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Comparison of tooth-borne and hybrid devices in surgically assisted rapid maxillary expansion: A randomized clinical cone-beam computed tomography study

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ABSTRACT

Purpose: The objective of this 2-arm, parallel, single-center trial was to compare the skeletal, dental, and periodontal effects of tooth-borne (TB) and hybrid devices in surgically assisted rapid maxillary expansion (SARME).

Materials and methods: Twenty consecutive patients (9 male and 11 female) with skeletal transverse maxillary deficiency seeking treatment at the Department of Orthodontics at Istanbul University in Istanbul, Turkey, were randomly assigned to 2 groups (10 patients each). Hybrid devices were inserted in the first group and TB (Hyrax) devices in the second. All of the patients had undergone SARME operations, which were carried out by the same surgeons using the same procedure (a Le Fort I osteotomy with pterygomaxillary dysjunction). All of the patients had similar transverse deficits, and 7 mm of expansion was achieved in all of them over 14 days. CBCT was carried out preoperatively (T0), at the end of the active expansion phase (T1), and after 6 months of retention (T2). Measurements were made using Mimics 16.0.

Results: Anterior skeletal maxillary widening parameters increased significantly in the T0–T1 and T0–T2 periods in the 2 groups ($P = 0.001$). There was significantly less dental expansion anteriorly with the hybrid devices (T0–T2: 4.03 mm vs. 6.29 mm). The first molars tipped buccally more in the group with TB devices during the T0–T1 phase ($P = 0.029$) and moved upright more than those in the group with hybrid devices during the retention phase ($P = 0.035$). Dental tipping, buccal alveolar bone resorption, and root resorption were observed significantly more often with the TB devices.

Conclusion: Hybrid RME devices, with similar skeletal effects, different dental movement patterns, and fewer dental and periodontal side effects, thus appear to be a beneficial alternative to TB devices for SARME procedures.

1. Introduction

Rapid maxillary expansion (RME) is a commonly used orthopedic procedure for correcting transverse maxillary discrepancies in growing children. Strong orthopedic forces are used to separate the maxilla into 2 halves at the midpalatal suture (Bell, 1982). Transverse maxillary hypoplasia is frequently seen in non-syndromic patients (Proffit and Moray, 1998). Nonsurgical, conventional expansion is usually carried out in patients younger than 13 years. Skeletally mature patients, however, cannot be treated using conventional maxillary expansion, as the palatal suture has already ossified. As described by Glassman et al. (1984), ossified palatal sutures can be treated with surgically assisted rapid maxillary expansion (SARME), with local bone osteotomy and either tooth-borne or bone-borne expanders (Mommaerts, 1999).

Tooth-borne expanders are the commonly used treatment choice after SARME in adult patients, and have been shown to be

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satisfactory. However, they often cause dental tipping, root resorption, periodontal damage, and alveolar deformation, which may even extend to fractures of the alveolar process (Timms and Moss, 1971). Mommaerts (1999) introduced the bone-borne SARME technique to prevent these side effects. The major advantage of bone-borne expanders is that forces are directly transmitted to the palatal bone, thus causing more skeletal expansion closer to the center of resistance, less periodontal bone loss, and less root resorption (Neyt et al., 2002). However, some studies have reported that bone-borne devices may increase the risk of root lesions or infections, asymmetric maxillary expansion, and periodontal damage. In addition, there is a risk of losing the distractor modules, and insertion and removal of the bone-borne devices are invasive, as they require flap preparation (Neyt et al., 2002; Seitz et al., 2008; Koudstaal et al., 2009; Verlinden et al., 2011).

Mini-implants have attracted considerable attention in recent years, as they are versatile, minimally invasive, low in cost, and easy to use clinically (Wilmes, 2008). More recently, expansion appliances have been developed that use palatal mini-implants to secure the expansion screw directly to the palate, reducing the forces that are placed directly on the teeth. Mini-implant–assisted RME has been developed in an effort to maximize skeletal expansion and to minimize dental tipping. The basis of bone-anchored rapid maxillary expansion is the idea of avoiding direct forces on the teeth in order to maximize the orthopedic effect. Bone-anchored rapid maxillary expander designs can vary widely. Harzer et al. (2004) introduced the Dresden Distractor, which is attached solely to an implant and a mini-implant. Cortese et al. (2010) developed an appliance consisting of four 8-mm mini-screw implants that secure 2 titanium mini-plates and a titanium jackscrew to the palate. Lagravere et al. (2010) also used a bone-anchored maxillary expander consisting of an expansion screw and 2 stainless steel onplants secured to the palate with 2 mini-screw implants.

