

Orthodontic anchoring techniques and its influence on pain, discomfort, and jaw function—a randomized controlled trial

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SUMMARY The aim of this trial was to evaluate and compare perceived pain, discomfort, and jaw function impairment between orthodontic treatments combined with skeletal anchorage and treatment using conventional anchorage with headgear or transpalatal bar. A total of 120 adolescent patients in order to start orthodontic treatment were consecutively recruited and randomized into three groups with different anchorage. Group A underwent installation of a skeletal anchorage (Onplant or Orthosystem implant), group B received headgear, and group C a transpalatal bar. Questionnaires were used to assess pain intensity, discomfort, analgesic consumption, and jaw function impairment from baseline to the end of treatment. Pain scores overall peaked on day 2 and were almost back to baseline on day 7. The site with the highest pain scores during treatment was incisors in contact but with no differences between groups. Pain intensity from molars was significantly less in the skeletal anchorage group A compared to the transpalatal bar group C the first 4 days in treatment and with no sign differences compared to headgear. The results confirm that there were very few significant differences between patients' perceptions of skeletal and conventional anchorage systems during orthodontic treatment. Consequently, these new appliances were well accepted by the patients in a long time perspective and can thus be recommended.

Introduction

Pain is reported to be the major side-effect during orthodontic treatment (Bergius *et al.*, 2000; Krishnan, 2007) and studies on both adults and adolescents reveal that 95 per cent of orthodontic patients report pain experience during treatment (Kvam *et al.*, 1987; Scheurer *et al.*, 1996). The pain progression after initial archwire placement is well documented (Ngan *et al.*, 1989; Wilson *et al.*, 1989; Jones and Chan, 1992; Scheurer *et al.*, 1996; Miller *et al.*, 2007). Pain increases about 4 hours after insertion of the initial archwire, peaks after about 24 hours, and decreases for most patients to almost baseline after 1 week (Brown and Moerenhout, 1991). It has, however, been reported that 25 per cent of orthodontic patients still report pain after the first week (Scheurer *et al.*, 1996). In addition, Jones and Chan (1992) have found that the pain experience after the initial archwire placement was much greater than after premolar extractions.

Experiences of pain are always multidimensional and contain the sensory as well as the affective aspects expressed as intensity and discomfort and can also be influenced by several other factors, such as emotional, cognitive, environmental, and cultural factors. Several studies have also pointed out that pain associated with orthodontic treatment has a potential impact on daily life, mainly in the

area of psychological discomfort (Kvam *et al.*, 1987; Scheurer *et al.*, 1996; Firestone *et al.*, 1999). Many studies considering patients' perceptions of pain in orthodontics have however limitations since treatment procedures are not always standardized and the different aspects of pain and discomfort are not thoroughly investigated.

After the introduction of skeletal anchorage, researchers have primarily dealt with the technical aspects of the new technique and patients' perception of the surgical procedures (Gunduz *et al.*, 2004; Feldmann *et al.*, 2007a). However, from an evidence-based point of view, there is also a need for studies concerning patient acceptance of these new approaches in a long time perspective. Randomized controlled trials (RCTs) have become the criterion standard for evaluation in an evidence-based manner but there are few RCTs that compare pain experiences between different orthodontic techniques over time.

Consequently, the aim of this study was to evaluate perceived pain intensity, discomfort, and jaw function impairment during a standardized orthodontic treatment from baseline to the retention phase. Furthermore, using RCT methodology, the aim was to compare perceived pain and discomfort between orthodontic treatments combined with skeletal anchorage and treatment using conventional anchorage with headgear or transpalatal bar where it was

hypothesized that there will be no differences between groups.

Materials and methods

Subjects and study design

The inclusion criteria for all patients in this trial were adolescents with a permanent dentition in need of orthodontic treatment and a 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 where an additional anchorage on the maxillary first molars was considered necessary. Patients with experiences from other dental care systems or patients who had previous experience of orthodontic treatment were excluded. A total of 168 patients from the Orthodontic Clinic, Gävle, Sweden, were consecutively invited to enter this trial. Forty-eight patients declined (26 boys and 22 girls) to participate and the main reasons were fear for the surgical insertion of the skeletal anchorage device or reluctance to wear a headgear. These 48 patients were not significantly different considering gender and age than those who entered the trial. Consequently, 120 patients were recruited to the study. The study sample involved both patients with large overjets and patients with crowding and the need for additional anchorage varied from moderate to maximum.

