Original Article

A randomized controlled trial of self-perceived pain, discomfort, and impairment of jaw function in children undergoing orthodontic treatment with fixed or removable appliances

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ABSTRACT

Objective: To compare patients' perceptions of fixed and removable appliance therapy for correction of anterior crossbite in the mixed dentition, with special reference to perceived pain, discomfort, and impairment of jaw function.

Materials and Methods: Sixty-two patients with anterior crossbite and functional shift were recruited consecutively and randomized for treatment with fixed appliances (brackets and archwires) or removable appliances (acrylic plates and protruding springs). A questionnaire, previously found to be valid and reliable, was used for evaluation at the following time points: before appliance insertion, on the evening of the day of insertion, every day/evening for 7 days after insertion, and at the first and second scheduled appointments (after 4 and 8 weeks, respectively).

Results: Pain and discomfort intensity were higher for the first 3 days for the fixed appliance. Pain and discomfort scores overall peaked on day 2. Adverse effects on school and leisure activities were reported more frequently in the removable than in the fixed appliance group. The fixed appliance group reported more difficulty eating different kinds of hard and soft food, while the removable appliance group experienced more speech difficulties. No significant intergroup difference was found for self-estimated disturbance of appearance between the appliances.

Conclusions: The general levels of pain and discomfort were low to moderate in both groups. There were some statistically significant differences between the groups, but these were only minor and with minor clinical relevance. As both appliances were generally well accepted by the patients, either fixed or removable appliance therapy can be recommended. (*Angle Orthod.* 2016;86:324–330.)

KEY WORDS: Orthodontic; Treatment; Pain; Discomfort

INTRODUCTION

Pain and discomfort are recognized side effects of orthodontic treatment.[1,2] Pain starts about 4 hours after insertion of the appliance, peaks between 12 hours and 3 days after insertion and then decreases for up to 7 days.[2–5] Almost all patients (95%) report and suffer pain or discomfort 24 hours after insertion of fixed appliances, and fixed appliances may produce higher pain responses than removable appliances.[6–8] Pain scores tend to be higher in anterior than in posterior teeth.[4]

Several studies have pointed out that pain associated with orthodontic treatment has a potential impact on daily life, primarily as psychological discomfort.[6,9] Moreover, swallowing, speech, and jaw function can be altered during orthodontic treatment.[4,7] Chewing hard food can be difficult, and reduced masticatory ability is reported 24 hours after fixed appliance insertion, with a return to baseline 4 to 6 weeks later.[4,10]

Both fixed and removable appliances have been shown to be equally effective in correcting anterior crossbite in the mixed dentition.[11,12] Other aspects of treatment, such as patient perceptions, now warrant investigation. To our knowledge, there are no published

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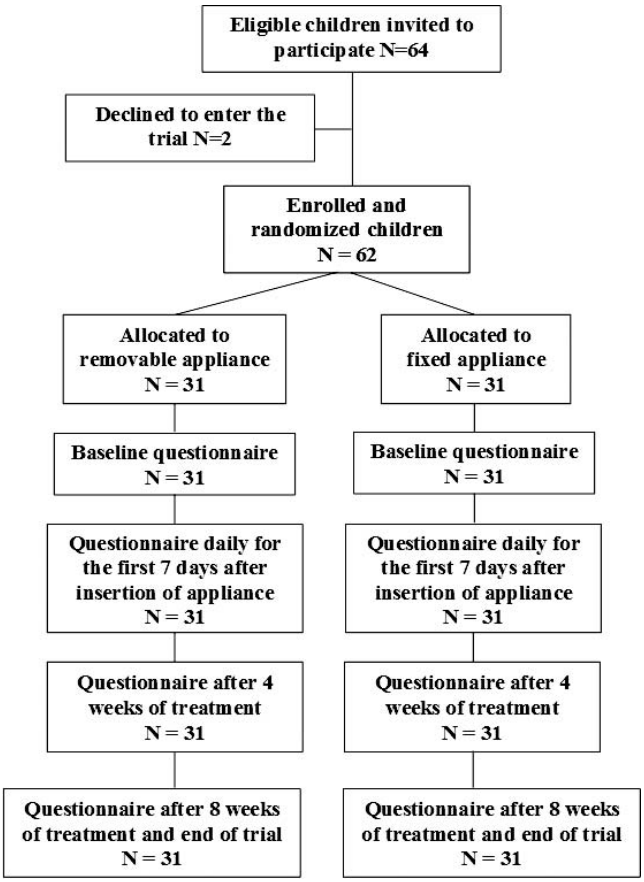

Figure 1. Flow diagram of the children and when the questionnaires were evaluated.

studies on pain, discomfort, or impairment of jaw function in relation to treatment of anterior crossbite by fixed or removable appliances. Therefore, the aim of this study was to evaluate and compare perceived pain, discomfort, and impairment of jaw function associated with correction of anterior crossbite in the mixed dentition, using fixed and removable appliances. The hypothesis to be tested was that there are minor differences between fixed and removable appliance therapy in terms of perceived pain intensity, discomfort, and impairment of jaw function.

