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THE EFFECT OF *ARNICA MONTANA* D6 ON THE LEVEL OF DISCOMFORT IN PATIENTS UNDERGOING ORTHODONTIC TREATMENT

A Minor-Dissertation presented to the Faculty of Health Sciences,
Technikon Witwatersrand,
as partial fulfillment for the

Masters Degree in Technology
in the Programme Homoeopathy
by

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Johannesburg 2003

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DECLARATION

I declare that this Dissertation is my own, unaided work. It is being submitted for the Degree of Master of Technology at the Technikon Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other Technikon or University.

(Signature of candidate)

12th day of May 2003

Dedicated to my wonderful husband,

Juan-Pierre

and my son,

Ruan

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ABSTRACT

Studies have shown that patients undergoing orthodontic tooth movement can experience varying degrees of discomfort.

The objective of this study was to determine whether a homoeopathic remedy called *Arnica montana* D6 can alleviate the discomfort experienced by patients undergoing orthodontic treatment.

A total of thirty patients from an orthodontic practice were included in a double-blind, randomized, parallel, placebo-controlled analgesic efficacy evaluation of *Arnica montana* D6. Patients were divided into two groups. Group A received *Arnica montana* D6, and group B received a placebo. The patients were instructed to take one tablet three times per day for 14 days following the insertion of orthodontic separators and arch wires. The level of discomfort was assessed using a visual analogue scale at 2, 6, and 24 hours and 2, 3, and 7 days after the insertion of either orthodontic separators or an initial arch wire.

A repeated measures analysis of variance showed that the discomfort experienced by the placebo group was not significantly greater than the discomfort experienced by the *Arnica montana* D6 group at all but one of the time intervals tested. When the action of chewing was evaluated at Time 3 (24 hours after insertion of separators), $p = 0.028$. When one however takes into account that this was the only area where a significant difference in the level of discomfort was reported, together with the fact that the overall difference in discomfort reported was not significant ($p = 0.063$), one has to conclude that this one incidence does not supply sufficient evidence to prove that *Arnica montana* D6 ameliorates orthodontic discomfort. This finding does, however warrant further investigation to determine why amelioration was experienced at that specific time interval.

The results of this study therefore do not support a recommendation for *Arnica montana* D6 as a preferred remedy in the treatment of discomfort caused by orthodontic treatment, but more studies should be conducted in this field using different potencies and complex remedies.

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NOMENCLATURE

Allopathic treatment	A system of treatment in which a troublesome symptom is treated by creating a state in which it cannot thrive
Arch wire	A wire fastened to two or more teeth through fixed attachments. It is used to guide tooth movement
Banding	The process in which arch wires are secured to teeth
Buccal mucosa	Mucous membranes of the mouth
Contusion	Bruising. An injury that does not break the skin; it is usually caused by a blow and marked by swelling, discolouration and pain
Discomfort index card	A card depicting the scale on which the discomfort experienced by patients is recorded
Emoticon	An icon that reflects an emotion
Distal	Side of a tooth furthest from the midline of the mouth
Haematoma	A collection of blood that has escaped from the vessels and becomes trapped in the tissues of the skin or in an organ. This can result from injury, and infection is a serious complication

Homoeopathy	A system of healing based on the theory that "like cures like". In practice, homoeopaths dilute substances in ratios of 1 to 10 or 1 to 100 to achieve the smallest dose of a substance necessary to control the symptoms experienced by a patient
Hyperalgesia	An increased perception of pain
Inate substance	Substance with no medicinal value
Inflammation	The response of the tissues of the body to irritation or injury. Inflammation may be acute or chronic. Its chief signs are redness, heat, swelling and pain
Ischaemia	Poor blood supply to an organ or part, often marked by pain
Mandibular teeth	Teeth in the lower jaw
Mastication	Chewing
Mesial	The side of a tooth closest to the midline of the mouth
Maxillary teeth	Teeth in the upper jaw
Oedema	The abnormal pooling of fluid in tissues, causing swelling

Oral epithelium	The tissues lining the mouth that may be changed by different types of diseases, injuries and treatments. The symptoms of damage to the oral epithelium include mouth pain or discomfort, mouth tumours or ulcers, and bleeding gums
Orthodontics	A branch of dentistry that deals with crooked teeth (malocclusion) and badly aligned teeth
Periodontal	The space around a tooth
Placebo	An inactive substance given as if it were a real dose of a needed drug. The substance used in this study had a sugar base. Placebos are used in drug studies to compare the effects of the inactive substance with those of an experimental drug
Placebo effect	A physical or emotional change occurring after a substance has been taken, the change not being the result of any special effect of the substance. The change may be for the better, meeting the results the patient expects
Prostaglandin (PG)	One of several strong hormone-like fatty acids that act in small amounts on certain organs
Separators	Small elastic bands placed between molar teeth to separate them slightly so that orthodontic appliances can be fitted
Stimulus	Anything that excites an organism or part to function, become active or respond

VAS	Visual Analogue Scale (refer to Appendix A and H).
Vasoconstriction	A narrowing of any blood vessel, especially the arterioles and the veins in the blood reservoirs of the skin and abdominal viscera. It is done by many means that together control blood pressure and the distribution of blood throughout the body
Vasodilation	Also referred to as **vasodilatation**. Widening or enlarging of blood vessels, particularly arterioles, usually caused by nerve impulses or certain drugs that relax smooth muscle in the walls of the blood vessels.

CHAPTER ONE – INTRODUCTION

1.1 Statement of the problem

Studies conducted by Ngan *et al.* (1989) and Reitan (1956) showed that patients undergoing orthodontic treatment could experience varying degrees of discomfort. The early phase of orthodontic tooth movement – where *Arnica montana* D6 demonstrated some action (refer to Table 4) - involves an acute inflammatory response, characterized by periodontal vasodilatation (Davidovitch *et al.*, 1988), and pain is a common sensation experienced by patients subjected to orthodontic forces (Ngan *et al.*,1989; Jones, 1984). Theoretically it should be possible to alleviate orthodontic discomfort by inhibiting the inflammatory response normally observed after orthodontic adjustments (Ngan *et al.*, 1994). Research has been conducted on the use of allopathic medication (Ngan *et al.*, 1994) and nonsteroidal anti-inflammatory agents such as aspirin and ibuprofen (White, 1984) to relieve the pain caused by the banding of teeth. But until now no research has been conducted on the effect of natural homoeopathic remedies on the alleviation of pain experienced during orthodontic procedures.

According to Hering (1997) *Arnica montana* is indicated following dental treatment, as it promotes the healing of damaged tissues when given internally. *Arnica montana* D6 was also chosen because it is relatively well known and available in most health shops and pharmacies. If proven effective it could just as easily be bought over the counter as other painkillers.

The purpose of this study was to test whether the administration of a homoeopathic remedy called *Arnica montana* D6 would alleviate the onset of pain normally resulting from inflammation as a result of orthodontic treatment in a clinical setting.

1.2 Aim and objective of the study

The aim and objective of this study was to investigate the effect of *Arnica montana* D6 on the level of discomfort experienced by a group of patients undergoing orthodontic treatment.

CHAPTER TWO – LITERATURE REVIEW

2.1 Normal dentition

The development of children's teeth is associated with a continuous movement externally. The mandibular teeth usually erupt before the maxillary teeth, and girls' teeth usually erupt sooner than boys' teeth. A child's dentition contains 20 deciduous teeth, and the complete adult dentition consists of 32 teeth. As the root of the tooth grows, the crown gradually erupts through the oral epithelium (Moore *et al.*, 1993).

Eruption of the deciduous teeth usually occurs between six and twenty-four months after birth. The mandibular medial or central incisors usually erupt six to eight months after birth. In healthy children, all 20 deciduous teeth are usually present by the end of the second year (Moore *et al.*, 1993).

The permanent teeth develop in a manner similar to deciduous teeth. As a permanent tooth grows, the root of the corresponding deciduous tooth is gradually resorbed by osteoclasts. Consequently, when the deciduous tooth is shed, it consists of only the crown and the uppermost portion of the root. The permanent teeth usually begin to erupt during the sixth year and continue to appear until early adulthood (Moore *et al.*, 1993).

The development of the face is affected by the development of the paranasal sinuses and by the growth of the maxilla and mandible to accommodate the teeth. It is the lengthening of the alveolar processes (the bony sockets which support the teeth) that results in the increase in the depth of the face during childhood (Moore *et al.*, 1993).