The ethics committee of Uppsala University, Uppsala, Sweden, approved the informed consent form and protocol. After written consent was obtained from the patient and parent, the patients were randomized in blocks and stratified by gender into three different anchorage groups. The allocation sequence was computer generated by a statistician at the Centre for Research and Development, Uppsala University/Gävleborg County Council, Gävle, Sweden, and concealed in envelopes until randomization. Group A comprised 30 boys and 30 girls (mean age 14.3 years, SD 1.79) with a skeletally anchored (Onplant or Orthosystem implant) 1.2 mm springhard stainless steel bar anchorage. Since the suprastructure of the Onplant bars and the Orthosystem bars as well as their connection to the maxillary molars was mainly identical, these two anchorage systems were pooled together and analysed as one group. Group B comprised 15 boys and 15 girls (mean age 14.0 years, SD 1.72) with a headgear with the force direction corresponding medium pull and an approximate force of 400 g and group C comprised 15 boys and 15 girls (mean age 14.4 years, SD 1.65) with a soldered stainless steel transpalatal bar 2.0 × 1.0 mm.

All patients were treated according a standard straight-wire concept with a .022 slot size and continues light forces (McLaughlin *et al.*, 2001). Two experienced orthodontists performed the treatments on all patients. The recommended archwire sequence was 0.016 heat-activated nickel–titanium

(HANT), 0.018 stainless steel (SS), 0.019 × 0.025 HANT, and finally 0.019 × 0.025 SS. Leveling/aligning was achieved with lace-back ligatures and space closure was carried out with active tie backs. During the trial, all patients received a recommendation to use non-prescription analgesics at their own discretion.

Outcome measures

Self-report questions from questionnaires that previously had been found to be reliable and valid were used to assess pain intensity, discomfort, analgesic consumption, and jaw function impairment (Stegenga *et al.*, 1993; Feldmann *et al.*, 2007b). Since the three anchorage techniques involved or affected different sites of the jaws and face, there were separate questions for pain from the teeth (incisors and molars), jaws, neck, palate, and tongue.

The patients were evaluated by the questionnaires before treatment start (baseline), every evening during the first 7 days in treatment, at the first rescheduled visit after 6 weeks, at the end of the leveling/aligning phase (mean 8.2 months, SD 4.18), at the end of the space closure phase (mean 17.4 months, SD 5.03), and at the first rescheduled visit (6 weeks) in the retention phase. Instructions on how to complete the questionnaires were given and 5–10 minutes were needed to complete the questionnaires.

Pain, discomfort, and analgesic consumption

All 17 questions are presented in Table 1. Questions 1–8 and 11–15 were graded on a visual analog scale (VAS) with the end phrases ‘not at all’ and ‘worst imaginable’. Questions 9 and 16 had binary responses (yes/no) followed by open-ended questions (10 and 17; Feldmann *et al.*, 2007 b).

Table 1 Self-reported questions concerning pain intensity and discomfort from the teeth, jaws and face, and analgesic consumption.

Pain intensity
1. Do you have pain in your jaws?
2. Do you have pain in your neck?
3. Do you have pain in your tongue?
4. Do you have pain in your palate?
5. Do you have pain in your incisors when they are in contact?
6. Do you have pain in your incisors when they are not in contact?
7. Do you have pain from your molars when they are in contact?
8. Do you have pain from your molars when they are not in contact?
9. Do you ever have a headache?
10. If yes, how often do you have headache?
Discomfort
11. Do you experience tension in your teeth?
12. Do you experience tension in your jaws?
13. Do you experience soreness from your braces?
14. Has wearing braces affected your mood?
15. Has wearing braces affected your appearance?
Analgesic consumption
16. Have you used analgesics for pain from your teeth, jaws or face?
17. If yes, what kind of analgesic did you use?

