

**A study to investigate discomfort associated
with fixed orthodontic appliances**

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Abstract

Aims

The aims of this study were:

- 1) To determine levels of pain experienced by patients following the placement of fixed orthodontic appliances
- 2) To determine if an acrylic bite wafer is effective in reducing the pain experienced after fixed appliance placement
- 3) To determine if an acrylic bite wafer is any more effective in reducing pain experience than merely providing advice

Null Hypotheses

- Chewing on an acrylic bite wafer following placement of fixed orthodontic appliances, does not reduce the pain and discomfort experienced
- Chewing on an acrylic bite wafer does not provide a significant reduction in pain experience as compared to providing advice and instructions

Method

60 subjects aged 12-16 years who were attending to begin fixed appliance treatment were randomly assigned to one of two groups. Participants were asked to rate their anxiety level on a questionnaire. Then they were asked to perform 4 simple biting exercises and mark their level of discomfort on a visual analogue scale. Those in the first group were given a bite wafer to chew for 15 minutes immediately after having their fixed orthodontic appliances placed. The second group had fixed appliances

placed in the normal manner and received standard advice. Both groups were then asked to complete a questionnaire rating discomfort at intervals over the next 7 days. ANOVA was used to compare group scores after various times. Pain scores between the two groups were compared using Two-sample t-tests where appropriate.

Results

The pain experienced after appliance placement (no wafer group) increased and peaked at 24 hours (mean VA scores 0.70, 0.75, 0.65 and 0.67 for the 4 exercises respectively). Thereafter the pain reduced and reached baseline levels at 7 days (mean VA scores 0.08, 0.19, 0.09 and 0.10). Chewing on the acrylic bite wafer immediately after appliance placement resulted in a slightly lower total pain experience over the first 7 days than if no wafer was used, although the difference between the groups was not significant ($t = -0.34/p = 0.74$, $t = -0.66/p = 0.52$, $t = -0.31/p = 0.76$, $t = -0.82/p = 0.43$).

Conclusions

Chewing on an acrylic bite wafer slightly reduced pain experience after appliance placement and was more effective than providing standard advice and instructions, although the pain reductions were not statistically significant.

Acknowledgements

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Chapter 1

Literature review

Chapter 1

1.1 Introduction

1.2 Discomfort associated with treatment involving fixed braces

- 1.2.1 How much pain/discomfort do patients experience during orthodontic treatment?
- 1.2.2 Types of pain
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1.1 Introduction

The possibility that pain may be experienced during orthodontic treatment is often mentioned during the consent process but perhaps little thereafter. Jones (1984) stated, “The discomfort involved in orthodontic tooth movement is a subject little discussed by clinicians, either between themselves or with their patients.” Pain is recognised as a factor that discourages patients from seeking routine dental treatment and this apprehension may extend to orthodontics, so that the fear of pain may discourage patients from seeking orthodontic treatment (Tayer and Burek, 1981; Oliver and Knapman, 1985).

Comparisons of particularly fearful and non-fearful dental patients have repeatedly implicated pain as a factor important to dental apprehension (Melamed, 1979). Problems associated with pain may also manifest once treatment has started and lead to difficulties with compliance. It has been found that of 26 per cent of patients who had discontinued orthodontic treatment had done so due to pain (Brattström et al. 1991). Brown and Moerenhout, (1991) studied pain experience and psychological adjustment to orthodontic treatment in preadolescents, adolescents and adults. Pain from the appliance and the intrusion of treatment into the patient’s daily social life were seen as major causes for the discontinuance of treatment. White, (1983) studied the toothbrushing pressures applied by orthodontic patients and reported that pain during orthodontic treatment could prevent some individuals from achieving effective plaque control.

Hence it is essential for the orthodontist to understand the nature, implications and methods used to prevent or resolve discomfort during orthodontic treatment.

1.2 Discomfort associated with treatment involving fixed appliances

Orthodontic pain in particular may be multi faceted. The notion of pain during treatment is not new, but detailed knowledge about the nature and properties of such pain are often vague. Although pain is a recognised consequence of orthodontic treatment in general, it is important to have knowledge in order to minimise and/or forewarn the patient of its occurrence.

1.2.1 How much pain/discomfort do patients experience during orthodontic treatment?

Pain perception is a subjective matter and it is difficult to quantify the amount of pain perceived by patients. Many variables have been postulated to influence a painful response.

Orthodontic pain is a complex problem. Jones, (1992) called it “A multifactorial phenomenon” that depends on such variables as the patient’s subjective perception of pain, conditioning from previous experiences, age, sex, social class, type of appliance, degree of initial crowding and consequent level of initial force and whether the upper or the lower arch was being considered. Added to this list are the *culture/ethnicity of the patient and their psychological well-being* (Krishnan, 2007).

1.2.2 Types of pain

Patients may experience different levels of discomfort during orthodontic treatment, such as feelings of tension, pressure or soreness of teeth, and sometimes the discomfort may become actual pain (Ngan et al., 1989). Orthodontic procedures that may produce some degree of pain include:

- separator placement
- archwire placement and activations
- application of orthopaedic forces
- elastic wear
- debonding (Krishnan, 2007)

There may be a correlation between the type of pain experienced and the type of appliance used. Sergl et al., (1998) concluded that patients treated with fixed or functional appliances reported significantly more tension, pressure, sensitive teeth, or pain than patients wearing one or two removable plates; over both short-term and long-term courses of treatment. It is important to recognise that pain is multifactorial in nature, due to the many structures associated with the orofacial complex.

Interestingly, there seem to be little relation between the amount of force applied and the intensity of pain.

Both pain and oral ulceration may follow the placement of fixed orthodontic appliances (Kvam et al., 1987). Generally the pain reported after archwire placement is a mixture of “toothache” from the pressure of the brackets and cheek or lip soreness from soft-tissue irritation (Jones, 1992).

1.2.3 Timing/duration of pain

Orthodontists should be aware that the placement and adjustment of appliances may elicit pain. Furstman, (1972) claimed that every clinician had experienced patients who complained of pain following appliance adjustment; the pain started about 2 hours after they left the orthodontist and lasted for approximately 3 days. Both the patient and parents were usually aggrieved because the child could not eat properly during that period. Orthodontic patients may experience discomfort within the first 4 hours after insertion of either separators or an initial arch wire. The level of discomfort tends to increase during the next 24 hour period but decreases to preplacement level over 7 days (Ngan et al., 1989). Jones and Chan, (1992) felt that more pain was experienced by patients in the 24 hours after placement of fixed appliances than most clinicians appreciate. About three quarters of the patients in the study felt that placement of an archwire affected their ability to chew for at least 24 hours. In an investigation into traumatic ulcers and pain during orthodontics, 95% of patients studied had experienced pain and half of them said that the most painful times were the days on which the archwires were changed (Kvam et al., 1987).

Adaptation to new appliances takes place within the first 7 days after fitting (Sergl et al., 1998). A significant reduction in the intensity of pressure, tooth sensitivity and pain was reported within 5 days and a significant decrease of perceived tension as early as 3 days after appliance insertion. Most of the discomfort associated with fixed appliances appears to be experienced during the initial 4-week adjustment period or coincides with appliance adjustment (Tayer and Burek, 1981). To highlight further the relevance of orthodontically related pain Brown, (1991) found that after

placement of a fixed appliance only two out of 30 patients reported no pain. There was a decreasing, although uneven, gradient of pain experience over the 16 days that followed appliance placement.

1.2.4 Site of pain

There are many potential sites of pain in the orofacial environment due to its rich innervation, including muscles, temporomandibular joints, periodontal ligaments and the soft tissues of the lips, cheeks, palate, tongue and gingiva. Placement of separators on posterior teeth tends to produce discomfort around the teeth involved (Ngan et al., 1985), whereas placement of archwires for initial alignment of anterior teeth tends to increase the level of discomfort on the front teeth. Small wounds caused by the fixed appliance were reported by 75.8% of patients and 2.5% suffered badly from ulceration. Ulceration (28.7%) and discomfort due to headgear (21.7%) were reported to be most annoying (Kvam, 1987).

In the case of fixed appliances, discomfort is probably based on adverse sensations in periodontal ligaments and surrounding structures, whereas the unfavourable effects of functional appliances are more likely to arise from pressure and tension in muscles and mucosa (Sergl et al., 1998).

Jones and Chan, (1992) found that nearly all patients who experienced pain following placement of fixed appliances reported some degree of gum soreness. This may have reflected both the periodontal origin of orthodontic pain and difficulty in

identifying the precise location of discomfort. Soreness of intra-oral tissues such as the palate, lips and tongue was also reported after initial archwire placement.

1.2.5 Intensity of pain

23 patients from a group of 30 suffered at least one episode of severe discomfort (Jones, 1984). Pain was usually worst at night and this correlated well with times when analgesics were most required. Furthermore, 75 per cent of the patients felt that replacement of an archwire affected their ability to chew for at least 24 hours (Jones and Chan, 1992). The severity of pain and discomfort experienced by patients wearing functional or fixed appliances was significantly worse than the pain felt by those treated with upper and/or lower removable plates (Sergl et al., 1998).

Kvam, (1987) found that 11% of subjects regarded orthodontic treatment as constantly painful. However, pain is a subjective and complex experience that includes sensations evoked by noxious stimuli and the reactions to such stimuli. Reactions to such sensations vary among individuals and can depend on a person's cultural background, past experiences and other forms of psychological input that give meaning to situations in which pain occurs (Dubner, 1968).

1.2.6 Psychological influences on the pain response

There is a definite relationship between the psychological well-being of the patient and orthodontic pain perception, with females expressing more pain than males and adolescents reporting higher levels of pain than pre-adolescents and adults. An individual's physiological and psychological susceptibilities can become significant factors in the intensity of tissue discomfort caused by the physical effects of appliances (Krishnan, 2007). Studies have reported that the pain experienced by patients depends on the psychological well-being of the patient rather than the magnitude of the force exerted by the appliance (Dubner, 1968; Brown and Moerenhout, 1991; Serogl et al., 1998). The last of these studies observed a direct correlation between a patient's attitude towards treatment and the discomfort experienced after appliance insertion. Brown and Moerenhout, (1991) stated that pain may be a somatisation of either anxiety or depression and that this may help the patient to translate these feelings into a tangible psychological problem. Krishnan, (2007) in an extensive review of the orthodontic literature with regards to pain, stated that there exists a non-linear relationship between age, gender, psychological state, and cultural background in pain perception following placement of orthodontic appliances and that these factors should be considered before embarking on treatment.

1.2.7 Effect of age

A significant difference has been found in the discomfort experienced in patients over or under 16 years of age, with statistically higher discomfort levels reported by older patients (Jones, 1984). However this study may not have taken into account variables such as emotions, attitude, and personality factors that may modify pain and discomfort sensations. One can also speculate that the reduced rate of cell turnover, longer treatment times and greater forces often utilised to treat adult patients may have caused more pain.

Ngan et al., (1989) found no significant difference in the level of discomfort of patients more than 16 years of age compared with those of 16 years and under. However Brown and Moerenhout, (1991) suggested interactions between patient age, the phases of treatment and reported pain and psychological well-being. The adolescent group (14 to 17 years) reported lower levels of psychological well-being and higher levels of pain after separator placement, banding, archwire placement and activations, compared to the preadolescent and adult groups.