MATERIALS AND METHODS

Subjects and Study Design

In all, 64 patients from the Department of Orthodontics, Faculty of Odontology, Malmö University, Malmö, Sweden, and from one Public Dental Health Service Clinic in Malmö, Skane County Council, Sweden, were consecutively recruited between 2004 and 2009. Sixty-two consented to participate in the study (Figure 1). All patients met the following inclusion criteria: early to late mixed dentition, anterior crossbite with functional shift (at least one maxillary incisor causing functional shift), no cleft lip/palate or syndrome patients, moderate space deficiency in the maxilla (ie, up to 4 mm), a no-extraction treatment plan, an ANB angle $>0^\circ$ (to avoid skeletal Class III patients), and no previous orthodontic treatment.

The ethics committee of Lund University, Lund, Sweden (Dnr: 334/2004), approved the protocol, and all patients at the clinic who met the inclusion criteria were invited to enter the study.

After the patients and parents received written information about the study and written consent was obtained by the parents, the 62 participants were randomized by an independent person in blocks of 10 for treatment by removable (RA) or fixed (FA) appliances. Seven opaque envelopes were prepared with 10 sealed notes in each (5 notes for each group). Thus, for every new patient in the study, a note was randomly extracted from the open envelope.

Treatment Methods

Two orthodontists and one postgraduate student in orthodontics, under supervision of an orthodontist, treated all patients according to a preset concept.

In group FA, the fixed appliance consisted of stainless-steel brackets (Victory, slot 0.022 inches, APC PLUS adhesive coated bracket system, 3M Unitek, Monrovia, Calif.). Usually, eight brackets were bonded to the maxillary incisors, deciduous canines, and either to the first deciduous molars or the first premolars. All patients were treated according to a standard straight-wire concept designed for light forces.[13] Archwire sequence was 0.016-inch heat-activated nickel-titanium (HANT), 0.019 $\times$ 0.025-inch HANT, and finally 0.019 $\times$ 0.025-inch stainless-steel wire. To avoid vertical interlock between incisors, composite was bonded to the occlusal surfaces of both mandibular second deciduous molars. Progress was evaluated every 4 weeks, until anterior crossbite was corrected.

In group RA, the removable appliance comprised an acrylic plate, with a protrusion spring for each incisor in anterior crossbite, bilateral occlusal coverage of the posterior teeth, an expansion screw, and stainless-steel clasps on either the first deciduous molars or first premolars and the permanent molars. The protrusion springs were activated once a month until normal incisor overjet was achieved. The patient was firmly instructed to wear the appliance day and night, except for meals and toothbrushing (ie the appliance was to be worn at least 22 hours a day). Progress was evaluated every 4 weeks, until anterior crossbite was corrected.

Outcome measures were sourced from questionnaires that have previously been shown to be valid and reliable.[14] Two new questions were included ("Do you

Table 1. Self-reported Questions on Pain and Discomfort From the Teeth, Jaws, Face, and Headache Pain

1. Do you have pain in your incisors when they are in contact?
2. Do you have pain in your maxillary incisors when they are not in contact?
3. Do you have pain in your lip?
4. Do you have pain in your palate?
5. Do you have pain in your tongue?
Discomfort
6. Do you experience tension in your maxillary incisors?
7. Do you experience tension in your jaws?
Headache
8. Do you ever have a headache? yes/no
9. If yes, is your headache sporadic, frequent, or constant?
10. If you answered that your headache occurs frequently or constantly, how often have you had a headache in the last 3-month period? 1–3 times a month, once or twice a week, every other day?

Table 2. Self-reported Questions on Impairment of Jaw Function

If you have pain or discomfort in your teeth and jaws, how much does that affect?
1. Your leisure time
2. Your speech
3. Your ability to bite with your front teeth
4. Your ability to chew hard food
5. Your ability to chew soft food
6. Your schoolwork
7. Drinking
8. Laughing
Eating requires taking a bite of food, chewing, and swallowing it. How difficult is it for you to eat?
9. Crisp bread
10. Meat
11. Raw carrots
12. Bread roll
13. Peanuts
14. Apples
15. Cake

have pain in your lip?"; "Do you think your orthodontic appliance disturbs your appearance?").

