Original Article

Pain Intensity and Discomfort Following Surgical Placement of Orthodontic Anchoring Units and Premolar Extraction

A Randomized Controlled Trial

Ingalill Feldmann[a]; Thomas List[b]; Hartmut Feldmann[c]; Lars Bondemark[d]

ABSTRACT

Objective: To evaluate and compare perceived pain intensity and discomfort between the placement of two different orthodontic anchoring units designed for osseointegration and premolar extraction in adolescent patients.

Materials and Methods: A total of 120 adolescent patients (60 girls and 60 boys) were recruited and randomized into three groups. Group A underwent installation of an onplant, group B installation of an Orthosystem implant, and group C premolar extraction. Pain intensity and discomfort, analgesic consumption, limitations in daily activities, and functional jaw impairment were evaluated the first evening and one week after the intervention.

Results: Pain intensity following surgical installation of an onplant was comparable to the pain intensity experienced after premolar extraction, but there was significantly less pain after surgical installation of an Orthosystem implant compared to installation of an onplant ($P = .002$) or premolar extraction ($P = .007$). The protective, vacuum-formed stent caused great discomfort, even more discomfort than the surgical sites following installation of the onplant or the Orthosystem implant.

Conclusion: The Orthosystem implant was better tolerated than the onplant in terms of pain intensity, discomfort, and analgesic consumption and was, therefore, the anchorage system of choice in a short-term perspective.

KEY WORDS: Adolescents; Orthodontics; Pain; Randomized trial; Skeletal anchorage

INTRODUCTION

Successful orthodontic treatment requires effective treatment methods, and continuous technique development. Systematic evaluations of these new treatment approaches are essential. Besides analyses of the effectiveness of new treatment methods, it is also necessary to explore patients' acceptance and experiences and possible side effects, especially if the new approach involves invasive techniques.

Pain intensity and discomfort are side effects during orthodontic treatment,[1] and it has been reported that every tenth patient drops out in the course of treatment due to pain experiences.[2] Pain has been defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage.[3] Experiences of pain are always subjective and contain both the sensory as well as the affective aspect expressed as intensity and discomfort. A common method for assessing patients' experiences of pain intensity and discomfort during treatment is the use of different scales such as the visual analog scale (VAS), which has been found to be reliable.[4–7]

In recent years, a variety of skeletal fixation methods have been used to provide orthodontic anchorage.[8–10] These fixation methods, usually palatal implants, are well tolerated by adults.[11] However, to our knowledge, no studies on the pain and discomfort related to skeletal anchoring devices in adolescents have been published. Moreover, no comparison of surgical proce-

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dures for skeletal anchoring methods with ordinary premolar extraction concerning perceived pain and discomfort has been reported in the literature.

It was hypothesized that there will be no difference in perceived pain intensity and discomfort between surgical installation of orthodontic anchoring units and premolar extraction. The aim of this study was to evaluate and compare perceived pain intensity and discomfort following installation of two different orthodontic anchoring units designed for osseointegration and premolar extraction in adolescent patients.

MATERIALS AND METHODS

Subjects and Study Design

A total of 120 patients from the Orthodontic clinic at the Public Dental Service, Gävleborg County Council, Gävle, Sweden were recruited to the study. All patients met the following inclusion criteria: adolescents in need of orthodontic treatment, permanent dentition, no previous experience of orthodontic treatment, treatment plan involving extraction of two upper premolars (in most cases, also two premolars in the lower jaw) followed by fixed appliances in both jaws and additional anchorage on the upper first molars considered necessary.

The ethics committee of Uppsala University, Uppsala, Sweden approved the informed consent form and protocol, and all patients at the orthodontic clinic who met the inclusion criteria were invited to enter the trial. The orthodontist provided the patient and parent with both oral and written information on details about the study. After written consent was obtained from the patient and parent, the patient was randomized in blocks and stratified by gender into one of three groups: onplant anchorage (group A), Orthosystem implant anchorage (group B), and premolar extraction (group C). Later, ie, after the trial period of this study, conventional anchorage was inserted in group C patients.

