Original Article

Patient-reported outcomes of slow vs rapid miniscrew-supported maxillary expansion in adolescents: secondary outcomes of a randomized clinical trial

Yomna M. Yacout[a]; Essam M. Abdalla[b]; Nadia M. El Harouny[b]

ABSTRACT

Objectives: To compare patient-reported experience between a Penn expander activated every other day vs twice daily.

Materials and Methods: A total of 30 patients aged 12–16 years with transverse maxillary deficiency were recruited from the outpatient clinic, Faculty of Dentistry, Alexandria University (February 2019–December 2020). They were randomly allocated to two groups using block randomization (block size of six) and an allocation ratio of 1:1, which was concealed using opaque, sealed, sequentially numbered envelopes. Both groups received Penn expanders anchored by four palatal miniscrews. The slow maxillary expansion (SME) group activated the appliance once every other day. The rapid maxillary expansion (RME) group activated the appliance twice daily. Outcome measures were pain, pressure, headache, dizziness, speech difficulty, chewing difficulty, and swallowing difficulty scores rated by the participants on an 11-point numeric rating scale (NRS) at the following four time points: before appliance insertion (t_1), after first activation (t_2), after 1 week of activation (t_3), and after last activation (t_4).

Results: Data of 24 patients in the SME group (n = 12, mean age = 14.30 ± 1.37 years) and RME group (n = 12, mean age = 15.07 ± 1.59 years) were analyzed. Median scores for all outcomes were in the bottom quartiles of the NRS. No difference was found between the two groups at t_1 or t_2. Significantly higher scores for all variables, except dizziness and headache, were reported in the RME group at t_4.

Conclusions: Activation of miniscrew-supported expanders resulted in mild to moderate discomfort and functional limitation. Slow activation resulted in a better overall patient experience compared with rapid activation. (*Angle Orthod.* 2023;93:151–158.)

KEY WORDS: Rapid maxillary expansion; Slow maxillary expansion; Miniscrew-supported expansion; Activation protocol; Pain

INTRODUCTION

Transverse maxillary deficiency is a common malocclusion that is often treated in adolescence using tooth-supported expanders.[1] The transmission of expansion forces to the mid-palatal suture through the anchoring teeth may result in unfavorable effects.[2] Miniscrew-supported maxillary expanders have offered orthodontists a viable treatment option to avoid such adverse effects[3] and expand the maxilla in patients with periodontally involved teeth and partially edentulous patients.[4,5]

Although previous studies[4,6–10] have demonstrated the effectiveness of maxillary expanders supported only by miniscrews, their optimal activation rate is still debatable. The decision to use a rapid or slow activation rate currently depends on the practitioner's clinical experience and personal preference.[11] Choi et al.[12] used a slow rate with miniscrew-supported expansion to reduce patient discomfort and tissue damage. Similarly, Zong et al.[13] recommended using a slower rate of activation if patients reported moderate

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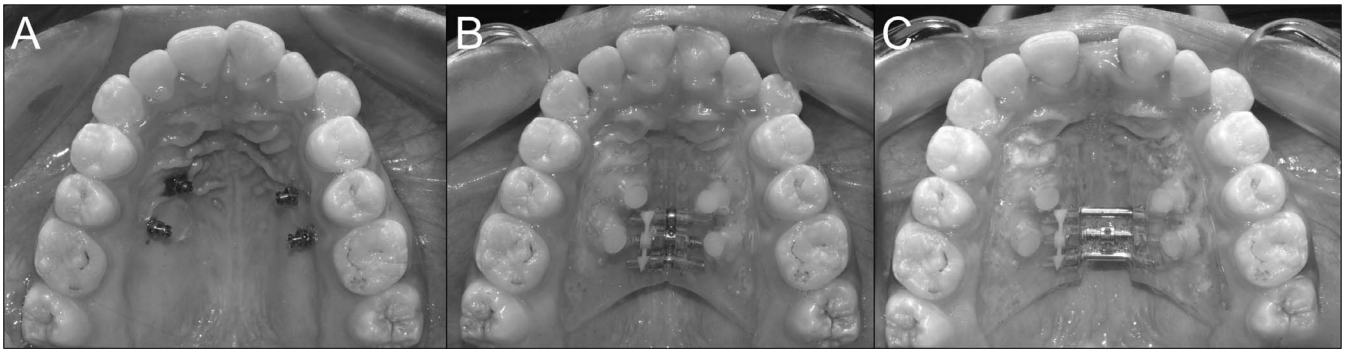

