

Subjective symptoms of RME patients treated with three different screw activation protocols: a randomised clinical trial

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Aims: The purpose of the present study was to evaluate the subjective symptoms of patients during the active phase of rapid maxillary expansion (RME) treatment, and further, to assess the differences between three different RME activation protocols.

Materials and methods: The clinical sample consisted of 60 patients (mean age 13.5 years) with maxillary transverse deficiency requiring expansion. The subjects were randomly divided into three groups on which different expansion protocols were performed. An evaluation of the subjective symptoms was carried out by a Numerical Rating Scale (NRS). The patients completed questionnaires after the first, fifth, tenth, twentieth and final activations. A Shapiro-Wilk test was applied to evaluate homogeneity; a Kruskal Wallis test was performed for gender-related differences and to compare the different activation schedules. The Wilcoxon test was used to compare the activations at the various time intervals.

Results: No gender-related differences were found. Ninety-eight percent of the patients reported pain during RME. There were no specific differences between groups except for the pain perceived at the twentieth activation. In all groups, pain, the sensation of pressure and its duration were highest at the fifth activation. Subjective symptoms tended to decrease after the fifth and tenth activations. Headache and dizziness were minimal.

Conclusion: Different activation protocols did not appear to alter subjective symptoms encountered during RME. The majority of the patients undergoing RME suffered pain and pressure sensations especially after the fifth activation.

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Introduction

Rapid maxillary expansion (RME) is a common clinical procedure for the treatment of posterior crossbite and reduced maxillary width. It is reported that over 90% of orthodontists offer RME as a treatment option.¹ RME and the rapid elimination of arch constriction by opening the mid-palatal suture, occupies a unique place in contemporary orthodontics. By generating a force which exceeds the limits of orthodontic tooth movement, an expansion appliance compresses the periodontal ligament, bends alveolar processes, tips anchor teeth, and gradually

affects the circummaxillary suture system but more specifically, the mid-palatal suture.² Maxillary changes are produced by separation of this facial bone from its craniofacial articulations.^{3,4} Numerous studies have investigated the effects of the procedure and process on the skeletal and dental structures^{5–10} as well as the surrounding soft tissues.^{11–13}

Besides its primary indication in the management of skeletal maxillary constriction, the literature has shown favourable RME effects in individuals suffering sleep disturbances,¹⁴ in children with conductive hearing loss,^{15,16} in patients with nasal respiratory problems^{17–19} and even in nocturnal enuresis cases.^{20,21}

Table I. Pain assessment form.

Date: _____ Expander Type: ☐ Memory Screw ☐ Hyrax two quarter turns/day ☐ Hyrax one quarter turn/day Patient's Name: _____ Number: _____ Activation (1st, 5th etc.): _____ Please grade your degree of pain and/or pressure marking a place between 0 and 100. Zero (0) means no discomfort, where as 100 corresponds to severe pain and/or pressure. 1. Did you feel pain when you turned the screw, if yes how severe? ☐ No ☐ Yes 0 50 100 2. Did you feel pressure sensation when you turn the screw if yes how severe? ☐ No ☐ Yes 0 50 100	3. How long did pressure sensation continue after the activation of the screw? A. Less than one minute B. 1 to 2 minutes C. 2 to 3 minutes D. 5 to 10 minutes E. 10 to 30 minutes F. 30 minutes to one hour G. More than one hour 4. Did you experience headache when you turned screw, if yes how severe? ☐ No ☐ Yes 0 50 100 5. Did you experience dizziness when you turned screw, if yes how severe? ☐ No ☐ Yes 0 50 100
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Although rarely reported, undesirable side effects of the RME procedure may be experienced. These include pain, oral ulceration, non-opening of the sutural articulations, extreme tooth tilting and bone and/or root resorption.²²⁻²⁴ Among these, RME-associated pain is less reported. Although clinicians are aware that patients frequently report pain during the RME procedure, only two studies^{25,26} have investigated its consequences.

The prevalence, timing and intensity of other subjective symptoms such as headache, dizziness, the sensation of pressure and its duration have not been documented. It is important for the clinician to inform his/her patients about likely experiences when undergoing treatment. The patient's psychological response and ability to cope might be improved with this pre-emptive guidance.^{26,27}

The present study aimed to investigate the subjective symptoms of RME and to determine whether there were any differences between three screw activation protocols.

