Original Article

Influence of activation protocol on perceived pain during rapid maxillary expansion

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ABSTRACT

Objective: To investigate the influence of two different activation protocols on the timing and intensity of pain during rapid maxillary expansion (RME).

Materials and Methods: A total of 112 prepubertal patients (54 males and 58 females, mean age 11.00 ± 1.80 years) with constricted maxillary arches underwent RME with two different activation protocols (group 1: one activation/day; group 2: two activations/day). Patients were provided with a numeric rating scale (NRS) and the Faces Pain Scale (FPS) to correctly assess their daily pain.

Results: Subjects treated with RME at two activations/day reported statistically significantly greater amounts of pain than subjects treated with RME at one activation/day. Differences related to gender and skeletal maturity were found.

Conclusion: The choice of activation protocol influences the perceived pain during RME, and less daily expansion is correlated to less pain. Pain reported during RME could be influenced by skeletal maturity and gender of the subjects under treatment. (*Angle Orthod.* 2015;85:1015–1020.)

KEY WORDS: Rapid maxillary expansion; Pain; Orthodontic appliance; Rapid palatal expansion

INTRODUCTION

Rapid maxillary expansion (RME) is a common clinical orthodontic procedure[1] used to treat maxillary arch constriction and posterior crossbite (prevalence ranging from 7.1% to 23.3%[2,3]) by opening the midpalatal suture. More than 90% of orthodontists offer this procedure as a treatment option[4] in primary, mixed, or permanent dentition.[5]

RME generates large forces to exceed the limits of orthodontic tooth movement; this produces maximum orthopedic repositioning and affects the circummaxillary suture system and, more specifically, the midpalatal suture. Moreover, RME causes the periodontal ligaments to compress, the alveolar processes to bend, and the anchoring teeth to tip, and it induces other skeletal and dental effects, as confirmed by numerous studies.[6–8]

The Hyrax appliance is the most common type of RME appliance. It features an expansion screw that is attached to two or four teeth that is usually activated once or twice daily for about 2 to 4 weeks.[5] The expansion force varies depending on the activation protocol; a single activation of the screw produces approximately 3 to 10 pounds of force.[9]

Clinicians are aware that children may report undesirable side effects during the expansion phase, such as pain, nonopening of the suture, and oral ulcerations.[10–12] In particular, several studies cited pain as the most frequently experienced effect, with a frequency of 93.9%.[13] Pain is dependent upon such factors as age, gender, stress, individual pain threshold, and cultural differences, as well as the magnitude of force applied. Joviliano et al.[14] concluded that the inflammatory reaction during sutural opening and the compression of the periodontal ligament may contribute to the pain experienced during RME.

Although multiple studies have reported on the pain associated with various orthodontic procedures,[15–17] only few have suggested an association between pain and RME.[5,18,19] In particular, two of these reports[5,18]

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showed that different amounts of daily expansion could be related to the pain perceived during RME.

The aim of this study was to investigate the influence of two different activation protocols on the timing and intensity of pain during RME.

MATERIALS AND METHODS

Study Group, Procedure, and Data Collection

A total of 112 prepubertal patients with constricted maxillary arches were enrolled in this study (54 males and 58 females, mean age 11.00 ± 1.80 years) at the University of Rome Tor Vergata. Individual skeletal maturity was determined for each subject with the cervical vertebral maturation method assessed on lateral cephalograms.[20] Exclusion criteria included age older than 15 years, cervical vertebral maturation more advanced than cervical stage 4 (CS4) (postpubertal), and the presence of previous periodontal disease, neurological disease, and/or genetic disease. This project was approved by the Ethics Committee of the University of Rome Tor Vergata, and informed consent was obtained from the patients' parents.

All the subjects underwent RME with a stainless steel banded expander cemented to the maxillary first molars and were randomly assigned to one of two groups according to the expansion protocol to be applied. In group 1, the expansion screw was activated at 1/4 turn per day (one activation, 0.2 mm per day), and in group 2, the expansion screw was activated at 2/4 turns per day (two activations, 0.4 mm per day). In both groups, the expansion screw was activated until the desired palatal expansion was reached.