Jaw function impairment

The scale included 18 items and is presented in Table 2. Eight questions related to mandibular function, seven to eating specific foods, and three to psychosocial activities. Each item was assessed on a four-point scale with the alternatives not at all, slightly, much, or extremely difficult (Stegenga *et al.*, 1993).

Statistical analysis

Median and interquartile range were calculated for each variable. Group differences were tested with the non-parametric Kruskal–Wallis and Mann–Whitney test for pain

Table 2 Self-reported questions concerning functional jaw impairment during orthodontic treatment.

Functional jaw impairment
If you have pain or discomfort in your teeth and jaws, how much does that effect
1. Your leisure time
2. Your speech
3. Your ability to take a big bite
4. Your ability to chew hard food
5. Your ability to chew soft food
6. Your schoolwork
7. Drinking
8. Laughing
9. Your ability to chew against resistance
10. Yawning
11. Kissing
Eating means taking a bite, chewing, and swallowing. How difficult is it for you to eat
36. Crispbread
37. Meat
38. Raw carrots
39. Roll
40. Peanuts
41. Apples
42. Cake

intensity and discomfort. Chi-square tests were used to determine differences between groups concerning functional jaw impairment, headache, and use of analgesics. For assessments of the relationship between VAS scores and age, the Spearman's rank correlation was utilized. The level of statistical significance was set at $P < 0.05$.

Results

One hundred and thirteen patients completed the trial. Six patients never started the orthodontic treatment, i.e. one moved from the area (group A), one became seriously ill (group C), and four were surgical failures (group A). In addition, one patient (group A) dropped out from the trial after leveling/aligning due to poor oral hygiene. Consequently, 54 patients in group A, 30 patients in group B, and 29 patients in group C completed the trial. The response rate for the separate questionnaires ranged from 94 to 100 per cent.

Pain intensity

Pain intensity for all 113 patients in the three anchorage groups from baseline to the retention phase peaked on day 2 and was almost back to baseline on day 7. The site with the highest pain scores during treatment was incisors in contact but the individual variation was large (Table 3). There was however no significant differences in perceived pain intensity between the three anchorage groups.

Pain intensity from molars in contact had the second highest pain scores over time and with significant differences between different anchorage groups (Table 4). Skeletal anchorage group A had significantly less pain intensity compared to the transpalatal bar group C the first 4 days in treatment and at the first rescheduled visit after 6 weeks but with no significant difference compared to the headgear

Table 3 Pain intensity from incisors in contact on a visual analogue scale (0–100) from baseline to retention phase during orthodontic treatment.

	Skeletal anchorage (group A), median (interquartile range)	Headgear anchorage (group B), median (interquartile range)	Transpalatal bar anchorage (group C), median (interquartile range)	Group differences
Baseline	0.0 (0.0–2.3)	1.0 (0.0–3.0)	1.0 (0.0–5.0)	NS
Day 1	24.0 (4.0–59.5)	41.0 (8.5–59.1)	48.5 (13.0–76.5)	NS
Day 2	46.0 (16.0–76.5)	43.8 (14.3–62.3)	57.0 (34.5–72.0)	NS
Day 3	35.5 (9.3–66.5)	30.8 (9.5–63.9)	45.0 (18.0–60.0)	NS
Day 4	27.0 (3.0–48.5)	15.0 (5.0–33.5)	26.0 (5.0–33.5)	NS
Day 5	11.8 (1.6–38.9)	14.0 (0.4–26.3)	16.0 (2.5–29.0)	NS
Day 6	8.0 (1.0–25.8)	5.8 (1.8–17.5)	7.0 (1.0–20.0)	NS
Day 7	2.3 (1.0–15.4)	2.0 (0.0–10.1)	7.5 (4.0–14.0)	NS
6 weeks	0.0 (0.0–1.0)	0.0 (0.0–2.0)	0.5 (0.0–3.0)	NS
End of leveling/aligning phase	0.0 (0.0–3.0)	0.0 (0.0–2.0)	1.0 (0.0–4.0)	NS
End of space closure phase	0.0 (0.0–1.4)	0.0 (0.0–2.0)	0.0 (0.0–2.5)	NS
Retention phase	0.0 (0.0–2.0)	0.0 (0.0–0.0)	1.0 (0.0–3.0)	NS

NS, not significant.