Group A comprised 15 boys and 15 girls (mean age 14.0 years, SD 1.6), group B 15 boys and 15 girls (mean age 14.6 years, SD 2.0), and group C 30 boys and 30 girls (mean age 14.2 years, SD 1.7). The patients in groups A and B were evaluated on the first evening and one week after installation of the onplant and the Orthosystem implant, respectively. Group C was evaluated on the first evening and one week after the last premolar extraction appointment. The patients were instructed on how to complete the questionnaire and asked to bring it to the clinic at the follow-up visit. About 5–10 minutes were needed to complete the questionnaire.

Table 1. Self-Reported Questions Concerning Pain and Discomfort, Analgesic Consumption, and Daily Activities Assessed the First Evening and One Week After Surgery/Extractions

Pain and discomfort
1. Did you have pain during the injection of the anesthetic?
2. Did you have pain during surgery/extraction?
3. Do you have pain from the surgery site/extraction site right now?
4. Did you have discomfort during the injection of the anesthetic?
5. Did you have discomfort during surgery/extraction?
6. Do you have discomfort from the surgery site/extraction site right now?
7. Do you have discomfort from the stent that protects the surgery site?
8. Do you have discomfort from the screw?
9. Did you experience any part of the surgery/extraction as particularly unpleasant?
10. If yes, which part did you experience as particularly unpleasant?
Analgesic consumption
11. Have you taken analgesics for pain?
12. If yes, what kind of analgesic did you use?
Daily activities
13. Did you stay at home from school the last week because of the pain from the surgery/extraction sites?
14. If yes, how many days did you stay home from school?
15. Did you refrain from your leisure activities the last week be cause of pain from the surgery/extraction site?
16. If yes, what activity did you refrain from?
17. Has your sleep been disturbed in the last week because of pain from the surgery/extraction sites?

Outcome Measures

The assessment included self-report questions from a previous study where reliability and face validity were found to be acceptable.[12] In addition, a few questions modified for this study were included.

Pain and Discomfort, Analgesic Consumption, and Daily Activities

All questions are presented in Table 1. Questions 1–8 concerning pain and discomfort were graded on a VAS with the end phrases ''no pain'' and ''worst pain imaginable'' or ''no discomfort'' and ''worst discomfort imaginable.''[7] Question 9 had a binary response (yes/no) and question 10 was open with space for written comments.

Question 11 about analgesic consumption had a binary response (yes/no) with an open-ended follow-up question 12. Questions 13, 15, and 17 concerning daily activities had binary responses (yes/no); questions 14 and 16 were open-ended.

Jaw Function Impairment

The scale included 18 items related to jaw function; eight were related to mandibular function, three to psychosocial activities, and seven to eating specific foods. Each item was assessed on a 4-point scale with options not at all, slightly, much, or extremely difficult.[13]

Surgical Procedures and Premolar Extraction

Installations of the onplant and the Orthosystem implant and premolar extraction were carried out by two experienced maxillofacial surgeons at the Maxillofacial Unit, Gävleborg County Council, Gävle, Sweden.

Local Anesthesia

Identical local anesthetic procedures were conducted prior to installment of the onplant and the Orthosystem implant, ie, a local anesthetic was injected bilaterally in the palate (1.8 mL of 20 mg/mL lidocaine with 12.5 μg/mL epinephrine). Prior to premolar extraction, the patient received a buccal and lingual infiltration of local anesthetic (20 mg/mL lidocaine with 12.5 μg/mL epinephrine) with an initial dose of 1.8 mL in the maxilla and 2.5 mL in the mandible.

Onplant

The patients were given a standard preoperative antibiotic prophylaxis (2 g amoxicillin, orally). Via a paramarginal incision, a tunnel was prepared under the palatal mucosa and extended slightly over the palatal midline (Figure 1a). The onplant—a subperiosteal implant (diameter 7.7 mm; Nobel Biocare, Göteborg, Sweden)—was slid through the tunnel into a position corresponding to the second premolar and as close to the midline as possible.