1.2.8 Effect of gender/social class

The consensus seems to be there is no significant difference in pain experience between the sexes as a result of orthodontic treatment (Jones 1984; Ngan et al., 1989; Sergl et al., 1998). The exception seems to be related to soft tissue factors, with more girls than boys reporting ulceration. An increase in the frequency of recurrent aphthous ulceration (RAU) was reported by 23.1% of girls but only 9.6% of boys

while they had fixed appliances (Kvam et al., 1987). This reflects the incidence of RAU in general, which has a slight female predilection (Scully et al., 1989). The findings also relate to social class, for instance more private patients experienced pain than those treated in a hospital orthodontic department. Interestingly, the majority of patients reporting RAU came from private offices (Kvam et al., 1987).

1.2.9 Effect of the initial archwire

A direct correlation between the force applied to a tooth and pain experience was suggested by Burstone, (1962). Larger forces may cause greater compression of the periodontal ligament and more pain (Gianelly and Goldman, 1971). This promoted the idea that light differential forces were more efficient, more biological and less painful than heavy orthodontic forces (Storey and Smith, 1952; Reitan, 1956). This theory has been disregarded by other authors who have not found an association between applied force and subsequent pain (Hixon 1969; Boester and Johnston 1974; Jones and Richmond, 1985). In the last study, the authors concluded that the pain response was not related to the type of wire used nor the degree of initial crowding, suggesting that forces generated by lighter archwires were not important in causing pain or discomfort during the early stages of fixed appliance therapy. Jones and Chan, (1992) suggested that the pain after initial archwire placement could be worse than the pain following tooth extraction, in some patients.

No significant difference was found between the initial pain reported by two groups treated using 0.014 and 0.016 inch initial archwires respectively, suggesting that different sized initial archwires have no direct effect on the degree of pain (Erdinc

and Dincer, 2004). These authors also found that patients reported greater pain in the front teeth than in the posterior teeth. They postulated that this may be due to the differences in root area between anterior and posterior teeth. Also, anterior teeth are moved further during levelling and aligning in the initial stages of fixed appliance therapy and are used more for biting actions (Ngan et al., 1989; Scheurer et al., 1996).

1.2.10 Effect of crowding

It seems reasonable to postulate that patients with a greater degree of crowding are likely to suffer more discomfort, especially in the initial stages of therapy when the forces on adjacent malaligned teeth are greatest. Jones and Richmond, (1985) proposed that, since the same brackets and fully engaged archwires were used in all patients, there may be some relationship between the degree of initial crowding and levels of discomfort. However they found this not to be true; there was no correlation between discomfort and crowding. It was suggested that the variable threshold of pain response among individuals may be more relevant than the effect of the forces applied.

1.2.11 Mechanism of pain

There appears to be an initial period of pain for 2-4 days following archwire placement/replacement (Soltis, 1971; Jones, 1984; Profitt, 1986; Roth, 1986; Ngan, 1989). Historically it was thought that orthodontic forces on teeth caused pressure,

ischaemia, inflammation and ultimately oedema, thereby contributing to nerve impingement and pain (Furstman, 1972). The perception of pain may be part of an inflammatory reaction which causes changes in blood flow following orthodontic force application (Krishnan, 2007). An association has also been reported between the use of excessive force to the teeth and pain (Foster, 1975). Proffit, (1986) has advocated using light forces to avoid pain. Burstone, (1962) noted that there was a wide range of individual responses when similar forces were applied to the teeth. He identified both immediate and delayed pain responses. The former was attributed to initial compression of the periodontal ligament immediately after placement of the arch wire. The latter response, which started a few hours later, was termed “hyperalgesia” of the periodontal ligament. This phenomenon can be defined as a condition of altered perception, such that stimuli which would normally induce a trivial discomfort cause significant pain. It may be the result of damage to nociceptors (sensory receptors that signal the perception of pain) within the tissues. Similarly prostaglandins have been shown to cause hyperalgesia, a sequelae of inflammation of gingival and periodontal tissues following orthodontic treatment. Prostaglandins may make the periodontal ligament more sensitive to released algogens such as histamine, bradykinin, serotonin and substance P (Ferreira et al., 1978; Polat et al., 2005). This in turn may lower the pain threshold (Ferreira et al., 1978; Higgs, 1983).

1.3 Methods used to relieve pain

1.3.1 Introduction

Treatments used to control pain after appliance adjustment can be broadly divided into pharmacological or mechanical methods. There are also subdivisions within these categories and some methods that do not fit neatly will be mentioned separately.

1.3.2 Drug treatment

White, (1984) found that 63% of patients experienced less discomfort following appliance adjustments after chewing analgesic chewing gum (Aspergum, Schering-Prouh Health Care Products, Inc., Memphis, Tenn).



Figure 1.1 Aspergum (www.insightpharma.com)

The use of analgesic tablets was studied by Ngan, (1994) in a double-blind randomised, parallel, placebo-controlled, single dose, analgesic efficacy evaluation of Ibuprofen (400mg) and Aspirin (650mg). The objective was to determine whether non-steroidal anti-inflammatory agents, which inhibit prostaglandin synthesis, could suppress orthodontic discomfort by inhibiting the inflammatory response normally observed after appliance adjustment. The results supported the use of Ibuprofen as the preferred analgesic.

The effect of Paracetamol, Ibuprofen and Misoprostol on prostaglandin E₂ synthesis and the degree and rate of tooth movement in guinea pigs was studied by Kehoe et al., (1995). Paracetamol was found to be the analgesic of choice for the relief of minor discomfort associated with orthodontic treatment. The drugs were administered 12 hourly at dosages which produced analgesia without adverse effects on behaviour or general health. Paracetamol was also related to the highest rate of tooth movement. However in a study by Kyrkanides, (2000) it was found that the use of a non-steroidal anti-inflammatory drug Indomethacin during tooth movement produced aberrant remodelling of periodontal vasculature and other structures. This may throw into question the use of drug treatment for post orthodontic pain.

1.3.3 Mechanical treatment

There has been a trend to recommend the use of lighter forces during orthodontic treatment than was the case when standard Edgewise appliances were used in association with stainless steel arches. Appliances using lighter wires that deliver less

force to the teeth may reduce discomfort (Burstone, 1980). However clinical studies by several investigators have not found a relationship between pain severity and orthodontic force and the topic is still controversial (Lim, 1995).

Chewing something hard after appliance adjustments has been recommended as a means of preventing or relieving inflammation and oedema. It is said to have an effect by loosening tightly grouped fibres around nerves and blood vessels, thus restoring normal vascular and lymphatic circulation around the dentition (Furstman, 1972). Proffit, (1986) felt that chewing gum or a plastic wafer during the first few hours after appliance activation would reduce pain by displacing the teeth enough to allow blood flow through compressed areas and preventing a build-up of metabolic products that stimulate pain receptors. In a study to investigate the effectiveness of chewing on a polymer arch, called KM Thera-Bite, during orthodontic treatment it was found that the majority of the patients found the procedure effective in reducing pain. However a number also reported increased discomfort after using the bite wafers. Both methods must be instituted before pain sets in, within 8 hours after activation, otherwise the teeth will be too tender for repetitive chewing (Lim, 1995).

A recent randomised clinical trial has compared the use of masticatory bite wafers with avoidance of mastication as methods of reducing pain and discomfort after fixed appliance fitting. More pain was reported in the bite wafer group, although this may have reflected the fact that subjects in the bite wafer group, who had not been instructed to avoid eating hard foods, were evoking a more painful response from the teeth due to their diet (Otasevic et al., 2006).

1.3.4 Pain reduction using vibratory stimulation

Marie et al., (2003) investigated vibratory stimulation as a method of reducing pain after orthodontic appliance adjustment, using a patient controlled appliance (Good Vibrations, Raintree Essix, Inc. New Orleans, LA). The concept was that vibration appeared to re-establish the blood supply and intercept the ischaemic response which caused pain following post orthodontic adjustment. Discomfort was significantly less at every time interval for those who used the vibratory apparatus, as long as it was instituted before the onset of pain. This implies that once the pain response sets in, patients are unable to tolerate the vibration and this method may prove to be of little benefit in treatment of established pain.

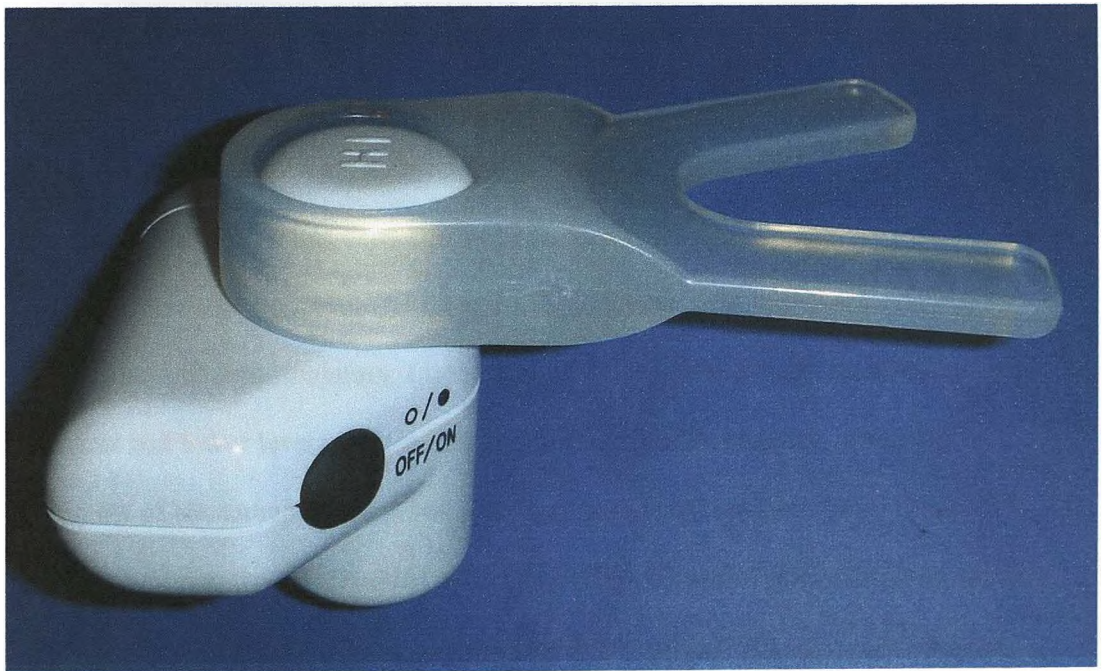


Figure 1.2 Tooth Masseur™

1.3.5 Other methods of pain management

Trans-cutaneous electrical nerve stimulation (TENS) is a non-pharmacological method of reducing orthodontic pain (Roth, 1986). TENS is a form of stimulation-produced analgesia, delivered via surface electrodes placed over the painful area or within the distribution of the nerve supply to the painful area. Roth found the technique to be effective within 6 seconds of electrode placement. However, there are no follow-up studies and the technique has not gained popularity.