Table 4 Pain intensity from molars in contact on a visual analogue scale (0–100) from baseline to retention phase during orthodontic treatment.

	Skeletal anchorage (group A), median (interquartile range)	Headgear anchorage (group B), median (interquartile range)	Transpalatal bar anchorage (group C), median (interquartile range)	Group differences
Baseline	1.0 (0.0–2.8)	0.8 (0.0–3.4)	1.5 (0.0–13.0)	NS
Day 1	6.0 (1.0–18.8)	9.5 (4.0–27.0)	21.0 (8.9–44.3)	A–C: $P = 0.009$, A–B = NS, B–C = NS
Day 2	14.0 (2.5–44.0)	10.8 (2.0–31.8)	28.5 (8.0–54.0)	A–C: $P = 0.046$, B–C: $P = 0.049$, A–B = NS
Day 3	7.5 (1.0–29.0)	16.0 (2.0–48.0)	17.0 (4.0–60.0)	A–C: $P = 0.025$, A–B = NS, B–C = NS
Day 4	2.0 (0.0–24.8)	4.0 (0.0–24.0)	14.0 (5.0–28.0)	A–C: $P = 0.012$, A–B = NS, B–C = NS
Day 5	2.0 (0.0–7.5)	2.5 (0.0–11.3)	9.0 (2.5–29.0)	NS
Day 6	1.8 (0.0–11.0)	1.5 (0.0–13.0)	3.0 (1.0–20.0)	NS
Day 7	1.5 (0.0–4.8)	0.5 (0.0–4.0)	4.0 (2.0–14.0)	NS
6 weeks	0.0 (0.0–0.8)	0.0 (0.0–2.0)	0.5 (0.0–3.0)	A–C: $P = 0.013$, A–B = NS, B–C = NS
End of leveling/aligning phase	0.0 (0.0–2.8)	0.0 (0.0–1.0)	0.0 (0.0–2.0)	NS
End of space closure phase	0.0 (0.0–4.5)	0.0 (0.0–2.0)	0.0 (0.0–2.0)	NS
Retention phase	0.0 (0.0–2.0)	0.0 (0.0–0.0)	1.0 (0.0–3.0)	NS

NS, not significant.

group B. The headgear group B had significantly less pain compared to the transpalatal bar group C on day 2.

Pain intensity scores from the jaw, neck, tongue, palate, and incisors and molars not in contact were considerably lower compared to incisors and molars in contact but followed the same pain pattern over time. Pain scores from the palate and tongue, although very low (median 0.0–2.0), demonstrated significant differences between groups during the first 6 weeks in treatment with higher levels in groups A and C compared to group B ($P = 0.005–0.043$).

The occurrence of perceived headache was assessed at baseline, after the leveling/aligning phase, after space closure phase, and in the retention phase. Significantly fewer patients experienced headache after leveling/aligning ($P = 0.0019$), after space closure ($P = 0.008$), and after active treatment ($P = 0.004$) compared to baseline levels but with no differences between groups.

It was also interesting to notice that pain scores from all sites were significantly lower compared to baseline measurements at the first rescheduled visit after 6 weeks and stayed so during treatment. The individual variation in perceived pain intensity was however overall large. The pain scores ranged from no pain at all to worst imaginable pain (VAS 0–100).

Discomfort

Tension from jaws and teeth as well as soreness from the appliance followed the pain curve and peaked on day 2. There were no significant differences in tension from jaws and teeth between groups but the patients reported significantly more soreness in the skeletal anchorage group A and transpalatal bar group C compared to the headgear group on day 2 (A/B $P = 0.006$, B/C $P = 0.048$), day 3 (AB/C $P = 0.030$), day 5 (AB/C $P = 0.010$), after 6 weeks (AB/C $P = 0.028$), after leveling/aligning (A/C $P = 0.012$, B/C $P = 0.011$), and after space closure (AB/C $P = 0.036$).

Assessment of how much orthodontic treatment affected the patient's mood and appearance peaked at the first rescheduled visit after 6 weeks (median = 14.0; median = 99.0) and with no differences between groups. Dissatisfaction with appearance continued throughout treatment.

