Pain and discomfort during the first week of rapid maxillary expansion (RME) using two different RME appliances: A randomized controlled trial

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ABSTRACT
Objectives: To evaluate and compare perceived pain intensity, discomfort, and jaw function impairment during the first week with tooth-borne or tooth-bone–borne rapid maxillary expansion (RME) appliances.

Materials and Methods: Fifty-four patients (28 girls and 26 boys) with a mean age of 9.8 years (SD 1.28 years) were randomized into two groups. Group A received a conventional hyrax appliance and group B a hybrid hyrax appliance anchored on mini-implants in the anterior palate. Questionnaires were used to assess pain intensity, discomfort, analgesic consumption, and jaw function impairment on the first and fourth days after RME appliance insertion.

Results: Fifty patients answered both questionnaires. Overall median pain on the first day in treatment was 13.0 (range 0–82) and 3.5 (0–78) for groups A and B, respectively, with no significant differences in pain, discomfort, analgesic consumption, or functional jaw impairment between groups. Overall median pain on the fourth day was 9.0 (0–90) and 2.0 (0–71) for groups A and B, respectively, with no significant differences between groups. There were also no significant differences in pain levels within group A, while group B scored significantly lower concerning pain from molars and incisors and tensions from the jaw on day 4 than on the first day in treatment. There was a significant positive correlation between age and pain and discomfort on the fourth day in treatment. No correlations were found between sex and pain and discomfort, analgesic consumption, and jaw function impairment.

Conclusions: Both tooth-borne and tooth-bone–borne RME were generally well tolerated by the patients during the first week of treatment. (Angle Orthod. 2017;87:391–396)

KEY WORDS: Rapid maxillary expansion; Pain and discomfort; Mini-implants; Questionnaire

INTRODUCTION
Rapid maxillary expansion (RME) is a common procedure in young children with a constricted maxilla and transverse discrepancies between the maxilla and the mandible.1,2 The primary goal of RME is to maximize dentofacial orthopedics and minimize orthodontic movement, but a recently published systematic review3 indicates that the skeletal effects (ie, the opening of the midpalatal suture) account for only approximately 20%–50% of the total screw expansion, meaning that the dentoalveolar effects in terms of molar tipping and alveolar bending account for over 50% of the total effect. To minimize these dental side effects, which likely increase the risk of relapse, skeletally anchored RME appliances have been introduced.4–6

Pain and discomfort are well-known side effects of orthodontic treatment with fixed appliances,7–9 but few studies10–12 have explored pain and discomfort during RME treatment. These few studies have concluded that most children undergoing RME report pain, which generally occurs during the initial phase and diminishes thereafter. The highest pain levels were reported during the first 10 activations and peaked on days 3 and 4. Activation protocols with two turns/d result in
greater pain levels than do protocols with only one turn/ 

d.\textsuperscript{11,13} With the introduction of skeletally anchored RME 
appliances, the question arises of how patients 
experience this new design, considering that they are 
mostly quite young. Earlier studies\textsuperscript{14,15} indicate that 
adolescent patients have very good tolerance of the 
sertion of mini-implant anchors both interradicularly 
and in the palate. These studies also concluded that 
age was not a predictor of pain and discomfort. To our 
knowledge, however, no studies have explored pain 
intensity and discomfort during treatment with skele-
tally anchored RME appliances.

The aim of this study was to evaluate and compare 
perceived pain intensity, discomfort, and jaw function 
impairment during the first week with tooth-borne or 
tooth-bone–borne RME (hybrid hyrax expander) appli-
ances; we hypothesized that there would be no 
differences between these two RME treatment modal-
ities.

MATERIALS AND METHODS

Subjects and Study Design

The regional ethical review board in Uppsala, 
Sweden, which follows the guidelines of the Declara-
tion of Helsinki, approved the study protocol (Dnr: 
2009/334). After receiving oral and written information 
about the clinical trial, both the patients and their 
parents/guardians signed informed consent forms. 

Fifty-four consecutive patients (28 girls and 26 boys) 
with a mean age of 9.8 years (SD 1.28 years) 
examined at the Postgraduate Dental Education 
Centre, Department of Orthodontics, Region Orebro 
County, Sweden, who met the eligibility criteria were 
recruited from September 2010 through December 
2015 and participated in this study.

The following inclusion criteria had to be fulfilled by 
the participants enrolled in the study:

• uni- or bilateral crossbite with constricted maxilla and 
• age at diagnosis of 8–13 years, with dental stage in 
the early or late mixed dentition.

Patients with previous or ongoing orthodontic treat-
ment, craniofacial syndromes, or cleft lip or palate were 
considered ineligible for the study.