2.2 Malocclusion

According to Edwards *et al.* (1991) a child's teeth should be inspected to determine whether they are healthy, present in adequate numbers and in correct apposition in the upper and lower jaws to allow efficient mastication. Inappropriate positioning of the teeth in the jaws or between the jaws themselves is common (Collier *et al.*,

1995). Those with prominent upper teeth are particularly prone to trauma, and those children at risk (e.g. from epilepsy), or those involved in contact sports, should be referred to an orthodontist (Collier *et al.*, 1995). Once referred, these children frequently receive treatment involving orthodontic appliances that cause them discomfort due to the release of prostaglandins (Arrayne *et al.*, 1977). Refer to 2.4.1.

2.3 Orthodontic treatment

Orthodontic treatment is divided into different phases (Ngan *et al.*, 1994), and this study was conducted during the first two phases in orthodontic treatment, namely the separation phase and the banding phase which involves placement of an initial arch wire. During the separation phase orthodontic separators are placed and left in at the mesial and distal contacts of the first molars in each of the four quadrants for a maximum period of 7 days. Banding takes place 2 to 7 days after separation (Ngan *et al.*, 1994). Banding refers to the use of orthodontic brackets and wires together with steel arches to align the teeth correctly. The teeth are thus subjected to orthodontic forces that guide them into the correct position. This early phase of orthodontic tooth movement involves an acute inflammatory response, characterized by periodontal vasodilatation (Davidovitch *et al.*, 1988) and pain (Ngan *et al.*, 1989; Jones, 1984).

2.4 Levels of discomfort

Orthodontic patients experience pain and discomfort to a varying degree during the course of treatment (Fujita, 1978; Jones, 1984; Sergl *et al.*, 1998; Soltis *et al.*, 1971; Storey *et al.*, 1952; White, 1984). Most of the discomfort associated with fixed appliances appears to be experienced during the initial 4-week adjustment period or coincides with appliance adjustment (Brown *et al.*, 1991).

Studies conducted by Brown *et al.* (1991) and Ngan *et al.* (1989) showed that no significant differences in the extent to which male and female subjects perceived pain caused by orthodontic procedures. When Ngan *et al.* (1989) compared the level of discomfort experienced by patients over the age of 16 to the level of discomfort

experienced by patients younger that 16, no significant difference was found. It is thus not necessary to differentiate between age and sex when conducting studies on the amount of pain experienced during orthodontic treatment.

The cause of the pain resulting from orthodontic tooth movement is not entirely clear. Furstman and Bernik (1972) suggested that periodontal pain was caused by a process of pressure, ischaemia, inflammation and oedema. The inflammatory response is initiated by the release of prostaglandins (PGs) (Arrayne *et al.*, 1977). Refer to Appendix H. Prostaglandins enhance the transmission of painful stimuli (Ferreira *et al.*, 1987; Higgs *et al.*, 1983). Soltis *et al.* (1971), found that patient discomfort was attributed to the lowering of the pain threshold and disruption of the normal mechanisms associated with proprioception input from the nerve endings in the periodontal ligament. Burstone (1962), in a study examining the pain caused by orthodontic appliances, speculated that immediate pain was related to the initial compression of the periodontal ligament immediately after the placement of the arch wire. The delayed pain response, which started a few hours later, was termed "hyperalgesia of the periodontal ligament".

2.4.1 The role of prostaglandins (PG) in the perception of pain

Research in the biochemical processes involved in pain perception has suggested that the mechanism of pain sensation could be related to substances such as prostaglandins (PG) and substance P around the periodontium. One study suggests that prostaglandins (PG) sensitise the pain receptor, resulting in long-lasting hyperalgesia and increased pain sensitivity to chemical stimuli such as histamine or bradykinin (Ferreira *et al.*, 1978, Higgs *et al.*, 1983). In an animal study, the level of prostaglandins (PG) was found to increase and peak at 24 hours and decrease in 7 to 14 days after the application of orthodontic forces (Kess *et al.*, 1987). In another study the level of substance P was found to increase and peak at 36 hours and decrease in 14 days after separation of incisors by orthodontic forces (Kamogashira *et al.*, 1988). These data, together with a study by Ngan *et al.* (1989) suggest that the discomfort experienced by patients after insertion of separators or arch wires may be related to the levels of prostaglandins (PG) and substance P in the periodontium.

Prostaglandins (PG) occur in almost all human tissues, and exert a broad spectrum of physiologic actions that include opening airways by relaxing smooth muscles, regulating blood pressure by increasing urinary output and excretion of sodium ions, and vasoconstriction and vasodilation (Arrayne *et al.*, 1977). Prostaglandins (PG) enhance the transmission of painful stimuli and have been shown to cause hyperalgaesia, which is an increased sensitivity to noxious agents (Ferreira *et al.*, 1987). In addition, sensitisation by prostaglandins (PG) reportedly enhances the noxious effects of certain biogenic amines and peptides such as histamine, bradykinin, serotonin, acetylcholine and substance P (Higgs *et al.*, 1983).

2.5 Homoeopathy

2.5.1 Samuel Hahnemann

Christian Frederick Samuel Hahnemann was born in Meissen, Germany on April 10, 1755 and died in Paris, France on July 2, 1843. He was a medical doctor and chemist who became increasingly disillusioned with conventional medical practice and was so disconcerted by the side effects of the medicines available to him, that he ceased to practice medicine (Van Wyk, 1998; Lockie *et al.*, 1995). Homoeopathy is a system of medical practice that originated from the research and work of Dr. Hahnemann after he stopped practicing medicine (Endler *et al.*, 1998).

The philosophy underlying homoeopathy recognises the body as a vital self-healing organism and homoeopathic medicines are prepared in such a way as to stimulate this innate healing ability of the body (Van Wyk, 1998).

2.5.1 The law of similars

Homoeopathy was born when Dr. Hahnemann observed a similarity between the kind of symptoms produced by a crude substance given in material doses to a healthy person and the symptoms of the disease that could be treated by the same substance, but in minute doses (Van Wyk, 1998). He described this phenomenon as *similia similibus curentur* or "like cures like" (Sankaran, 1997), which forms the fundamental basis of homoeopathy (Lockie *et al.*, 1995; Roberts, 1997).

This phenomenon became known as the "Law of Similars" (Vithoulkas, 1993), whereby a disease can be cured by a substance that causes the symptoms of disease in a healthy person. Homoeopathic remedies thus produce similar symptoms as those experienced by the patient, and in doing so the remedy provokes the body into throwing off these symptoms (Boyd, 1989). The correct remedy for a specific case is called the simillimum (Vithoulkas, 1993).

2.5.2 The law of infinitesimals

Hahnemann also tried to diminish the toxic effect of the crude substance. He did this by diluting the original substance until only a very small amount remained in the final remedy. Pharmacologically speaking, dilution alone could dramatically reduce the therapeutic effect of the drug (Van Wyk, 1998), but this process gave rise to what Hahnemann called "The Law of Infinitesimals". This law states that the lower the dose of a curative agent, the more effective it is. A low dose is achieved by diluting the curative substance a number of times until only a low concentration of the curative substance remains in a large amount of the dilutent (Davidson, 2001). The minute quantities of material substance that remain in the remedies thus have profound abilities to cure disease (Van Wyk, 1998).

2.5.4 Homoeopathic remedies

2.5.4.1 The source of homoeopathic remedies

Homoeopathic remedies can be prepared from any substance which either has a toxic effect on the body or which exerts a chemical change in the body (Boyd, 1989). These remedies are harvested from the three kingdoms of nature, namely the plant kingdom, the animal kingdom and the mineral kingdom. If the source of the remedies is physiological with active principles, the remedies are called sarcodes, and if the source of the remedies is pathological secretions or products, they are called nosodes (Eizayaga, 1991).

2.5.4.2 The homoeopathic potency

Hahnemann devised a two-step process whereby he diluted each remedy by "succussing", or shaking it vigorously, and banging it down on a hard surface, at each stage of the dilution. To Hahnemann's surprise, not only did the diluted medicines cease to produce such strong aggravations, but they also seem to act faster and more effectively than more concentrated solutions. Although they were weaker, they were actually more potent. For this reason Hahnemann called his new homoeopathic remedies "potentisations". In homoeopathy, "potency" is used to describe the dilution, or strength of a remedy (Lockie *et al.*, 1995). A higher potency carries a higher energy allowing the remedy to be deeper acting and more potent (Solomon, 2002). All homoeopathic remedies are prepared according to this process that is also known as dynamisation (Endler *et al.*)

There are two ranges of potencies, namely the decimal scale and the centesimal scale. The decimal scale is a 1 in 10 dilution and is called 'X' or 'D' potencies, and the centesimal scale is a 1 in 100 dilution and is called 'C' potencies (Boyd, 1989).