After two sutures were placed at the incision (Figure 1b), the patient received a Viscogel trimmed (Dentsply, York, Pa), vacuum-formed stent to protect the surgery site, prevent hematoma formation, and facilitate the adaptation of the onplant onto the bone surface (Figure 2).

Orthosystem Implant

The patients were given a standard preoperative antibiotic prophylaxis (2 g amoxicillin, orally). The Orthosystem implant (diameter 3.3 mm, length 4 mm; Institut Straumann AG, Basel, Switzerland) was placed in the midline of the anterior maxilla, at the approximate level of the first premolar. After the mucosa was punched (Figure 3a), a specially designed bur created an implant site, and the implant was installed with finger force (Figure 3b). The patient received a vacuum-formed stent to protect the implant from parafunctional activity of the tongue (Figure 2).

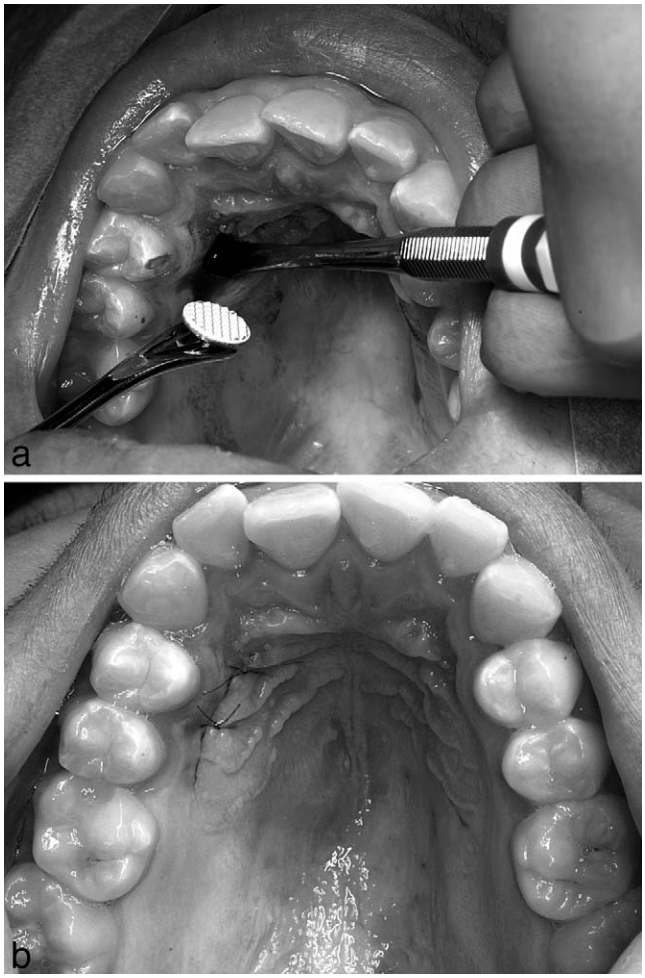

Figure 1. (a) Onplant placement; (b) onplant in place and the incision closed with sutures.

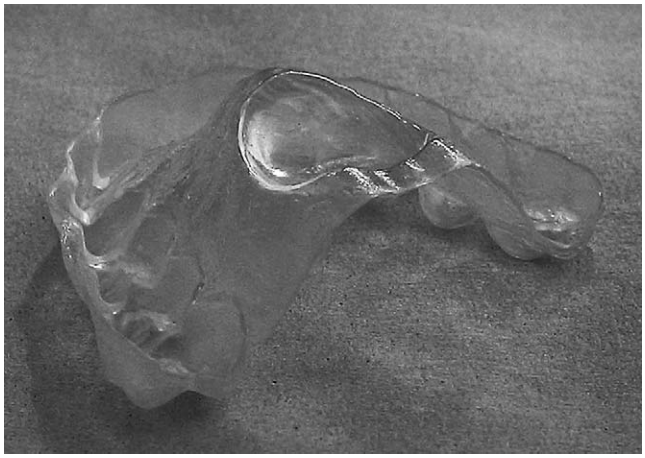

Figure 2. Vacuum-formed protective stent used for both onplant and Orthosystem implant.