The patients in both groups completed the questionnaires at a number of time points: before insertion of the appliance (baseline), later on the day of insertion and every day/evening for the following seven days, at the first scheduled appointment after 4 weeks and finally at the second scheduled appointment, 8 weeks after insertion of the appliance (Figure 1). The patients were given instructions on how to complete the questionnaire. About 10 minutes were needed to complete the questionnaire. At baseline and at the first and second scheduled appointments, the patients filled in the questionnaires at the clinic. During the first 7 days of treatment, the patients filled in the questionnaires daily at home. The evaluations of the questionnaires were blinded (ie, the assessor was unaware of the group to which the patient belonged).

Pain and Discomfort

All questions are presented in Table 1. Questions 1 to 7, on pain and discomfort, were graded on a visual analogue scale (VAS) with the end phrases "no pain" and "worst pain imaginable" or "no tension" and "worst tension imaginable."[14] Question 8 had a binary response (yes/no). For questions 9 and 10, there were multiple-choice responses, whereby one answer was to be selected from the 3 presented (Table 1).

Impairment of Jaw Function

There were 15 questions on jaw function: 3 on mandibular function, 5 on psychosocial activities, and 7 on eating specific foods (Table 2). Each item was assessed on a 4-point scale, with the options "not at all," "slightly," "very difficult," or "extremely difficult."[14]

Self-estimated Disturbance to Appearance

One question related to the patient's perception of the influence of the appliance on personal appearance: "Do you think your orthodontic appliance disturbs your appearance?" and was graded on a VAS with the end phrases "not at all" and "very much." The question was answered 8 weeks after insertion of the appliance.

Statistical Analysis

Median values and interquartile ranges were calculated for each pain and discomfort assessment variable and the variable for self-estimated disturbance to appearance. Because the normality test with Kolmogorov-Smirnov indicated that a nonparametric test should be used, intergroup differences for these variables were tested with the nonparametric Mann-Whitney test.

For categorical variables, Pearson chi-square tests were used to determine intergroup differences in impairment of jaw function, headache, and affected daily activities. Fisher exact test was used when the expected cell value in a 2×2 table was less than 5. Differences with a P value less than 5% ($P < .05$) were considered statistically significant.

RESULTS

All 62 randomized patients completed the trial (Figure 1). Group FA comprised 12 girls and 19 boys (mean age, 10.4 years; SD, 1.65) and group RA, 13 girls and 18 boys (mean age, 9.1 years; SD, 1.19). The groups were similar in gender distribution and the number of incisors in anterior crossbite before treatment. The average treatment time, including 3 months'

Table 3. Pain Intensity on a Visual Analogue Scale (0–100) From Baseline on Day of Insertion and up to 8 Weeks of Orthodontic Treatment With Fixed or Removable Appliances (Groups FA and RA)[a]

1. Do You Have Pain in Your Incisors When They are in Contact?			
	Group FA Median (Interquartile Range)	Group RA Median (Interquartile Range)	Group Differences FA/RA *P*
Baseline	0.0 (0.0–0.0)	0.0 (0.0–0.0)	.185
Day 1	27.0 (5.2–49.8)	5.0 (0.0–36.0)	.096
Day 2	53.5 (9.5–73.0)	12.5 (0.0–46.7)	.017*
Day 3	15.0 (0.0–48.2)	3.0 (0.0–28.5)	.373
Day 4	7.0 (0.0–38.2)	0.0 (0.0–18.2)	.304
Day 5	0.0 (0.0–14.2)	0.0 (0.0–16.0)	.756
Day 6	0.0 (0.0–11.2)	0.0 (0.0–10.0)	.638
Day 7	0.0 (0.0–10.0)	0.0 (0.0–13.0)	.412
4 weeks	0.0 (0.0–10.2)	0.0 (0.0–1.7)	.475
8 weeks	0.0 (0.0–0.0)	0.0 (0.0–0.0)	.330

[a] Median, interquartile range, and intergroup differences analyzed by the Mann-Whitney test.
* $P < .05$; ** $P < .01$; *** $P < .001$.

retention, was 5.5 months (SD, 1.4) in the FA group and 6.9 months (SD, 2.8) in the RA group.

The response rate for the separate questions ranged from 90% to 100%. No gender differences were found for the responses to any of the questions. At baseline (ie, before insertion of the appliances), there were no significant intergroup differences in responses to any of the questions.

