Original Article

Pain and discomfort following insertion of miniscrews and premolar extractions: *A randomized controlled trial*

Niels Ganzer[a]; Ingalill Feldmann[b]; Lars Bondemark[c]

ABSTRACT

Objective: To investigate and compare the experience of pain and discomfort between insertion of miniscrews and premolar extractions in adolescent patients.

Materials and Methods: A total of 80 adolescents were recruited and randomized into groups A and B. Both groups were treated with extraction of the upper first premolars and fixed appliance. Beyond the fixed appliance, patients in group A received anchorage reinforcement with miniscrews. Miniscrews were inserted buccally between the second premolar and first molar when space closure started. Space closure was performed as en masse retraction with immediate loading by 150-g coil springs. Pain, discomfort, impact on daily activities, and functional jaw impairment were assessed with patient-reported questionnaires. Questionnaires were filled in at baseline, the evening after tooth extraction, 1 week after tooth extraction, the evening after screw placement, and 1 week after screw placement.

Results: Patients reported significantly lower levels of pain ($P < .001$) and discomfort ($P = .012$) after screw placement compared with premolar extractions. The ability to drink ($P = .035$) and the ability to take a big bite ($P < .001$) were also significantly less disturbed in the evening after screw placement. During the first week after screw placement, the impact on leisure time activities was significantly lower ($P = .015$) compared with premolar extractions.

Conclusion: The use of miniscrews in adolescents can be recommended from a pain and discomfort perspective. (*Angle Orthod.* 2016;86:891–899)

KEY WORDS: Orthodontics; Orthodontic anchorage procedures; Miniscrew; TAD; Temporary anchorage device; MSI

INTRODUCTION

Orthodontic treatment is often correlated with discomfort and pain. Soreness and aching are certainly reported after insertion of the initial archwire.[1,2] Since invasive skeletal anchorage has become a common technique in orthodontics, yet another potentially painful moment has become part of the orthodontic treatment plan.

The use of skeletal anchorage devices is a multifactor scenario in which the type of screw, insertion site, anesthesia, and pre- or postoperative medication make difference. Because of the variety of screw types and their usage, only a few general conclusions can be drawn for the experience of pain and discomfort related to the use of miniscrews.[3] Lehnen et al.[4] showed that the drilling of a pilot hole was reported to be as uncomfortable as the pressure that self-drilling screws cause in the bone, and when treatment includes flap surgery or soft tissue punching, patients report even higher pain levels.[5,6] Lee et al.[7] showed in a cohort study that patients expect the buccal placement of miniscrews to be more painful than it finally is.

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To evaluate the experience of pain and discomfort under and after insertion of skeletal anchorage devices, a reference procedure is needed. Tooth extractions can serve as a reference since this procedure is commonly used and accepted in orthodontics.[8] Earlier randomized clinical trials showed that palatal implants, in comparison to tooth extractions, cause pain and discomfort on an acceptable level.[9] However, individual pain levels range from *no pain at all* to *worst pain imaginable*. There are large uncertainties concerning the experience of pain and discomfort since different types of miniscrews, study designs, and statistical methods are used. Consequently, there is a knowledge gap in the management of pain and discomfort when miniscrews are used.

The purpose of this study was to investigate and compare the experience of pain and discomfort between the insertion of miniscrews and premolar extractions in adolescent patients. Our hypothesis was that insertion of miniscrews causes lower pain levels than extraction of premolars.

MATERIALS AND METHODS

The study protocol, questionnaires, and informed consent were approved by the Regional Ethical Review Board, Uppsala University, Uppsala, Sweden (Dnr.2009/188). After receiving oral and written information about the treatment plan and about the clinical trial, both the patient and the parents signed informed consent. This study is registered at Clinicaltrials.gov, NCT92644811.

Subjects

Patients were recruited from the Orthodontic Clinic at the Public Dental Service, Gävleborg County Council, Gävle, Sweden.

The inclusion criteria were adolescents in need of orthodontic treatment with a fixed appliance, treatment plan including extraction of the maxillary first premolars, need for anchorage reinforcement, permanent dentition including the maxillary second molars in occlusion, and regular dental care from 3 years of age. Patients with previous orthodontic treatment or need for orthognathic surgery were excluded from the study.

