Original Article

Pain and discomfort perception during miniscrew-anchored maxillary protraction: secondary data analysis of a randomized clinical trial

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ABSTRACT

Objectives: To compare the perception of pain and discomfort of patients and guardians during treatment between miniscrew-anchored maxillary protraction (MAMP) therapy using Hybrid (HH) and Conventional Hyrax (CH) expanders.

Materials and Methods: Group HH was composed of 18 subjects (8 female, 10 male; initial age: 10.80 years) with Class III malocclusion treated with a hybrid expander in the maxilla and two miniscrews in the anterior region of the mandible. Class III elastics were used from maxillary first molar to mandibular miniscrews. Group CH was composed of 14 subjects (6 female, 8 male; initial age: 11.44 years) treated with a similar protocol except for conventional Hyrax expander. Pain and discomfort of patients and guardians were assessed using a visual analog scale immediately after placement (T1), after 24 hours (T2), and 1 month after appliance installation (T3). Mean differences (MD) were obtained. Intergroup and intragroup timepoint comparisons were performed using independent *t*-tests, analysis of variance for repeated measures and Friedman test ($P < 5\%$).

Results: Both groups demonstrated similar levels of pain and discomfort with a significant decrease after 1 month of appliance placement (MD: 4.21; $P = .608$). Compared to patient perceptions, guardians reported a higher level of pain and discomfort at all timepoints (MD, T1: 13.91, $P < .001$; T2: 23.15, $P < .001$; T3: 9.35, $P = .008$).

Conclusions: MAMP therapy with HH and CH produced similar levels of pain and discomfort after appliance installation until 1 month after treatment. Pain and discomfort may not influence the choice between HH and CH expanders. (*Angle Orthod.* 2023;93:313–319.)

KEY WORDS: Orthodontics; Interceptive; Malocclusion; Angle Class III; Palatal expansion technique

INTRODUCTION

Facemask therapy is the most common method used for treating growing patients with Class III malocclusion and maxillary deficiency.[1] However, innovative studies have recently emerged to explore other methods for orthopedically treating Class III malocclusion in adolescents. Significant maxillary advancement was observed during adolescence using titanium miniplates and miniscrews to anchor Class III elastics.[2–8]

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Bone-anchored maxillary protraction (BAMP) therapy uses full-time Class III elastics connected to titanium miniplates installed in the infrazygomatic crest of the maxilla and mesial to the mandibular canines, bilaterally.[2,3] By applying orthopedic forces directly to the bones, the BAMP protocol produced favorable skeletal effects, adequate vertical control, and minor dental effects isolated to the maxilla.[2,3] Miniscrew-anchored maxillary protraction (MAMP) therapy replaces the titanium miniplates with orthodontic miniscrews to decrease surgical complexity and cost.[7,8] In MAMP therapy, Class III elastics are anchored to a hybrid expander in the maxilla and two miniscrews are placed in the anterior region of the mandible.[7,8] MAMP therapy is associated with favorable changes in the skeletal, facial, and dental sagittal relationships with adequate vertical control.[7,8] A previous study reported approximately 2 mm increase in the Wits appraisal after treatment with MAMP therapy anchored in the Hybrid expander in adolescent patients.[8] Favorable increases in SNA, ANB, and overjet were observed (1.47°, 1.83°, and 2.99 mm, respectively).[8]

The discomfort perceived by patients during orthodontic treatment is a common experience, also related to emotional, cognitive, and cultural factors.[9] Subjectivity of patient pain perception and its relevance to treatment adherence led to scientific efforts for developing patient-centered studies.[9–18] Pain and discomfort caused by orthodontic treatment are a concern raised by patients and parents seeking orthodontic treatment. Previous studies demonstrated that pain was reported as one of the worst aspects of treatment and the main reason for discontinuing treatment.[10] More positive attitude toward orthodontic treatment was found in patients who experienced less pain during treatment.[11] In addition, previous studies also demonstrated that there was great interindividual variation in response to the application of orthodontic force.[12] Previous studies investigating pain and discomfort during rapid maxillary expansion (RME) treatment in children reported that pain occurred more often during the initial phase of expansion.[13–15] The peak of pain was reported to occur between the third and fourth day of activation of the expander screw.[13,15,16] In addition, the activation protocol with one turn per day resulted in lower pain levels than the protocol with two turns per day.[15,16] Previous studies indicated that children and adolescents had high tolerance to miniplate and miniscrew insertion in the palate and between the dental roots.[17,18] Conventional and hybrid hyrax elicited similar pain and discomfort scores during RME from 8 to 13 years of age.[19]