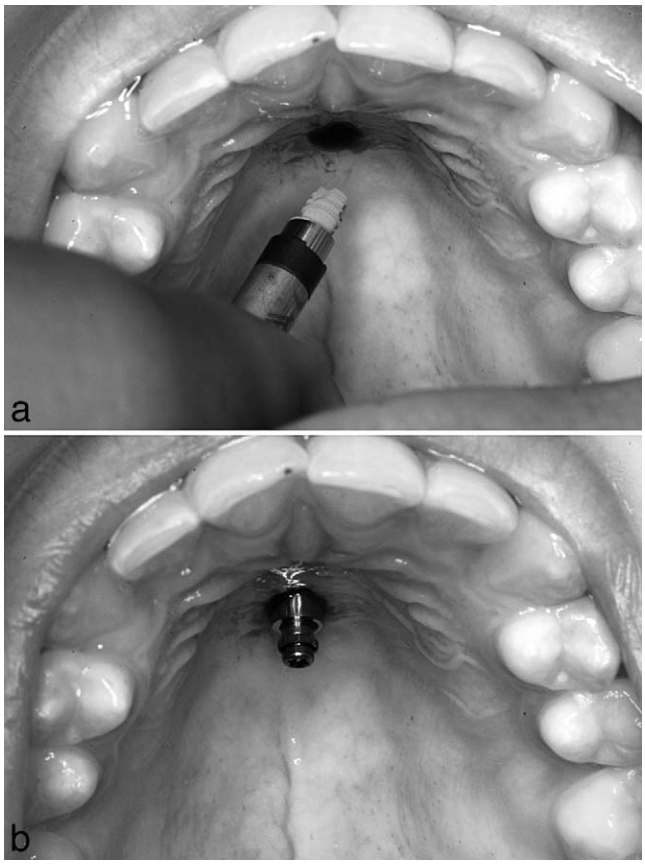

Figure 3. (a) Orthosystem implant placement; (b) Orthosystem implant in place.

Premolar Extraction

On the first occasion, 51 patients had one maxillary and one mandibular premolar extracted on the same side and eight patients had two maxillary premolars extracted. At a second session, the maxillary and mandibular premolars on the other side were extracted in the 51 patients.

Post-operative Care

All patients and their guardians received thorough postoperative information, including a recommendation to use nonprescription analgesics at their own discretion.

Stent

The Essix stents (thickness 1 mm; Raintree Essix, Los Angeles, Calif) were constructed by two orthodontic technicians, and efforts had been made to manufacture the stents as identically as possible for both groups (Figure 2). Patients in group A wore the stent 24 hours a day for one week; patients in group B wore the stent 24 hours a day for two weeks.

Statistical Analysis

Median value, interquartile range, and range were calculated for each variable. Differences between groups were tested with the nonparametric Kruskal-Wallis and Mann-Whitney test for pain and discomfort. Chi-square tests were used to determine differences between groups in functional jaw impairment, affected daily activities, and use of analgesics. Differences with a P value less than 5% ($P < .05$) were considered statistically significant.

RESULTS

Of the 120 randomized patients, 118 completed the trial: one girl in group A (onplant) moved, and one boy in group C (premolar extraction) was unable to participate. The response rate for the questions ranged from 90% to 100%.

Pain Intensity

Pain intensity related to the surgical installation of an onplant or an Orthosystem implant and to premolar extraction is presented in Figure 4. The first evening after the intervention, groups A ($P = .002$) and C ($P = .007$) had significantly more pain intensity compared to group B. The difference in pain intensity between onplant installation and premolar extraction was nonsignificant.

One week after the interventions, pain intensity was still significantly higher in group C compared to group B, which had undergone installation of an Orthosystem implant ($P < .001$). Differences between groups A and B were nonsignificant.