Figure 1. (A) Four miniscrews inserted in the palate. (B) Intraoral photo showing Penn expander bonded to miniscrews with flowable composite. (C) The expansion screw activated.

to severe pain. The rationale was that pain is affected by the magnitude of the applied force,[14] which in turn varies according to the activation protocol. A single activation produces approximately three to 10 pounds of force.[15]

Pain is a common adverse effect of using maxillary expanders,[16,17] and the soreness resulting from their use may interfere with the patient's daily activities, such as speech, chewing, and swallowing.[16] The perception of pain is subjective and shows individual variation. The numeric rating scale (NRS) can be used for grading pain and its effect on function.[18] The most frequently used NRS is the 11-point scale ranging from 0 to 10, in which the patient chooses an integer that best denotes the intensity of the effect.[19] A score of 0 to 4 represents mild intensity, a score of >4 to 7 represents moderate intensity, and a score of >7 to 10 represents severe intensity.[20]

The objective of this study was to compare the adolescent patient-reported experience between a miniscrew-supported expander activated every other day vs twice per day. The hypothesis was that the rate of activation would affect the reported discomfort and interference with daily activities.

MATERIALS AND METHODS

Trial Design

This was a single-center randomized clinical trial with two parallel arms. The protocol was registered at Clinicaltrials.gov (identifier number: NCT04225637). No changes were made after trial commencement.

Ethical Approval

The study was conducted following the ethical guidelines of the institutional review board (IRB) at the Faculty of Dentistry, Alexandria University (IRB: 00010556–IORG: 0008839). The parent or guardian signed an informed consent before trial commencement. An oral assent was obtained from the participants.

Participants, Eligibility Criteria, and Setting

The sample consisted of adolescents with transverse maxillary deficiency in which skeletal maxillary expansion was considered the treatment of choice. Participants were selected during the period from February 2019 to December 2020 from patients attending the outpatient clinic, Faculty of Dentistry, Alexandria University. Transverse maxillary deficiency was diagnosed on digital casts by measuring the difference between the maxillary buccal width at the mesio-buccal cusp of the first molars and the mandibular width at the WALA ridge at the mesio-buccal groove of first molars.[21] All participants met the following inclusion criteria: aged 12–16 years, permanent dentition, and acceptable oral hygiene. Patients were excluded according to the following criteria: previous orthodontic treatment, craniofacial anomalies or maxillofacial trauma, bone metabolic disease, or use of pain-altering medication.

Interventions

Patients were randomly allocated into two groups: slow maxillary expansion (SME), where the appliance was activated every other day, or rapid maxillary expansion (RME), with two turns of activation daily. All treatment procedures were carried out by the primary investigator. Four palatal miniscrews (1.6 × 10 mm, H-screw, Hubit Co Ltd, Ojeon-Dong, Korea) were inserted at the following sites bilaterally: between the first and second premolars and between the second premolar and the first molar (Figure 1). A miniscrew-supported acrylic expander was fabricated as shown in Figure 1 using a 9-mm expansion screw (Leone Orthodontic Products, Sesto Fiorentino, Firenze, Italy) with four holes accommodating the head of the miniscrews that were subsequently filled with light-cure flowable composite (Te-econom flow, Ivoclar Vivadent, Schaan, Liechtenstein). Expansion was considered sufficient when the transverse maxillary

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discrepancy measured on digital dental casts was corrected.[21]