Eizayaga (1991) stated that there is not only a relationship between the medicines and the illness, but also between the 'morbid plane' and the potency of the medicines. According to him the deepest dynamic pathological process corresponds to the lowest potency of the remedy, i.e. with the lowest degree of dynamization. The most profound level belongs to the mental plane, the next level to the vital organs, and the most superficial or peripheral level to that of the extremities, the skin and the mucous membranes. For the purposes of this study *Arnica montana* was selected in a D6 potency, because of the involvement of the buccal mucosa in orthodontic treatment (Furstman *et al.*, 1972).

2.6 *Arnica montana* D6

The importance of *Arnica montana* as a healing herb was first recognised in the 16th century by St. Hildegard of Bingen (1099 - 1179). She was a nun and very well schooled in medicine, and she wrote extensively about *Arnica montana* (Lockie *et al.*, 1995).

Arnica montana is a flower that grows in the Swiss Alps (www.anthroposophy.org.nz) and is a member of the *Compositae* family (Jouanny, 1984). It is also known as Leopard's Bane, Fall Herb and Panacea Lapsorum (Gibson, 1994). The mother tincture is prepared from the root, flowers and leaves after removal of the larvae of the *Arnica* fly, which are commonly found on the plant. For many years extracts from this plant have been used in both herbal and homoeopathic form to minimize the immediate effects of tissue trauma and assist in the healing process. *Arnica montana* reduces inflammation and therefore soothes pain (www.anthroposophy.org.nz).

Other indications include a general hypersensitivity to heat, cold and touch when associated with a bruised sensation all over; widespread hypersensitivity and soreness accompanied by throbbing and burning and if the condition is aggravated by any sudden movement or jolts. It reduces soreness of gums and teeth after traumatic injuries, especially when the pain is worsened by the least touch or motion (Boericke, 1927; Murphy, 1993).

The remedy is used to treat intolerable pain and is indicated before, during and after dental procedures, and it is used to reduce swollen gums (www.ahealtyme.com). Gibson (1994) also recommends that the remedy should be given before and after dental or surgical procedures because it reduces swelling and alleviates pain. It is also prescribed for discomfort immediately after any other type of dental treatment, especially when severe trauma and bruising is involved (Lockie *et al.*, 1995).

Another noticeable correlation with the sensations documented by provings on *Arnica montana* D6, is the extreme sensitivity to any form of touch inside the mouth that is experienced. In a study conducted by Miyawaki *et al.* (1999), 57% to 76% of patients complained of teeth pain and difficulty in tooth brushing after the bonding of lingual appliances. *Arnica montana* D6 is used when reducing pain and swelling of the gums in instances where patients are extremely sensitive to touch (Boericke, 1927, Murphy, 1993, Gibson, 1994, Vermeulen, 1997).

This homoeopathic remedy is also indicated when patients undergoing orthodontic treatment complain of the sensation of their teeth being forced from their sockets (Hering, 1997, Vermeulen, 1997).

Arnica montana D6 is the remedy usually considered in all instances where the type of pain experienced is similar to the pain experienced after trauma or contusion. According to Jouanny (1993) it should be administered at an early stage because the sooner it is administered, the sooner it takes effect.

Very little research has been conducted on *Arnica montana*. According to a study entitled 'Homoeopathic arnica: just a placebo' (Author unknown, 2001), four different potencies of *Arnica montana* was no more effective than the placebo. The researchers failed to state which potencies were used, or which disease processes or symptoms they were tested on.

Another study stated that *Arnica* 30X is ineffective for muscle soreness after long distance running (Vickers *et al.*, 1998). When one takes into consideration that Eizayaga (1991) states that the extremities are the most peripheral or superficial level of a human being, it appears that the remedy was ineffective because the potency was too high. According to Eizayaga (1991) the lowest potency of a remedy should be used when treating extremities.

According to a study conducted by Chakrabarti *et al.* (2001), mice fed with *Arnica* 30 showed reduced genotoxicity when exposed to radiation. In another study Traumeel S (a complex remedy containing *Arnica*) was proven effective in the treatment of blood–induced inflammation in rats (Lussignoli *et al.*, 1999). These studies indicate that *Arnica montana* is not merely a placebo as so many are led to believe.

No studies could be found where *Arnica montana* was utilised to alleviate pain caused by orthodontic procedures.

2.7 Other relevant remedies and potencies

It is difficult to find literature that recommends the use of higher potencies in the treatment of pain. It is, however, common practice for classical homoeopaths to use high potencies to successfully alleviate pain. Dr. K. Peck (2002) believes that *Arnica* in a 30CH potency is very effective in alleviating pain. She also suggested combining *Arnica* and *Hypericum* to alleviate orthodontic discomfort, especially as there is involvement of the periodontal ligament during orthodontic procedures that involve tooth movement (Burstone, 1962). According to her, the first dose should be administered about 10 minutes before the insertion of separators, and the remedy should be administered three to four times daily.

Another classical homoeopath, Dr. L.R. Brom (2002), recommends that one combine *Arnica* in a 30CH or 200CH potency together with *Ruta* and/or *Symphytum* to alleviate orthodontic discomfort. He suggested administering the remedy one or two days before commencement of treatment, and he believes the remedy should be administered three times daily.

CHAPTER THREE – METHODS AND MATERIALS

3.1 Sample

A total of 750 questionnaires, patient information forms and consent forms (Appendix A, Figures 1, 2 and 3) together with 375 vials containing *Arnica montana* D6 and 375 vials containing placebo tablets were distributed to several orthodontic practices. Only subjects that completed their questionnaires according to specification (Appendix A, Figure 2) were used in this study. The subjects for this study were selected for the first (separator) and second (initial arch wire) phases of comprehensive orthodontic treatment at professional orthodontic practices and were randomly divided into two groups, each group consisting of 15 patients.

There were 20 female and 10 male participants, with ages ranging from 6 to 33 years. No participants under the age of 5 years were selected, as Scott *et al.* (1977) stated that only children of 5 years and older adapt well to the use of the Visual Analogue Scale (refer to Appendix H).

The total sample that completed the entire questionnaire ($n = 30$), were classified as follows: (1) *Arnica montana* D6 group ($n = 15$); and (2) placebo group ($n = 15$). See Table 1.

3.2 Procedure

The nature of the research study was explained to the patients after which they were asked to sign a consent form (Appendix A, Figure 3). Adult subjects as well as juvenile subjects and their parents, were given both a verbal and a written (Appendix A, Figure 2) explanation of the research study and instructions as to the completion of the questionnaire. A demonstration was given as to the correct way in which to indicate the level of discomfort experienced at a particular time. After the demonstration, patients were asked to draw a vertical line on a horizontal line to ensure that the method is clearly understood.

Randomisation ensured that each participating patient received either a placebo or *Arnica montana* D6 in a double-blind fashion. Patients were administered study medication using a double-blind technique. Both groups were instructed to dissolve one tablet under the tongue three times daily. They had to start taking the tablets immediately after insertion of the separators. It was not possible to administer the tablets before insertion of the separators, because the teeth have to be clean for the procedure. The researcher was uncertain of the effect that brushing with toothpaste would have on the action of the study medication, therefore patients were instructed to start taking the remedy immediately after the procedure had been completed.

The tablets for both groups were identical in appearance, taste and odour, i.e. they were round, white and biconvex with a lactose base. The *Arnica montana* D6 tablets and placebo tablets were obtained from the Natura Homoeopathic Laboratory in Pretoria (see Appendix I).

Patients were instructed to complete the discomfort index card at 2, 6 and 24 hours, and 2, 3 and 7 days after the insertion of separators or initial arch wires (Appendix A, Figure 1).

No additional medication for pain, such as prescription, nonprescription, or home remedies, were to be taken simultaneously with the study medication. Whenever the study medication did not provide sufficient pain relief, patients were permitted to take additional medication as recommended by the supervisor. These patients were then excluded from the study, and the drop out rate was recorded.