An independent person conducted the randomization as follows: computer-generated randomization list and preparation of numbered and sealed opaque envelopes containing an allocation note (ie, random allocation to either group A or group B). The envelope was then handed to the patient, and the allocation to the study groups was revealed by the patient opening the envelope.

Patients in group A were treated with extraction of the first maxillary premolars (Figure 1a) and fixed appliance in the maxilla or in both jaws. When the space closing phase started, miniscrews were buccally and interradicularily inserted between the maxillary second premolars and first molars (Figure 1b). Space closure was performed as an en masse retraction with closed coil springs.

Group B was also treated with extraction of the first maxillary premolars (Figure 1a) and fixed appliance in the maxilla or in both jaws. Anchorage was reinforced with molar blocks, a stainless steel ligature connecting the second maxillary premolar with the first and second molar. Space closure was performed as an en masse retraction with type 1 active tiebacks.

All patients in both groups were treated by two orthodontists (N.G., I.F.) and in line with a standard straight-wire concept[10] (Victory, 0.022 slot size, MBT prescription, 3M Unitek, St Paul, Minn). The recommended archwire sequence was 0.016-inch heat-activated nickel-titanium (HANT), 0.019 × 0.025-inch HANT, and 0.019 × 0.025-inch stainless steel posted.

Tooth Extraction Protocol (Group A and B)

The patients' general practitioner performed the tooth extractions according to the following protocol:

1. Topical anesthesia with 5% lidocaine gel (APL, Sweden)
2. Buccal and palatal infiltration of Xylocaine Dental Adrenalin (lidocaine hydrochloride 20 mg/mL, adrenaline 12.5 μg/mL, Dentsply Pharmaceutical, Weybridge, Surrey, UK)
3. Tooth extraction after careful mobilization

Miniscrew Insertion Protocol (Group A Only)

All miniscrews were inserted by one orthodontist (NG) according to the following protocol:

1. Topical anesthesia with 5% lidocaine gel (APL)
2. Buccal infiltration of 0.3 mL Xylocaine Dental Adrenalin per site (lidocaine hydrochloride 20 mg/mL, adrenaline 12.5 μg/mL, Dentsply Pharmaceutical)
3. Chlorhexidine mouth rinse for 60 seconds (Corsodyl 2 mg/mL, SmithKline Beecham Ltd, Brentford, UK)
4. Insertion of two miniscrews (Spider Screw K1 SCR-1510 or SCR-1508, Health Development Company, Sarcedo, Italy), one on the right and one on the left side, buccally and interdentally with 30°–40° of angulation between the maxillary second premolar and first molar
5. Periapical radiographs
6. Immediate loading of the miniscrews as direct anchorage with 150-g closed-coil springs (TAD Coil