Outcomes

The primary outcomes of the study were previously reported.[22] The patient-reported outcomes investigated were NRS scores for pain, pressure, headache, dizziness, speech difficulty, chewing difficulty, and swallowing difficulty. Participants were asked to rate their experience for each variable between 0 (least severity) and 10 (maximum severity).[18] Scores were recorded at the following four time points: t_1, before appliance insertion (after a minimum of 7 days following miniscrew insertion); t_2, after first activation of the appliance; t_3, after 1 week of activation; and t_4, after the last activation. The participants were advised to avoid the use of analgesics and were instructed to contact the orthodontist in cases of severe pain. The trial was discontinued if the patient requested appliance removal for severe pain or discomfort.

Sample Size Calculation

Sample size estimation was based on the primary outcome of the clinical trial.[22]

Randomization

A randomization sequence was generated using computer software[23] with a 1:1 allocation using a block size of six. The allocation sequence was concealed from the investigators in sequentially numbered, opaque, and sealed envelopes. The patients' names were written on the envelopes sequentially as they were deemed eligible and consented to participation in the trial. Corresponding envelopes were opened only after the baseline assessment at the time of appliance fabrication.

Blinding

It was not possible to mask the intervention from either the participants or the investigators.

Statistical Analysis

Descriptive statistics were calculated for sample characteristics and patient-reported outcomes at the different time points. A Friedman test for multiple comparisons was used for comparisons of the time points in each group followed by post hoc tests with Bonferroni correction. The Mann-Whitney *U*-test was applied for comparisons between the two groups at each time point.

All statistical analyses were conducted using IBM SPSS software, version 25 (IBM Corp., Armonk, N.Y.). The significance level was set at $P \leq .05$.

RESULTS

The flow of participants through the trial is shown in Figure 2. Sample demographic and clinical data are reported in Table 1. Descriptive statistics and box plots of the scores for each outcome are shown in Table 2 and Figure 3, respectively.

Median scores approximated zero for all the variables measured after appliance placement before activation of the expansion screw except for swallowing, where median scores were 2 ± 4.8 and 2 ± 2.8 in the SME and RME groups, respectively, with some patients reporting a score of 10 at t_1 (Figure 3). All patients experienced some form of discomfort and functional limitation with the activation of the expanders. However, the median scores were in the two bottom quartiles of the NRS for all outcomes.

The general trend of change in scores in the SME group was a statistically significant increase in reported scores following activation that subsequently decreased significantly at the end of expansion. This was true for pressure, speech, and swallowing, where significantly higher scores were reported at t_2 and/or t_3 compared with t_1, with no statistically significant difference between scores at t_1 and t_4.

In the RME group, scores significantly increased from baseline to the subsequent time points, with a statistically significant increase at t_4 compared with t_1 for pain, pressure, and chewing difficulty scores. In contrast, speech scores demonstrated no statistically significant difference between t_1 and t_4: 0 ± 1.8 and 3 ± 4, respectively. It was interesting to note that, as the median score increased from baseline to the final activation, the IQR also increased, rendering the difference between the medians not statistically significant.

Intergroup comparisons showed statistically significantly higher pain and chewing difficulty scores after 1 week of rapid activation compared with slow activation. Significantly higher scores for all variables were reported in the RME group after t_4 except for dizziness and headache. Headache scores showed no statistically significant difference between RME and SME at any time point. The reported median dizziness score at all time points for both groups was zero.

Harms

After removal of the expander, inflammation of the palatal mucosa was observed in the form of redness, enlargement of soft tissues, bleeding, or mild pain.