3.3 Data collection – discomfort index card

A questionnaire was used for the collection of data (Appendix A, Figure 1). The subjects were instructed to start completing the questionnaire 2 hours after the separation phase of treatment. The questionnaire also contained a written explanation of the research study and the instructions for completion (Appendix A, Figure 2).

In summary, time 1 (T1) refers to 2 hours after insertion of separators; time 2 (T2) to 6 hours after insertion of separators; time 3 (T3) to 24 hours after insertion of separators; time 4 (T4) to 2 days after insertion of the initial arch wire which was 9 days after separation; time 5 (T5) to 3 days after insertion of the initial arch wire; and time 6 (T6) to 7 days after insertion of the initial arch wire.

The level of discomfort after the insertion of orthodontic separators (phase I) and an initial arch wire (phase II) were assessed for each patient by means of a discomfort index card with visual analogue scale (Appendix A, Figure 1). The discomfort index card consisted of four questions regarding the intensity of discomfort during chewing, biting, fitting or clamping the front teeth together, and fitting on the back teeth. The VAS (visual analogue scale) was used to measure the discomfort in each case. In this study, the VAS scale consisted of a 10 cm line weighed at both ends by descriptive terminology i.e. "very comfortable" versus "very uncomfortable", as well as small pictograms i.e. "happy" and "sad" emoticons. VAS scoring was performed by measuring the distance in millimeters from the starting point of the line from the left side to the vertical mark made by the patient in his/her response to each question. VAS has been proven to be a very reliable method of assessing pain (refer to Appendix H).

3.4 Data analysis

Because the responses to chewing, biting, fitting front teeth together and fitting back teeth together were all different (Tables 5; 8; 11 and 14), each action was evaluated separately. Mauchly's test of sphericity was conducted on all 4 factors (chewing, biting, fitting front teeth together and fitting back teeth together), refer to tables 6; 9; 12 and 15. As $p < 0.05$, sphericity was not assumed and Huynh-Feldt tests were conducted.

These Huynh-Feldt tests were conducted to compare the effect of *Arnica montana* D6 to the placebo at the 6 different time intervals. This repeated-measures analysis of variance (ANOVA) was used to determine whether there were any significant differences in the amount of discomfort reported between the *Arnica montana* D6

and placebo groups after placement of either separators or an initial arch wire (Tables 7; 10; 13; and 16). The level of statistical significance was set at $p < 0.05$.

For the purpose of statistical analysis the zero hypothesis over time was tested (Tables 17 to 22), and rejected as $p < 0.05$. Therefore the alternative hypothesis, that there is indeed a difference over time, is true for the four different means of occluding teeth (i.e. chewing, biting, fitting back teeth together and fitting front teeth together).

CHAPTER FOUR – RESULTS

4.1 Introduction - chewing

Thirty patients were evaluated with regard to the discomfort they experienced during chewing after orthodontic separators and arch wires were fitted to their teeth. Fifteen of the patients received the homoeopathic remedy *Arnica montana* D6, and the other 15 received a placebo (Table 1). Twenty females and 10 males participated in the study (Table 2). The mean age of the participants was 12.20 years (Table 3). The results of the two groups were evaluated and compared after 14 days of treatment.

4.1.1 Results and discussion - chewing

The amount of discomfort experienced by patients, as indicated by the response parameter in the area of chewing after insertion of either separators or an initial arch wire, is shown in Fig. 4.

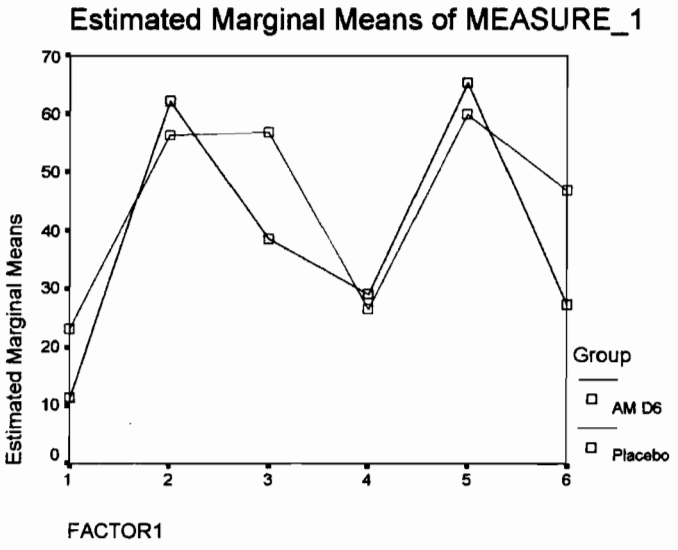

Fig. 4 The overall level of discomfort (discomfort index) experienced by patients when chewing (FACTOR1) during a 14 day period after taking *Arnica montana* D6 and a placebo

Mauchly's test of sphericity was conducted for chewing (FACTOR1) and $p = 0.000$ (Table 6). Sphericity was thus not assumed.

Huynh-Feldt tests were then conducted for chewing (FACTOR1) in the *Arnica montana* D6 and placebo groups (Table 7). When the 6 different time intervals were compared, $p = 0.000$. When the group that received *Arnica montana* D6 was compared to the placebo group at the 6 different time intervals, $p = 0.063$.

4.1.2 Conclusions - chewing

Because the p value over time was < 0.05, one can conclude that there is a significant difference in the perception of pain over time as shown in Tables 17 to 22. This coincides with findings of Ngan (1989, 1994) that the level of discomfort changes over time after insertion of either separators or an initial arch wire.

The only significant difference between the *Arnica montana* D6 and placebo groups was found at T3 ($p = 0.028$), refer to Table 4. But because the mean p value for the two groups was not < 0.05 ($F = 2.381$; $df = 3.608$; $p = 0.063$, Table 7) the conclusion was made that statistically speaking there is no significant difference between the pain profiles of the *Arnica montana* D6 and placebo groups. This finding does however necessitate further investigation and provides an opportunity for future study.

In light of the mean statistical evidence it thus appears that *Arnica montana* D6 does not alleviate the discomfort experienced during chewing by patients undergoing orthodontic treatment.

4.2 Introduction - biting

Thirty patients were evaluated with regard to the discomfort they experienced during biting after orthodontic separators and arch wires were fitted to their teeth. Fifteen of the patients received the homoeopathic remedy *Arnica montana* D6, and the other 15 received a placebo (Table 1). Twenty females and 10 males participated in the study (Table 2). The mean age of the participants was 12.20 years (Table 3). The results of the two groups were evaluated and compared after 14 days of treatment.

4.2.1 Results and discussion - biting

The amount of discomfort experienced by patients, as indicated by the response parameter in the area of biting after insertion of either separators or an initial arch wire, is shown in Fig. 5.

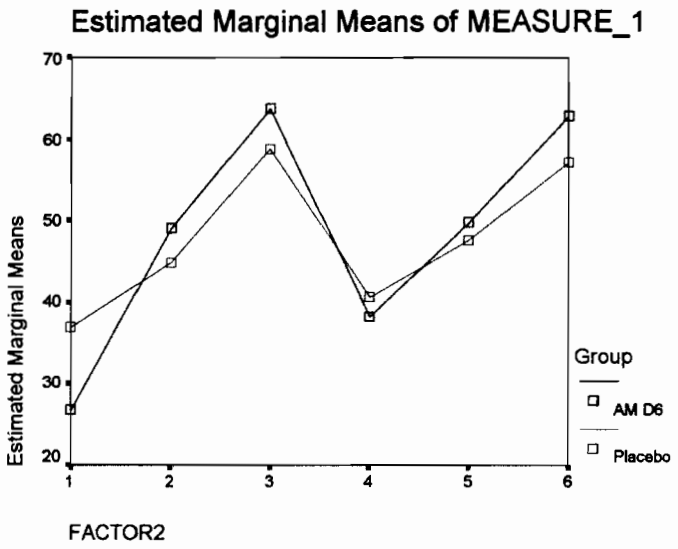

Fig. 5 The overall level of discomfort (discomfort index) experienced by patients when biting (FACTOR2) during a 14 day period after taking *Arnica montana* D6 and a placebo

Mauchly's test of sphericity was conducted for biting (FACTOR2) and $p = 0.000$ (Table 9). Sphericity was thus not assumed.