Discomfort

Discomfort related to the surgical installation of an onplant or an Orthosystem implant and to premolar extraction is presented in Figure 5. Group A experienced significantly more discomfort on the first evening compared to group C ($P = .040$). No significant differences were found between groups A (onplant) and B (Orthosystem) or between groups B and C (premolar extraction).

One week after the intervention, group B exhibited significantly less discomfort than group A ($P = .005$) and group C ($P = .021$). However, group B replied more often that they had experienced a particular part of the intervention as especially unpleasant compared to groups A (difference nonsignificant) and C ($P = .047$). The main complaint in group B was associated with drilling during surgery. The complaints during onplant surgery and premolar extraction were few.

Discomfort caused by the protective vacuum-formed stent compared to discomfort from the actual surgery

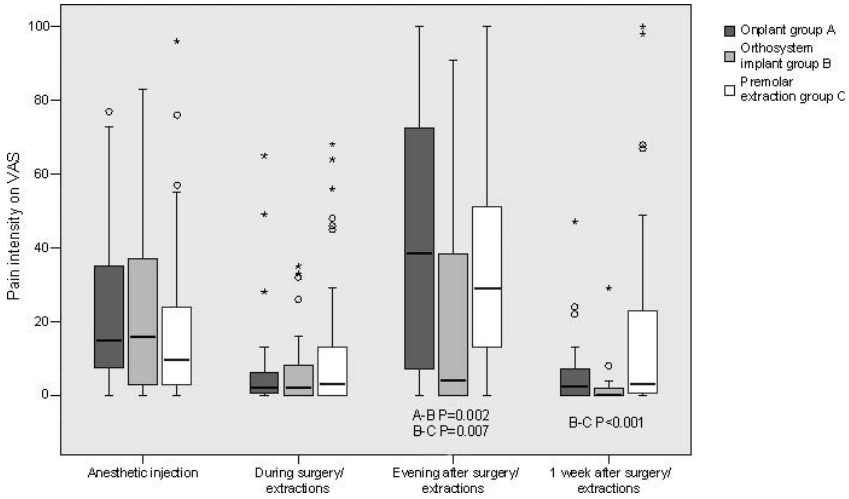

Figure 4. Median values, interquartile ranges, and ranges concerning pain intensity related to surgical installation of an onplant, surgical installation of an Orthosystem implant, and premolar extraction.

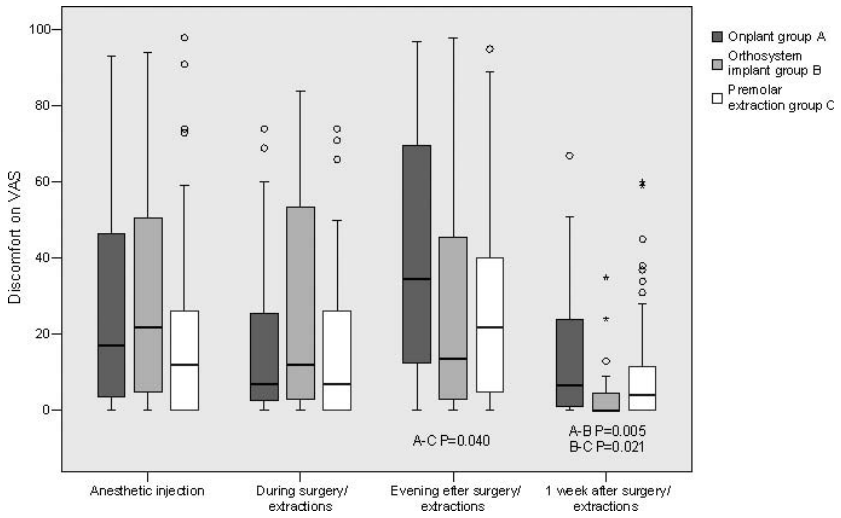

Figure 5. Median values, interquartile ranges, and ranges concerning discomfort related to surgical installation of an onplant, surgical installation of an Orthosystem implant, and premolar extraction.

site is presented in Figure 6. The first evening after surgery, the stent caused more discomfort than did the onplant and Orthosystem implant surgery sites; however, the difference was only significant in group B ($P = .020$). One week after intervention, both groups still reported significantly more discomfort from the stent than from the surgery sites ($P < .001$).