Low level laser therapy has been shown to produce analgesic effects in clinical applications such as pain, wound healing, inflammation and oedema. Lasers may have a role in dentistry in the management of dentine hypersensitivity, post extraction healing, viral infections, neuropathy (paraesthesia and trigeminal neuralgia), aphthous ulceration, TMJDS and post-oncology treatment of mucositis and healing (Parker, 2007). The mechanism of laser analgesia has not been established, although it has been attributed to anti-inflammatory and neuronal effects. Due to the low energy output and intensity of the lasers used the effects are mainly non-thermal and biostimulatory. Lim et al., (1995) found that teeth exposed to laser treatment had lower levels of pain compared to those with placebo, following placement of elastomeric separators. The laser probe was applied onto the buccal mucosa overlying the middle third of the root of the separated premolar, five minutes after separators had been placed. The subjects then completed pain questionnaires over 5 days using visual analogue scales. Analysis of the data showed that the difference between treatments and placebo within each subject was not statistically significant.

Acupuncture has been widely practised in China to treat various diseases for many centuries. The insertion of fine needles into various acupuncture points stimulates small myelinated nerve fibres in muscles which send impulses to activate the spinal cord, midbrain and pituitary/hypothalamus. Various endogenous substances may be involved in this process such as beta-endorphine, noradrenaline, enkephalin and serotonin. Acupressure follows the same principles except that gentle finger pressure is used instead of needles and it may not be as effective. Vachiramon and Wang, (2005) demonstrated a technique using acupuncture or acupressure techniques to reduce orthodontic post-adjustment pain. Based on their experience alone they stated that this technique was safe and seemed to benefit a number of their adult orthodontic patients. However, no randomised controlled clinical trial is available to corroborate this suggestion.

Chapter 2

Materials and methods

Chapter 2 – Materials and methods

- 2.1 Study aims
- 2.2 Null hypotheses
- 2.3 Study design
- 2.4 Subjects
- 2.5 Sample size
- 2.6 Method
- 2.7 Measurements
- 2.8 End points
- 2.9 Study plan
- 2.10 Ethical issues
- 2.11 Resource requirements
- 2.12 Statistical analysis
- 2.13 Supervision
- 2.14 Dissemination and outcome

2.1 Study aims

The aims of this study are:

- 1) To determine the levels of pain experienced by patients following placement of fixed orthodontic appliances
- 2) To determine if an acrylic bite wafer is effective in reducing the pain experienced after fixed appliance placement
- 3) To determine if an acrylic bite wafer is any more effective in reducing pain experience than merely providing advice

2.2 Null hypotheses

The null hypotheses to be tested in the present study are:

- Chewing on an acrylic bite wafer following placement of fixed orthodontic appliances, does not reduce the pain and discomfort experienced
- Chewing on an acrylic bite wafer does not provide a significant reduction in pain experience as compared to providing advice and instructions

2.3 Study design

The design will be a prospective study of subjects after placement of fixed orthodontic appliances. Subjects will be randomly assigned into 2 groups using random number tables.

Subjects in the first group will bite on acrylic wafers prefabricated by the orthodontic laboratory at Birmingham Dental Hospital for a 15 minute period immediately after placement of fixed orthodontic appliances. Subjects will then be asked to perform 4 simple biting exercises and complete a standardised series of questions related to their discomfort by marking a visual analogue scale at recognised intervals; immediately before appliance placement, immediately after placement, then 2 hours, 6 hours, 24 hours and daily up to 7 days post-placement. The investigator assigning the subjects to each group will be aware of the group of each but the individual responsible for analysing the questionnaires will be blinded. Also, participants will have no knowledge of an alternative group. All subjects will receive the usual advice and instructions that are given to patients when fixed appliances are fitted and normal treatment will not be withheld.

The second cohort of subjects will be provided with all the usual post-placement advice and will receive the same questionnaires to complete. This group will act as a control group as the conditions will be identical except for use of the bite wafer. Once again, the subjects will be unaware of the alternative group.

2.4 Subjects

Participants will be recruited from the Orthodontic departments at Birmingham Dental Hospital and University Hospital of North Staffordshire. They will be patients whose treatment plan includes fixed orthodontic appliances in both dental arches. This will be irrespective of gender, sexual orientation, race, religion or belief. They will be in the 12-16 year age group as this is the age range most

frequently treated in orthodontics and avoids possible bias due to age-related perceptions of pain. Subjects will be fit and healthy volunteers.

Inclusion criteria:

- Consent to take part in the study
- Fixed orthodontic appliances in both arches

Exclusion criteria:

- Patients who have had previous orthodontic treatment will be excluded from the study. This is because they are likely to have some understanding of the discomfort expected and this could bias the results
- Patients who are unable to understand or complete the questionnaires will be excluded. This may prevent obtaining informed consent

2.5 Sample size

The study will require two separate groups of subjects. There will be 30 subjects in each group, thus requiring a total of 60. Lack of data from comparable studies makes it impossible to carry out a meaningful power calculation. 30 subjects will be included in each group to overcome the effects of variance.

2.6 Method

At the appliance placement appointment, participants will first be asked to rate their anxiety level on a questionnaire. They will be asked to mark on a visual analogue scale marked at either end by a happy face (not worried at all) and a sad face (very worried) respectively. This will permit comparison of the levels of pre-treatment anxiety in the 2 groups, since anxiety may be correlated to the degree of pain experienced.

Subjects will then be asked to perform 4 simple biting exercises and to mark their level of discomfort on the questionnaire. The 4 exercises will be; chewing, biting, fitting the back teeth together and fitting the front teeth together.

The intervention (i.e. the bite wafer group) will be administered immediately after placement of fixed orthodontic appliances and will be carried out in a private treatment room. The bite wafer will be hand-held by the patient and they will be asked to chew on it for a timed period of 15 minutes.

The second group will have their fixed appliances placed in the normal manner and receive standard postoperative advice.

Both groups will be provided with the exercises/questionnaires to complete at the aforementioned time intervals. No regular treatment will be withheld from either group.

The bite wafers will be manufactured in-house by the Orthodontic laboratory at Birmingham Dental Hospital. They will be constructed from 3mm transparent DrufoSoft® material (Dreve, GmbH). This is ethylene-vinylacetate, a form of silicone (Figure 2.1). The material is commonly used for the production of:

- Orthodontic retainers
- Sports mouthguards
- Positioners
- Medical splints
- Duplication forms

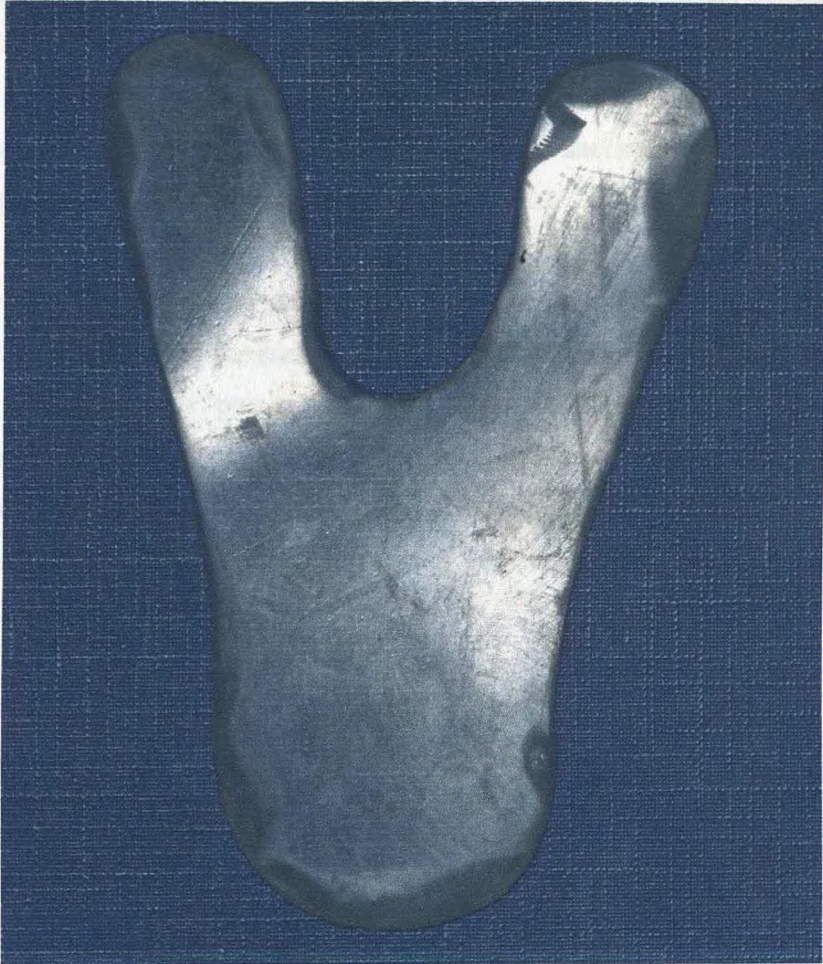


Figure 2.1 Laboratory made bite wafer

2.7 Measurements

Questionnaires rate the severity of discomfort experience using visual analogue scales (VAS). The scale is a line 10cm long, the extremes of which are taken to represent the limits of the pain experience. Each end of the line is thus marked with the appropriate descriptor “very comfortable” or “very uncomfortable,” and also with a happy and sad face respectively.

Subjects will be asked to mark the line at a point corresponding to the severity of their pain. The distance of the mark from the end of the scale is then taken to represent pain severity or “pain score.” Most subjects with pain understand the concept and can quickly make the measurement (Huskisson, 1974). Children aged 5 and over also adapt well to its use and there is a high correlation between successive measurements of pain severity on a VAS, confirming the reliability of the method (Scott et al., 1979).

The questionnaires used are shown on pages 28-37.

PATIENT ID NUMBER:

AGE:

SEX:

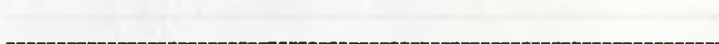
TIME/DATE OF APPLIANCE PLACEMENT:

LEVEL OF ANXIETY BEFORE PLACEMENT OF BRACES

Please make a small vertical line on each horizontal line below, indicating how much anxiety/apprehension you have or how nervous/worried you are about having your braces fitted e.g. (---|-----)

Not Worried At All

Very Worried



ANALGESIC (Painkiller) CONSUMPTION RECORD

Please indicate below if you required any pain relieving medication and please state the exact time(s) and date(s), type of painkiller (e.g. Paracetamol) and dosage consumed. Please continue on a separate sheet if required.