Materials and methods

The study was conducted in the Departments of Orthodontics, Faculties of Dentistry, Atatürk and Abant İzzet Baysal Universities and approved by the University Ethics Committee (2006/20). A power analysis indicated that 60 patients were required.

Seventy-five consecutive patients (45 female, 30 male) aged between 10 and 15 years and presenting with a bilateral posterior crossbite were included in the study. All of the subjects were in the permanent dentition with fully erupted first premolar teeth. Because analgesic drugs were consumed or patients incompletely completed the questionnaire, 15 subjects were excluded from the study. A final evaluation was performed on 60 patients (aged between 10.25 and 14.6 years with a mean of 13.5 years). All subjects were treated by one author (KH) and the questionnaires were prepared and evaluated by the other authors.

Informed consent for each patient and their parents was obtained. The subjects were randomly divided into



Figure 1. Occlusal photograph at the end of expansion of RME produced by the memory screw.



Figure 2. Occlusal photograph at the end of expansion of RME produced by the Hyrax screw.

three groups according to an expansion protocol to be applied. The first group (10 female, 8 male) received a nickel titanium rapid maxillary expansion screw - memory screw (Forestadent, Pforzheim, Germany) introduced by Wichelhaus et al.²⁸ It is a modified Hyrax screw comprised of nickel titanium open coil springs in the screw bed which aimed to reduce the expansion forces. The memory screw, combining intermittent and continuous force modules, was activated 6 quarter-turns a day. The second group (10 female, 10 male) received a conventional Hyrax appliance (Forestadent, Pforzheim, Germany) which was activated twice daily until the mid-palatal suture opened, after which, activation was reduced to one quarter-turn a day. The third group (13 female, 9 male) also received a conventional Hyrax screw which was activated two quarter-turns a day during the entire expansion phase. All of the devices were tooth-borne and cemented to the maxillary anchor teeth. Mid-palatal suture separation was verified by occlusal radiographs in all patients.

The patients were provided with questionnaires at the 1st, 5th, 10th, 20th and at the final activations (Table I). The subjects were asked to complete the forms soon after the cessation of pain and/or the other subjective symptoms and to avoid the use of analgesics during the active expansion phase. Statistical evaluation was provided by the Shapiro-Wilk test which determined that the distribution of data was non-homogeneous. The Kruskal-Wallis test was applied for gender-related differences and for the screw activation protocols. The differences between the 1st, 5th, 10th, 20th and the final activation were analysed by the Wilcoxon test.

Results

Gender differences

The Kruskal-Wallis test was applied separately to each of the three groups and revealed no gender-related differences, therefore female and male subjects were pooled in each group.

Comparison of the different activation schedules

The Kruskal-Wallis test further demonstrated that there were no differences between the three activation protocols regarding the subjective symptoms of the patients except for pain perceived at the 20th activation (Table II). This difference was at a level of confidence represented by $p < 0.5$ and may be considered as negligible. Thus, the groups were combined for the evaluation of the differences between the 1st, 5th, 10th, 20th and the final activation time points.

Comparison of the subjective symptoms perceived at different activation time points

The differences between the 1st, 5th, 10th, 20th and the final activations were determined by the Wilcoxon test and the results are shown in Table III.

Pain

Fifty-nine of the 60 subjects reported pain during RME. The perception of pain peaked at the 5th

Table II. Comparison of three different screw activation programs.

	First activation				Fifth activation				Tenth activation				Twentieth activation				Final activation			
	1	2	3	z	1	2	3	z	1	2	3	z	1	2	3	z	1	2	3	z
Pain	13.89	16.67	25.29	2.60	33.33	29.33	34.70	0.53	29.44	37.33	22.35	3.33	37.78	18.00	22.94	8.89*	18.33	19.33	18.82	0.19
Pressure	21.67	22.67	26.47	0.31	32.78	40.00	24.70	3.97	32.22	34.67	22.94	2.89	34.44	25.33	28.24	2.23	16.67	25.33	21.18	2.42
Duration	7.89	7.20	8.21	0.34	10.58	2.57	10.76	4.40	7.69	3.83	11.85	1.30	4.83	3.40	10.38	2.46	6.03	4.13	4.18	0.70
Headache	5.00	10.00	8.23	0.83	5.00	8.00	9.41	1.61	3.33	10.67	9.41	0.71	4.44	6.67	10.00	1.02	1.67	4.00	7.64	1.19
Dizziness	.00	.00	2.35	3.96	3.89	5.33	1.76	1.33	3.33	2.67	2.35	0.15	1.11	5.33	1.76	1.53	.56	4.00	1.17	0.04

* $p < 0.05$ **Table III.** Differences between the first, 5th, 10th, 20th and the final activations.