Huynh-Feldt tests were then conducted for biting (FACTOR2) in the *Arnica montana* D6 and placebo groups (Table 10). When the 6 different time intervals were compared, $p = 0.002$. When the group that received *Arnica montana* D6 was compared to the placebo group at the 6 different time intervals, $p = 0.649$.

4.2.2 Conclusions - biting

Because the p value over time was < 0.05, one can conclude that there is a significant difference in the perception of pain over time as shown in Tables 17 to 22. This coincides with findings of Ngan (1989, 1994) that the level of discomfort changes over time after insertion of either separators or an initial arch wire.

Because the mean p value for the two groups was not < 0.05 ($F = 0.473$; $df = 2.263$; $p = 0.649$, Table 10) one must conclude that no significant difference was found between the pain profiles of the *Arnica montana* D6 and placebo groups. It thus appears that *Arnica montana* D6 does not alleviate the discomfort experienced during biting by patients undergoing orthodontic treatment.

4.3 Introduction – fitting back teeth together

Thirty patients were evaluated with regards to the discomfort they experienced when fitting their back teeth together after orthodontic separators and arch wires were fitted to their teeth. Fifteen of the patients received the homoeopathic remedy *Arnica montana* D6, and the other 15 received a placebo (Table 1). Twenty females and 10 males participated in the study (Table 2). The mean age of the participants was 12.20 years (Table 3). The results of the two groups were evaluated and compared after 14 days of treatment.

4.3.1 Results and discussion – fitting back teeth together

The amount of discomfort experienced by patients, as indicated by the response parameter in the area of fitting back teeth together after insertion of either separators or an initial arch wire, is shown in Fig. 6.

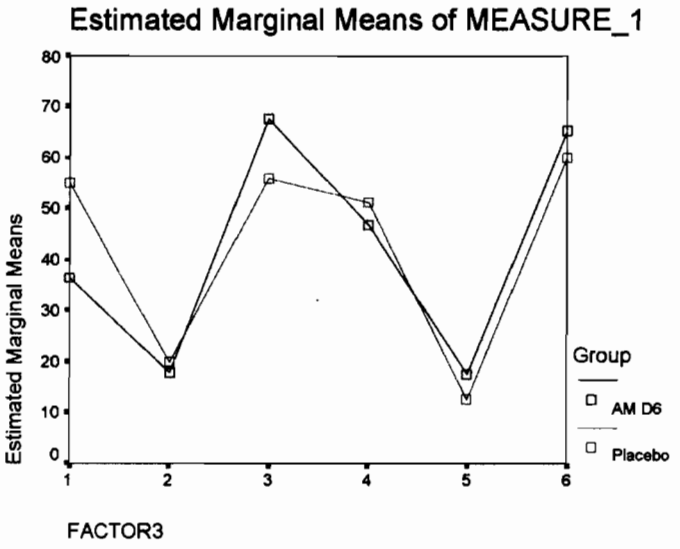

Fig 6 The overall level of discomfort (discomfort index) experienced by patients when fitting back teeth together (FACTOR3) during a 14 day period after taking *Arnica montana* D6 and a placebo

Mauchly's test of sphericity was conducted for fitting back teeth together (FACTOR3) and $p = 0.000$ (Table 12). Sphericity was thus not assumed.

Huynh-Feldt tests were then conducted for fitting back teeth together (FACTOR3) in the *Arnica montana* D6 and placebo groups (Table 13). When the 6 different time intervals were compared, $p = 0.000$. When the group that received *Arnica montana* D6 was compared to the placebo group at the 6 different time intervals, $p = 0.106$.

4.3.2 Conclusions – fitting back teeth together

Because the p value over time was < 0.05, one can conclude that there is a significant difference in the perception of pain over time as shown in Tables 17 to 22. This coincides with findings of Ngan (1989, 1994) that the level of discomfort changes over time after insertion of either separators or an initial arch wire.

Because the mean p value for the two groups was not < 0.05 ($F = 1.985$; $df = 3.758$; $p = 0.106$, Table 13) one must conclude that no significant difference was found between the pain profiles of the *Arnica montana* D6 and placebo groups. It thus appears that *Arnica montana* D6 does not alleviate the discomfort experienced by patients undergoing orthodontic treatment when fitting back teeth together.

4.4 Introduction – fitting front teeth together

Thirty patients were evaluated with regards to the discomfort they experienced when fitting their front teeth together after orthodontic separators and arch wires were fitted to their teeth. Fifteen of the patients received the homoeopathic remedy *Arnica montana* D6, and the other 15 received a placebo (Table 1). Twenty females and 10 males participated in the study (Table 2). The mean age of the participants was 12.20 years (Table 3). The results of the two groups were evaluated and compared after 14 days of treatment.

4.4.1 Results and discussion – fitting front teeth together

The amount of discomfort experienced by patients, as indicated by the response parameter in the area of fitting front teeth together after insertion of either separators or an initial arch wire, is shown in Fig. 7.

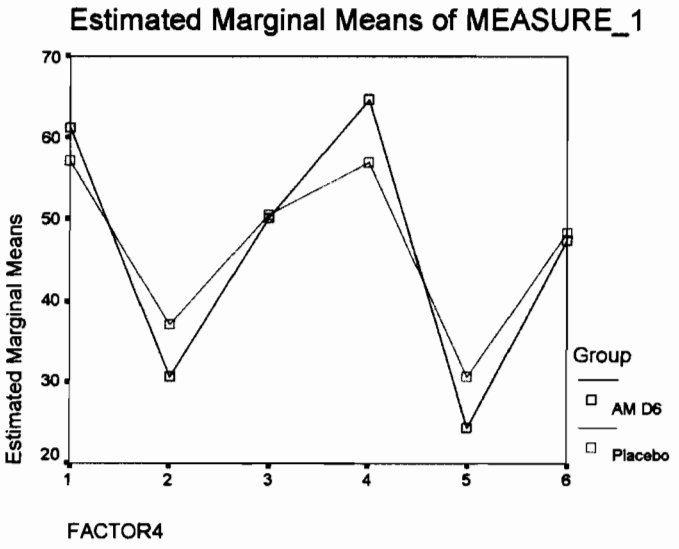

Fig. 7 The overall level of discomfort (discomfort index) experienced by patients when fitting front teeth together (FACTOR4) during a 14 day period after taking *Arnica montana* D6 and a placebo

Mauchly's test of sphericity was conducted for fitting front teeth together (FACTOR4) and $p = 0.000$ (Table 15). Sphericity was thus not assumed.

Huynh-Feldt tests were then conducted for fitting front teeth together (FACTOR4) in the *Arnica montana* D6 and placebo groups (Table 16). When the 6 different time intervals were compared, $p = 0.000$. When the group that received *Arnica montana* D6 was compared to the placebo group at the 6 different time intervals, $p = 0.682$.

4.4.2 Conclusions – fitting front teeth together

Because the p value over time was < 0.05, one can conclude that there is a significant difference in the perception of pain over time as shown in Tables 17 to 22. This coincides with findings of Ngan (1989, 1994) that the level of discomfort changes over time after insertion of either separators or an initial arch wire.

Because the mean p value for the two groups was not < 0.05 ($F = 0.440$; $df = 2.402$; $p = 0.682$, Table 16) one must conclude that no significant difference was found between the pain profiles of the *Arnica montana* D6 and placebo groups. It thus appears that *Arnica montana* D6 does not alleviate the discomfort experienced by patients undergoing orthodontic treatment during chewing.

CHAPTER FIVE – DISCUSSION

5.1 Results

A total of 750 questionnaires were distributed to several orthodontic practices. Ninety four questionnaires (12.53%) returned incomplete. Twelve of the participants that returned incomplete questionnaires, took additional medication for pain and were thus advised not to continue with the study. When the percentage of participants that took additional medication for pain are calculated according to the number of questionnaires that were handed out, it appears that very few people needed additional pain relief (1.60%). However, one has to take into consideration that 87.47% of the questionnaires that were handed out, were not returned. Therefore there is no accurate means by which one can determine the actual percentage of patients that had to take additional medication for pain.

Thirty seven of the patients (4.93%) returned completed questionnaires for both the first (separator) and second (initial arch wire) phases of the study. Thirty of these questionnaires (4.0%) were completed according to the specifications explained to the participants and could be used in this study. Reasons for not using certain questionnaires included markings other than a vertical line such as crosses, ticks or circles to indicate the level of discomfort, and in some instances the vertical line drawn on the questionnaire did not touch the horizontal line, in which case an accurate measurement could not be taken.