- | | | | |
|----|------------|-------|---------|
| 1) | Time/Date: | Type: | Dosage: |
| 2) | Time/Date: | Type: | Dosage: |
| 3) | Time/Date: | Type: | Dosage: |
| 4) | Time/Date: | Type: | Dosage: |
| 5) | Time/Date: | Type: | Dosage: |
| 6) | Time/Date: | Type: | Dosage: |

DISCOMFORT INDEX CARD TO EVALUATE PATIENT EXPERIENCE OF PAIN FOLLOWING ARCHWIRE (BRACE) PLACEMENT

1) BEFORE BRACE PLACEMENT

Please make a small vertical line on each horizontal line below, indicating how much discomfort you are experiencing in the following areas: e.g. (-----|-----)

Very Comfortable

Very Uncomfortable

1. Chewing



-----|-----



2. Biting



-----|-----



3. Fitting your back teeth together



-----|-----



4. Fitting your front teeth together



-----|-----



2) AFTER INITIAL BRACE PLACEMENT

IMMEDIATELY FOLLOWING BRACE PLACEMENT

Please make a small vertical line on each horizontal line below, indicating how much discomfort you are experiencing in the following areas: e.g. (-----|-----)

Very Comfortable

Very Uncomfortable

5. Chewing



-----|-----



6. Biting



-----|-----



7. Fitting your back teeth together



-----|-----



8. Fitting your front teeth together



-----|-----



TWO HOURS AFTER BRACE PLACEMENT

Please make a small vertical line on each horizontal line below, indicating how much discomfort you are experiencing in the following areas: e.g. (-----|-----)

Very Comfortable**Very Uncomfortable**

9. Chewing



-----|-----



10. Biting



-----|-----



11. Fitting your back teeth together



-----|-----



12. Fitting your front teeth together



-----|-----



SIX HOURS AFTER BRACE PLACEMENT

Please make a small vertical line on each horizontal line below, indicating how much discomfort you are experiencing in the following areas: e.g. (-----|-----)

Very Comfortable**Very Uncomfortable**

13. Chewing



14. Biting



15. Fitting your back teeth together



16. Fitting your front teeth together



24 HOURS AFTER BRACE PLACEMENT

Please make a small vertical line on each horizontal line below, indicating how much discomfort you are experiencing in the following areas: e.g. (-----|-----)

Very Comfortable**Very Uncomfortable**

17. Chewing





18. Biting





19. Fitting your back teeth together





20. Fitting your front teeth together





TWO DAYS (48 HOURS) AFTER BRACE PLACEMENT

Please make a small vertical line on each horizontal line below, indicating how much discomfort you are experiencing in the following areas: e.g. (-----|-----)

Very Comfortable**Very Uncomfortable**

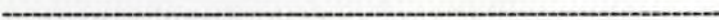
21. Chewing



22. Biting



23. Fitting your back teeth together



24. Fitting your front teeth together



THREE DAYS (72 HOURS) AFTER BRACE PLACEMENT

Please make a small vertical line on each horizontal line below, indicating how much discomfort you are experiencing in the following areas: e.g. (-----|-----)

Very Comfortable**Very Uncomfortable**

25. Chewing



-----|-----



26. Biting



-----|-----



27. Fitting your back teeth together



-----|-----



28. Fitting your front teeth together



-----|-----



SEVEN DAYS AFTER BRACE PLACEMENT

Please make a small vertical line on each horizontal line below, indicating how much discomfort you are experiencing in the following areas: e.g. (-----|-----)

Very Comfortable**Very Uncomfortable**

29. Chewing



-----|-----



30. Biting



-----|-----



31. Fitting your back teeth together



-----|-----



32. Fitting your front teeth together



-----|-----



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 discomfort that you may have experienced, or anything else you may have done to reduce the discomfort. Also, was the discomfort associated with the teeth or with ulcers?

2.8 End points

The primary end-points will be:

- Chewing on an acrylic bite wafer following placement of fixed orthodontic appliances, reduces pain and discomfort
- Chewing on an acrylic bite wafer provides significant reduction in pain as compared to following standard advice alone

The secondary end-point will be:

- Pain experience is less at all time intervals for those patients who used the bite wafer immediately after appliance fitting.

The effect of the end-points would be such as to recommend or reject the use of the bite wafer after placement of fixed orthodontic appliances in order to reduce the pain experience.

2.9 Study plan

The study progressed in the following order and is now being reported:

- Protocol
- Literature review
- Questionnaire design
- Pilot study
- Ethical approval
- Subject recruitment and consent
- Intervention
- Questionnaire collection
- Data analysis and post-hoc power calculation

- Data interpretation
- Write-up
- Publication

The study was carried out entirely between the Orthodontic Departments at Birmingham Dental Hospital and University Hospital of North Staffordshire. The study started as soon as ethical approval was obtained and completed by 31/09/2008.

2.10 Ethical issues

There were no significant ethical issues involved with the study; those suggested here are theoretical issues that may have occurred:

- Providing a potential source of pain relief (i.e. the bite wafer) vs. none
- Small possibility that chewing the bite wafer may have increased the pain experience
- Inconvenience to subjects due to study participation
- Increased awareness of pain following inclusion in the study

It was not anticipated that there would be any potential risks to the subjects or operator due to the intervention. It may in fact have benefited the subjects in the intervention group by reducing their pain experience. There was a small possibility that they may have experienced increased discomfort due to the wafer and they were forewarned, with the option to stop using it if they wish. There were no adverse effects from withholding the bite wafer as it is not currently used in everyday practice. Subjects may have been inconvenienced by completing the questionnaires but this was likely to be minimal as the questions were short, simple and caused little disruption. The patients would be free to withdraw from the study at any time should they wish to do so without any effect on their treatment. Also, the contact details of the investigators were provided if there were any concerns.

Ethical approval was sought following preparation of the required documents. This commenced with completion of the online ethical approval form via the National Research Ethics Service of the National Patient Safety Agency at <http://www.nres.npsa.nhs.uk>. The website is very comprehensive and guides one through the Ethics Application and Ethical Approval Process. The whole process can take up to a maximum of 60 days. It is therefore important to submit the application at least 3 months before it is aimed to start the research.

In addition NHS Ethical Approval & NHS R&D (Research and Development) Approval is required before any research project can start. For both processes, the following documents are required:

(1) COREC Application Form

Parts A and B of the COREC Form and all supporting information are required. A signed paper copy, a PDF and an xml is required.

(2) Site-Specific Information Form (SSI Form)

If the research requires Site-Specific Assessment the SSI Form will need to be submitted.

A signed paper copy, a PDF and an xml is required.

(3) Student Research Registration Form

This form applies to projects undertaken as part of an undergraduate and masters course. This form should be completed by the Chief Investigator.

(4) Clinical Supervisor Form

A Clinical Supervisor will need to complete the form attached to the Student Research Registration Form. The project supervisor is required to confirm that the research protocol has been verified and checked and all necessary processes are in place for the research to be carried out successfully.

(5) Evidence that you have gained permission to conduct your research at all research sites (if applicable)

As the research involves NHS Staff, Patients, Patient Notes, Facilities and Resources, written confirmation is required.

(6) Research Sponsorship & Insurance/Indemnity Agreement

A letter from the University of Birmingham which confirms (1) they will adhere to the responsibilities of the Sponsor as outlined in the Research Governance Framework; (2) there are arrangements in place to ensure the research is covered for insurance/ indemnity purposes; (3) the details of your academic supervisor.

(7) Ethics Approval Letter, including Site Specific Assessments - when received.

(7) Research Proposal and all supporting information with the appropriate signatures, date and version number clearly stated:

- Summary C.V. for the chief investigator
- Summary C.V. for supervisor
- Research participant information sheet
- Research participant consent form
- Letters of invitation to participants

- Statement of indemnity arrangements
- Letter from sponsor
- Letter from statistician
- Letter from funder
- Referees' or other scientific critique report
- Summary, synopsis or diagram (flowchart) of protocol in non-technical language
- Interview schedules or topic guides for participants
- Validated questionnaire

The application was submitted to Coventry Research Ethics Committee. The REC reference number is 07/H1210/94. Site-specific approval was also obtained from South Birmingham Research Ethics Committee and North Staffordshire Local Research Ethics Committee. Local NHS R & D approval was also obtained for the two sites.

2.11 Resource requirements

- Time – planning, ethical/R & D approval, recruitment of participants, consent process, intervention, collection of questionnaires, analysis, write-up
- Bite wafers – laboratory manufacturing time, cost
- Separate private clinical room to administer the intervention
- Patient factors – longer appointment time, time taken to complete the questionnaires

2.12 Statistical analysis

VAS scores are numerical values rather than grades so that parametric statistical tests were appropriate. ANOVA was used to compare group scores after various times. Pain scores between the two groups were compared using Two-sample t-tests where appropriate.

2.13 Supervision

The principal investigator was Preetpal Singh Bhogal, Specialist Registrar in Orthodontics at Birmingham Dental Hospital and University Hospital of North Staffordshire. The supervisor for the project was Dr W P Rock, Reader in Orthodontics and Head of Orthodontic Department, School of Dentistry, University of Birmingham.

2.14 Dissemination and outcome

The project was submitted for internal publication as an MPhil thesis. It is subsequently to be submitted for publication in an orthodontic peer-reviewed journal.

If favourable outcomes were established then the technique may be recommended for use after placement of fixed orthodontic appliances. This would be an alternative to effective current methods of pain control, which are largely drug-related. There is significant potential for use of such a technique as the bite wafers are easily made in a dental laboratory.

Chapter 3

Results

Chapter 3 – Results

3.1 Demographics

3.2 Levels of anxiety before appliance fitting

3.3 Summary data for discomfort throughout the study

3.4 ANOVA for pain scores at each time interval

3.4.1 Pain on chewing

3.4.2 Pain on biting

3.4.3 Pain with front teeth together

3.4.5 Pain with back teeth together

3.5 Analgesic drug consumption

3.6 Additional comments

3.1 Demographics

Thirty subjects were recruited to the non wafer group and thirty subjects were also recruited to the wafer group.

Group	Number	Female	Male	Mean age (years)
No wafer group	30	17	13	14.0
Wafer group	30	16	14	13.7

Table 3.1 Demographic data for subjects

All subjects were between the ages of 12 and 16 years. The mean ages and the proportion of females to males are specified in the table above.

3.2 Levels of anxiety before appliance fitting

	N	Mean	St Dev	Min	Max
No wafer group	30	0.35	0.25	0	0.96
Wafer group	30	0.34	0.19	0	0.80

Table 3.2 Levels of anxiety before appliance fitting

The mean VA anxiety scores over the 7 days were 0.35 and 0.34 for the non wafer group and wafer group respectively.

There was no statistically significant difference between the wafer group and non wafer groups for the level of anxiety before the fixed appliances were fitted, $t=0.19$, $p=0.854$.

3.3 Summary data for discomfort throughout the study

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.11	0.15	0	0.64
Biting	30	0.14	0.18	0	0.60
Closing on back teeth	30	0.22	0.21	0	0.83
Closing on front teeth	30	0.23	0.24	0	0.89

Table 3.3 Mean VA scores before appliance fitting for the no wafer group

Subjects recorded low levels of discomfort when closing their teeth, before the appliances were fitted.

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.11	0.12	0	0.45
Biting	30	0.15	0.15	0	0.47
Closing on back teeth	30	0.21	0.23	0	0.71
Closing on front teeth	30	0.25	0.26	0	0.78

Table 3.4 Mean VA scores before appliance fitting for the wafer group

Mean discomfort levels before appliance fitting in the wafer group were almost identical to those in the no wafer group.

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.23	0.11	0	0.45
Biting	30	0.29	0.13	0	0.47
Closing on back teeth	30	0.29	0.16	0	0.69
Closing on front teeth	30	0.21	0.12	0	0.45

Table 3.5 Mean VA scores for discomfort immediately after appliance fitting for the no wafer group

There were increases in discomfort following fitting of the fixed appliances for all the actions except closing on the front teeth.

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.37	0.24	0	0.78
Biting	30	0.29	0.21	0	0.75
Closing on back teeth	30	0.38	0.24	0	0.81
Closing on front teeth	30	0.40	0.25	0	0.82

Table 3.6 Mean VA scores for discomfort immediately after appliance placement for the wafer group

There were increases in the pain experience following appliance fitting and these were larger than the increase for the no wafer group. This was following 15 minutes of wafer chewing, a temporal difference that may be a contributing factor to the differences in discomfort noted at this stage. Closing on the front teeth was most painful with a mean VA score of 0.40.