There are no previous studies in the literature that evaluated the degree of pain and discomfort caused by MAMP therapy in adolescent patients. The aim of this study was to compare the perception of pain and discomfort of patients and their guardians between treatment with miniscrew-anchored maxillary protraction therapy using hybrid and conventional Hyrax expanders. The null hypothesis was that maxillary protraction with Hybrid Hyrax (HH) and Conventional Hyrax (CH) expanders produced similar levels of pain and discomfort.

MATERIAL AND METHODS

Trial Design and Settings

This study was a secondary data analysis from a randomized clinical trial (NCT03712007), with two parallel arms and a 1:1 allocation ratio.[8] The study was approved by the Ethics in Research Committee of Bauru Dental School, University of São Paulo, Brazil (protocol number 67610717.7.0000.5417). All participants and parents signed the written informed consent before treatment. The initial sample consisted of 40 patients with Class III malocclusion and age ranging from 9 to 13 years. Inclusion criteria included patients with Class III malocclusion with maxillary deficiency (Wits appraisal of less than −1 mm) and anterior crossbite (or edge-to-edge incisor relationship), late mixed, or early permanent dentition. Exclusion criteria included individuals with a history of previous orthodontic treatment, unerupted mandibular permanent canines, and patients with special needs or syndromes.

Sample Size Calculation

The sample size was calculated considering the primary outcomes of the randomized controlled trial, including the sagittal skeletal changes.[8] To provide a power of 80%, an alpha error of 5%, and a minimum intergroup difference of 2 mm for maxillary length (CoA) changes, with a standard deviation of 1.4 mm,[3] a minimum sample of nine patients was required for each group.

Interventions

The HH group was treated with Class III elastics anchored on a HH expander in the maxilla and two miniscrews placed distal to the mandibular permanent canines (Figure 1). The palatal miniscrews (1.8 mm in diameter, 7 mm in length, 4 mm in transmucosal length) were positioned in the expander slots using an implant motor with 35N force and 30 rotations/min. The mandibular miniscrews (1.6 mm in diameter, 6 mm in length, 1 mm in transmucosal length) were placed manually using the mucogingival line as reference. The CH group was treated with a similar protocol except for the use of a CH expander without miniscrews in the