Analgesics

In group A (onplant), significantly more patients had taken analgesics compared to the patients in group C ($P = .037$) on the first day. In the week following the intervention, analgesic consumption was significantly lower in group B than in groups A and C ($P = .004$). Acetaminophen (paracetamol), ibuprofen, and aspirin were the most commonly used analgesics.

Daily Activities

Staying home from school and refraining from leisure-time activities occurred in a few cases, but the differences between the three groups were nonsignificant. The patients in group A (onplant), however, reported disturbed sleep more often than did group C ($P = .033$).

Functional Jaw Impairment

There were no significant differences in jaw impairment, based on summary scores of the 18 items, between groups A (median 22, range 17–57), B (median 21, range 19–33), and C (median 20, range 15–46). When the items on the scale were analyzed individually, speech was found to be significantly more affect-

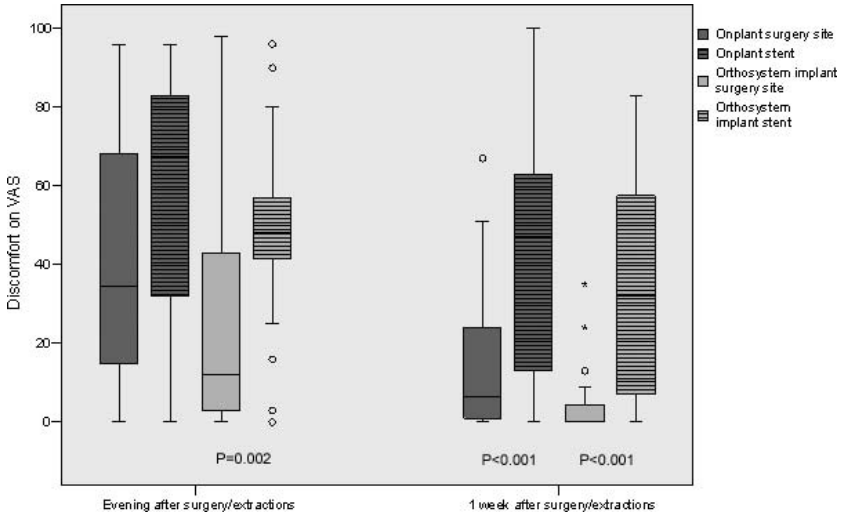

Figure 6. Median values, interquartile ranges, and ranges for discomfort following surgical installation of an onplant, surgical installation of an Orthosystem implant, and the corresponding stents.

ed in groups A and B compared to group C (premolar extraction, $P < .001$). Differences between groups A (onplant) and C in chewing hard ($P = .023$) and soft food ($P = .002$) and eating specific food such as carrots ($P = .009$) and apples ($P = .006$) were significant, as were differences between groups B (Orthosystem) and C concerning chewing soft food ($P = .039$) and chewing against resistance ($P = .041$).

Gender Differences

Gender differences were few. Girls consumed more analgesics the day following the intervention ($P = .042$) and reported a higher intensity of pain one week after surgery or extraction ($P = .039$). Girls also complained more about chewing against resistance ($P = .046$) and eating specific foods such as crispbread ($P = .032$) and apples ($P = .039$).

DISCUSSION

The most important finding of this study was that the Orthosystem implant was tolerated better than the onplant concerning pain intensity, discomfort, and analgesic consumption. Pain intensity after surgical installation of an onplant was comparable to pain after premolar extraction, and in this respect, the initial hypothesis, that there was no difference in perceived pain intensity between installation of orthodontic anchoring units designed for osseointegration and premolar extraction, was confirmed. Furthermore, the protective stent caused greater discomfort than did the actual site of surgery.