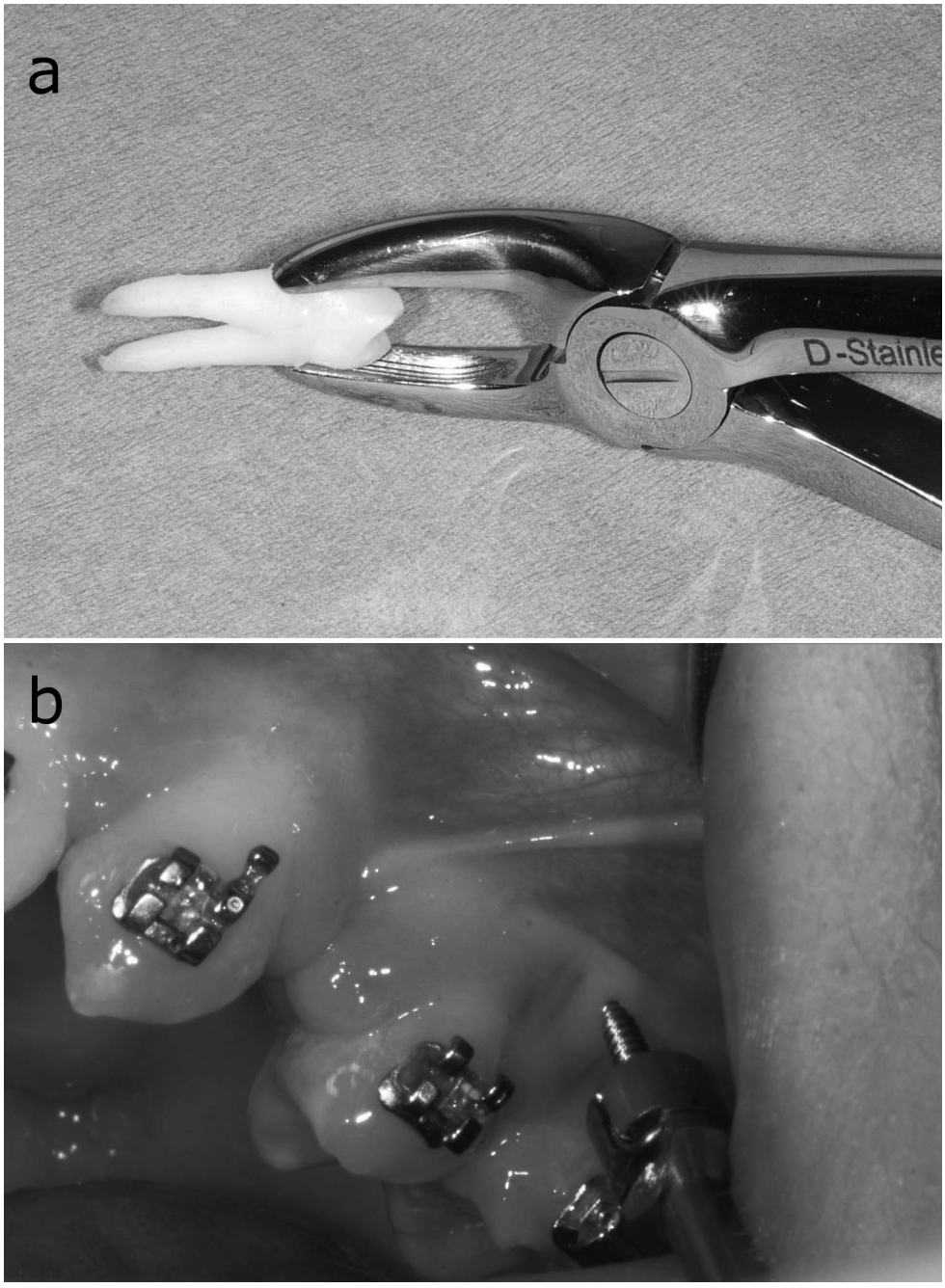

Figure 1. (a) Extracted maxillary premolar. (b) Miniscrew installation.

Spring, medium force 150 g, Ortho Technology, Tampa, Fla)

7. After screw insertion, patients were instructed to apply chlorhexidine gel onto the miniscrews once a day for 2 weeks.

Postoperative Instructions

When experiencing pain after tooth extractions (group A and B) or installation of the miniscrews (group A), patients were advised to use over-the-counter analgesics according to their personal judgment.

Questionnaires

Treatment motivation and expectation, experience of pain and discomfort, analgesic consumption, and the impact on daily activities were assessed using self-report questionnaires. These questionnaires have

Table 1. Self-report Questionnaires Concerning Pain and Discomfort, Analgesic Consumption, and Daily Activities Assessed the First Evening after Premolar Extraction and Insertion of the Miniscrews, Respectively