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.34	0.15	0	0.61
Biting	30	0.34	0.15	0	0.63
Closing on back teeth	30	0.32	0.17	0	0.67
Closing on front teeth	30	0.35	0.22	0	1.00

Table 3.7 Mean VA scores for discomfort 2 hours after appliance fitting for the no wafer group

Discomfort levels had increased further after 2 hours. There was no great difference in discomfort between the four actions.

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.31	0.21	0	0.96
Biting	30	0.39	0.24	0	0.97
Closing on back teeth	30	0.32	0.21	0	0.93
Closing on front teeth	30	0.40	0.22	0	0.93

Table 3.8 Mean VA scores for discomfort 2 hours after appliance fitting for the wafer group

The mean levels of discomfort after 2 hours fell for chewing and closing on the back teeth, closing on the front teeth was again the most painful. The difference between the groups at this interval had decreased.

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.58	0.18	0.30	1.00
Biting	30	0.58	0.18	0.30	1.00
Closing on back teeth	30	0.65	0.23	0	1.00
Closing on front teeth	30	0.52	0.29	0.03	1.00

Table 3.9 Mean VA scores for discomfort 6 hours after appliance fitting for the no wafer group

Discomfort levels had increased and almost doubled for most of the four actions by 6 hours. Closing on the back teeth was most painful.

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.54	0.26	0	1.00
Biting	30	0.51	0.25	0	0.95
Closing on back teeth	30	0.52	0.22	0	0.93
Closing on front teeth	30	0.51	0.24	0	0.95

Table 3.10 Mean VA scores for discomfort 6 hours after appliance fitting for the wafer group

Discomfort levels had increased again by 6 hours. The increase was not as large as that demonstrated in the no wafer group. There was no appreciable difference between the four actions.

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.70	0.22	0.03	1.00
Biting	30	0.75	0.21	0.07	1.00
Closing on back teeth	30	0.65	0.24	0	1.00
Closing on front teeth	30	0.67	0.25	0.10	1.00

Table 3.11 Mean VA scores for discomfort 24 hours after appliance fitting for the no wafer group

Discomfort levels at 24 hours after appliance fitting had increased again. Chewing and biting actions were most painful.

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.56	0.24	0	0.87
Biting	30	0.58	0.20	0	0.88
Closing on back teeth	30	0.39	0.21	0	0.83
Closing on front teeth	30	0.48	0.23	0	0.84

Table 3.12 Mean VA scores for discomfort 24 hours after appliance fitting for the wafer group

Discomfort for the chewing and biting actions 24 hours after appliance placement were slightly higher than after 6 hours. The pain experience had dropped for closing on the front and back teeth. Discomfort levels were lower at this interval than for the no wafer group.

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.56	0.25	0	0.99
Biting	30	0.61	0.22	0	0.99
Closing on back teeth	30	0.47	0.23	0	0.88
Closing on front teeth	30	0.50	0.23	0	0.87

Table 3.13 Mean VA scores for discomfort 48 hours after appliance fitting for the no wafer group

Discomfort levels at 48 hours after appliance fitting had reduced from the 24 hour values for all four actions. These reductions were most marked when closing on the front or back teeth.

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.38	0.20	0	0.70
Biting	30	0.38	0.22	0	0.78
Closing on back teeth	30	0.31	0.19	0	0.68
Closing on front teeth	30	0.37	0.20	0	0.79

Table 3.14 Mean VA scores for discomfort 48 hours after appliance fitting for the wafer group

Discomfort levels showed a large decrease from 24 hours. The discomfort was now comparable for all four actions. Closing on the back teeth was least uncomfortable. Discomfort levels at 48 hours were lower for all four actions than in the no wafer group.

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.42	0.20	0	0.95
Biting	30	0.43	0.20	0	0.96
Closing on back teeth	30	0.38	0.21	0	0.98
Closing on front teeth	30	0.46	0.22	0	1.00

Table 3.15 Mean VA scores for discomfort 72 hours after appliance fitting for the no wafer group

Discomfort levels after 72 hours had fallen again. The levels of discomfort were comparable for all four actions. Closing on the back teeth was the least uncomfortable. The largest reduction from 48 hours was for biting.

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.32	0.20	0	0.68
Biting	30	0.30	0.21	0	0.73
Closing on back teeth	30	0.26	0.17	0	0.62
Closing on front teeth	30	0.29	0.21	0	0.62

Table 3.16 Mean VA scores for discomfort 72 hours after appliance fitting for the wafer group

Discomfort levels had reduced further after 72 hours following appliance fitting. There was less discomfort when performing all four exercises than in the no wafer group.

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.08	0.06	0	0.23
Biting	30	0.19	0.09	0	0.33
Closing on back teeth	30	0.09	0.08	0	0.30
Closing on front teeth	30	0.10	0.09	0	0.43

Table 3.17 Mean VA scores for discomfort 7 days after appliance fitting for the no wafer group

Discomfort levels after 7 days had decreased considerably from the 72 hour levels for all four exercises. Three of the discomfort levels were lower than the discomfort experienced before appliance fitting.

Stimulus	N	Mean	St Dev	Min	Max
Chewing	30	0.15	0.10	0	0.43
Biting	30	0.12	0.09	0	0.30
Closing on back teeth	30	0.16	0.13	0	0.59
Closing on front teeth	30	0.14	0.13	0	0.52

Table 3.18 Mean VA scores for discomfort 7 days after appliance fitting for the wafer group

Discomfort levels after 7 days had decreased for all four exercises. All four exercises were comparable for discomfort experienced. The levels of discomfort were now comparable to, or less than those before appliance fitting. Overall the level of discomfort after 7 days was slightly greater for the wafer group.

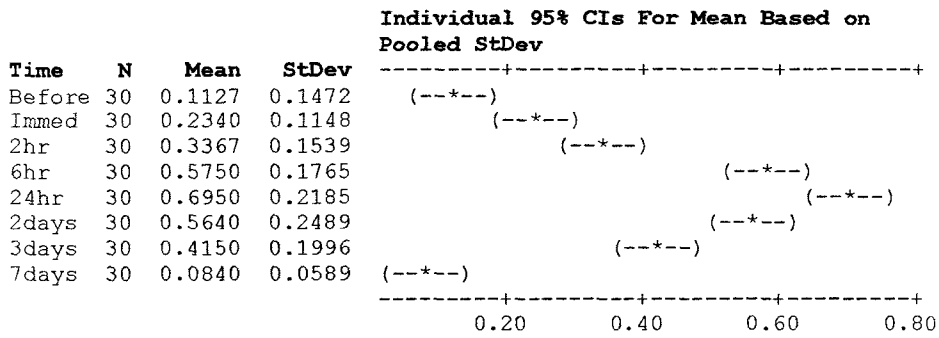
Assessment	N	Mean	St Dev	Min	Max
Chewing (no wafer)	8	0.34	0.16	0.11	0.56
Chewing (wafer)	8	0.38	0.23	0.08	0.70
Biting (no wafer)	8	0.34	0.16	0.12	0.59
Biting (wafer)	8	0.41	0.23	0.12	0.74
Closing on back teeth (no wafer)	8	0.32	0.11	0.16	0.52
Closing on back teeth (wafer)	8	0.38	0.20	0.09	0.65
Closing on front teeth (no wafer)	8	0.36	0.13	0.14	0.51
Closing on back teeth (wafer)	8	0.38	0.19	0.10	0/67

Table 3.19 Average VA scores for the 8 assessment intervals

Results for Analysis of Variance of pain scores for each of the four assessments at each time interval are shown as Figures 3.1-3.8.

Pain experience over the duration of the study is shown graphically in Figures 3.9-3.12.

3.4 ANOVA for pain scores at each time interval



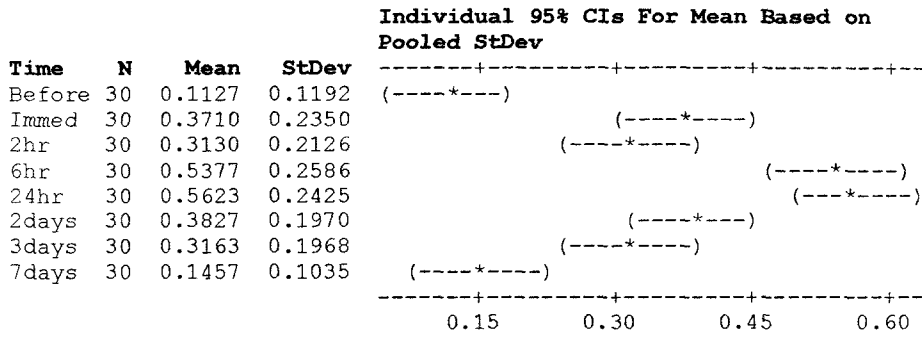
ANOVA F=50.10, P=0.000, R-Sq (adj)=58.98%

Figure 3.1 Pain on chewing for the no wafer group

The no wafer group reported a significant increase in pain after 2 hours $t=-5.76, p<0.001$.

Pain continued to increase up to 24 hours and fell back to a similar level to that at the start;

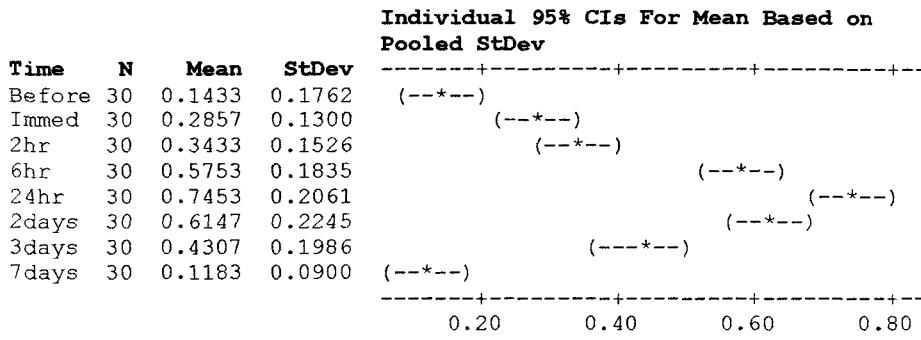
for start vs. 7 day scores $t=0.99, p=0.328$.



ANOVA F=18.99, P=0.000, R-Sq (adj)=34.51%

Figure 3.2 Pain on chewing for the wafer group

The wafer group reported a significant increase in pain immediately after appliance fitting $t=-4.5$, $p<0.001$. There was then a slight reduction in pain intensity up to 2 hours. After 2 hours there was a significant increase in pain up to 24 hours after which discomfort fell back to the starting level; for start vs. 7 day scores $t=-1.14$, $p=0.257$.



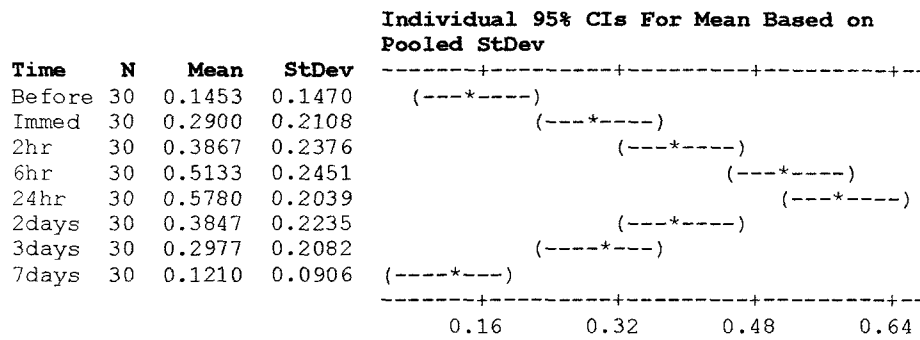
ANOVA F=50.04, P=0.000, R-Sq (adj)=58.95%

Figure 3.3 Pain on biting for the no wafer group

The non wafer group reported a significant increase in pain after 2 hours $t=-4.7$, $p<0.001$.