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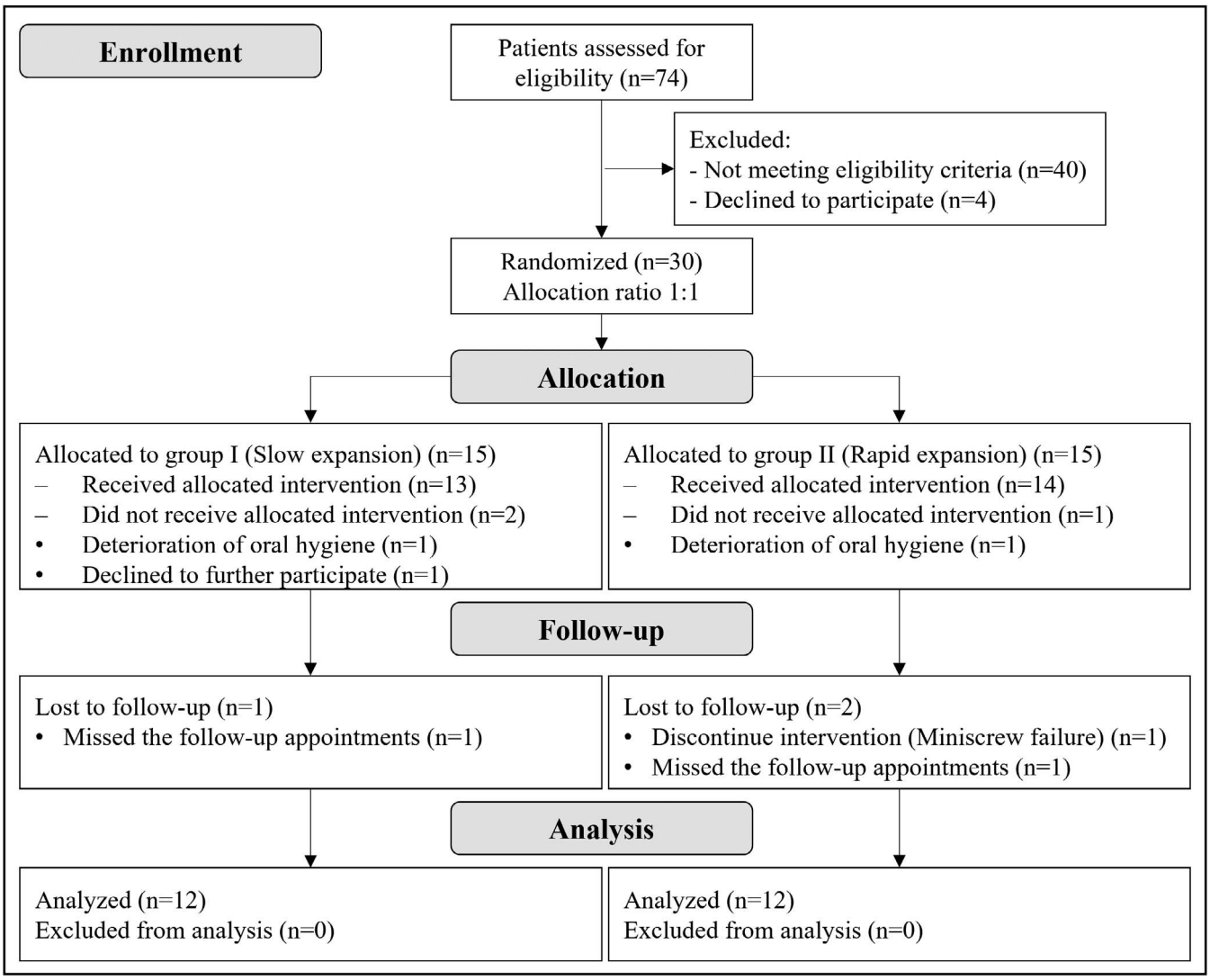

Figure 2. Consolidated Standards of Reporting Trials (CONSORT) flowchart showing the patient flow during the trial.