Analgesic consumption

Analgesic consumption for all patients followed the pain pattern and demonstrated no significant differences between groups. Thirty-eight per cent of all subjects used analgesics on day 2 while less than 5 per cent used analgesics from day 5. Acetaminophen (Paracetamol), ibuprofen, and aspirin were the most commonly used analgesics.

Jaw function impairment

Limitations in daily life and jaw function were throughout the trial low to moderate and with no differences between

anchorage groups. Compared to baseline, the orthodontic treatment did not interfere with leisure-time activities, schoolwork, drinking, laughing, yawning, and kissing. However, speech and eating habits were substantially affected during the whole treatment period. Chewing hard food, chewing against resistance, and eating crispbread, raw carrots, and apples ($P < 0.001$) were especially difficult.

Gender and age

Gender differences were few but from days 3 to 7, there was a distinct pattern that the girls complained significantly more about pain, discomfort, and difficulty to eat hard food compared to the boys. No correlation between pain assessments and age was found.

Discussion

An important finding of this study was that there were very few significant differences between patients' perceptions of skeletal and conventional anchorage systems. Skeletal anchorage aimed for osseointegration is a relatively new technique, which involves surgical installation of an anchorage device prior to the orthodontic treatment. Previous studies have confirmed that the surgical procedures are well tolerated by the patients (Feldmann *et al.*, 2007a; Sandler *et al.*, 2008; Baxmann *et al.*, 2010) but it is also important to explore the patients' experiences of skeletal anchorage devices throughout the whole treatment period and compare it to conventional anchorage systems. Consequently, this trial is in that aspect unique and examined and compared the patients' perception of pain, discomfort, and jaw function impairment during the orthodontic treatment from baseline to the end of treatment.

The site with the highest pain scores overall was incisors in contact but with no difference between anchorage groups. This result could be expected since the three groups in this aspect were comparable as the anchorage systems in no part involved the incisors. All anchorage systems were connected to the molars and molars in contact were the site with the second highest levels of pain over time and with significantly less pain intensity the first 4 days in treatment for the skeletal anchorage group compared to the transpalatal bar group but with no significant difference compared to the headgear group. Our hypothesis was therefore partly confirmed. The reported difference in pain intensity between these two groups with lower levels in the skeletal anchorage group compared to the transpalatal bar group was considered to be an effect of anchorage capacity. In general, the headgear group reported less pain from the molars (although not statistically significant) than did the transpalatal bar group, which was somewhat surprising since the headgear is used only during parts of the day and the force application therefore is of intermittent character. However, since we know that cooperation with the headgear was very good

during this first week of treatment, it is likely that the molars, exactly as in the skeletal anchorage group, were stabilized in both horizontal and vertical direction and therefore less painful.

Pain intensity from the palate and tongue was significantly higher in the skeletal anchorage group and the transpalatal bar group compared to the headgear group. This in combination with more discomfort in form of soreness was probably an effect of the inconvenience with palatal appliances. However, this did not affect the eating habits and speech.

In a previous article, we have reported that Onplant and Orthosystem implant (skeletal anchorage) were stable as anchorage during space closure after premolar extractions compared to headgear and transpalatal bar (Feldmann and Bondemark, 2008). Moreover, in another article, patient's perceptions of the surgical placement of these anchoring devices were comparable to or less than premolar extractions (Feldmann *et al.*, 2007a). The results from this study confirm that the patients' perceptions of these new anchoring devices are favourable also in a long time perspective.

The most expected finding in this study was that the pain pattern from teeth, jaws, neck, palate, and tongue for all patients in all three anchorage groups demonstrated a peak on day 2 and was back to baseline at day 7. This pattern is in agreement with other studies after insertion of an initial archwire (Ngan *et al.*, 1989; Scheurer *et al.*, 1996; Miller *et al.*, 2007). The use of pain relief also reflected the pain intensity pattern with the highest number of subjects (38 per cent) using analgesics on day 2 and less than 5 per cent from day 5. This finding is also in agreement with earlier studies concerning pain perception during orthodontic treatment (Scheurer *et al.*, 1996; Erdinc and Dincer, 2004; Krukemeyer *et al.*, 2009). Thorough information about pain during orthodontic treatment as well as pain management should therefore be routine measures before every orthodontic treatment.