The overall mean age of the study population was 12.20 +/- 6.419 years (See Table 3). The frequency distribution of males and females amongst the two groups was 33.3% males to 66.7% females (See Table 2). This was no cause for concern, as Brown *et al.* (1991) concluded that no significant differences are found for any of the response variables between male and female subjects.

Mauchly's test of sphericity was conducted for chewing, biting, fitting front teeth together and fitting back teeth together. In all these tests $p < 0.05$, and sphericity could thus not be assumed.

Huynh-Feldt tests were then conducted for chewing, biting, fitting front teeth together and fitting back teeth together. Comparisons between the 4 different groups for each time period after separator and initial arch wire placement (Fig 2 – Fig 5) indicated that the discomfort experienced by the placebo group was not significantly greater than the discomfort experienced by the *Arnica montana* D6 group at every time phase, as p was not < 0.05. There was one exception during chewing at T3 (24 hours after insertion of separators) where $p = 0.028$. This single area of significance was however not sufficient to prove that *Arnica montana* D6 alleviates orthodontic discomfort, as the mean p values for chewing (FACTOR 1) were not < 0.05. This finding does however require further investigation to determine a reason for the significant difference.

5.2 Discussion

This clinical trial compared the effectiveness of *Arnica montana* D6 and placebo for the treatment of pain resulting from orthodontic treatment. This is the first report relating orthodontic procedures (e.g. separators and initial arch wires placement) being used as a means of evaluating the analgaesic properties of *Arnica montana* D6. This is significant in that orthodontic procedures are noninvasive and therefore provoke a primarily inflammatory response due to the release of prostaglandins (refer to 2.4.1).

The frequency distribution of males and females amongst the two groups might appear significant (see Table 2), but if one looks at previous studies conducted on orthodontic treatment (Brown *et al.*, 1991; Ngan *et al.*, 1989) it is clear that this is a trend in all of them. The reason for this could be that females are more concerned about their appearance and thus more likely to seek orthodontic treatment to correct a malocclusion. Furthermore, in the study conducted by Brown et al. (1991) no significant differences were found for any of the response variables between male and female subjects. In another study conducted by Ngan *et al.* (1989), no significant difference was found between the sexes with either separators ($F = 0.05$, $p < 0.83$) or arch wires ($F = 0.12$, $p < 0.78$).

Ngan *et al.* (1989) also concluded that no significant difference was found in the level of discomfort experienced by patients over the age of 16, compared to those 16 years of age and younger. Therefore it was not necessary to differentiate between age and sex in this study.

The results of this study indicate that there is discomfort associated with either the insertion of orthodontic separators or arch wires. This confirms the findings of others who have used various means of measuring discomfort (Storey *et al.*, 1952, Soltis *et al.*, 1971, Fujita, 1978, White, 1984, Jones, 1984).

The aim of this study was to assess whether *Arnica montana* D6 would alleviate orthodontic discomfort, whatever the cause of the discomfort might be. The results of this study indicate that *Arnica montana* D6, compared to the placebo, did not significantly decrease the level of discomfort, and therefore do not confirm the effectiveness of *Arnica montana* D6 for relieving orthodontic discomfort. The fact that some patients did record an alleviation of symptoms after taking the placebo, could infer a psychological effect of having taken what appears to be medications.

The challenge now facing future researchers is to determine why a remedy that is so highly acclaimed in textbooks for its analgesic properties (Boericke, 1927; Murphy, 1993; Gibson, 1994; Vermeulen, 1997 and Hering, 1997) performs so poorly when tested in a clinical setting. The following points should be taken into consideration:

5.2.1 Potency

The potency in which *Arnica montana* is most commonly found in pharmacies and health shops is D6. This leads one to believe that D6 should be the most effective potency to use. The researcher is reluctant to claim that the potency was incorrect, as this can only be proven if more studies are conducted on *Arnica montana* using higher potencies. It is however a fact that quite a few homoeopaths in private practice actually prefer using *Arnica montana* in higher potencies such as 30CH or 200CH (Peck, 2002; Brom, 2002).

5.2.2 Timing of administration

Most textbooks and practitioners advise that *Arnica montana* be administered before commencement of treatment (Gibson, 1994; Jouanny, 1993; Peck, 2002 and Brom, 2002). In this study the participants had to start taking the study medication immediately after the separators have been inserted, as the researcher did not want to take the risk of jeopardising the action that *Arnica montana* might have had by introducing toothpaste into the study environment. Future studies in which the study medication is administered just before commencement of treatment should prove valuable.

5.2.3 Combining different remedies

The homoeopaths that the researcher has consulted (Brom, 2002; Peck, 2002 and Solomon, 2002) all felt that the best results would be achieved if *Arnica montana* is used in conjunction with other remedies such as *Ruta*, *Symphytum* and *Hypericum*. This does pose a problem in that one can then never be certain as to which remedy actually alleviated the symptoms. Future studies where the other remedies are tested separately and in combination with each other should aid in giving more insight.

CHAPTER SIX - CONCLUSION

In view of the evidence presented here, further studies are definitely warranted in an effort to determine the most effective homoeopathic remedy and potency for treating patients undergoing orthodontic treatment.

This study aimed at assessing the analgesic effects of homoeopathically prepared *Arnica montana* on patients undergoing orthodontic treatment. The D6 potency of *Arnica montana* used in this study did not sufficiently alleviate of the pain experienced during orthodontic treatment. Despite the fact that the overall results indicated that *Arnica montana* D6 did not have the desired effect on the treatment of pain, the researcher believes that further studies should be undertaken to determine the reason(s) for significant alleviation during one specific time interval of this study, that is at T3.

Higher potencies of *Arnica Montana* and different remedies to alleviate orthodontic discomfort should also be investigated.

To conclude, the results of this study do not support a recommendation for *Arnica montana* D6 as a preferred analgesic in the treatment of discomfort caused by orthodontic treatment.

6.1 Recommendations

The following recommendations should be considered when future studies are conducted in a similar field:

- More people should be included in the study to facilitate an accurate account of the amount of discomfort experienced.

- An effort should be made to ensure that a larger percentage of questionnaires are returned. Compliance could be improved by scheduling appointments at the orthodontist when the questionnaire is to be completed. Closer

supervision should also ensure that more questionnaires are completed according to specification.

- A wider range of potencies should be explored to determine the most effective potency for this specific area of treatment.

- Remedies other than *Arnica montana* that are indicated for the treatment of orthodontic discomfort should be studied - remedies such as *Hypericum*, *Ruta* and *Symphytum*.

- The effect of complex remedies such as *Traumeel* (Heel) and *Pein* (Natura) should be studied.

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www.ahealthyme.com/arnica

www.anthroposophy.org.nz/arnica

APPENDICES

APPENDIX A – The visual analogue scale (VAS), patient information form and consent form

Please draw a small vertical line on each of the horizontal lines below so as to indicate the amount of discomfort you are experiencing now in the following areas.

(e.g. ☺___|_____☹)

Very comfortable	Mild discomfort	Very uncomfortable

1.1) Chewing

☺_____☹

1.2) Biting

☺_____☹

1.3) Fitting your back teeth together

☺_____☹

1.4) Fitting your front teeth together

☺_____☹

Fig. 1 Discomfort index card depicting a visual analogue scale (VAS). The scale is 10 cm in length. The extent of discomfort perceived by the patient was assessed by measuring the left end of the scale to the vertical line drawn by the patient

PATIENT INFORMATION FORM

Your son/daughter will soon start with his/her orthodontic treatment. This treatment is often associated with discomfort. We are thus requesting him/her to participate in a research study that will help us determine whether a homoeopathic remedy called *Arnica montana* will be effective in alleviating the pain associated with this type of treatment.

If your child decides to participate in this study, he/she will be placed in one of two groups. The one group will receive the homoeopathic remedy, and the other group will receive inactive tablets. Neither the participant nor the researcher will know to which group he/she belongs. All the study medication will be distributed free of charge, and your child should take one tablet three times daily for two weeks. The first tablet should be taken immediately after the separators have been inserted.

Your child is requested to document the amount of pain that he/she is experiencing at certain time intervals on a questionnaire called a visual analogue scale. A vertical line should be drawn on the horizontal line printed on the questionnaire between the "happy" and "sad" emoticons. A longer distance between the vertical line and the left or "happy" emoticon represents a higher the level of pain.

