72	21.13	5
89	9.49	9.49	14.86	18.23	11.81	55.98	5
90	49.28	28.45	49.26	48.97	92.54	8.40	5

Subject number	Comments about anxiety	Final comments	
1	White marks, feeling of loose teeth		
2			
3			
4			
5			
6			
7	Marks		
8			
9	Bleeding gums		Given how long and painful it was to get them on, expected it to be much more lengthy and painful getting them off!
10			
11			
12			
13			
14			
15	Having molds, not being able to eat properly, white marks		
16			
17			
18			
19			
20			
21	Staining front 2 teeth		
22			
23			
24	Uncomfortable		
25			
26			
27			
28	White marks, will teeth hurt afterwards		Biting on something makes the pain less
29			
30			
31			
32			
33			
34			
35			
36			
37			
38			
39	Rumours of pain		No pain at all, just a bit sensitive on lower front teeth when glue removed
40			
41			
42			
43			
44			
45			
46			
47			
48			
49			
50			
51			
52			
53	White marks Prev trauma to front tooth, worried		The noise was the only disturbing thing

54	will be damaged	
55		
56	It's a horrible experience	
57	No, it'll be fine	
58	discomfort	
59		
60		
61		No pain. Very good result :)
62	Hurt	
63	Marks	
64		
65		
66		
67		
68		
69		
70	white marks	
71		
72	White marks, pain	
73	Teeth going out of shape	
74	Pain	
75	Pain, What the teeth will feel like	Worst thing was the glue removal from the back teeth
76	White marks	
77	White marks, teeth moving easily once braces removed	
78		
79	Having bands removed	
80	Pain	
81		
82		
83	Might hurt removing brackets	
84		
85	Impressions	Didn't feel any pain, very pleased!
86		
87		
88	Pain, how mouth will feel after	
89	No worries	
90	Pain!	

Reliability	Overall FA pain	Pain during adjustment	Pain at 24 hours
1	18.59	12.63	25
2	4.56	2.99	15
3	29.55	54.36	67
4	16.07	15.71	26
5	54.48	0.85	1
6	0	0	14
7	30.73	26.05	33
8	20.42	25.26	62
9	28.89	10.26	57
10	5.95	2.47	11
11	78.14	14.37	87
12	21.3	39.45	0
13	26.03	22.67	36
14	59.46	0	81
15	17.58	4.36.	38

Reliability	Anxiety	Expected pain overall	Expected upper posteriors	Expected upper anteriors	Expected lower posteriors	Expected lower anteriors	Expected composite removal
1	19.42	59.04	34.67	62.02	55.46	66.26	77.23
2	0.71	1.68	8.01	2.37	5.1	5.64	6.28
3	0.71	50.79	71.95	15.95	83.89	12.04	76.75
4	1.04	30.53	21.88	0	0.81	0.44	.0
5	0	0	0	0	0	0	.57
6	0	0	0	0	0	0	.0
7	0	0.1	0.1	0	0	0.25	.56
8	0.86	59.52	67.64	68.28	61.62	58.95	20.03
9	92.7	76.74	79.43	78.42	77.76	80.87	16.41
10	1.09	3.74	9.42	4.2	3.5	3.37	12.14
11	5.44	45.11	65.36	31.93	30.55	5.53	46.27
12	19.34	43.08	45.37	16.07	47.9	11	46.01
13	44.15	35.38	14.04	41.69	16.66	34.23	37.63
14	62.34	33	54.79	30.12	55.38	46.97	18.31
15	3.39	3.38	3.85	5.82	16.15	8.95	3.75

Reliability	Overall pain	Pain upper posteriors	Pain upper anteriors	Pain lower posteriors	Pain lower anteriors	Pain composite removal	Most painful sextant
1	48.06	65.87	70.81	40.44	35.46	15.72	1
2	20.06	7.06	17.82	13.17	23.76	11.27	5
3	38.54	35.4	4.14	41.48	2.19	0	1
4	0	0	1.04	0	0	0	6
5	25.58	0.75	1.38	62.45	22.6	0	6
6	8.4	29.15	0.24	26.92	0	0	1
7	12.55	1.77	0.59	11.02	0	3.36	6
8	57.47	59.9	55.04	61.09	59.41	29.75	5
9	5.82	5.39	5.29	4.48	4.77	0	5
10	5.21	5.49	7.14	3.43	4.97	0	1
11	9.71	20.16	3.44	13.54	11.67	25.47	6
12	28.84	64.43	18.32	64.05	19.59	0.59	1
13	18.43	26.54	22.33	21.91	20.21	29.88	1
14	14.91	25.09	55.08	27.79	0.66	6	0
15	38.82	10.39	18.18	11.82	11.46	8.19	1

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