	Scale
Pain and discomfort, analgesic consumption	
1. Did you have pain during the injection of the anesthetic?	VAS
2. Did you have pain during tooth extraction/insertion of the miniscrews?	VAS
3. Have you taken analgesic today?	Yes/No
- If YES, what kind and which dose of analgesic did you use?	Plain text
4. Did you have discomfort during the injection of the anesthetic?	VAS
5. Did you have discomfort during tooth extraction/insertion of the miniscrews?	VAS
6. Did you experience any part of the tooth extraction/insertion of the miniscrews as particularly unpleasant?	Yes/No
- If YES, which part did you experience as particularly unpleasant?	Plain text
7. Do you have pain from the extraction site/insertion site right now?	VAS
8. Do you have discomfort from the extraction site/insertion site right now?	VAS
Daily activities and functional jaw impairment	
If you have pain or discomfort in your teeth and jaws, how much does that affect	
9. Your leisure time	5-point scale
10. Your speech	5-point scale
11. Your ability to take a big bite	5-point scale
12. Your ability to chew hard food	5-point scale
13. Your ability to chew soft food	5-point scale
14. Your schoolwork	5-point scale
15. Drinking	5-point scale
16. Laughing	5-point scale
17. Your ability to chew against resistance	5-point scale
18. Yawning	5-point scale
19. Kissing	5-point scale
Eating means taking a bite, chewing, and swallowing. How difficult is it for you to eat	
20. Crisp bread	5-point scale
21. Meat	5-point scale
22. Raw carrots	5-point scale
23. Roll	5-point scale
24. Peanuts	5-point scale
25. Apples	5-point scale
26. Cake	5-point scale
27. Did you stay at home from school today because of pain from the extraction site/insertion site?	Yes/No
28. Did you refrain from your leisure activities today because of pain from the extraction site/insertion site?	Yes/No
- If YES, what activity did you refrain from?	Plain text

Table 2. Self-report Questionnaire Concerning Pain and Discomfort, Analgesic Consumption, and Daily Activities Assessed 1 Week After the First Tooth Extraction and Insertion of the Miniscrews, Respectively

	Scale
Pain and discomfort	
1. Do you have pain from the extraction site/insertion site right now?	VAS
2. Do you have discomfort from the extraction site/insertion site right now?	VAS
Daily activities and functional jaw impairment	
If you have pain or discomfort in your teeth and jaws, how much does that affect	
3. Your leisure time	5-point scale
4. Your speech	5-point scale
5. Your ability to take a big bite	5-point scale
6. Your ability to chew hard food	5-point scale
7. Your ability to chew soft food	5-point scale
8. Your schoolwork	5-point scale
9. Drinking	5-point scale
10. Laughing	5-point scale
11. Your ability to chew against resistance	5-point scale
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14. Crisp bread	5-point scale
15. Meat	5-point scale
16. Raw carrots	5-point scale
17. Roll	5-point scale
18. Peanuts	5-point scale
19. Apples	5-point scale
20. Cake	5-point scale
21. Did you stay at home from school this week because of pain from the extraction site/insertion site?	Yes/No
- If YES, how many days did you stay home from school?	Plain text
22. Did you refrain from your leisure activities this week because of pain from the extraction site/insertion site?	Yes/No
- If YES, what activity did you refrain from?	Plain text
23. Has your sleep been disturbed in the last week because of pain from the extraction site/insertion site?	Yes/No
Analgesic consumption	
24. Have you taken analgesic because of pain during the last week?	Yes/No
- If YES, what kind and which dose of analgesic did you use?	Plain text

been found to be reliable and with sufficient internal consistency in earlier studies.[9,11–13]

The baseline questionnaire was administrated after the randomization process and comprised questions about treatment motivation and expectation, pain and discomfort, and limitations in daily activities.[11] Table 1 presents the questions used at the evening after premolar extraction and at the evening after insertion of the miniscrews. The questions displayed in Table 2 were administrated 1 week after premolar extraction and miniscrew insertion, respectively. Consequently, patients in group A were evaluated at baseline, after premolar extractions, and after miniscrew insertion. Patients in group B were evaluated at baseline and after premolar extractions only.