Previous use of *Arnica montana* tablets showed no side-effects or undesirable symptoms.

The potential benefits for patients using *Arnica montana* include:

- alleviation of the pain and discomfort associated with orthodontic treatment;
- subsequent improvement in the quality of life.

It is not necessary to stop taking any medication that is currently being used, as long as it is brought to the researchers attention so that it can be documented. You will, however not be allowed to administer any additional medication for pain once the study has commenced. In the event that additional medication is needed, your child

CONSENT FORM

I have fully explained the procedures and their purpose, I have asked whether or not any questions have arisen regarding the procedures and have answered these questions to the best of my ability.

Date: _____ Researcher: _____

I have been fully informed as to the procedures to be followed, and have been given a description of the discomforts, risks and benefits to be expected and the appropriate alternate procedures. In signing this consent form I agree to this method of treatment and I understand that I am free to withdraw my consent to participate in this study at any time. I understand also that if I have any questions at any time, they will be answered.

Date: _____ Volunteer: _____

or Parent/Guardian (if under 21 years of age) : _____

Fig. 3 Consent form

APPENDIX B – General list of tables

Table 1 Distribution of patients between experimental and control groups

	Group	
	Count	%
AM D6	15	50.0%
Placebo	15	50.0%

Table 2 Demographic distribution of patients participating in the study

	Sex	
	Count	%
Female	20	66.7%
Male	10	33.3%

Table 3 Age distribution of patients participating in the study

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Age	30	6	33	12.20	6.419
Valid N (listwise)	30				

Table 4 Significant difference between *Arnica montana* D6 and placebo at T3 (24 hours after insertion of orthodontic separators)

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	FACTOR1	Type III Sum of Squares	df	Mean Square	F	Sig.
FACTOR1	Level 1 vs. Level 2	52962.008	1	52962.008	66.052	.000
	Level 2 vs. Level 3	4013.633	1	4013.633	4.968	.034
	Level 3 vs. Level 4	11860.408	1	11860.408	11.447	.002
	Level 4 vs. Level 5	36261.633	1	36261.633	36.152	.000
	Level 5 vs. Level 6	19635.208	1	19635.208	14.080	.001
FACTOR1 * GROUP	Level 1 vs. Level 2	2403.075	1	2403.075	2.997	.094
	Level 2 vs. Level 3	4344.033	1	4344.033	5.377	.028
	Level 3 vs. Level 4	3172.408	1	3172.408	3.062	.091
	Level 4 vs. Level 5	64.533	1	64.533	.064	.802
	Level 5 vs. Level 6	4600.408	1	4600.408	3.299	.080
Error(FACTOR1)	Level 1 vs. Level 2	22451.167	28	801.827		
	Level 2 vs. Level 3	22620.833	28	807.887		
	Level 3 vs. Level 4	29010.933	28	1036.105		
	Level 4 vs. Level 5	28084.833	28	1003.030		
	Level 5 vs. Level 6	39046.633	28	1394.523		

APPENDIX C – List of tables relating to chewing

Table 5 The overall level of discomfort (discomfort index) experienced by patients when chewing during a 14 day period after the placement of separators and an initial arch wire

Descriptive Statistics

	Group	Mean	Std. Deviation	N
T 1 - Chew	AM D6	11.267	13.5526	15
	Placebo	23.267	32.0785	15
	Total	17.267	24.9537	30
T 2 - Chew	AM D6	62.233	34.0267	15
	Placebo	56.333	25.1195	15
	Total	59.283	29.5392	30
T 3 - Chew	AM D6	38.633	24.7484	15
	Placebo	56.800	30.6581	15
	Total	47.717	28.8927	30
T 4 - Chew	AM D6	29.033	30.3688	15
	Placebo	26.633	27.9767	15
	Total	27.833	28.7154	30
T 5 - Chew	AM D6	65.267	31.2638	15
	Placebo	59.933	27.1667	15
	Total	62.600	28.9051	30
T 6 - Chew	AM D6	27.300	18.9509	15
	Placebo	46.733	33.2517	15
	Total	37.017	28.3693	30

Table 6 Results of Mauchly's test of sphericity for chewing (FACTOR1)

Mauchly's Test of Sphericity[b]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
FACTOR1	.110	57.667	14	.000	.613	.722	.200

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b.
Design: Intercept+GROUP
Within Subjects Design: FACTOR1

Table 7 Results of the Huynh-Feldt tests over time and between the *Arnica montana* D6 and placebo groups when chewing (FACTOR1)

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
FACTOR1	Sphericity Assumed	47790.190	5	9558.038	21.513	.000
	Greenhouse-Geisser	47790.190	3.065	15590.273	21.513	.000
	Huynh-Feldt	47790.190	3.608	13245.992	21.513	.000
	Lower-bound	47790.190	1.000	47790.190	21.513	.000
FACTOR1 * GROUP	Sphericity Assumed	5288.224	5	1057.645	2.381	.042
	Greenhouse-Geisser	5288.224	3.065	1725.142	2.381	.074
	Huynh-Feldt	5288.224	3.608	1465.735	2.381	.063
	Lower-bound	5288.224	1.000	5288.224	2.381	.134
Error(FACTOR1)	Sphericity Assumed	62200.961	140	444.293		
	Greenhouse-Geisser	62200.961	85.831	724.693		
	Huynh-Feldt	62200.961	101.021	615.722		
	Lower-bound	62200.961	28.000	2221.463		

APPENDIX D – List of tables relating to biting

Table 8 The overall level of discomfort (discomfort index) experienced by patients when biting during a 14 day period after the placement of separators and an initial arch wire

Descriptive Statistics

	Group	Mean	Std. Deviation	N
T 1 - Bite	AM D6	26.733	23.9716	15
	Placebo	36.900	33.7984	15
	Total	31.817	29.2508	30
T 2 - Bite	AM D6	49.033	29.7342	15
	Placebo	44.833	33.1413	15
	Total	46.933	31.0099	30
T 3 - Bite	AM D6	63.833	30.1275	15
	Placebo	58.800	26.9999	15
	Total	61.317	28.2252	30
T 4 - Bite	AM D6	38.233	30.9930	15
	Placebo	40.500	33.7200	15
	Total	39.367	31.8428	30
T 5 - Bite	AM D6	49.767	27.9808	15
	Placebo	47.567	30.8880	15
	Total	48.667	28.9793	30
T 6 - Bite	AM D6	62.900	32.0954	15
	Placebo	57.050	25.6024	15
	Total	59.975	28.6808	30

Table 9 Results of Mauchly's test of sphericity for biting (FACTOR2)

Mauchly's Test of Sphericity[b]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
FACTOR2	.003	147.833	14	.000	.405	.453	.200

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b.
Design: Intercept+GROUP
Within Subjects Design: FACTOR2

Table 10 Results of the Huynh-Feldt tests over time and between the *Arnica montana* D6 and placebo groups when biting (FACTOR2)

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
FACTOR2	Sphericity Assumed	19762.507	5	3952.501	6.675	.000
	Greenhouse-Geisser	19762.507	2.026	9753.003	6.675	.002
	Huynh-Feldt	19762.507	2.263	8731.319	6.675	.002
	Lower-bound	19762.507	1.000	19762.507	6.675	.015
FACTOR2 * GROUP	Sphericity Assumed	1399.616	5	279.923	.473	.796
	Greenhouse-Geisser	1399.616	2.026	690.725	.473	.628
	Huynh-Feldt	1399.616	2.263	618.367	.473	.649
	Lower-bound	1399.616	1.000	1399.616	.473	.497
Error(FACTOR2)	Sphericity Assumed	82904.763	140	592.177		
	Greenhouse-Geisser	82904.763	56.736	1461.227		
	Huynh-Feldt	82904.763	63.375	1308.155		
	Lower-bound	82904.763	28.000	2960.884		

APPENDIX E – List of tables relating to fitting back teeth together

Table 11 The overall level of discomfort (discomfort index) experienced by patients when fitting back teeth together during a 14 day period after the placement of separators and an initial arch wire