The randomization procedure was as follows: a 
computer-generated randomization list was created 
using SPSS software (version 17.0; SPSS, Chicago, 
Ill) and stored with a research secretary at the 
Postgraduate Dental Education Centre. Each time a 
patient gave his/her consent, the secretary was 
contacted by e-mail and the information about which 
type of expander the patient should receive was 
acquired. After informed consent was obtained from 
both patients and their parents/guardians, the patients 
were randomized into two groups: group A was treated 
with a conventional banded hyrax expander (n = 27) 
(Figure 1a) and group B with a hybrid hyrax expander 
with two 1.7 × 8–mm miniscrew implants (Orthoeasy\textsuperscript{t}; 
Forestadent, Pforzheim, Germany) attaching the ex-
pander to the palate surface (n = 27) (Figure 1b).

Both expanders were activated two quarter turns per 
day (0.5 mm) until the palatal cusps of the maxillary 
first molars contacted the buccal cusps of the 
mandibular first molars. The patients were advised to 
use nonprescription analgesics at their own discretion. 
All patients in both groups were treated by the same 
orthodontist. The questionnaires were analyzed by one 
of the coauthors, who was blinded to the study and 
performed no orthodontic treatment on the patients.

Questionnaires

The questionnaires included self-report questions 
concerning pain intensity, discomfort, analgesic con-
sumption, and jaw function impairment on the first and
In addition, three questions, modified for this study, were included in the questionnaire for the first day in treatment. These questions concerned the patient’s experiences of pain and discomfort during the placement of the appliances and whether any moments were particularly unpleasant. The VAS was measured to the nearest 0.5 mm using a standard 100-mm metric ruler.

**Statistical Analysis**

Median value, interquartile range, and range were calculated for each variable. Differences between groups were tested using the nonparametric 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 within groups were tested using the Wilcoxon signed-rank test. Differences with a $P$ value of less than 5% ($P < .05$) were considered statistically significant.

**RESULTS**

Fifty of the enrolled 54 patients completed both questionnaires. One boy and one girl each in group A and group B did not submit their questionnaires despite several reminders. Consequently, group A consisted of 25 patients (ie, 12 boys and 13 girls) with a mean age of 9.7 years (SD 1.39 years), and group B comprised 25 patients (ie, 12 boys and 13 girls) with a mean age of 10.0 years (SD 1.16 years). There were no significant differences in age and gender between the two groups. The overall response rate was 91%.

**Pain Intensity and Discomfort**

Patient assessments of pain and discomfort during placement of the RME appliance were low overall and did not differ significantly between groups. Median values for pain were 8.0 (range 0–50) and 3.0 (0–82) for groups A and B, respectively, and median values for discomfort were 17.0 for both groups (range 0–63 and 0–100, respectively). Twenty-two of 50 study patients replied that they had experienced a particular part of the placement to be especially unpleasant, but with no significant difference between groups. The main complaint concerned pressure when the RME appliances were cemented.

Overall pain and pain from molars and incisors on the first and fourth days in treatment are presented in Figure 2. There were no significant differences in pain levels between groups, although patients with the conventional hyrax appliance generally scored high-
er. There were also no significant differences in pain levels between days 1 and 4 in group A. Group B, however, scored significantly lower concerning pain from molars ($P = .042$) and incisors ($P = .024$) on day 4 compared with the first day in treatment. Pain levels from the jaw ($M = 1.0$ for both groups), palate ($M = 2.0$ for both groups), and tongue ($M = 0$ and $1.0$, respectively, for groups A and B) were minor and did not differ significantly within or between groups.

Discomfort values, expressed as tension and soreness on the first and fourth days in treatment, are presented in Figure 3. There were no significant differences in discomfort between groups. There were also no significant differences in discomfort between days 1 and 4 in group A, but group B scored significantly lower with regard to jaw tension ($P = .001$) on day 4.

**Analgesic Consumption**

Analgesic consumption was low and did not differ significantly within or between groups (Table 2). Paracetamol and ibuprofen were the most commonly used analgesics.

**Jaw Function Impairment**

Daily activities such as schoolwork and leisure time were generally not affected by treatment with RME appliances. However, several patients in both groups complained about great to extreme difficulties in eating hard food, meat, and crisp bread, but with no significant differences between groups.

**Age and Gender**

There were significant positive correlations between age and overall pain ($P = .017$), pain from incisors ($P = .014$), tension from teeth ($P = .006$), soreness ($P = .028$), and pain when laughing ($P = .042$), yawning ($P = .030$), and swallowing ($P = .022$) on the fourth day in treatment. There were very few gender differences in this study, although the girls complained more about tension from the teeth than did the boys ($P = .048$).