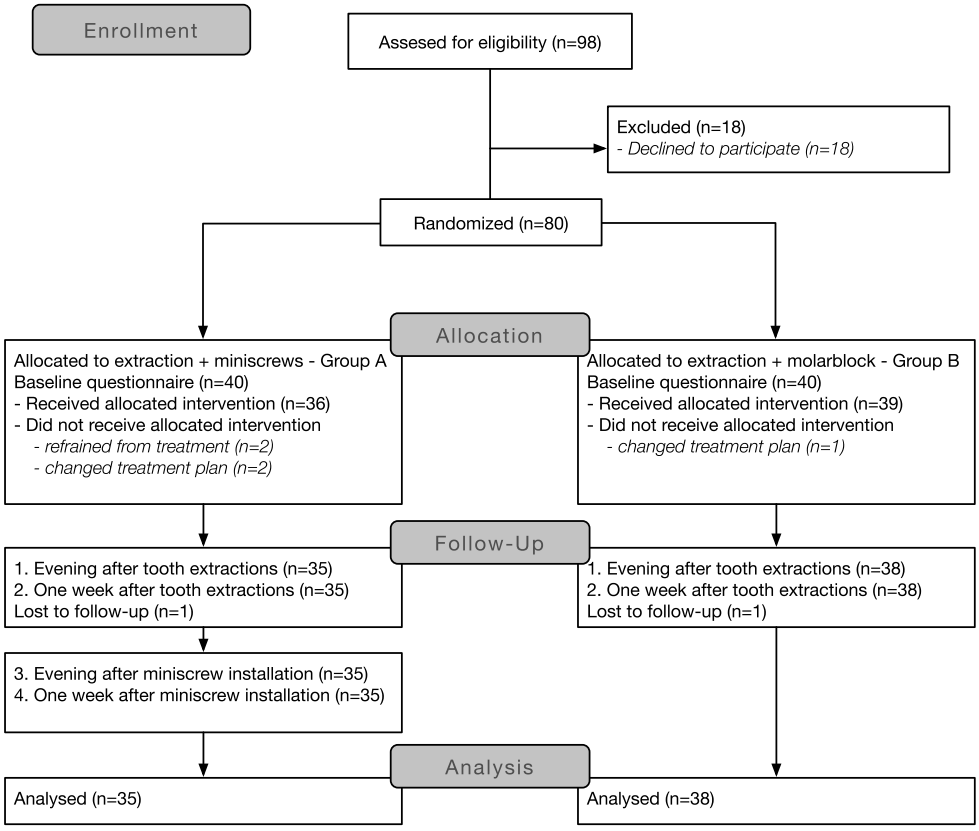

Figure 2. CONSORT flow diagram of the patients.

We used horizontal visual analogue scales (VAS; 100 mm) with the end phrases *not at all* and *worst imaginable*.

The five-point scale consisted of the alternatives *not at all*, *slightly difficult*, *difficult*, *much difficult*, and *extremely difficult*.

The patients in both groups were instructed to complete the questionnaire on their own. They were asked to bring it to the clinic at the follow-up visit. Approximately 10 minutes were needed to fill in the questionnaire.

Measurements

The VAS was assessed to the nearest 0.5 mm by using a standard 100-mm metric ruler. For blinding purposes, a new random identification number was assigned to each patient prior to measurements; thus, the investigator was unaware of patient's name, age, sex, or group assignment.

Statistical Analysis

Differences between groups were tested with the Mann-Whitney *U*-test (ordinal data) and Fisher exact test (nominal data). The Wilcoxon signed rank test was used to analyze differences between tooth extractions and insertion of the miniscrews within group A. To examine associations between the baseline questionnaire and later experience of pain and discomfort, Spearman correlation coefficients were calculated. *P* values were then adjusted for multiple comparisons with the Holm-Bonferroni correction. *P* values less than 5% were considered statistically significant. Statistical analysis was performed with IBM SPSS Statistics version 22 and in R version 3 (New York, NY).

RESULTS

Ninety-eight patients matched the inclusion criteria and were invited to participate in this investigation, but 18 patients declined to participate. Thus, informed consent was collected from 80 patients before they were enrolled into the trial. The patients who declined comprised eight boys and 10 girls (mean age, 15.1 years; SD, 1.85) and were not significantly different with regard to age or gender compared with the patients who entered the study.