DISCUSSION

It was hypothesized that a slower rate of activation of miniscrew-supported maxillary expanders would result in a better patient experience. With miniscrews serving as anchorage, the rationale of using a rapid activation rate of conventional expanders to minimize dentoalveolar adverse effects[24] no longer seems valid. A slow activation rate has been advocated with miniscrew-supported expanders to allow dissipation of stresses,[25,26] avoid palatal bone fracture,[4] and, therefore, in addition to other benefits, reduce pain and discomfort.[12]

Table 1. Demographic and Clinical Data of Patients in the SME and RME Groups[a]

	SME (n = 12)	RME (n = 12)
Mean age at start of treatment ± SD, y	14.30 ± 1.37	15.07 ± 1.59
Sex, n		
Male	4	3
Female	8	9
Mean transverse discrepancy ± SD, mm	4.44 ± 0.84	4.66 ± 0.85
Mean jackscrew opening ± SD, mm	5.75 ± 0.76	5.90 ± 0.68
Mean duration of expansion ± SD, d	58.50 ± 7.36	16.58 ± 2.06

[a] SD indicates standard deviation.

An 11-point NRS was used for grading patient self-reported outcomes.[18] The numeric pain rating scale was shown to be both reliable and valid.[18] In addition, it was considered more straightforward for patients and more practical for the purpose of research compared with other methods.[18]

Median scores for most variables were near zero at t_1, with narrow IQRs from 0 to 1.8. However, swallowing scored a median of 2 in both groups. In addition, the IQRs were wider for swallowing (4.8) as well as for chewing (3.8) in the SME group. Initial scores were taken after miniscrew insertion. Although at least 7 days were allowed following miniscrew

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Table 2. Medians and IQRs of Scores of Each Patient-Reported Outcome in the Two Groups[a]

	Time Points				
	t_1 Median (IQR)	t_2 Median (IQR)	t_3 Median (IQR)	t_4 Median (IQR)	*P* Value[b]
Pressure					
SME	0 (0.8)[A]	3 (2.8)[B]	3 (2.5)[B]	2 (1.8)[A,B]	<.0001[c]
RME	0 (0.0)[A]	3.5 (1.8)[B]	4 (2.8)[B]	3 (2.0)[B]	<.0001[c]
P value[d]	.799	.219	.060	.010[c]	
Pain					
SME	0 (0.8)	0.5 (2)	1 (1)	1 (2)	.093
RME	0 (0)[A]	1.5 (2.8)[A,B]	4 (1.5)[B,D]	5 (1.8)[C,D]	<.0001[c]
P value[d]	.799	.266	.001[c]	<.0001[c]	
Headache					
SME	0 (1)	0 (1)	1 (1.8)	1 (1)	.194
RME	0 (0)[A]	0 (1)[A]	1.5 (2)[A]	1 (2.8)[A]	.003[c]
P value[d]	.630	.932	.887	.347	
Dizziness					
SME	0 (0)	0 (0)	0 (0)	0 (0)	.329
RME	0 (0)	0 (0)	0 (1.5)	0 (0)	.101
P value[d]	1.00	1.00	.319	.713	
Speech difficulty					
SME	1 (1)[A,C]	2.5 (2.5)[B]	3 (2.5)[B]	0.5 (1.8)[C,D]	<.0001[c]
RME	0 (1.8)[A]	3 (2.8)[A,B]	3.5 (4)[B,C]	3 (4.0)[A,C]	.003[c]
P value[d]	.755	.713	.977	.024[c]	
Chewing difficulty					
SME	0 (3.8)	0.50 (2.8)	0.5 (1)	0 (0.8)	.303
RME	0 (1.5)[A]	2 (5.3)[A,B]	3 (3)[B]	3 (3)[B,C]	.001[c]
P value[d]	.713	.410	.001[c]	.001[c]	
Swallowing difficulty					
SME	2 (4.8)[A]	4 (2.8)[A]	1.50 (1.8)[A,B]	0 (1)[A,B]	<.0001[c]
RME	2 (2.8)[A]	4 (3.5)[B]	2 (1.8)[A]	1.5 (3.3)[A]	.001[c]
P value[d]	.887	.977	.143	.006[c]	

[a] n = 12 (per group at each time point). IQR indicates interquartile range. Different uppercase letters indicate statistically significant differences within each group.
[b] Within-group comparison using the Friedman test and pairwise comparisons with Bonferroni correction.
[c] Statistically significant at $P \leq .05$
[d] Between-group comparison using the Mann-Whitney *U*-test.