Pain Intensity

The general intensity of pain was low to moderate in both groups, although on day 2, a few children, primarily in the FA group, reported high pain levels. Also, the intensity of pain was significantly higher for fixed appliances on day 1 when maxillary incisors were not in contact ($P = .040$). Furthermore, on day 2, when maxillary incisors were in contact, the fixed appliance revealed significant higher pain intensity than the removable appliance (Table 3). Overall, the pain intensity peaked after 2 days of treatment in both groups. After 2 days of treatment, no significant difference was found in pain intensity between the groups.

Although the intensity of pain was low, the patients in group RA experienced more pain in their palate ($P = .021$) after 6 days of treatment. After 7 days, group RA also reported more pain from the lips than the FA group ($P = .040$).

The difference in pain intensity between group RA and group FA was nonsignificant for any pain-related question at both rescheduled appointments, after 4 and 8 weeks of treatment. Very low levels of pain were experienced in the tongue at any time for both appliances.

Overall, none of the patients reported any use of analgesics during the trial period.

Table 4. Discomfort on a Visual Analogue Scale (0–100) From Baseline on Day of Insertion and up to 8 Weeks of Orthodontic Treatment With Fixed or Removable Appliances (Groups FA and RA)[a]

6. Do You Experience Tension in Your Teeth?			
	Group FA Median (Interquartile Range)	Group RA Median (Interquartile Range)	Group Differences FA/RA *P*
Baseline	0.0 (0.0–0.0)	0.0 (0.0–0.0)	.329
Day 1	29.0 (0.0–53.0)	6.5 (0.0–29.0)	.056
Day 2	51.5 (6.7–72.2)	11.0 (0.0–34.5)	.015*
Day 3	15.5 (0.0–47.0)	3.5 (0.0–14.7)	.036*
Day 4	0.0 (0.0–34.7)	0.0 (0.0–10.0)	.323
Day 5	0.0 (0.0–10.5)	3.0 (0.0–11.5)	.462
Day 6	0.0 (0.0–0.0)	0.0 (0.0–11.0)	.007**
Day 7	0.0 (0.0–0.0)	0.0 (0.0–10.2)	.001***
4 weeks	8.5 (0.0–19.2)	0.0 (0.0–15.0)	.221
8 weeks	0.0 (0.0–9.0)	0.0 (0.0–0.0)	.335

[a] Median, interquartile range, and intergroup differences analyzed by the Mann-Whitney test.
* $P < .05$; ** $P < .01$; *** $P < .001$.

Discomfort

The general self-perceived tension or discomfort revealed low to moderate levels of discomfort for both groups and peaked for both appliances on day 2. On days 2 ($P = .015$) and 3 ($P = .036$), patients in group FA experienced more tension in their teeth than patients in group RA (Table 4). On the other hand, patients in group RA experienced slightly more tension in their teeth after 6 ($P = .007$) and 7 days of treatment ($P = .001$; Table 4). At no time during treatment was there any significant intergroup difference with respect to tension in the jaws.

Headache

Before treatment, 5 patients in group RA reported headache 1 to 3 times a month, and in group FA, 5 patients suffered from headache 1 to 3 times a month and 2 patients once or twice a week. After 8 weeks of treatment, 3 of the patients in group RA and 2 in group FA declared that they suffered from headache 1 to 3 times a month. No significant difference between the groups was found at any time.

Impairment of Jaw Function

Daily activities. Seven patients in group RA and three in group FA reported that schoolwork was adversely affected 1 day after the appliance was inserted, with no significant intergroup difference. After 3 days of treatment, schoolwork was reported to be adversely affected by five children in group RA but none in group FA ($P = .022$). After 4 or more days of treatment, two to five patients in the RA group reported that treatment adversely affected their schoolwork.

After 1 day of treatment, leisure activities were reported to be affected in five of the patients in group RA and six patients in group FA. In group RA, the effect on leisure activities persisted to the final evaluation, while in group FA, none reported effects after 5 days of treatment. Thus, leisure activities were significantly more affected in group RA than FA after 6 days ($P = .010$) and 4 weeks of treatment ($P = .004$).

Speech and laughter. Speech was mostly affected after 2 days of treatment, and difficulties were reported significantly more frequently in group RA (22 patients affected) than in group FA (1 patient affected; $P = .001$). After 3 days of treatment, none of the patients in group FA reported affected speech, while in group RA, 10 patients reported a persistent effect on speech after 8 weeks of treatment ($P = .001$).

Only a few patients reported difficulty laughing during treatment, but on the day of insertion, patients in group FA experienced significantly more difficulty laughing than those in group RA ($P = .040$).