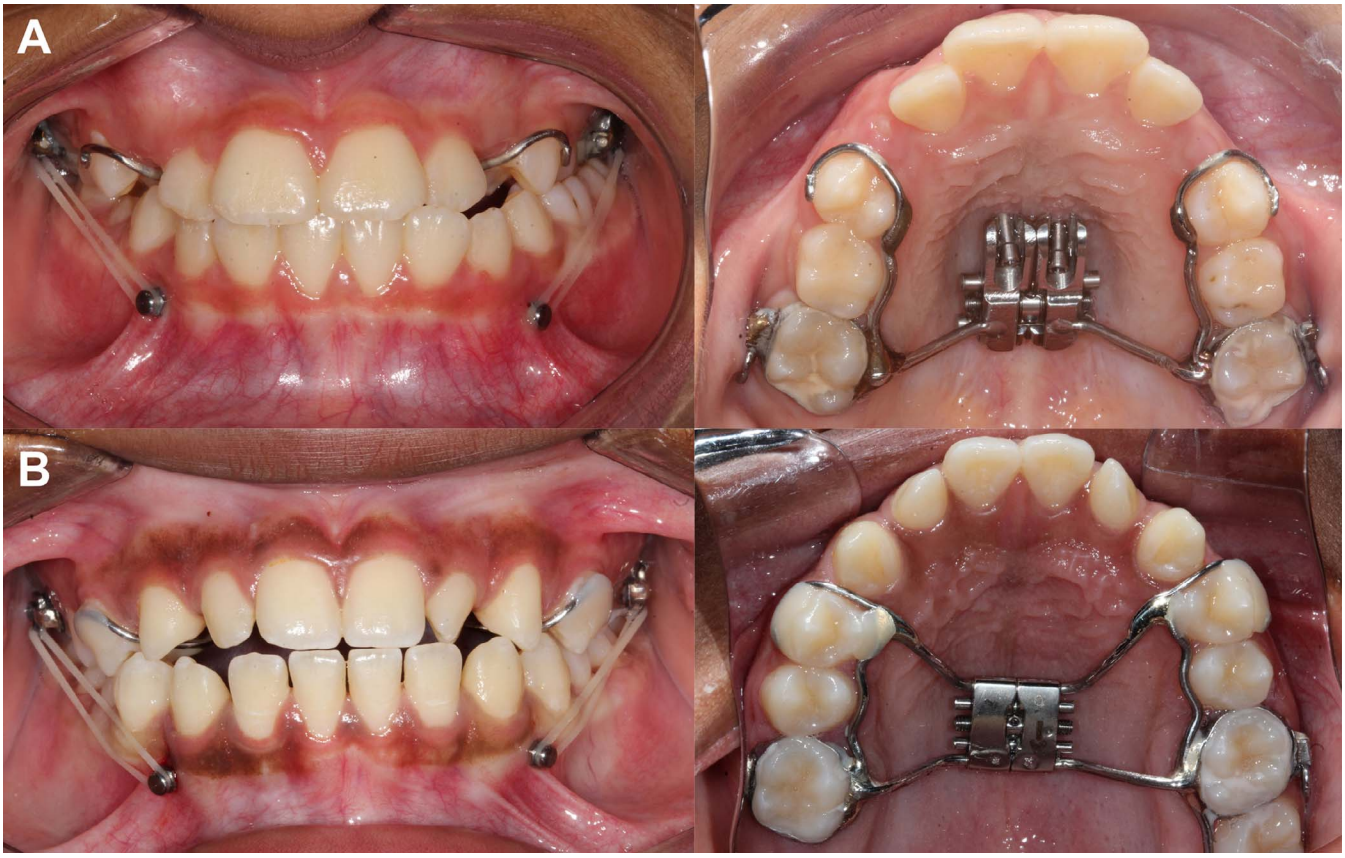

Figure 1. MAMP treatment in the Hybrid Hyrax group (A) and Conventional Hyrax group (B). MAMP indicates miniscrew-anchored maxillary protraction.

maxilla (Figure 1). The final treated sample of HH group consisted of 18 patients (8 females, 10 males; mean initial age: 10.8 years). The final treated sample of CH group consisted of 14 patients (6 female, 8 male; mean initial age: 11.4 years).

Both groups were treated similarly by the same orthodontist. Before the installation of palatal and mandibular miniscrews, topical (20% benzocaine gel) followed by local anesthesia (mepivacaine 3%) was performed. Patients were instructed to maintain adequate oral hygiene levels during treatment. Periimplant chlorhexidine gel (2%) was prescribed twice a day after oral hygiene during all active treatment time. The importance of maintaining a high level of oral hygiene was reinforced at every consult. The activation of the expander screw was one-quarter turn twice a day for 14 days, starting 1 day after expander installation. Patients were instructed to use nonprescription analgesics at their own preference if there was any pain or discomfort. The use of Class III elastics was similar for both groups. Traction started with a load of 150 g force per side in the first month and 250 g per side after the second month. Patients were instructed to wear the elastics full time, changing them every 12 hours.

Table 1. Questionnaire Administered to Patients and Guardians After 1 Month of Placement

Q1.	How was it to adapt to speech?
Q2.	How was it to adapt to chewing?
Q3.	How was it to adapt to swallowing?
Q4.	How was it to adapt to the appearance?
Q5.	How much pain or discomfort did you feel immediately after installing the appliance?
Q6.	How much pain or discomfort did you feel after 1 day of installing the appliance?
Q7.	How much pain or discomfort did you feel after 1 month of installing the appliance?
Q8.	How long did it take to get used to the appliance in your mouth?
Q9.	In general, how do you feel about your treatment?