Descriptive Statistics

	Group	Mean	Std. Deviation	N
T 1 - Back	AM D6	36.533	25.9584	15
	Placebo	54.933	33.5202	15
	Total	45.733	30.9077	30
T 2 - Back	AM D6	17.867	19.6582	15
	Placebo	20.133	24.8182	15
	Total	19.000	22.0282	30
T 3 - Back	AM D6	67.533	28.2074	15
	Placebo	55.833	25.0882	15
	Total	61.683	26.8955	30
T 4 - Back	AM D6	46.733	27.7559	15
	Placebo	51.133	31.0302	15
	Total	48.933	29.0130	30
T 5 - Back	AM D6	17.500	21.4218	15
	Placebo	12.667	18.0324	15
	Total	15.083	19.6100	30
T 6 - Back	AM D6	65.433	30.7210	15
	Placebo	60.000	26.7508	15
	Total	62.717	28.4380	30

Table 12 Results of Mauchly's test of sphericity for fitting back teeth together (FACTOR3)

Mauchly's Test of Sphericity[b]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
FACTOR3	.178	44.996	14	.000	.635	.752	.200

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b.
Design: Intercept+GROUP
Within Subjects Design: FACTOR3

Table 13 Results of the Huynh-Feldt tests over time and between the *Arnica montana* D6 and placebo groups when fitting back teeth together (FACTOR3)

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
FACTOR3	Sphericity Assumed	63957.279	5	12791.456	30.715	.000
	Greenhouse-Geisser	63957.279	3.176	20137.629	30.715	.000
	Huynh-Feldt	63957.279	3.758	17020.483	30.715	.000
	Lower-bound	63957.279	1.000	63957.279	30.715	.000
FACTOR3 * GROUP	Sphericity Assumed	4134.212	5	826.843	1.985	.084
	Greenhouse-Geisser	4134.212	3.176	1301.701	1.985	.118
	Huynh-Feldt	4134.212	3.758	1100.208	1.985	.106
	Lower-bound	4134.212	1.000	4134.212	1.985	.170
Error(FACTOR3)	Sphericity Assumed	58304.467	140	416.460		
	Greenhouse-Geisser	58304.467	88.928	655.635		
	Huynh-Feldt	58304.467	105.215	554.148		
	Lower-bound	58304.467	28.000	2082.302		

APPENDIX F – List of tables relating to fitting front teeth together

Table 14 The overall level of discomfort (discomfort index) experienced by patients when fitting front teeth together during a 14 day period after the placement of separators and an initial arch wire

Descriptive Statistics

	Group	Mean	Std. Deviation	N
T 1 - Front	AM D6	61.200	33.1360	15
	Placebo	57.100	26.3711	15
	Total	59.150	29.4981	30
T 2 - Front	AM D6	30.667	23.8722	15
	Placebo	37.167	32.4057	15
	Total	33.917	28.1603	30
T 3 - Front	AM D6	50.200	31.0131	15
	Placebo	50.567	33.9926	15
	Total	50.383	31.9716	30
T 4 - Front	AM D6	64.700	30.7128	15
	Placebo	56.967	26.0257	15
	Total	60.833	28.2459	30
T 5 - Front	AM D6	24.333	18.5825	15
	Placebo	30.633	32.4948	15
	Total	27.483	26.2053	30
T 6 - Front	AM D6	47.467	29.7918	15
	Placebo	48.367	31.2841	15
	Total	47.917	30.0193	30

Table 15 Results of Mauchly's test of sphericity for fitting front teeth together (FACTOR4)

Mauchly's Test of Sphericity[b]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
FACTOR4	.006	131.547	14	.000	.427	.480	.200

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b.
Design: Intercept+GROUP
Within Subjects Design: FACTOR4

Table 16 Results of the Huynh-Feldt tests over time and between the *Arnica montana* D6 and placebo groups when fitting front teeth together (FACTOR4)

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
FACTOR4	Sphericity Assumed	27073.507	5	5414.701	10.006	.000
	Greenhouse-Geisser	27073.507	2.137	12668.218	10.006	.000
	Huynh-Feldt	27073.507	2.402	11272.873	10.006	.000
	Lower-bound	27073.507	1.000	27073.507	10.006	.004
FACTOR4 * GROUP	Sphericity Assumed	1190.007	5	238.001	.440	.820
	Greenhouse-Geisser	1190.007	2.137	556.827	.440	.659
	Huynh-Feldt	1190.007	2.402	495.495	.440	.682
	Lower-bound	1190.007	1.000	1190.007	.440	.513
Error(FACTOR4)	Sphericity Assumed	75758.611	140	541.133		
	Greenhouse-Geisser	75758.611	59.839	1266.033		
	Huynh-Feldt	75758.611	67.246	1126.585		
	Lower-bound	75758.611	28.000	2705.665		

APPENDIX G – Tables relating to the overall level of discomfort experienced over time

Table 17 The overall level of discomfort (discomfort index) experienced by patients 2 hours after insertion of separators (T1)

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
T 1 - Chew	30	.0	100.0	17.267	24.9537
T 1 - Bite	30	.0	100.0	31.817	29.2508
T 1 - Back	30	1.0	100.0	45.733	30.9077
T 1 - Front	30	6.0	100.0	59.150	29.4981
Valid N (listwise)	30				

Table 18 The overall level of discomfort (discomfort index) experienced by patients 6 hours after insertion of separators (T2)

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
T 2 - Chew	30	4.5	100.0	59.283	29.5392
T 2 - Bite	30	.0	100.0	46.933	31.0099
T 2 - Back	30	.0	72.0	19.000	22.0282
T 2 - Front	30	.0	100.0	33.917	28.1603
Valid N (listwise)	30				

Table 19 The overall level of discomfort (discomfort index) experienced by patients 24 hours after insertion of separators (T3)

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
T 3 - Chew	30	1.0	100.0	47.717	28.8927
T 3 - Bite	30	6.5	100.0	61.317	28.2252
T 3 - Back	30	5.0	100.0	61.683	26.8955
T 3 - Front	30	.0	100.0	50.383	31.9716
Valid N (listwise)	30				

Table 20 The overall level of discomfort (discomfort index) experienced by patients 2 days after insertion of the initial arch wire (T4)

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
T 4 - Chew	30	1.0	89.5	27.833	28.7154
T 4 - Bite	30	3.0	100.0	39.367	31.8428
T 4 - Back	30	1.0	100.0	48.933	29.0130
T 4 - Front	30	6.0	100.0	60.833	28.2459
Valid N (listwise)	30				

Table 21 The overall level of discomfort (discomfort index) experienced by patients 3 days after insertion of the initial arch wire (T5)

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
T 5 - Chew	30	2.5	100.0	62.600	28.9051
T 5 - Bite	30	.0	100.0	48.667	28.9793
T 5 - Back	30	.0	70.0	15.083	19.6100
T 5 - Front	30	.0	100.0	27.483	26.2053
Valid N (listwise)	30				

Table 22 The overall level of discomfort (discomfort index) experienced by patients 7 days after insertion of the initial arch wire (T6)

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
T 6 - Chew	30	.0	100.0	37.017	28.3693
T 6 - Bite	30	5.0	100.0	59.975	28.6808
T 6 - Back	30	6.0	100.0	62.717	28.4380
T 6 - Front	30	.0	100.0	47.917	30.0193
Valid N (listwise)	30				

APPENDIX H – Validity and reliability of the visual analogue scale (VAS)

According to Huskisson (1983) the visual analogue scale (VAS) is an established method for assessing pain responses by experimental subjects. The VAS is a line (usually 10 cm in length) of which the ends are anchored and defined by appropriate verbal descriptors such as very comfortable or very uncomfortable. The participant is asked to mark the line at a point representing the severity of their discomfort. The distance of the mark from the end of the scale is then taken to represent discomfort severity or the discomfort score. Most patients with discomfort understand the concept and can quickly make the measurement (Huskisson, 1974). Children of 5 years and older adapt well to its use (Scott *et al.*, 1977). One of the advantages of using the VAS over the verbal descriptor scale is the increased sensitivity of the former with respect to measuring successive responses to treatment (Melzack, 1971). In addition, there is a high correlation between successive measurements of pain severity on a VAS, confirming the reproducibility of the method (Dubner, 1968).

APPENDIX I – Manufacturing

Arnica montana D6 tablets and placebo tablets used in this study was manufactured by:

NATURA HOMOEOPATHIC LABORATORY

Physical address:
Natura Building
No. 8 18th Street
Hazelwood
Pretoria
0081

Postal address:
P.O. Box 35189
Menlo Park
0102

Telephone and fax numbers:
Tel: (012) 346 – 0008
Fax: (012) 460 – 9929