After randomization and before treatment start, two patients from group A were excluded because of refrainment from orthodontic treatment. Further, two patients from group A were excluded because no spaces were apparent after levelling and alignment, implying no

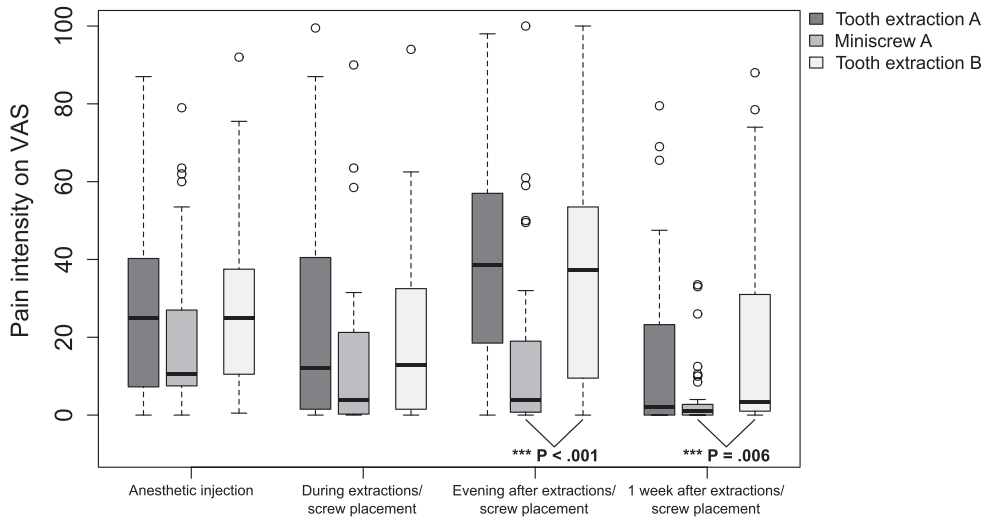

Figure 3. Pain intensity on visual analogue scale presented as Tukey boxplot with median values and interquartile range.

need for space closure. In addition, the extraction procedure had to be changed for one patient in group B because of a pathological finding on preoperative x-rays, and this patient was also excluded from the trial (Figure 2).

One patient in group A and one in group B were lost to follow-up because of questionnaires that were not returned. Consequently, group A consisted of 35 patients (24 girls, 11 boys; mean age, 16.3 years; SD, 0.28 years) and group B of 38 patients (26 girls, 12 boys; mean age, 14.9 years; SD, 0.3 years). The overall response rate was 87.8%.

Baseline Questionnaire

The baseline questionnaire showed no significant differences between groups A and B concerning pain and discomfort and limitations in daily activities. However, patients in group A (miniscrews) more often answered that it was their own decision to undergo orthodontic treatment ($P = .028$) and that they expected it to be more difficult to wear braces ($P = .047$). There were no correlations between later experience of pain and discomfort and the baseline assessments.

Pain Intensity

Patient-reported pain intensity is presented in Figure 3 and Table 3. There were no significant differences in experience of pain between tooth extractions in group A or B.

Comparing pain intensity for tooth extractions and miniscrew installation, we found significantly lower pain levels at the evening and 1 week after placement of the miniscrews compared with tooth extractions.

Discomfort

Patient-reported discomfort is presented in Figure 4 and Table 4. There were no significant differences in experience of discomfort between tooth extractions in groups A and B. Patients experienced significant less discomfort at the evening and 1 week after installation of the miniscrews compared with tooth extractions.

Table 3. Patient-Reported Pain Intensity (Median Values and Tukey's Hinges)

	Extractions A	←P→	Miniscrews A	←P→	Extractions B
Anesthetic injection	Q1 = 7.25	.388	Q1 = 7.50	.063	Q1 = 10.50
	Median = 25.00		Median = 10.50		Median = 25.00
	Q3 = 40.25		Q3 = 27.00		Q3 = 37.50
During screw placement/extractions	Q1 = 1.50	.088	Q1 = 0.25	.082	Q1 = 1.50
	Median = 12.00		Median = 4.00		Median = 13.00
	Q3 = 40.50		Q3 = 21.25		Q3 = 32.50
Evening after screw placement/extractions	Q1 = 18.50	<.001	Q1 = 0.75	<.001	Q1 = 9.50
	Median = 38.50		Median = 4.00		Median = 37.25
	Q3 = 57.00		Q3 = 19.00		Q3 = 53.50
One week after screw placement/extractions	Q1 = 0.00	.013	Q1 = 0.00	.006	Q1 = 1.00
	Median = 2.00		Median = 1.00		Median = 3.25
	Q3 = 23.25		Q3 = 2.75		Q3 = 31.00