**DISCUSSION**

To our knowledge, this is the first study comparing pain intensity and discomfort during RME treatment with a conventional hyrax appliance vs a skeletally anchored appliance. The most important finding was
that there were no significant differences in pain and discomfort during the first week of RME treatment between groups. This is in agreement with our hypothesis and an important result when considering future RME treatment anchored on mini-implants.

Pain intensity levels reported here were low overall compared with those reported in studies examining pain during conventional RME treatment\textsuperscript{10,13} and pain in the first week with a fixed appliance,\textsuperscript{7–9} indicating that RME treatment, both conventional and skeletal, is well accepted by patients in this young age group. Analgesic consumption was consequently low.

The site with the highest pain scores in both groups was the first maxillary molars, which is logical because the appliances are connected to the molars and because the expansion pattern during RME results in dentoalveolar expansion (including dental tipping) being larger than skeletal expansion.\textsuperscript{3} Pain scores from the palate, however, were almost negligible in both groups, even though the appliance in group B was anchored on two miniscrews in the anterior palate.

The studied patients completed a questionnaire the day after the appliance was cemented (activation day 1) and on day 4. Earlier studies\textsuperscript{10–12} of pain during conventional RME treatment have stated that pain and discomfort levels peaked on days 3 and 4 and thereafter remained relatively constant. The present results, however, indicate significantly lower levels of pain from molars and incisors and of jaw tension on day 4 than on day 1 in the group with skeletally anchored appliances. It could be speculated that the center of applied force induced by each activation is closer to the midpalatal suture in the hybrid RME than the conventional appliance, which might relieve and minimize the magnitude of the force distributed to the dentition. This could explain why patients in the hybrid group experienced less pain and thus assigned lower scores.

From earlier studies\textsuperscript{14} we know that pain following miniscrew placement is concentrated in the first days after insertion and is almost negligible after 1 week. We therefore consider the risk of confounding factors due to miniscrew placement to be low because the patients in group B had their miniscrews placed 10–14 days before the appliance was cemented. Pain during placement also did not differ significantly between groups.

Median values of pain intensity and discomfort during the first week of RME treatment were low, but some patients described the pain and discomfort as the worst imaginable. Perception of pain intensity is subjective and is influenced by many factors, such as anxiety levels and motivational attitude.\textsuperscript{18} However, as the oral health of most studied patients was excellent, they had little or no experience with ordinary dental care, which could have contributed to the range of experienced pain intensity and discomfort.

There was no significant difference in pain levels between the groups in this study, although the values were generally lower in the skeletal group. This could be due to the force distribution mechanics discussed earlier.

Although some studies\textsuperscript{7,19} have reported that girls report more pain and discomfort than do boys, we found no major gender differences in experienced pain intensity and discomfort in this study. Interestingly, there was a positive correlation between age and overall pain, pain from incisors, tension from teeth, soreness, and pain when laughing, yawning, and swallowing, but only on the fourth day in treatment. With increasing age, interdigitation of the midpalatal suture increases,\textsuperscript{20} meaning that somewhat higher forces are required to induce expansion. This might give rise to higher pain, discomfort, and tension scores in older patients.

The studied patients were homogeneous in age and gender distribution and were therefore representative of the most common age for RME treatment as well as the fact that questionnaires with documented good reliability and validity were used. In addition, selection bias was avoided because consecutive patients were invited and randomized into two groups in which the treatments were standardized and the only variable that differed was how the RME appliance was anchored.

This study has some limitations, however. The power analysis (not included) was based on skeletal effects of RME and not on pain measurements. A larger sample size might have been beneficial.

CONCLUSIONS

- Although the hybrid RME generally resulted in lower pain and discomfort scores, no statistically significant differences were found between the groups.

Table 2. Analgesic Consumption the First and Fourth Day in Treatment

<table>
<thead>
<tr>
<th></th>
<th>Group A (N = 25)</th>
<th>Group B (N = 25)</th>
<th>Total (N = 50)</th>
<th>Group Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesic the first day</td>
<td>9</td>
<td>7</td>
<td>16</td>
<td>NS</td>
</tr>
<tr>
<td>No analgesic the first day</td>
<td>16</td>
<td>18</td>
<td>34</td>
<td>NS</td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td>25</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Analgesic the fourth day</td>
<td>5</td>
<td>2</td>
<td>7</td>
<td>NS</td>
</tr>
<tr>
<td>No analgesic the fourth day</td>
<td>20</td>
<td>23</td>
<td>43</td>
<td>NS</td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td>25</td>
<td>50</td>
<td></td>
</tr>
</tbody>
</table>

NS = Not significant
• Age was positively correlated with overall pain and discomfort.
• Both types of appliances were generally well tolerated by the patients the first week in treatment.

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REFERENCES