Median values for pain intensity and discomfort were comparatively moderate, but some patients described it as the worst imaginable. It is well known that perception of pain is subjective, with no or little relation between the objective strength of a pain stimulus and the response and personal experience of pain. Moreover, perception of pain intensity is also subjective and influenced by many other factors, such as anxiety levels and motivational attitude (Sergl *et al.*, 1998; Doll *et al.*, 2000). It can also be noted that the oral health of the majority of the patients was excellent. This implies that most of the patients had no or little experience of ordinary dental care, which could have contributed to the range of pain intensity and discomfort. This lack of previous pain and discomfort experiences could also be the explanation to why the levels of pain and discomfort were generally lower at the first rescheduled visit after 6 weeks compared to baseline. The range was overall large, which indicate that the results would have benefit from a larger sample size.

Discomfort in form of tension and soreness followed the pain curve and was back to or below baseline values after 6 weeks for all patients in all three groups while affected mood and complaints about appearance followed an opposite pattern and peaked at the first rescheduled visit after 6 weeks. It was especially interesting that median value on how much the appliance affected appearance peaked at 99 of 100 and continuously stayed around 50 throughout the whole treatment. In this questionnaire, there was unfortunately only one question that covered this area but it certainly indicated that this is an important issue for our patients and can besides pain constitute a risk for patients to cease treatment in advance.

The most sensitive age is reported to be between 13 and 16 years (Tucker *et al.*, 1989), which coincide with the most common age for orthodontic treatment. In this study, there was no correlation between age and pain assessments probably because the subjects were relatively homogeneous in age. Gender is also considered to be a predictor of pain and previous studies from different areas show that girls are more sensitive to pain and are more likely to use pain control (Kvam *et al.*, 1987; Scheurer *et al.*, 1996). This was partly confirmed in this study since from days 3 to 7, girls complained more about pain, discomfort, and limitation in eating habits compared to boys.

Since pain, discomfort, and jaw function impairment are subjective experiences, patients' self-reports have suggested to be the criterion standard for such assessments. The scales used in this trial were VAS and verbal rating scale, which also earlier have been the most commonly used for assessments of pain and discomfort. These scales have also been proven to be valid for children and adolescents (Abu-Saad, 1984; McQuary and Moore, 1998).

The strengths of this study were that methods with documented good reliability and validity (Feldmann *et al.*, 2007b; Stegenga *et al.*, 1993) were used and that the material was homogenous in age and gender distribution and therefore representative for the most common age for adolescents undergoing orthodontic treatment. The age distribution of the patients was also similar to that in other studies of adolescents undergoing orthodontic treatment with fixed appliances (Brown and Moerenhout, 1991; Sergl *et al.*, 1998; Firestone *et al.*, 1999). In evidence-based medicine, the importance of patient-important outcomes has been emphasized i.e. measures that reflect meaningful outcomes for the patient. In this study, measures such as pain intensity, discomfort, and jaw function impairments, e.g. eating and chewing, reflect such domains. In addition, the selection bias was avoided since consecutive patients were invited and randomized into three different anchorage groups. The treatments were standardized and the only variable that differed between the three groups was the anchorage system. Since the different anchorage systems involved different parts of the jaws and face, for example, for group B, the head and neck

were involved and for group A, the anchorage system was inserted in the palate, separate questions considering pain intensity from different sites were used. Even if there are a few reports (Scheurer *et al.*, 1996; Erdinc and Dincer, 2004) confirming that pain and discomfort are mainly localized at the teeth, it can be pointed out that most studies have assessed pain as overall pain experiences, which diminish the possibility to localize from where the pain is originated.

Conclusions

There were very few significant differences between patients' perceptions of skeletal and conventional anchorage systems during orthodontic treatment. Consequently, these new appliances were well accepted by the patients in a long time perspective and can thus be recommended.

Funding

This work was supported by the Centre for Research and Development, Uppsala University/Gävleborg County Council, Gävle, Sweden.

Acknowledgements

We thank statistician Hans Högberg for valuable help with the statistical analysis.

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