Pain continued to increase up to 24 hours and fell back to a similar level to that at the start;

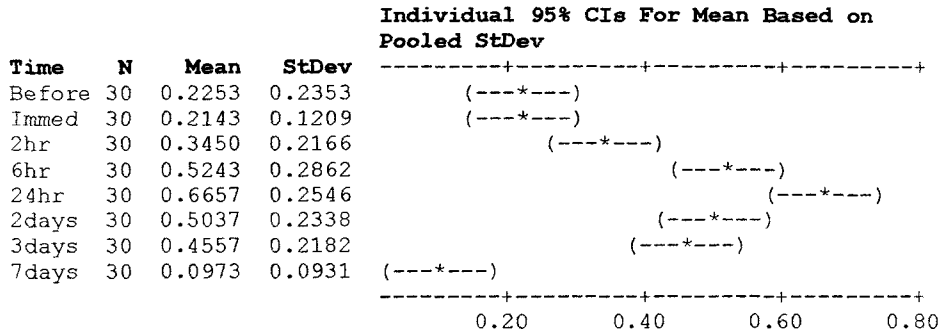
for start vs. 7 day scores $t= 0.69$, $p=0.493$.



ANOVA F=19.06, P=0.000, R-Sq (adj)=34.59%

Figure 3.4 Pain on biting for the wafer group

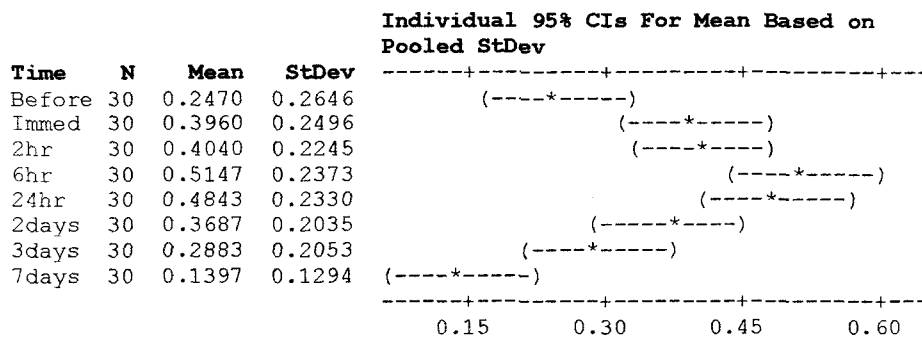
The wafer group reported a steady increase in pain up to 24 hours. The level of pain then fell back to that at the start, $t=0.77$, $p=0.444$.



ANOVA F=23.43, P=0.000, R-sq (adj)=39.64%

Figure 3.5 Pain on placing the front teeth together for the no wafer group

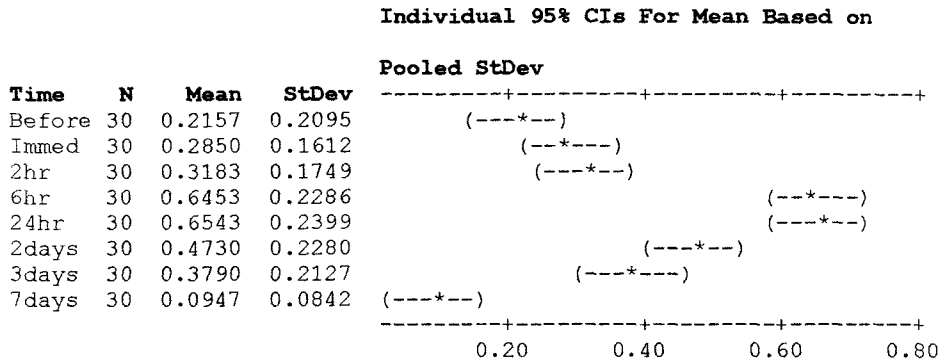
The pain in the non wafer group increased steadily up to 24 hours and then fell back to a level significantly below that at the start; for start vs. 7 day scores $t=2.77$, $p=0.009$.



ANOVA F=9.49, P=0.000, R-sq (adj)=19.92%

Figure 3.6 Pain on placing the front teeth together for the wafer group

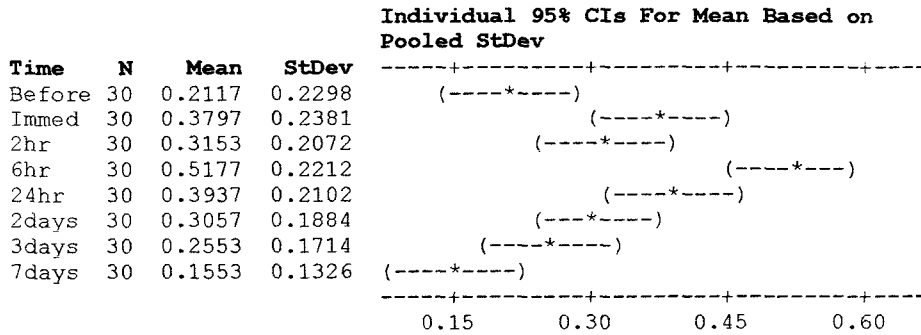
Pain in the wafer group increased for up to 6 hours after appliance fitting. Pain then fell to a level below that at the start although the difference between the two readings was not significant; for start vs. 7 day scores $t=2.00$, $p=0.052$.



ANOVA F=30.02, P=0.000, R-sq (adj)=45.95%

Figure 3.7 Pain on placing the back teeth together for the no wafer group

The pain in the non-wafer group had increased significantly to a maximum 24 hours after appliance fitting, $t=-2.06$, $p=0.04$. Pain then fell to a level significantly below that at the start; for start vs. 7 day scores $t=2.94$, $p=0.006$.



ANOVA F=9.54, P=0.000, R-sq (adj)=20.00%

Figure 3.8 Pain on placing the back teeth together for the wafer group

Pain in the wafer group increased significantly after appliance fitting, $t=-2.78$, $p=0.007$ and then fell slightly up to 2 hours. There was then a further increase in pain up to 6 hours, after which the pain level decreased to a level slightly below that at the start; for start vs. 7 day scores $t=1.16$, $p=0.251$.

3.4.1 Pain on chewing (Figure 3.9)

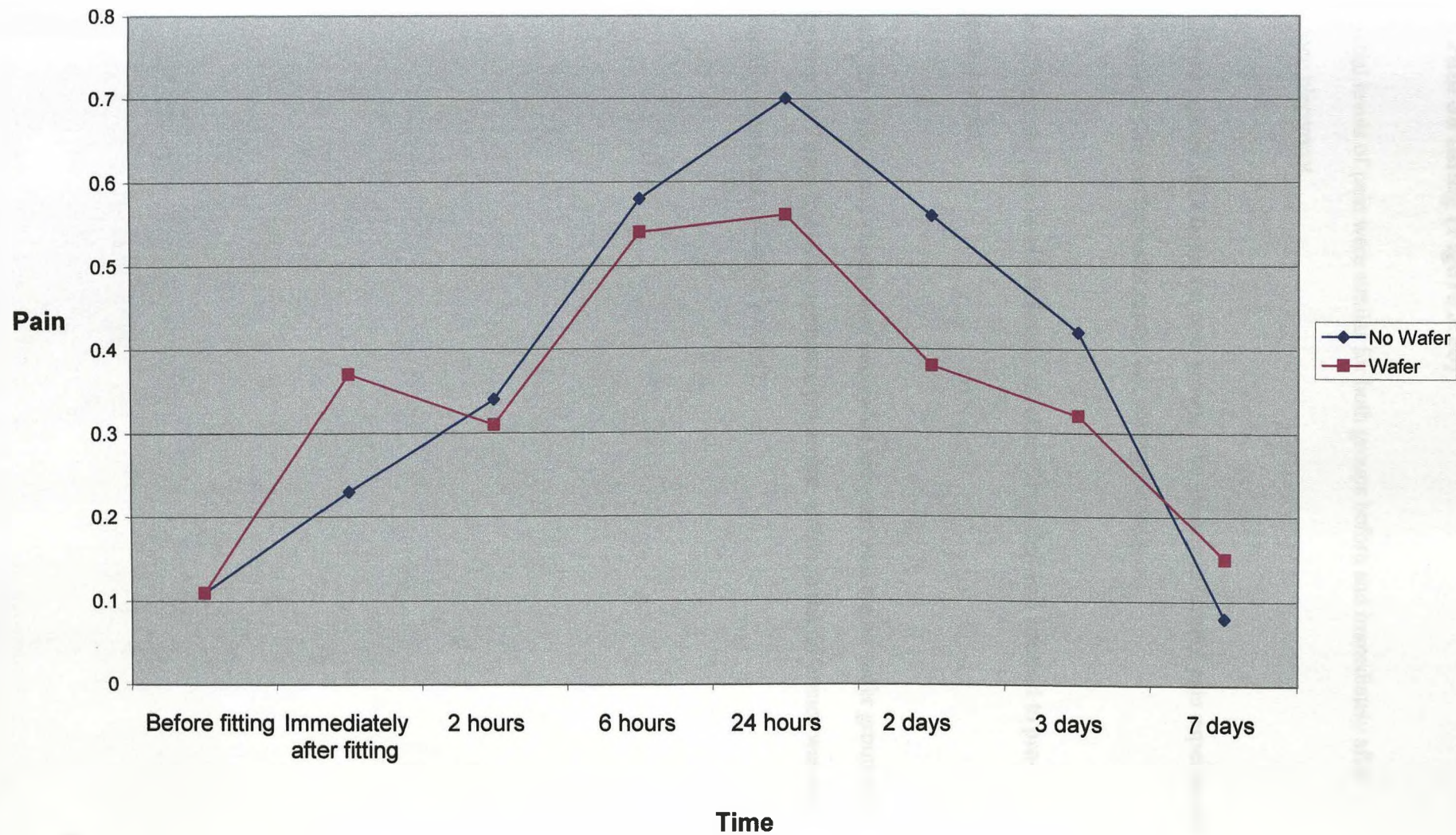
The initial levels of pain were similar for both groups. Immediately after appliance placement there was a marked increase in pain. The intensity of pain continued to rise in the non wafer group, with the steepest increase between 2 and 6 hours. In the wafer group pain decreased between appliance placement and the 2 hour time interval, suggesting that the wafer had an immediate pain-relieving effect. After 2 hours however, pain again increased, almost to the 6 hour level of the no wafer group.

Pain levels peaked at 24 hours for both groups. The maximum level of pain was slightly less for the wafer group.

After 24 hours pain levels declined in both groups, until after 7 days the level of pain had returned to pre-placement levels.

Overall, the experience of pain on chewing over the 7 days following appliance placement was comparable for the two groups; $t = -0.34$, $p = 0.74$.