Patients were provided with a combination of a numeric rating scale (NRS) and the Wong-Baker Faces Pain Scale (FPS) (Figure 1) to assess their pain.[21] Verbal instructions were given to the parent and child about how to correctly assess pain; hence, the patients were asked to report daily the corresponding amount of pain 15 minutes after the activation of the expander. No subjects used analgesics during the active expansion phase.

Statistical Analyses

The distributions of demographic were summarized as percentages for discrete variables, or as means and standard deviations (SDs) for continuous variables.

Variables of primary interest for the study, i.e., days of active treatment (number of activations) and reported pain during treatment, were also summarized as means and SDs and compared between the two treatment groups using the Wilcoxon rank-sum test. The number of days of treatment for the two treatment groups was graphically compared with Kaplan-Meier curves.

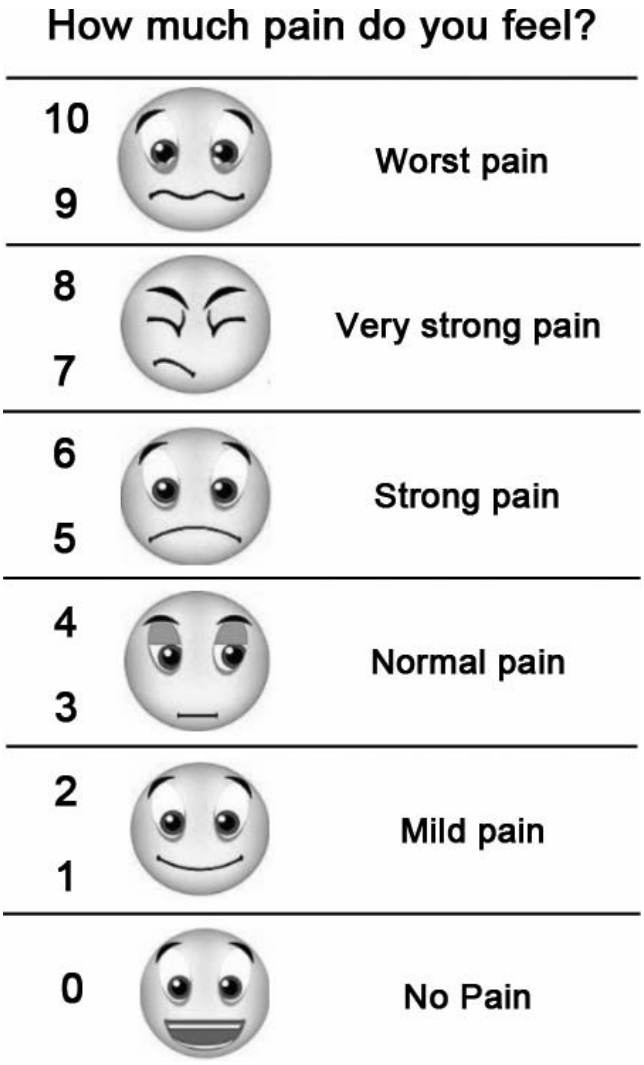

Figure 1. The numeric rating scale (NRS) and Faces Pain Scale (FPS) used for pain evaluation.

The trend of average pain over time for the two treatment groups was studied graphically, and the differences were evaluated with Wilcoxon rank-sum tests. To ensure an equivalent comparison between the two groups, this analysis was based on activations rather than days as the unit of measurement. In particular, since the daily pain observations in group 2, who received two activations per day, refer to two activations, the time unit for the comparison of trends over time was two activations. Therefore, in this analysis, the reported pain variable for patients in group 1, who received one activation per day, was a transformation of the original daily pain variable. This new variable was derived by averaging the daily pain observations in group 1, two by two; hence, in this analysis, the first observation for group 1 referred to the activations of the first 2 days of treatment and corresponded to the day 1 observations of group 2.