Questionnaires related to pain and discomfort were administered to patients in both groups after 1 month of appliance installation (Table 1). The questions were answered using a visual analog scale (VAS). The VAS consisted of a standard 100-mm metric ruler, where 0 corresponded to minor and 100 to greater levels of pain or discomfort. Patients were asked about the level of pain and discomfort immediately after appliance installation (T1), 1 day after placement (T2), and 1 month after placement (T3) (Figure 2). At T3, patients

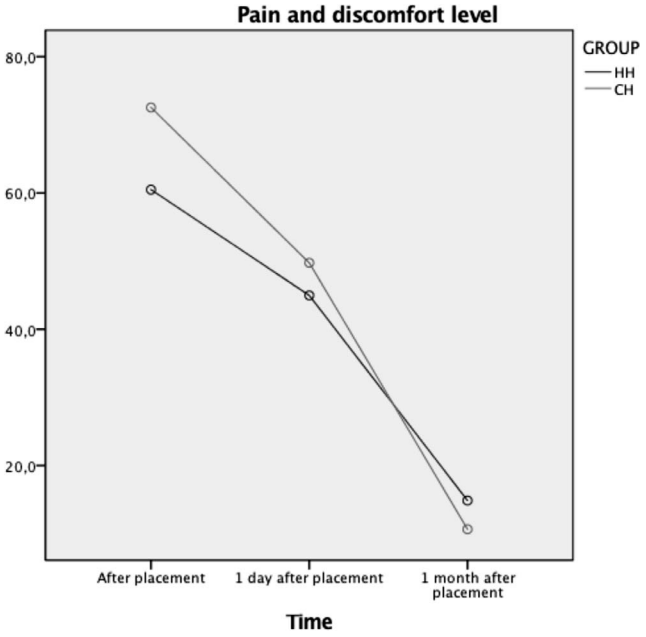

Figure 2. Level of pain and discomfort reported by patients in group HH (darker line) and CH (lighter line). CH indicates Conventional Hyrax; HH, Hybrid Hyrax.

were also questioned on the level of adaptation for speech, chewing, swallowing, and appearance. The guardians' perception of pain and discomfort caused by the therapy was also assessed. The same questionnaire was administered to the patients' guardian 1 month after appliance placement in a separate environment. Parents/guardians were blinded to their child's answers.

Randomization and Blinding

Randomization was performed electronically using the Randomization.com website (http://www.randomization.com). Opaque, sealed, and numbered envelopes containing the group name were organized and opened according to the sequence generated by the randomization.

Data were deidentified before statistical analysis. Therefore, only simple blinding was achieved, once both operator and patient were aware of the type of treatment performed.

Table 2. Intergroup Comparison for Age and Sex Ratio at Baseline (*t*-Test and Chi-Square Tests)[a]

		Group HH N = 13		Group CH N = 12		
Variable		Mean	SD	Mean	SD	*P* Value*
Initial age (y)		10.9	1.05	11.3	1.26	.381[A]
Sex	Female	5		6		.561[B]
	Male	8		6		

[a] CH indicates Conventional Hyrax; HH, Hybrid Hyrax; SD, standard deviation.
* Statistically significant at $P < .05$; [A] *t*-test; [B] chi-square test.

Statistical Analysis

Normal distribution was verified using the Shapiro-Wilk test. Intergroup age and sex ratio at baseline were assessed using *t*-test and chi-square test, respectively. Intergroup comparisons were performed using *t* or Mann-Whitney *U*-tests, depending on the presence of data normal distribution. Repeated-measures analysis of variance was used to compare the intergroup difference regarding the level of pain and discomfort at all timepoints. The Friedman test followed by the Durbin-Conover test was used to evaluate the intragroup changes for the level of pain and discomfort. Statistical analyses were performed on an intention-to-treat basis. Multiple imputation was used to deal with missing data. The open-source statistical software Jamovi software (version 1.2) (https://www.jamovi.org.) and the SPSS Statistical Software Package (Version 21.0; SPSS, Chicago, IL) were used. Results were considered significant at $P < .05$.