	Activations					I-II	I-III	I-IV	I-V	II-III	II-IV	II-V	III-IV	III-V	IV-V
	First (I)	Fifth (II)	Tenth (III)	Twentieth (IV)	Final (V)										
Pain	18.60	32.60	29.40	26.80	18.80	-3.39***	-2.57**	-1.99*	-0.11	-1.32	-1.69	-3.14*	-0.73	-3.06*	-2.39
Pressure	23.60	32.20	29.80	29.60	20.80	-2.39*	-1.40	-1.38	-1.16	-0.72	-1.19	-3.21***	-0.11	-2.89*	-3.49***
Duration	7.79	8.24	7.95	6.29	4.83	-0.77	-1.15	-1.02	-1.75	-0.22	-2.34*	-1.18	-2.31*	-2.25*	-1.48
Headache	7.60	7.40	7.60	7.00	4.40	-0.24	-0.05	-0.04	-1.23	-0.16	-0.28	-1.29	-0.26	-1.68	-1.52
Dizziness	0.80	3.60	2.80	2.60	1.80	-1.88	-1.63	-1.38	-0.54	-1.03	-0.79	-1.25	-0.37	-0.78	-1.63

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

activation and lessened thereafter. There was no difference in pain perception between the first and the last activations. However, there were significant differences between the 1st and the 5th ($p < 0.001$), the 1st and the 10th ($p < 0.01$), and the 1st and the 20th activations ($p < 0.05$). Statistically significant differences were also observed between the 5th and the final activations ($p < 0.05$) and between the 10th and the final activations ($p < 0.05$).

Sensation of pressure

In keeping with the experience of pain, pressure perception reached its highest level at the 5th activation and diminished thereafter. There were significant differences between the 5th and the 20th activations ($p < 0.001$) and between the 20th and the final activations ($p < 0.001$). In addition, the 1st and the 5th activations, and also the 10th and the final activations were different at the $p < 0.05$ significance level.

Duration of pressure

The duration of pressure was longest at the 5th activation. There were significant differences between

the 5th and the 20th ($p < 0.05$), the 10th and the 20th ($p < 0.05$) and between the 10th and the final activations ($p < 0.05$).

Headache

To a mild degree, patients who were treated with RME appliances experienced headache. However, discomfort had reduced by the last activation. No statistically significant difference was observed between the activations.

Dizziness

RME patients reported slight dizziness during the procedure, but there was no significant difference between activations.

Discussion

The clinical monitoring of RME treatment often uses pain as a guide, and the correct interpretation of pain is of paramount importance.³ Although numerous RME reports have investigated patient discomfort, there have been few studies regarding subjective

symptoms. Early investigations^{1,22,29} cited pain among the side effects and, more recently, it has been revealed that the vast majority of patients undergoing RME, report pain.²⁵ De Felipe et al.²⁶ indicated that 93.9% of respondents experienced pain and discomfort from their palatal expanders (Hyrax, Haas, banded and quad-helix).

Needleman et al.²⁵ evaluated pain perceptions in children undergoing RME by using Visual Analogue Scale scores. However, the study evaluated and compared pain arising from two different RME protocols. It was reported that during the first 10 activating turns, patients whose rate of expansion was two turns per day were more likely to experience pain compared with children whose rate of expansion was less frequent. As twice daily activation is the most commonly applied program, it is recommended that the preferred protocol be twice daily for the first four to five days, followed by one activation per day throughout the remainder of the expansion process.³⁰ The present study aimed to compare the activation protocols with a memory screw which was activated six times a day. Wichelhaus et al.²⁸ postulated that the memory expansion screw, which generates lighter forces compared with conventional screws, produced maxillary expansion over a shorter period of time, was more effective and caused minimal patient discomfort.