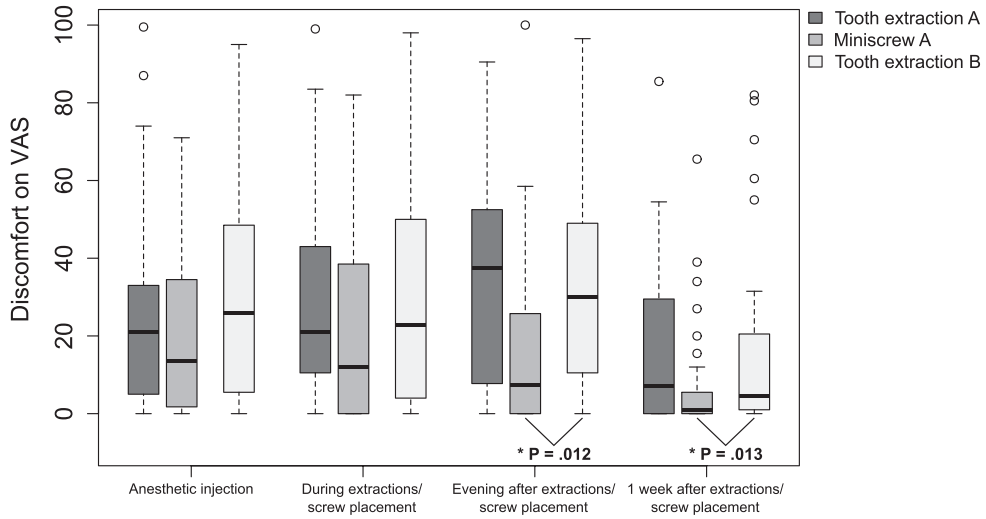

Figure 4. Discomfort on visual analogue scale presented as Tukey boxplot with median values and interquartile range.

Analgesics

In total, 57.4% of our patients used analgesics at the evening after premolar extractions and/or placement of the miniscrews, while 29.6% used analgesics during the first week after the procedures. There were no significant differences between analgesic consumption after miniscrew placement in group A and premolar extractions in group B, although pain levels were significantly lower after miniscrew placement. Prescription-free compositions of paracetamol or ibuprofen were most commonly used.

Daily Activities and Functional Jaw Impairment

Patients reported significantly more problems taking a big bite ($P < .001$) and drinking ($P = .035$) at the evening after the tooth extractions than at the evening after installation of the miniscrews. Leisure time activities were more often reported to be disturbed during the first week after tooth extractions than after installation of the miniscrews ($P = .015$).

In total, 19.4% of our patients stayed home from school the day of the tooth extractions or installation of the miniscrews, although 13.0% stayed home at least 1 day during the first week after tooth extractions or installation of the miniscrews. There were no other significant differences between groups A and B.

Gender Differences

Girls complained more frequently about tension in the jaw ($P = .018$) and headache ($P = .027$) in the baseline questionnaire. Moreover, girls reported higher summary scores (ie, more disturbances) for daily activities in the baseline questionnaire ($P = .037$).

Boys stayed home from school more frequently ($P = .011$) the day of the tooth extraction compared with girls. Boys also refrained more often from leisure time activities ($P = .046$) on the day of the tooth extractions.

Differences concerning experience of pain and discomfort during and after premolar extractions and/or miniscrew placement were nonsignificant.