Figure 3.9 Pain on chewing



3.4.2 Pain on biting (Figure 3.10)

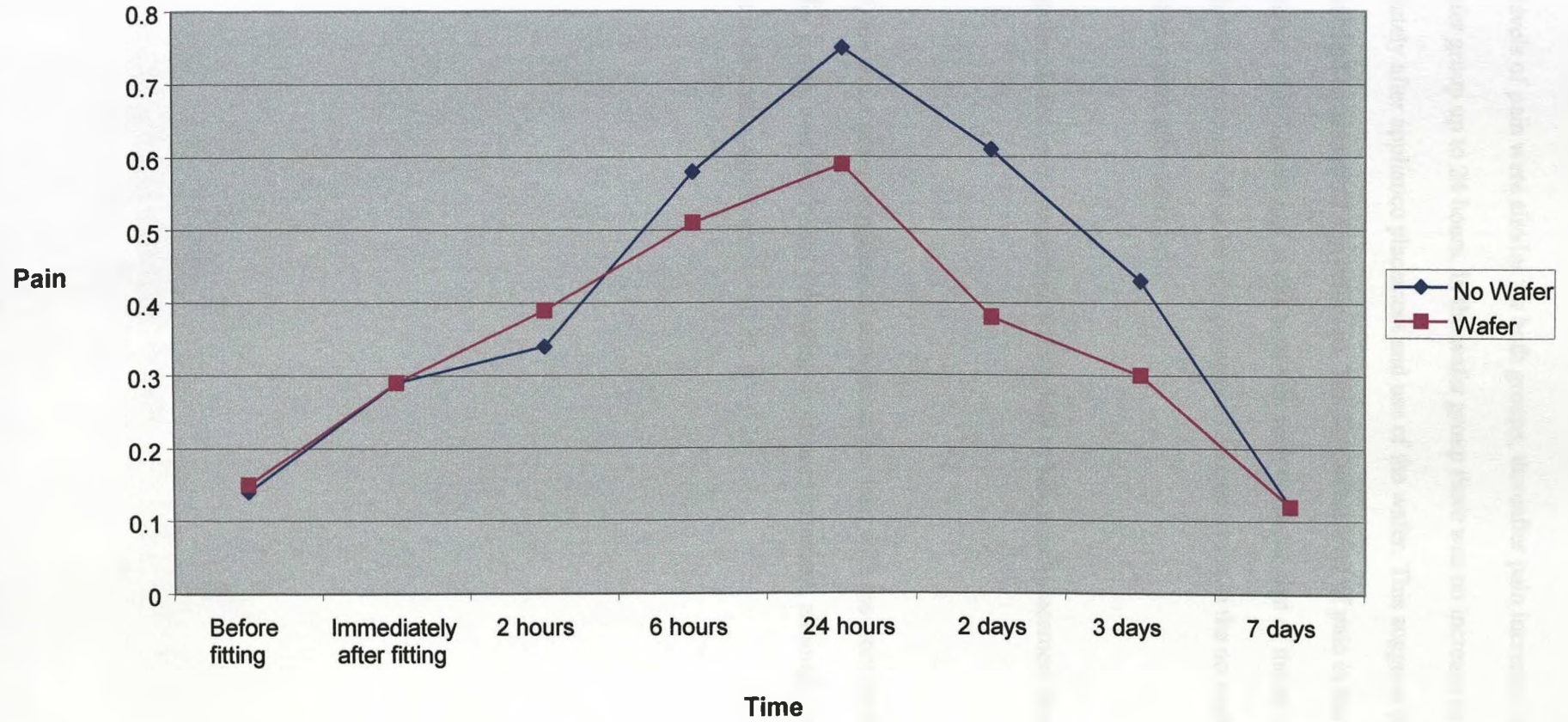
The initial levels of pain were similar for both groups before and immediately after appliance placement.

Pain levels peaked at 24 hours for both groups. The maximum level of pain experienced was slightly lower for the wafer group, but not significantly so.

After 24 hours the pain levels declined until after 7 days they had returned to pre-placement levels.

Overall, the wafer group experienced somewhat less pain than the no wafer group on biting over the 7 days following appliance placement, although the difference was not statistically significant, $t = -0.66$, $p = 0.52$.

Figure 3.10 Pain on biting



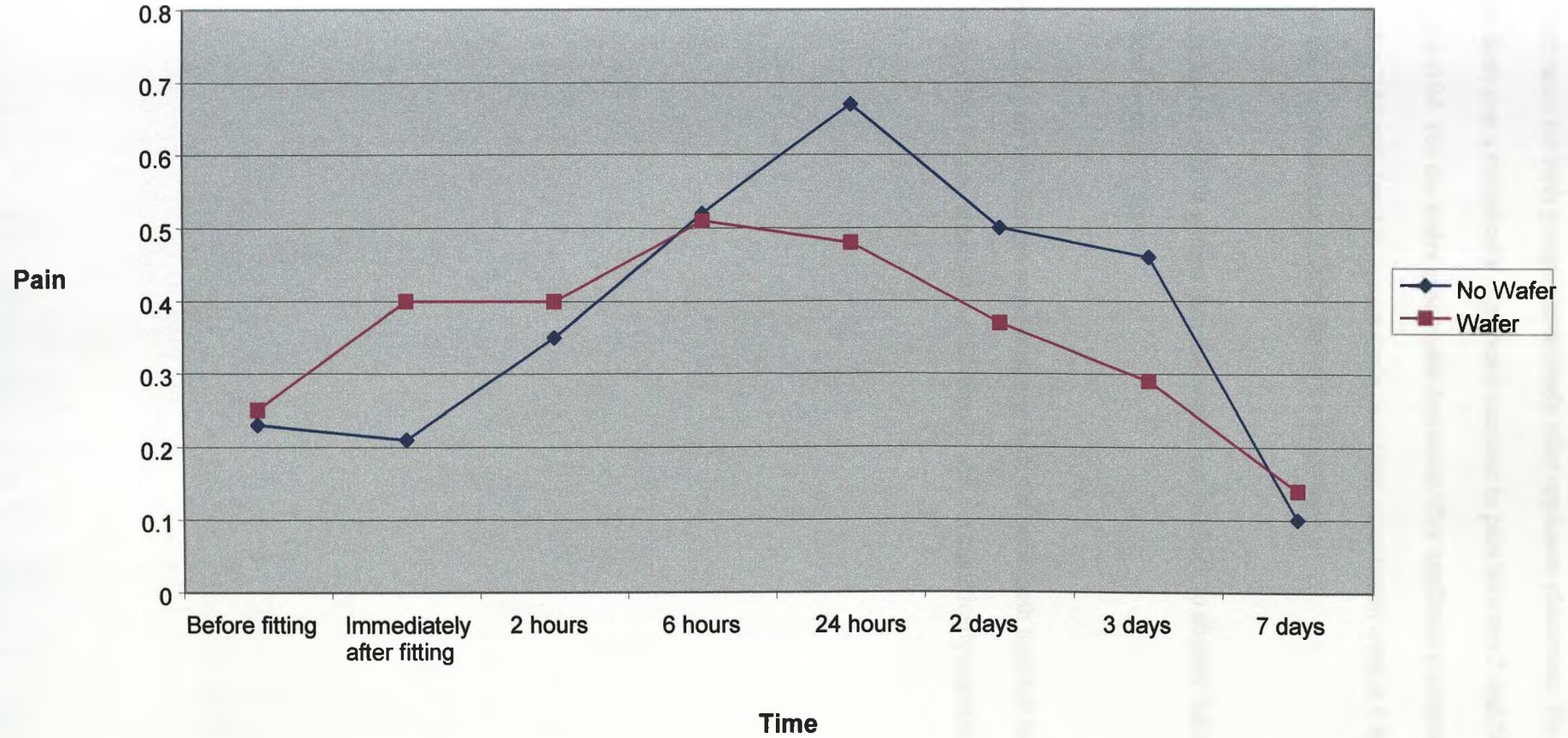
3.4.3 Pain with front teeth together (Figure 3.11)

Initial levels of pain were similar for both groups, thereafter pain increased steadily for the non wafer group up to 24 hours. In the wafer group there was no increase in pain immediately after appliance placement and use of the wafer. This suggests that the wafer may have had a pain restricting response. The maximum level of pain in the wafer group was reached after 6 hours and at this time was very similar to that of the no wafer group. After this time pain in the wafer group began to decline whilst in the no wafer group it climbed to a peak after 24 hours.

The pain levels for both groups then fell slightly to below pre-placement levels after 7 days.

Overall, the wafer group experienced somewhat less pain with the front teeth together than the wafer group, over the 7 days following appliance placement, although the difference was not statistically significant, $t = -0.31$, $p = 0.76$.

Figure 3.11 Pain with front teeth together



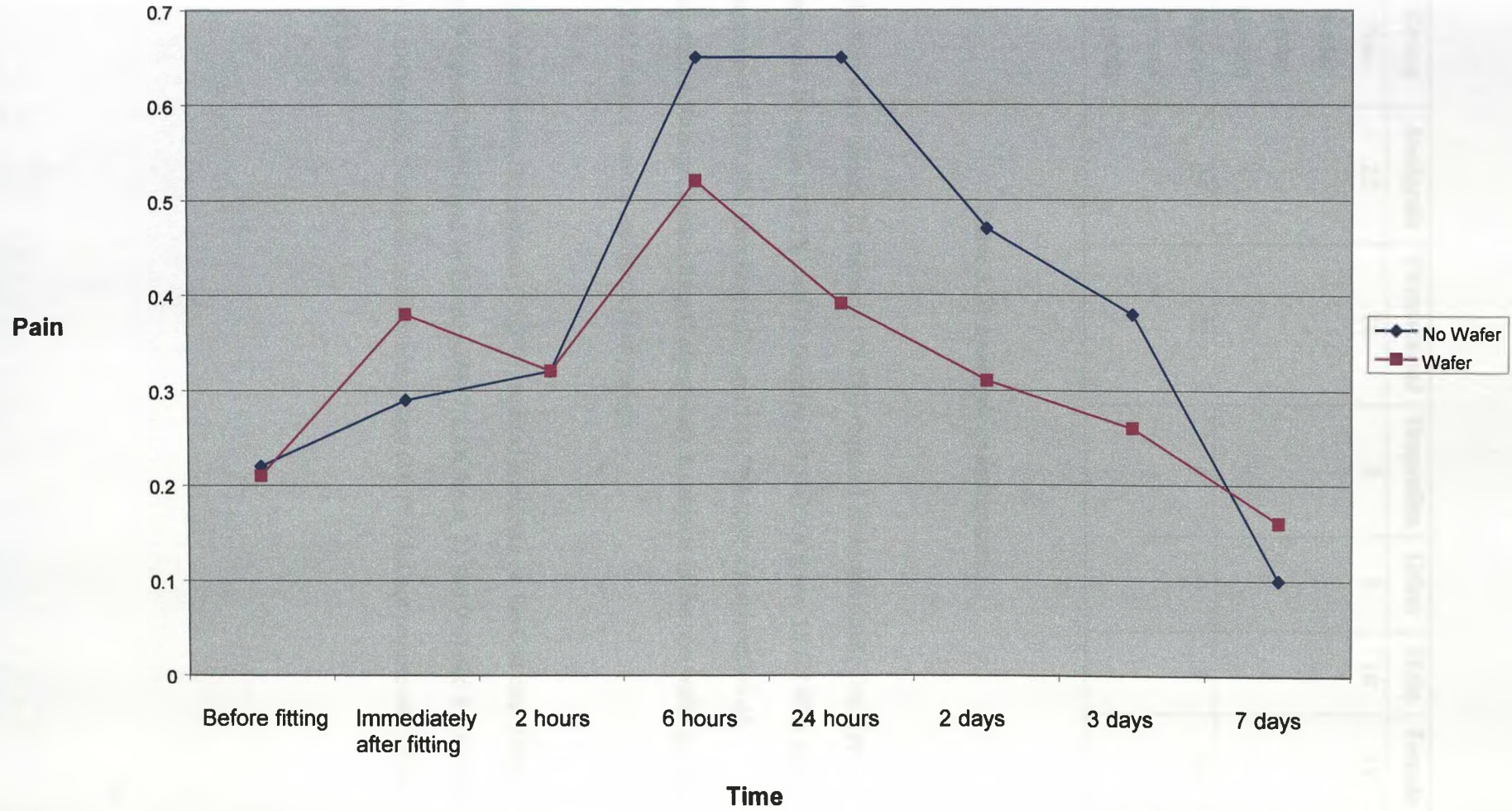
3.4.4 Pain with the back teeth together (Figure 3.12)

Pain increased for both groups immediately after appliance placement. For the no wafer group there was a statistically significant increase in pain between 2 and 24 hours, $t = -2.06$, $p = 0.04$. For the wafer group pain decreased after appliance placement and use of the wafer. The pain level then rose again, reaching a maximum level at 6 hours that was below the maximum recorded by the no wafer group.