The present study found that the subjects wearing the memory Hyrax appliance (6 activations/day) reported more pain than those in the other two groups at the 20th activation. In all other respects, there was no statistically significant difference between groups. This effect could possibly be explained by an accumulation of residual forces. Since expansion of 20 quarter turns in the memory screw group was achieved by the fourth day, residual loads might not have dissipated over the short time frame. Importantly, the 20th activation in the second and third groups took place on the 15th and 10th days respectively, which allowed more time for residual forces to dissipate. At the final activation, pain scores were similar in all groups.

The duration of pressure sensation, the severity of headache and dizziness were statistically similar between the groups. As there was no difference (except for the pain score at the 20th activation), the groups were pooled and the differences between the 1st, 5th, 10th, 20th and the final activations assessed.

The overall pattern indicated that pain reached a maximum at the 5th activation and thereafter gradually

decreased by the 10th and the 20th activations. At the final activation, the pain score recorded was similar to that experienced at the first activation. This finding is in agreement with those of Needleman et al.,²⁵ who found the highest levels of pain during the first 10 turns with the greatest intensity during the first 6 turns. This is likely explained by the mid-palatal suture starting to react at that time. Timms³ cited rigidity of the facial skeleton and mechanical interlocking and synostosis of the mid-palatal suture as reasons for pain during RME. Furthermore, histological studies³¹⁻³³ have demonstrated the presence of an inflammatory reaction with concomitant pain in the suture during RME.³⁴ However, a recent animal study by Joviliano et al.³⁵ concluded that RME-induced neural activation in the same nociception-related structures that were also activated during tooth movement. Therefore compression of the periodontal ligament of the anchor teeth may contribute to the pain experienced during RME.

The inflammatory reaction during sutural disruption may account for the source of pain in the early phase of RME, but the presence of high pain scores after sutural opening may infer that other factors are involved. These may be residual forces accumulating at the circummaxillary articulations as well as periodontal pain.

Pressure sensation scores showed a similar pattern to those of pain. A zenith was reached at the 5th activation which steadily decreased thereafter. This may be explained by the close proximity of pain and pressure receptors and also the difficulty that children might have in distinguishing pain from pressure. The duration of the pressure sensation was reported to be 7.76 minutes on average at the 1st activation and 8.24 minutes by the 5th activation, thereafter it decreased. It was clear that the demonstrated duration of the pressure sensations matched those of pain and followed a similar progress. Headache and dizziness were minimal and were not significantly different at any observation point.

In the present study, there was no gender-related difference in any of the parameters. Although it is known that mechanical pain thresholds are similar between the genders,³⁶ it is believed that females are more sensitive to pain while males are more stoic.³⁷ Conflicting results have been reported on this issue. While earlier reports have indicated that females experience more pain during fixed appliance

therapy,^{38,39} others recorded no gender difference.⁴⁰ In accordance with the present results, Needleman et al.²⁵ found that the gender of the patient was not a significant factor in predicting RME pain.

In a histological study, Persson and Thilander⁴¹ found that the earliest loss of sutural responsiveness was in a 15-year-old subject. Therefore, the present study did not incorporate subjects older than 15 years. In addition, there was the assumption that maxillary expansion generated more pain in older adolescents.³ However, there are differing reports regarding pain and its association with age. It is known that resistance to maxillary expansion increases with age, but at the same time, pain threshold levels also increase from 5 to the age of 25 years.⁴² Moreover, studies^{25,26} evaluating pain during RME did not find any difference between older and younger age groups. Nevertheless, the present study confined the age of the subjects to a narrow band (10.25 - 14.6 years).

The numerical rating scale (NRS) is one of the common methods of assessing pain in orthodontics,³⁷ and so it was used with confidence to provide a quantitative assessment of RME pain. However, as it is recognised that pain is a complex perceptual phenomenon and a subjective experience, it is impossible to precisely evaluate the pain of others.³⁷

Conclusions

The majority of patients undergoing RME suffered a degree of pain and a sensation of pressure.

Headache and symptoms of dizziness were relatively mild and rare.

Except for reported pain at the 20th activation, the memory screw produced similar responses to the other Hyrax groups in relation to pain, pressure sensation, duration of pressure, headache and dizziness at all of the evaluation time points. Therefore, the completion the active expansion phase in approximately one week by using a memory screw, activated 6 times a day, did not cause an increase in subjective symptoms.

When all subjects in the study were taken collectively, subjective symptoms were seen to peak during the first 10 activations, especially at the 5th activation, and decrease thereafter.

The data may be utilised in patient information and education processes.

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