Table 4. Patient-Reported Discomfort (Median Values and Tukey's Hinges)

	Extractions A	←P→	Miniscrews	←P→	Extractions B
Anesthetic injection	Q1 = 5.00	.503	Q1 = 1.75	.052	Q1 = 5.50
	Median = 21.00		Median = 13.50		Median = 26.00
	Q3 = 33.00		Q3 = 34.50		Q3 = 48.50
During surgery/extractions	Q1 = 10.50	.258	Q1 = 0.00	.171	Q1 = 4.00
	Median = 21.00		Median = 12.00		Median = 22.75
	Q3 = 43.00		Q3 = 38.50		Q3 = 50.00
Evening after surgery/extractions	Q1 = 7.75	.007	Q1 = 0.00	.012	Q1 = 10.50
	Median = 37.50		Median = 7.50		Median = 30.00
	Q3 = 52.50		Q3 = 25.75		Q3 = 49.00
One week after surgery/extractions	Q1 = 0.00	.009	Q1 = 0.00	.013	Q1 = 1.00
	Median = 7.00		Median = 1.00		Median = 4.50
	Q3 = 29.50		Q3 = 5.50		Q3 = 20.50

DISCUSSION

The main finding in this trial was that patients experienced significant less pain and discomfort after placement of miniscrews compared with tooth extractions. Consequently, our hypothesis was confirmed.

The reported pain intensity and discomfort levels were generally moderate. In addition, the median values for pain intensity found in our study were lower than median values reported for the first days for insertion of Onplant, headgear, or transpalatal arch.[14] However, individual experiences ranged from *no pain/discomfort at all* to *worst imaginable*. It is important to recognize that the study population consisted of adolescents with good to excellent dental health. Thus, most of these patients never experienced painful dental treatments before and therefore had a limited perspective when it comes to pain. This homogeneity of the study population might also explain why we found no significant correlations between the baseline questionnaire and later experiences of pain and discomfort. The assessments from the baseline questionnaire showed very few interindividual differences, which probably would have been different in a population with poorer dental health or in an adult population.

Since our results also showed that anesthetic injection is reported to be as painful and uncomfortable as the procedures itself, it can be discussed whether the use of topical anesthesia only would be sufficient.[15] Kwong et al.[16] showed that different types of topical anesthetics can achieve sufficient numbness of the gingiva and to some degree even of the periosteum. However, when placing miniscrews interradiculary, it is important that the patient does not move during the procedure. Therefore, full numbness of the gingiva, periosteum, and cortical plate is necessary. To use the advantages of local infiltration and reduce the experience of pain and discomfort at the same time, a computerized injection system such as The Wand could be used.[17]

An unexpected significant difference in patients' age was found. Nevertheless, all patients had the same dental age because full permanent dentition with the second molar in occlusion was one of the inclusion criteria.

Analysis of perception of pain and discomfort of tooth extractions in group A vs group B revealed no significant differences. Comparison of tooth extractions vs miniscrew placement within group A showed the same results as tooth extractions in group B. Therefore, it can be assumed that groups A and B were equal in perception of pain and discomfort. However, miniscrews were placed after tooth extractions and installation of fixed appliance. The preceding intervention might cause an increase or decrease in pain values for miniscrew placement through sensitization or habituation.[18] Nevertheless, the results show a robust difference in experience of pain and discomfort after the intervention. Thus, the conclusions still remain the same (i.e., tooth extractions caused more discomfort and pain than miniscrew placement).

In total, 73 of 80 patients were analyzed. Two patients in group A refrained from treatment after randomization. Whether these patients were anxious about miniscrew placement is not known, and this may be a source of selection bias. The seven patients who were excluded from the analysis showed no significant differences in the baseline questionnaire, except they reported significantly lower values for how well informed they were about the treatment ($P = .039$). This might be considered a source of survivorship bias. Since the number of nonparticipants was small and both groups were affected, the overall risk for bias was regarded as low. Furthermore, some patients did not answer all questions in the questionnaires. Nevertheless, the overall response rate was high.

In summary, this trial used validated and reliable questionnaires for a study population relevant for orthodontic treatment in industrial countries. We found good internal validity.

CONCLUSIONS

- Installation of miniscrews causes moderate pain and discomfort.
- Pain intensity and discomfort were significant lower for miniscrew installation than tooth extractions.
- From the perspective of pain and discomfort, the use of miniscrews in adolescents can be recommended.

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