RESULTS

In the HH group, 13 patients answered the questionnaire (5 female, 8 male; mean initial age: 10.9 years). In the CH group, 12 patients answered the questionnaire (6 female, 6 male; mean initial age: 11.3 years). Five patients in the HH group and two patients in the CH group were excluded from the analysis due to errors when filling out the questionnaires or due to failure to attend the appointment 30 days after appliance placement. Similar initial age and sex distribution were found for both groups (Table 2).

Both groups demonstrated similar levels of adaptation for speech, chewing, swallowing, and appearance after the first month of treatment (Table 3).

The level of pain and discomfort was similar in both groups for the three timepoints (Tables 3 and 4; Figure 2). In the intragroup analysis, the level of pain/discomfort significantly decreased 1 month after appliance installation in group HH. In group CH, the level of pain/discomfort decreased 1 day and 1 month after appliance placement (Table 5). Guardians reported higher VAS scores than patients at all timepoints (Tables 6 and 7; Figure 3).

No complications were observed during miniscrew placement. After placement, palatal miniscrew instability was observed in one out of 38 patients (2.6%). Mandibular miniscrew instability was 15.7% in the HH group and 17.8% in the CH group, but it often occurred after 1 month of treatment. Deficiency in the level of compliance in wearing the Class III elastics was

Table 3. Intergroup Comparisons of Patient's Perception (Intention-to-Treat Analysis; Independent *t*-Test or Mann-Whitney *U*-Test)[a]

	Group HH		Group CH			95% CI	
	Mean Changes (SD)	Median	Mean Changes (SD)	Median	Diff Mean	Lower, Upper	*P* Value*
Q1	43.07 (22.04)	50.0	35.64 (13.44)	39.10	7.42	−6.26, 21.11	.277[A]
Q2	54.32 (30.39)	56.35	43.39 (22.04)	49.20	10.93	−8.78, 30.64	.266[A]
Q3	32.43 (30.57)	21.85	26.40 (24.97)	28.75	6.02	−14.55, 26.6	.554[A]
Q4	22.39 (30.51)	10.0	15.87 (13.52)	19.40	6.52	−10.30, 10.0	.727[B]
Q5	60.49 (27.33)	65.45	72.55 (14.77)	68.60	−12.05	−28.62, 4.51	.148[A]
Q6	44.98 (29.77)	40.0	49.76 (28.42)	46.45	−4.77	−26.02, 16.47	.649[A]
Q7	14.87 (23.40)	5.0	10.66 (8.65)	11.10	4.21	−10.0, 10.0	.608[B]
Q8	7.14 (4.15)	7.00	6.39 (2.97)	6.90	0.75	−1.50, 3.10	.907[B]
Q9	89.66 (19.29)	100.0	89.42 (13.89)	91.70	0.24	−4.63, 10.00	.208[B]

[a] CH indicates Conventional Hyrax; CI, confidence interval; HH, Hybrid Hyrax.
* Statistically significant at $P < .05$; [A] *t*-test; [B] Mann-Whitney *U*-test.

reported for approximately 15% of the patients in each group.

DISCUSSION

This is the first study to evaluate patients' and guardians' perception of pain and discomfort caused by miniscrew-anchored maxillary protraction. In the primary study, the dentoskeletal changes promoted by MAMP therapy anchored on Hybrid and Hyrax expanders were compared.[8] However, there is an important concern of patients and guardians regarding the level of pain and discomfort caused by these therapies. Patient-centered outcomes are essential during the development of new techniques and procedures. The most useful diagnostic strategies for pain and discomfort include characterization of subjective pain perception by the patient.[11,20] Other methodologies were proposed to obtain more objective measures, such as the local application of stimuli such as pressure, cold, and heat; however, results are still subjective since the perceived pain sensations would be verbally expressed by the subjects.[20]