insertion to ensure that the procedure had no effect on the patient response, the presence of miniscrews may have interfered with swallowing and chewing. Discomfort resulting from contact between the tongue and the palatal miniscrews was reported previously.[27]

Participants in both groups reported higher median scores following appliance activation for most of the measured variables. Previous research showed increased pressure and pain following the placement of expansion appliances[17,28] as well as difficulties with chewing and swallowing.[16] Maxillary expansion has been associated with speech problems.[16] The presence of palatal appliances may restrict tongue movements during speech, thus affecting alveolar consonants /t/ and /d/.[29]

Median pain scores significantly increased immediately and 1 week following appliance activation in the RME group. Conversely, Altieri et al.[30] reported higher pain scores on the first day of activation that declined to lower scores after 1 week of activation of rapid bone-borne expanders. Unlike the present study, Altieri et al.[30] inserted the miniscrews, inserted the appliance, and activated it in the same visit as the first score was measured. Also, the rate of screw activation was four times on the first day followed by activation three times per day. In contrast, in the current study, appliance insertion and pain assessment were performed after a minimum of 7 days of miniscrew insertion, and the appliances were activated only twice per day in the RME group.

At the end of expansion, SME patients reported mild pain scores. Lagravère et al.[4] showed that bone-borne expanders activated every other day resulted in pain scores in the lower quartile of the visual analog scale at different time points. RME patients reported mild pain at t_1 and t_2 that increased to moderate pain at t_4 as classified by Brailo et al.[20] In contrast, moderate to severe pain has been reported in association with tooth-supported maxillary expanders.[16,28,31,32] The compression of the periodontal ligaments of anchor teeth may have added to the pain experienced due to the inflammation response during the opening of the mid-

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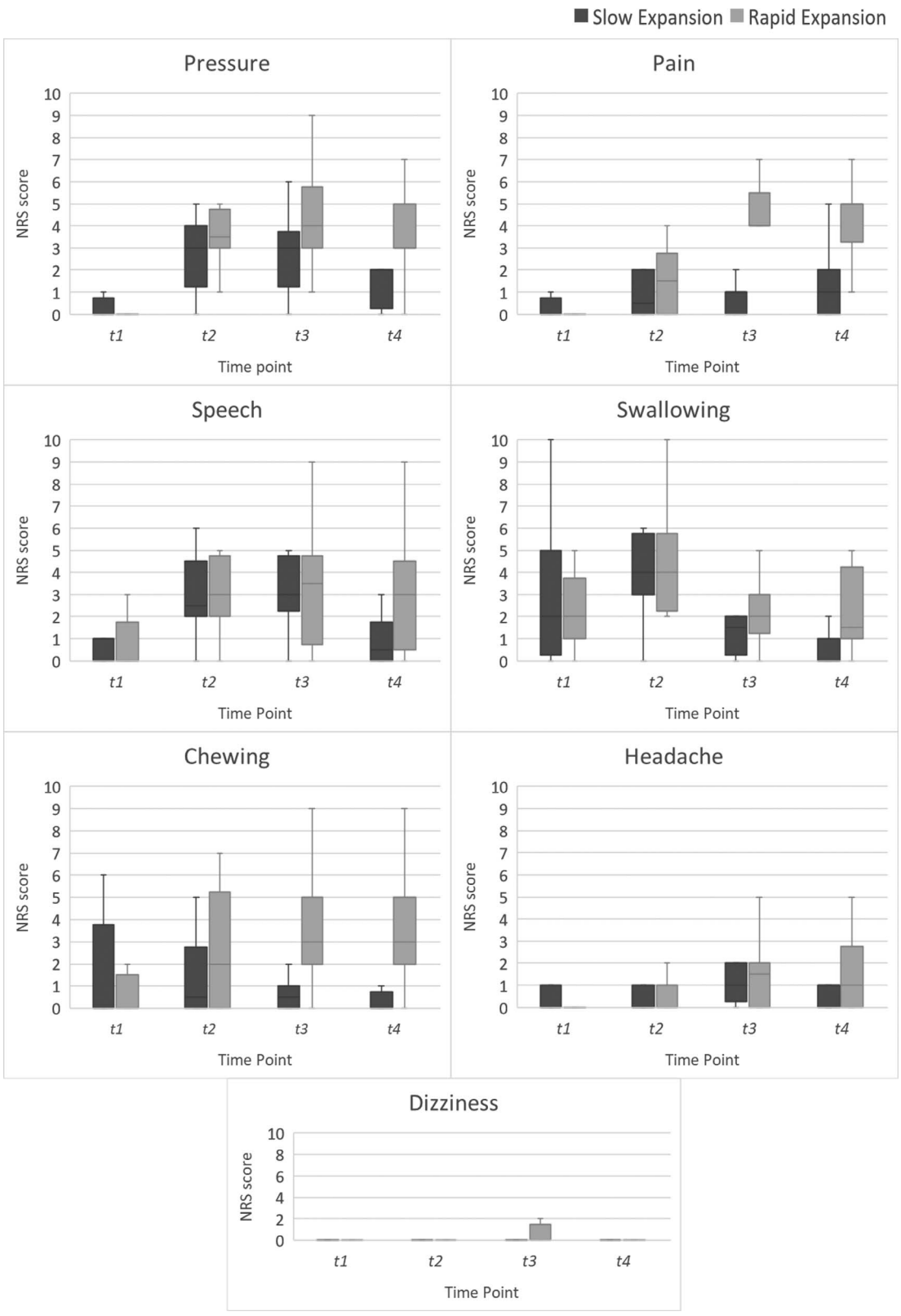