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Table 1. Characteristics of the Study Sample

Variable	Group 1 N = 56		Group 2 N = 56		Total N = 112	
Sex, no. (%)						
Female	32	(57.1)	26	(46.4)	58	(51.8)
Male	24	(42.9)	30	(53.6)	54	(48.2)
Age at entry, mean (SD)						
	10.9	(1.78)	11.1	(1.83)	11	(1.80)
Cervical stage, no. (%)						
1	22	(39.3)	20	(35.7)	42	(37.5)
2	28	(50.0)	23	(41.1)	51	(45.5)
3	6	(11.7)	13	(23.2)	19	(17.0)

Secondary analyses, stratified by sex and cervical stage, were also performed. However, cervical stage 3 was excluded from these stratified analyses because of the limited number of subjects. All analyses were performed with STATA software version 12.1.

RESULTS

The characteristics of the 112 subjects in the two treatment groups are shown in Table 1. Randomization assigned more female and lower cervical stage subjects to the group that received one activation per day; nevertheless, Pearson's chi-square test confirmed the hypothesis of independence in both cases. Likewise, age was, on average, the same in the two treatment groups.

Figure 2 summarizes the duration of the treatment in both terms of (1) needed days of treatment and (2) average pain over time in the two groups. As expected, the subjects who received one activation per day (group 1) needed to be treated for a significantly longer number of days to achieve the desired amount of palatal expansion compared to the patients in group 2, i.e., "two activations/day" (Figure 2a). The numbers of subjects in the second study group dropped more quickly, and by the end of the second week, i.e., day 14, more than two-thirds (73.2%) of the sample had already successfully completed treatment. During the same interval, in contrast, fewer than 1 of 4 patients (23.2%) in group 1 had achieved the desired result.

In Figure 2b and the following figures, group lines are shown only if at least 5 subjects were left in a group. In group 1, the average pain rating fluctuated between 0.5 and 1 and remained fairly constant during active treatment (Figure 2b). In group 2, in contrast, after an initial peak (average pain rating of 2.3) on the second day, we observed a constant decline in the average pain. The differences in pain were statistically significantly different, especially in the interval between the fifth and 10th activations of the device, i.e., days 3 to 5 in group 2 and days 5 to 10 in group 1.

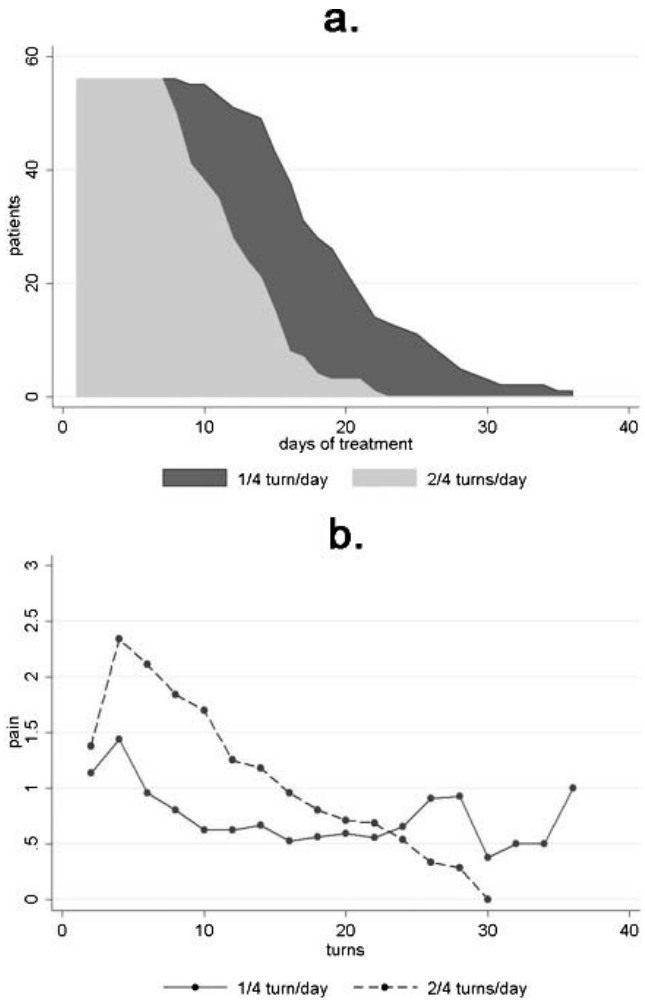

Figure 2. Treatment efficacy evaluated by (a) days of treatment and (b) average level of pain over time in the two groups.