In this study, two designs of MAMP therapy were compared. In group HH, two miniscrews were placed in the anterior region of the palate and two miniscrews were placed in the anterior region of the mandible, distal to the permanent canines. In group CH, only the mandibular miniscrews were used. Both groups demonstrated similar levels of adaptation to speech, chewing, swallowing, and appearance after 1 month of placement (Table 3). In addition, the groups expressed similar levels of pain and discomfort for all evaluated timepoints (Table 3). Scores of 60–70 for pain/discomfort were assigned right after appliance installation (Figure 2). One month after treatment, scores decreased to less than 20. It may be hypothesized that the level of pain and discomfort caused by MAMP therapy is mostly related to the placement of the mandibular miniscrews. A previous study found similar levels of pain and discomfort during the first week of RME treatment using conventional hyrax expanders and hybrid expanders in a sample of growing patients (mean: 9.8 years).[19] Overall, low levels of pain intensity were reported for both types of expanders (median pain level: 13.0 and 3.5 for the conventional and hybrid expander, respectively).[19] In contrast, a previous study demonstrated that miniscrew placement caused moderate pain and discomfort in a sample of adolescent patients.[18] However, compared to a more invasive procedure as tooth extraction, miniscrew placement demonstrated a lower level of pain and discomfort.[18] In this study, the chief complaint by patients after placement was the pain and discomfort caused in the mandibular miniscrew area. It was believed that this greater sensitivity in the mandibular miniscrew site was caused by anatomical limitations such as proximity between roots and soft tissue thickness. In addition, mandibular miniscrews may be touching the sensitive labial mucosa. On the other hand, the palatal miniscrews were inside the slots of the maxillary expander, causing less discomfort.

In both groups, the highest peak of pain level and discomfort was reported after placement, with significant decreases 1 month after the procedure. This difference was expected since the findings were in agreement with previous studies that reported significant decreases in pain intensity with time after miniscrew placement.[18,21] In addition, the pain and discomfort levels decreased significantly after 1 month of placement in both groups (approximately 80%

Table 4. Repeated-Measures ANOVA for Intergroup Comparison[a]

	DF	F	*P*
Time	3	47.43	<.001*
Time * GROUP	3	1.98	.123
Residual	90		

[a] Intention-to-treat analysis. ANOVA indicates analysis of variance; DF, degrees of freedom; F, test statistic; * statistically significant at $P < .05$.

Table 5. Intragroup Comparisons of Pain And Discomfort During First Month of Therapy (Friedman Test Followed by Durbin-Conover Test; Intention-To-Treat Analysis)[a]

	T1		T2		T3		
	Mean	Median	Mean	Median	Mean	Median	*P*
Group HH	60.5[A]	65.4	45.0[A]	40.0	14.9[B]	5.0	<.001*
Group CH	72.5[A]	68.6	49.8[B]	46.5	10.7[C]	11.1	<.001*

[a] T1 indicates immediately after appliance installation; T2, 1 day after placement; T3, 1 month after placement.
* Statistically significant at $P < .05$. Different letters indicate statistically significant differences.

reduction in pain intensity). This finding sums up to the hypothesis that pain and discomfort levels reported can be considerate postoperative impairment that will decrease significantly over time.[21]

Parents and guardians were concerned with the level of pain and discomfort caused by MAMP therapy. For this reason, patients and their guardians answered the questionnaires independently 1 month after placement. Similar findings were found when comparing the guardian's perception of pain and discomfort of both groups. This was an unexpected finding since the CH group required a less invasive procedure, and since only two miniscrews were required in this group. In contrast, this finding can be associated with the hypothesis that mandibular miniscrews were the major reason for the discomfort caused after the placement of MAMP therapy. Interestingly, the guardian's perception of pain and discomfort was higher than the reported levels of pain by patients at all timepoints (Figure 3). Conversely, a previous study showed that, in a sample of patients 4–6 years of age, there was agreement between the scores of dental pain by the patients and their parents.[22] It may be hypothesized that guardians tended to show greater perception of discomfort than the real level of discomfort experienced by patients due to the complexity of surgical procedures, previous self-experience, and caring tendency.