Chewing, eating, and drinking. During the first 3 days of treatment, patients in group FA experienced significantly more difficulty biting and chewing hard and soft food than those in group RA (P values between .000 and .031). Eating a carrot or apple was reported to be the most difficult, and patients in group FA still perceived these as significantly more difficult to eat at the 4- and 8-week appointments (P values between .019 and .003). The ability to drink was little affected, with no significant difference between the groups.

Self-estimation of Disturbance to Appearance

No significant intergroup difference was found for self-estimated disturbance of appearance because of the appliances.

DISCUSSION

In evidence-based dentistry, it is important to highlight aspects of treatment that are important to the patient. Patients undergoing orthodontic appliance therapy may experience pain, discomfort, and impairment of jaw function. The main finding of this trial was that there were some minor, statistically significant differences between patients' perceptions of fixed and removable appliances, but this seems to have minor clinical relevance since both appliances were generally well accepted by the patients and either appliance can be recommended. Thus, the results confirmed the hypothesis that there were minor differences between fixed and removable appliance therapy with respect to perceived pain intensity, discomfort, and impairment of jaw function.

It was also noted that the reported general levels of pain intensity and discomfort were low to moderate in both groups, although a few children reported high levels. Overall, the intensity of pain in the incisors peaked after 2 days of treatment in both groups; after 4 days of treatment, no significant difference was found in pain intensity between the groups. This finding is in accordance with reports from earlier studies.[6,15] However, it is of interest to note that none of the patients reported any use of analgesics during the trial period, even though patients in group FA reported high levels of pain intensity on day 2 (Table 3). This finding was unexpected and is not consistent with reports from previous studies in which medication for relief of pain is common during the first week of treatment with orthodontic appliances.[4,6] That the patients in the present study did not use any analgesics may be attributable to the fact that the self-perceived intensity of pain was low to moderate.

Pain intensity, discomfort, and impairment of jaw function are subjective experiences, self-reported by patients. The VAS and verbal rating scales are most

commonly used to asses these experiences; the validity of such scales has also been verified in children.[16] An important strength of this study was that the questionnaire had previously been shown to have good reliability and validity.[14] Although some of the patients in this trial were younger than those evaluated in the previous validity study[14] and thereby may reduce the validity, the overall validity for our trial was considered fairly good. Another strength was that no attrition occurred during the trial, and the response rate to the individual questions in the questionnaire was greater than 90%.

Notwithstanding the instruction that the patients/children should fill in the questionnaires by themselves at home, we have no control over whether the parents helped the children or not. Of course, if the children were helped, this limitation may have biased the answers.

No gender differences were found in this study, which agrees with another study,[17] whereas other studies have indicated that girls are more prone to pain.[4,6]

In a previous review, it was claimed that fixed appliances tend to induce painful responses because of the application of constant force, whereas with removable appliances, the application of force is more intermittent.[2] Our study indicated similar findings, namely, short and more intense pain during the first 2 days of fixed appliance therapy and a somewhat more prolonged, less intense pain with the removable appliance.

It was of particular interest that the number of patients who suffered from headache before treatment decreased during treatment. It may be speculated that elimination of the anterior functional shift during treatment was a contributing factor.

Patients in both groups reported most difficulty chewing hard food on day 2, and this correlated well with the high scores for pain intensity in the incisors. The fixed appliance group reported more pain than the removable appliance group when eating, and this might be due to the fact that patients in the removable appliance group were instructed to remove the appliance during meals. On the other hand, patients in the removable appliance group experienced more problems with speech during the trial. Conceivably, the removable appliance reduces and alters the intraoral space, implying difficulty for the tongue in creating the speech sounds. Speech problems in the removable appliance group may also be a contributing factor to the negative effect on schoolwork and leisure activities reported in this group.

Self-estimated disturbance of appearance associated with appliance therapy was low overall. Thus, neither fixed nor removable appliances seemed to affect the patients' self-estimate of appearance.

CONCLUSIONS

- The general levels of pain intensity and discomfort were low to moderate in both groups.
- The level of pain and discomfort intensity was higher for the first 3 days in the fixed appliance group and peaked on day 2 for both appliances.
- Adverse effects on school and leisure activities as well as speech difficulties were more pronounced in the removable than in the fixed appliance group, whereas in the fixed appliance group, patients reported more difficulty eating different kinds of hard and soft food.
- Thus, while there were some statistically significant differences between patients' perceptions of fixed and removable appliances, these differences were only minor and seem to have minor clinical relevance. As fixed and removable appliances were generally well accepted by the patients, both methods of treatment can be recommended.

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