Table 2 presents detailed results of the comparison of pain scores reported by the two study groups. Confirming the previous results, subjects in group 1 required, on average, 6 more days for treatment than patients in group 2 did (18.8 vs 12.8 days for groups 1 and 2, respectively, $P < .01$). However, it should be noted that, in terms of the number of activations, group 2 patients, in whom the device was activated twice per day, were treated significantly longer than the other group (18.8 vs 25.6, $P < .01$). Overall, the pain reported during treatment was significantly higher in group 2 (on average, 0.8 vs 1.2, $P < .01$). Stratified analyses led to similar findings in every subsection of the sample, particularly in female patients and CS1 patients (0.9 vs 2.2 and 0.9 vs 2.0, respectively; $P < .01$ in both cases). Three subjects in group 1 and 10 in group 2 recorded a pain score above 5 at least once.

The fluctuations in the levels of pain over time in the two groups and in particular according to sex, are further illustrated in Figure 3. This analysis highlighted

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Table 2. Treatment Results in the Two Arms, According to Sex and Cervical Stage (CS)

		Group 1		Group 2		
Category	N	N = 56		N = 56		*P* Value
Pain during treatment, mean (SD)						
Overall	112	0.82	(1.38)	1.24	(1.87)	< .01
Female	58	0.92	(1.59)	1.62	(1.76)	< .01
Male	54	0.72	(1.09)	0.95	(1.90)	.60
CS 1	42	0.68	(1.23)	1.4	(2.01)	< .01
CS 2	51	0.90	(1.50)	1.11	(1.88)	.36
Pain between activations 5 and 10, mean (SD)						
Overall	112	0.80	(1.22)	1.88	(2.15)	< .01
Female	58	0.88	(1.34)	2.21	(1.89)	< .01
Male	54	0.68	(1.04)	1.60	(2.32)	.02
CS 1	42	0.89	(1.30)	2.02	(2.35)	< .01
CS 2	51	0.71	(1.19)	1.65	(2.11)	< .01

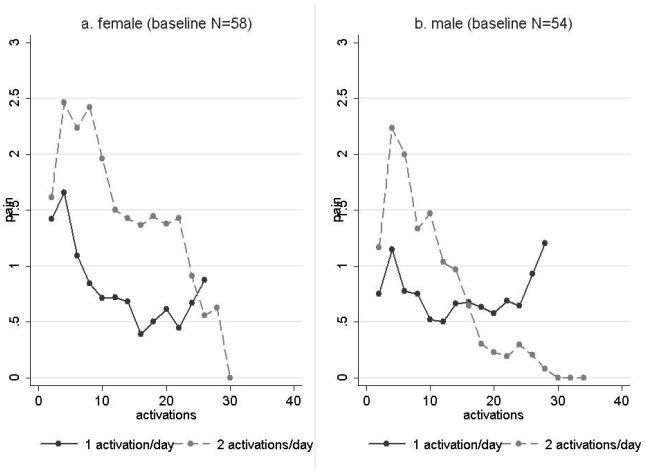

Figure 3. Average level of pain reported over time according to sex and treatment group, by number of turns.

the differences in the level of pain between groups among the female subjects. Moreover, patients in group 1 seemed to have experienced similar levels of pain regardless of sex. Among the group 2 subjects, instead, the differences in terms of pain between sexes were more evident, especially at the beginning of the second week, i.e., after the 14th activation.

Analyses stratified by CS highlighted that less developed (CS1) subjects experienced different levels of pain related to their treatment group. Moreover, subjects in CS2 recorded a higher level of pain than those in CS1 at the beginning of the study.