Figure 3. Box plots of the measured variables. *NRS*, numeric rating scale; *t1*, before activation; *t2*, after first activation; *t3*, after first week; *t4*, after last activation.

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palatal suture.[14] Using miniscrews in tooth-bone-borne expanders has been shown to reduce pain from maxillary molars.[17]

Comparing both activation rates, the difference in patient-reported outcomes was demonstrated following 1 week of activation. Patients in the RME group experienced more pain and chewing difficulty than patients in the SME group. At the end of expansion, the RME group reported higher scores than the SME group for all measured variables except headache and dizziness.

Several studies reported greater pain associated with RME compared with SME.[31–33] In addition, the higher pain scores in the RME group may have resulted in greater difficulty to chew food.[34] The association of pain and pressure may be attributed to the histological proximity of mechanoreceptors to nociceptors.[28] The greater speech difficulty at the end of expansion may be attributed to the larger median diastema in RME patients compared with SME.[35] In addition, the longer duration of expansion in the SME group may have allowed a longer time for the patients to adapt and for interference with daily activities to return to baseline values.[16,36] Hence, the null hypothesis can be rejected.

There were no statistically significant differences in the reporting of headache and dizziness between the RME and SME patients at any time point. However, patients treated by tooth-supported maxillary expanders have previously reported slight headache and dizziness.[28] It may be postulated that both headache and dizziness are more associated with increased pressure on the teeth from tooth-borne expanders.

Limitations

Although sample size estimation was not based on secondary outcomes of the clinical trial, this investigation may serve as a pilot study for future definitive clinical trials with sample size estimation based on patient-reported outcomes, or it may contribute data to a future prospective meta-analysis.

Another shortcoming was the 20% dropout rate. However, dropouts in both groups took place before receiving the appliance or shortly after the first activation; hence, they were not related to the patients' responses to the intervention. In addition, the frequency of dropouts was similar in both groups.

CONCLUSIONS

- All patients experienced some form of discomfort and functional limitation with the activation of miniscrew-supported expanders. However, it was generally mild to moderate.
- A slow activation rate of miniscrew-supported maxillary expanders resulted in a better patient experience compared with a rapid activation rate.

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