This study evaluates experienced pain related to a surgical intervention in a short-term perspective. The most common method of evaluating acute pain is to analyze the intensity and discomfort of the experience. The scale most commonly used to assess this experience is VAS. There is considerable evidence that this scale is reliable and valid among adults and adolescents.[4–7] Reliability and validity of a question are important criteria for drawing generalized conclusions. The majority of the questions were taken from a questionnaire that had been used in a previous study[12] where reliability and face validity were evaluated and found to be good to excellent. The age distribution in this study was also similar to that in other studies of adolescents undergoing orthodontic treatment with fixed appliances.[14–18] In addition, selection bias was avoided since consecutive patients were randomized into three groups.

In this study, no major gender differences in experiences of pain intensity and discomfort were found. Although a few studies[17,18] have reported that girls report more pain and discomfort than boys, correlations between gender and perception of pain and discomfort during orthodontic treatment are sparse in the literature.[19–21] Nevertheless, in this study, differences in gender distribution should not have influenced the results since the trial was randomized.

In this study, pain intensity and discomfort following surgical installation of an onplant or an Orthosystem implant were compared. The indications for these anchorage systems are the same and both surgical procedures were simple and took only about 10–15 minutes to perform. One explanation of the higher pain intensity and discomfort reported by the onplant group is that the onplant installation involved a larger area of the palate than the Orthosystem implant.

The patients in groups A and B were all given a vacuum-formed stent directly after the surgical proce-

dure: in group A (onplant) to protect the surgery site, prevent hematoma formation, and facilitate the adaptation of the onplant onto the bone surface; and in group B to protect the short implant from parafunctional activity of the tongue. It was surprising that the stent caused such great discomfort, even more discomfort than was caused by the actual site of surgery (Figure 6). A plausible explanation was that many of the patients had severe crowding and the semi-elastic stent may have initiated uncontrolled forces and tensions on the teeth. An alternative design of the stent, with a different form of retention, can therefore be recommended in the future.

Moreover, it was found that groups A and B, who had received an onplant or an Orthosystem implant, were significantly more inconvenienced than group C when talking and eating specific foods. Additional discomfort from the protective stent, which groups A and B wore 24 hours a day, was probably an aggravating factor in this aspect.

Median values for pain intensity and discomfort following surgery and premolar extraction were comparatively moderate, but some patients described it as the worst imaginable. Perception of pain intensity is subjective and influenced by many other factors such as anxiety levels and motivational attitude.[1,22] Since the oral health of the majority of the patients in this study was excellent, they had no or little experience of ordinary dental care, which could have contributed to the range in pain intensity and discomfort.

In orthodontic treatment of crowding or overjet, premolar extraction followed by orthodontic appliances is a common treatment strategy. It was, therefore, valuable to compare surgical procedures for skeletal anchoring methods with ordinary premolar extraction. Such a comparison has never been performed. The most optimal study design would have been to compare one surgical intervention per group, ie, one anchorage system with extraction of only one premolar. However, the standard clinical procedure is to extract two premolars simultaneously, and it was therefore decided to use this intervention as the most clinically relevant comparison.

The use of analgesics on the first day after surgery or premolar extraction was 70%, which is higher than on the first day after insertion of orthodontic fixed appliances,[16,18] but considerably lower than after third molar surgery.[23]

CONCLUSIONS

- Pain intensity after surgical installation of an Orthosystem implant was less than after installation of an onplant or premolar extraction.
- Pain intensity after surgical installation of an onplant was comparable to pain after premolar extraction.
- In terms of pain intensity, discomfort, and analgesic consumption, the Orthosystem implant is the anchorage system of choice compared to the onplant in a short-term perspective.
- The protective, vacuum-formed stent caused great discomfort, even more than discomfort was caused by the surgical site after installation of an onplant or an Orthosystem implant.