DISCUSSION

Numerous articles have reported the pain associated with various types of orthodontic procedures,[15,22] but, although several RME reports cited pain among the side effects, few studies have evaluated the pain associated with this common clinical procedure.[5,18,19] This study analyzed the influence of two different activation protocols on pain timing and intensity during RME using daily recorded pain values in two groups of 56 children each. Previously, Needleman et al.[5] recorded pain associated with RME on a daily basis as well, but their main analyses did not focus on how pain varied between different activation protocols. On the other hand, Halicioğlu et al.[18] studied the difference in pain between three distinct activation protocols for RME but recorded the pain sensations of each patient involved in the study at time intervals of 5 and 10 activations.

Pain is a complex sensation that varies from one individual to another; thus, its objective quantification is difficult. The measurement of pain in children can be even more difficult and has been a frequent subject of discussion.[21,23] Studies have shown that children 3 years and older are capable of understanding the concept of hurt and its varying degrees of intensity, if provided with an appropriate device. This study used a combination between two common validated rating scales, an NRS and the Wong-Baker FPS, for a correct pain assessment in children.[21] This is in agreement with work published by Needleman et al.,[5] which used a combination of the FPS and the Color Analog Scale, and that of Halicioğlu et al.,[18] who used an NRS. Agreement between the FPS and the standard visual analog scale used by Gecgelen et al.[19] was previously documented.[24]

It is well established that most children undergoing RME experience pain, especially during the early phase of expansion. This study showed, instead, that in subjects undergoing one activation/day, the average pain rating fluctuated only between 0.5 and 1 and remained fairly constant during the days of treatment. On the other hand, in subjects who received two activations/day, after an initial peak on the second day, we observed a constant decline in pain sensation (average pain of 2.3). In contrast to the findings of Halicioğlu et al.,[18] our results showed a statistically significant difference in pain between the two different activation protocols. Moreover, when focusing on the most critical interval, i.e., between activations 5 and 10, this difference was especially evident, as subjects in group 2 reported that they suffered more than twice as much as the patients in group 1. This finding is in agreement with those of other studies.[5,18,19] In fact, human and animal studies have shown that, in early phases, the rapid expansion of sutural tissues results in the creation of a highly vascular disorganized connective tissue of an inflammatory nature, which results in a perception of pain.[5] Afterward, less disruption of the midpalatal tissue occurs, and children may become more comfortable with the procedure with each activation of the expander. An additional clinically

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important result is that about 5% of the subjects in group 1 recorded a pain rating higher than 5 at least once, vs about 20% of the group 2 subjects.

Medical pain thresholds are similar between genders; it is believed that females are more sensitive to pain than males, although there are conflicting reports in the literature on this issue.[16,17] Our results highlighted that the level of pain was influenced by gender, especially under the two activations/day protocol, in which males experienced less pain. This finding could help explain the conflicting results in the literature. Needleman et al.[5] and Halicioğlu et al.[18] did not find any influence of gender on perceived pain during RME, whereas Gecgelen et al.[19] observed statistically significantly higher pain scores in females, in agreement to what we observed in this study in group 2.

This study evaluated the influence of skeletal maturity on perceived pain, and cervical vertebral maturity was used as an indicator of bone growth. There are several reports regarding pain and its association with age. Resistance to maxillary expansion increases with age, and, likewise, pain threshold levels increase from 5 to 25 years.[25] Needleman et al.[5] and Gecgelen et al.[19] did not find any difference between older and younger subjects. Conversely, in this study, skeletal maturity seemed to influence the perception of pain during RME, although it should be noted that we had to limit our analyses to only CS1 and CS2 because of the small number of subjects in CS3. According to our results, subjects in CS1 appeared to be influenced more strongly by the daily amount of expansion (activation protocol), whereas subjects in CS2 seemed to experience more pain during the first expansion phase.

CONCLUSIONS

- The choice of activation protocol influenced the perceived pain during RME. A smaller amount of daily expansion was correlated to lower levels of reported pain, especially between the fifth and 10th activations, which was the most painful phase of the expansion.
- Younger and female patients were more sensitive to the activation protocol.
- Pain reported during RME could be influenced by the skeletal maturity of the subject under treatment.

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