The limitation of this study was the small sample size due to missing data from dropouts. To overcome this limitation, an intention-to-treat analysis was used for comparison. In addition, this was the first study to demonstrate the level of pain and discomfort of patients treated with MAMP therapy with or without hybrid expanders. Future studies with greater sample sizes should analyze the impact of medication for pain on the MAMP therapy level of discomfort.

CONCLUSIONS

The null hypothesis was not rejected:

- Miniscrew-anchored maxillary protraction associated with either hybrid or conventional hyrax expanders promoted similar levels of adaptation for speech, chewing, swallowing, and appearance after 1 month of placement.
- Similar levels of pain and discomfort were found between groups immediately after appliance placement, 1 day, and 1 month after.
- Time was an important factor in decreasing pain and discomfort perception during therapy.

Table 6. Intergroup Comparisons of Guardian's Perception (Mann-Whitney *U*-Test)[a]

	Group HH		Group CH			95% CI	
Variable	Mean Changes (SD)	Median	Mean Changes (SD)	Median	Diff Mean	Lower, Upper	*P* Value*
T1	77.03 (20.12)	78.95	83.09 (13.50)	80.75	−6.06	−18.30, 4.00	.331
T2	69.69 (18.49)	68.55	70.91 (20.71)	71.30	−1.21	−15.20, 10.00	.446
T3	24.46 (17.82)	22.45	19.70 (20.11)	20.35	4.76	−3.30, 16.80	.260

[a] CH indicates Conventional Hyrax; CI, confidence interval; HH, Hybrid Hyrax; SD, standard deviation; T1, immediately after appliance installation; T2, 1 day after placement; T3, 1 month after placement.
* Statistically significant at $P < .05$.

Table 7. Comparison Between Guardian's and Patient's Perception of Pain and Discomfort (Paired *t*-Test or Wilcoxon Test)[a]

	Patients		Guardians			95% CI	
Variable	Mean changes (SD)	Median	Mean changes (SD)	Median	Diff Mean	Lower, Upper	*P* Value*
T1	65.8 (23.2)	67.2	79.7 (17.5)	80.3	−13.91	−20.1, −7.74	<.001*[A]
T2	47.1 (28.8)	46.0	70.2 (19.2)	70.4	−23.15	−33.3, −12.79	<.001*[A]
T3	13.0 (18.3)	10.0	22.4 (18.7)	21.2	−9.35	−19.3, −6.70	.008*[B]

* Statistically significant at $P < .05$; [A] paired *t*-test; [B] Wilcoxon test.
[a] CI indicates confidence interval; SD, standard deviation; T1, immediately after appliance installation; T2, 1 day after placement; T3, 1 month after placement.

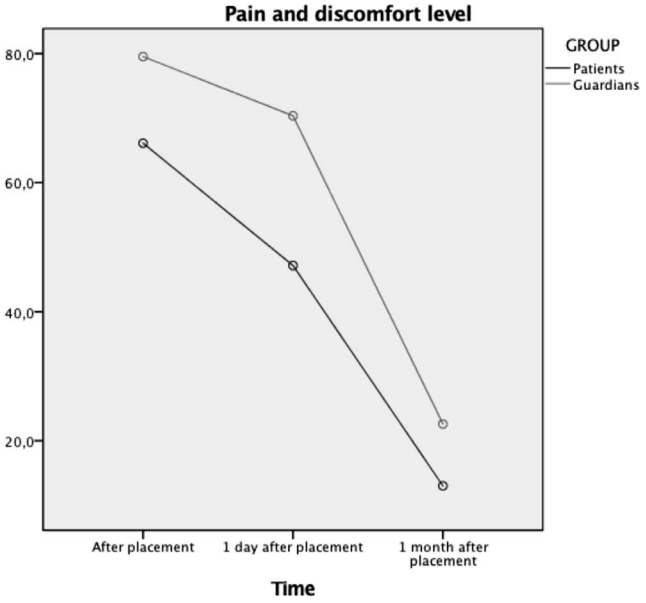

Figure 3. Level of pain and discomfort reported by patients (darker line) and by guardians (lighter line).

- Pain and discomfort may not influence the choice between hybrid and conventional expanders for MAMP therapy.
- Guardians demonstrated a perception of greater pain and discomfort levels compared to the patients.

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