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REFERENCES

1. Bergius M, Kiliaridis S, Berggren U. Pain in orthodontics. A review and discussion of the literature [in English and German]. *J Orofac Orthop/Fortschr Kieferorthop.* 2000;61:125–137.
2. Patel V. *Non-Completion of Orthodontic Treatment: A Study of Patient and Parental Factors Contributing to Discontinuation in the Hospital Service and Specialist Practice* [thesis]. Heath Park, UK: University of Wales; 1989.
3. Merskey H, Bogduk N. *Classification of Chronic Pain. Descriptions of Chronic Pain Syndromes and Definitions of Pain Terms.* Seattle, Wash: IASP press; 1994.
4. Wahlund K, List T, Dworkin S. Temporomandibular disorders in children and adolescents: reliability of a questionnaire, clinical examination and diagnosis. *J Orofac Pain.* 1997;12:42–51.
5. McQuary H, Moore A. *An Evidence-Based Resource for Pain Relief.* Oxford: Oxford University Press, 1998:14–18.
6. Abu-Saad H. Assessing childrens response to pain. *Pain.* 1984;19:163–171.
7. Seymour RA, Simpson JM, Charlton JE, Philips ME. An evaluation of length and end-phrase of visual analogue scales in dental pain. *Pain.* 1985;21:177–185.
8. Block MS, Hoffman DR. A new device for absolute anchorage for orthodontics. *Am J Orthod Dentofacial Orthop.* 1995; 107:251–258.
9. Wehrbein H, Feifel H, Diedrich P. Palatal implant anchorage reinforcement of posterior teeth: a prospective study. *Am J Orthod Dentofacial Orthop.* 1999;116:678–686.
10. Costa A, Raffainl M, Melsen B. Miniscrews as orthodontic anchorage: a preliminary report. *Int J Adult Orthodon Orthognath Surg.* 1998;13:201–209.
11. Gündüz E, Schneider-Del Savio TT, Kucher G, Schneider B, Bantleon HP. Acceptance rate of palatal implants: a questionnaire study. *Am J Orthod Dentofacial Orthop.* 2004; 126:623–626.
12. Feldmann I, List T, John MT, Bondemark L. Reliability of a questionnaire assessing experiences of orthodontic treatment in adolescents. *Angle Orthod.* 2006. In press.
13. Stegenga B, de Bont LG, de Leeuw R, Boering G. Assessment of mandibular function impairment associated with temporomandibular joint osteoarthrosis and internal derangement. *J Orofac Pain.* 1993;7:183–195.

14. Sergl HG, Klages U, Zentner A. Pain and discomfort during orthodontic treatment: causative factors and effects on compliance. *Am J Orthod Dentofacial Orthop.* 1998;114:684–691.
15. Firestone AR, Scheurer PA, Bürgin WB. Patients' anticipation of pain and pain-related side-effects and their perception of pain as a result of orthodontic treatment with fixed appliances. *Eur J Orthod.* 1999;21:387–396.
16. Erdinc A, Dincer B. Perception of pain during orthodontic treatment with fixed appliances. *Eur J Orthod.* 2004;26:79–85.
17. Kvam E, Gjerdet NR, Bondevik O. Traumatic ulcers and pain during orthodontic treatment. *Community Dent Oral Epidemiol.* 1987;15:104–107.
18. Scheurer P, Firestone A, Burgin W. Perception of pain as a result of orthodontic treatment with fixed appliances. *Eur J Orthod.* 1996;18:349–357.
19. Jones M. An investigation into the initial discomfort caused by placement of an archwire. *Eur J Orthod.* 1984;6:48–54.
20. Fernandes LM, Ögaard B, Skoglund L. Pain and discomfort experienced after placement of a conventional or a superelastic NiTi aligning archwire. *J Orofac Orthop.* 1998;59:331–339.
21. Ngan P, Kess B, Wilson S. Perception of discomfort by patients undergoing orthodontic treatment. *Am J Orthod Dentofacial Orthop.* 1989;96:47–53.
22. Klingberg G. *Dental Fear and Behavior Management Problems in Children* [thesis]. Göteborg University, Sweden: Faculty of Odontology; 1995.
23. White R, Shugars D, Buckley M. Recovery after third molar surgery: Clinical and health-related quality of life outcomes. *J Oral Maxillofac Surg.* 2003;61:535–544.