The pain levels in both groups then decreased and fell back to slightly below pre-placement levels at 7 days.

Overall, the pain levels were somewhat less with the back teeth together in the wafer group over the 7 days, although the difference was not statistically significant, $t = -0.82$, $p = 0.43$.

Figure 3.11 Pain with back teeth together



3.5 Analgesic drug consumption

Group	Analgesia	Paracetamol	Ibuprofen	Other	Male	Female
Non wafer group (n=30)	22	18	3	1	10	12
Wafer group (n=30)	25	21	4	0	9	16

Table 3.20 Analgesic consumption

In the non wafer group, 22 subjects (73.3%) required analgesia on the first day.

There were 10 males (45.5%) and 12 females (54.5%). Of these, 18 (81.8%) took Paracetamol, 3 (13.6%) took Ibuprofen and 1 (4.5%) took a combination of Paracetamol 500mg/Codeine 8mg (Solpadeine). 8 subjects in the non wafer group (26.7%) did not require analgesia at any stage.

In the wafer group, 25 subjects (83.3%) required analgesia on the first day. There were 9 males (36.0%) and 16 females (64.0%). Of these, 21 (84.0%) and 4 (16.0%) took Paracetamol. 5 subjects in the wafer group (16.7%) did not require analgesia at any stage.

The mean dose of Paracetamol in the non wafer group was 889mg. The mode was 1000mg.

The mean dose of Paracetamol in the wafer group was 714mg. The mode was 1000mg.

The mean dose of Ibuprofen in the non wafer group was 333mg. The mode was 400mg.

The mean dose of Ibuprofen in the wafer group was 250mg. The mode was 200mg.

For both groups, most analgesics were consumed in the first 24 hours following fixed appliance placement and dosage usually was discontinued by the third day.

3.6 Additional comments

Twenty subjects (33.3%) completed the additional comments section. 10 subjects (50% of this sample) reported aching in the teeth, which was generally the first symptom of discomfort experienced after fitting of fixed appliances.

Six subjects (30%) reported pain whilst eating as the most uncomfortable aspect of having fixed appliances on their teeth.

Twelve subjects (60%) complained of ulcers or soreness, which generally appeared after 4-5 days.

Chapter 4

Discussion

Chapter 4 – Discussion

4.1 Demographic data

4.2 Anxiety levels

4.3 Pain scores

4.4 Analgesic consumption

4.5 Additional comments

4.1 Demographic data

Sixty subjects participated in the study. There were 30 in the non wafer group and 30 in the wafer group. Therefore the number of participants required for each group, as specified in the protocol, was achieved.

There were slightly more females than males in both groups. There is evidence to support that females suffer more pain than males (Ngan et al., 1989; Erdinc and Dincer, 2004; Scheurer et al., 1996) although several studies have found no statistically significant difference between males and females for reported levels of pain (Jones, 1984; Brown and Moerenhout, 1991; Jones and Chan, 1992).

The mean ages of subjects were 14.0 years for the non wafer group and 13.7 years for the wafer group. Therefore the two groups were evenly matched. Some studies suggest that adolescents experience more pain than pre-adolescents and adults (Brown and Moerenhout, 1991; Scheurer et al., 1996). There are conflicting findings from other studies suggesting that adults experience more pain than younger patients (Jones and Richmond, 1985; Jones and Chan, 1992). Ngan et al. (1989), found no statistically significant difference in pain perception between adolescents and adults. In the present study all participants were aged between 12 and 16 years, in order to avoid potential variation in pain perception due to age. The mean ages reflect the typical ages of the most frequently treated age group on the orthodontic departments at both hospitals.

4.2 Anxiety levels

Studies have shown that the pain experienced by patients depends heavily on the psychological well-being of the individual (Dubner, 1968; Brown and Moerenhout, 1991; Sergl et al., 1998).

There were no statistically significant differences between anxiety levels pre-treatment for the two groups, the mean pain scores being 0.35 and 0.34 for the non-wafer group and wafer group respectively. This reflects low, but not non-existent, anxiety levels. This agrees anecdotally with the situation clinically. Orthodontic patients are generally relaxed and in some cases excited about having their fixed braces placed.

4.3 Pain scores

Pain scores for both groups were similar before the placement of fixed appliances, indicating that the groups were well matched (Table 4.1).

Immediately after appliance placement, both groups reported higher levels of pain. Three of the four assessments indicated that increases were greater for the wafer group. This may have been due to the fact that stimulation of the teeth, through the exercises, increased the awareness of altered sensations with appliances in situ.

After the first time interval, i.e. 2 hours, the wafer group generally showed lower levels of pain than the non wafer group although the differences did not reach the level of statistical significance for any between-group comparison. This may have been due in part to the wide range of pain reports from the subjects in both groups, with consequent high standard deviations. For two of the assessments, pain on chewing and pain with back teeth together, there was a reduction in pain and the pain on front teeth was stabilised at the previous level. This suggests that the wafer group had experienced some pain relief or pain control.

The steepest rise in pain levels occurred between 2 hours and 6 hours after appliance placement, for both groups.

Pain levels peaked at 24 hours. The only difference was that for the wafer group, pain with the front teeth or back teeth together peaked sooner at 6 hours.

After 24 hours there was a gradual decline in pain. By day 7, the pain levels had returned to levels similar to or slightly below baseline values. This follows the patterns observed in other studies (Ngan et al. 1989; Jones, 1984; Scheurer et al, 1996; Jones and Chan, 1992).

Overall, pain experience was less for the wafer group. This finding applies to the whole test period, from appliance placement, to the pain experience at 7 days. The finding also applies for each of the exercises performed by the test groups. It is possible that free use of the wafer or repeated controlled use may have increased this effect. This may be an area for further study.

Pain levels were higher for the two exercises involving repeated movements, i.e. chewing and biting. This suggests that repetitive stimulation of the teeth and the periodontal ligaments after appliance placement, such as masticatory movements, increase pain experience.

Time		Before fitting	Immediately after fitting	2 hrs	6 hrs	24 hrs	2 days	3 days	7 days	Mean
Chewing	Wafer	0.11	0.37	0.31	0.54	0.56	0.38	0.32	0.15	0.34
	No wafer	0.11	0.23	0.34	0.57	0.70	0.56	0.42	0.08	0.37
Biting	Wafer	0.15	0.29	0.39	0.51	0.59	0.38	0.30	0.12	0.34
	No wafer	0.14	0.29	0.34	0.58	0.74	0.61	0.43	0.12	0.40
Closing on back teeth	Wafer	0.21	0.38	0.32	0.52	0.39	0.30	0.26	0.16	0.31
	No wafer	0.22	0.29	0.32	0.65	0.65	0.47	0.38	0.09	0.38
Closing on front teeth	Wafer	0.25	0.40	0.40	0.51	0.48	0.37	0.29	0.14	0.36
	No wafer	0.23	0.21	0.35	0.52	0.67	0.50	0.46	0.10	0.38

Table 4.1 Mean pain scores for assessments at each time interval

4.4 Analgesic consumption

More of the participants in the wafer group required analgesia on the first day, although the between-group difference was not significant, $p > 0.05$. In addition, the non wafer group took lower doses of analgesics than the wafer group.

More females in both groups required analgesia than males. This may be related to the fact that females are more sensitive to pain than males (Ngan et al., 1989; Erdinc and Dincer, 2004; Scheurer et al., 1996).

Paracetamol was the favoured analgesic. This may be due to the fact that the recommendations for pain relief after appliance placement were for the patient to take whatever they took commonly for a headache. Ibuprofen was the other main analgesic used. These two drugs are the most readily available over the counter analgesics.

Ngan et al., (1992), compared Ibuprofen, Aspirin and a placebo in managing orthodontic pain and concluded that Ibuprofen was the most effective analgesic. These drugs generally act by inhibiting the inflammatory response caused by an applied force.

There is a theoretical risk that Ibuprofen may reduce the rate of tooth movement since it inhibits cyclooxygenase activity and therefore alters vascular and extracellular collagen remodelling (Kyrkanides et al., 2000). In practise however the effects are minimal and Ibuprofen may be preferred to Paracetamol due to its *superior analgesic properties*.

4.5 Additional comments

Only a third of all subjects completed this section.

The first symptom experienced was aching in the teeth. Pain whilst eating was reported to be the most uncomfortable aspect by 30% of those who commented. This correlates with pain being highest during those exercises involving repeated stimulation and loading of the teeth. Scheurer et al., (1996), found that the pain experience was worse in anterior teeth due to the differences in root surface area, increased involvement of anterior teeth during levelling and greater use of anterior teeth for biting. This is reflected to some degree by the results of the present study.

60% of subjects who replied to the “Additional comments” section reported ulcers or a sore mouth. This agrees with previous work that reported levels between 50% and 70% (Kvam et al., 1987).

Chapter 5

Conclusions

Aims of the study

The pain experience of the subjects in the present study agrees with that for previous studies, in that pain increases after appliance placement, especially after 2 hours. The maximum pain experienced peaks at 24 hours and then reduces steadily back to baseline levels or below by day 7. The pain experienced is also significant enough to warrant the need for analgesia in some cases. The most common analgesics taken are Paracetamol and Ibuprofen. Pain is worse with movements involved in mastication, such as chewing and biting.

Overall pain experience for the bite wafer group was slightly less than for the no wafer group for each of the four types of assessment, although none of the reductions were statistically significant. Hence it can also be concluded that chewing on a bite wafer reduces pain experience slightly as against providing the usual advice alone.

Null hypotheses

- Chewing on an acrylic bite wafer following placement of fixed orthodontic appliances, does not reduce the pain and discomfort experienced significantly
- Chewing on an acrylic bite wafer does not provide a significant reduction in pain as compared to providing advice and instructions

The first null hypothesis is rejected.

The second null hypothesis is demonstrated.

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