In 2008, Wilmes et al. introduced a hybrid RME device (hybrid Hyrax), an expander that is both tooth-borne and bone-borne (Wilmes and Drescher, 2008; Wilmes et al., 2010). The hybrid RME device is attached to 2 orthodontic mini-implants in the anterior palate and to the first molars. The anterior palate is the preferred location for mini-implant insertion, due to the excellent bone quality and thin attached mucosa in the area, resulting in a relatively low failure rate (Karagkiolidou et al., 2013). In addition, there is virtually no risk of tooth damage (Wilmes et al., 2014). Ludwig et al. (2011) have described suitable sites for palatal miniscrew insertion. They suggest that the anterior palate is the optimal site for supporting various treatment mechanisms, including rapid maxillary expansion.

The literature includes only a few published studies on hybrid RME: Wilmes et al. (2010) investigated the dental and skeletal effects of hybrid Hyrax combined with a face mask in 13 patients (mean age 11.2 years) and reported that the side effects of RME can be minimized using a hybrid Hyrax in growing children. Similarly, Ludwig et al. (2010) reported a case series on mini-implant–supported class III treatment with a hybrid rapid palatal expansion advancer. Wilmes et al. (2011) used a hybrid Hyrax in combination with a Mentoplate for early class III treatment. Using cephalograms, Nienkemper et al. (2013) investigated maxillary protraction using a hybrid Hyrax–face mask combination in 16 children (mean age 9.5 ± 1.3 years). These studies focus mostly on the hybrid Hyrax–face mask combination for orthopedic treatment in growing class III patients and use 2-dimensional radiographs or dental casts. However, there have been no studies to date examining whether hybrid SARME can have a positive effect in comparison to conventional dentally anchored SARME.

The objective of the present study was therefore to compare the dental and skeletal effects of tooth-borne and tooth-borne/bone-borne (hybrid) appliances in SARME.

2. Material and methods

2.1. Trial design

This was a single-center, 2-arm, parallel, randomized, clinical trial with a 1:1 allocation ratio.

2.2. Participants, eligibility criteria, and settings

Consecutive patients with skeletal transverse maxillary deficiency seeking treatment at the Department of Orthodontics at Istanbul University in Istanbul, Turkey, between December 2012 to January 2014 were invited to participate (Table 1). Data were collected from December 2012 until the end of January 2014. The inclusion criteria were skeletal maturity, skeletal transverse maxillary deficiency, and no developmental deformity. Exclusion criteria included age younger than 18 years, absence of maxillary first molars, previous periodontal disease, previous orthodontic treatment, and genetic disease. All patients provided informed consent. The study protocol was approved by the Clinical Research Ethics Committee of Istanbul University Medical Faculty (reference number 2012/641-1044).

2.3. Interventions

All orthodontic clinical manipulations were performed by same orthodontist (E.K.). In 10 randomly assigned patients, a tooth-borne (TB) expansion device (Hyrax; Forestadent, Pforzheim, Germany) was cemented onto dental bands fitted onto the first premolars and first molars a few days before the operation. In the remaining 10 patients, a hybrid RME device was inserted in accordance with the procedures described in previous studies by Wilmes et al. and Ludwig et al. (Fig. 1) (Ludwig et al., 2010; Wilmes et al., 2010). After the application of local anesthetic, 2 miniscrews (Ortho Easy, 10.0 × 1.7 mm; Forestadent) were inserted into the anterior palate, perpendicular to the palatal bone surface, at 2 mm paramedian to the suture and between the canine and first premolar contact points and first and second premolar contact points (Ludwig et al., 2011). Bands fitted to the upper first molars and laboratory abutments were attached to the mini-screw heads. A silicone impression of the maxillary arch was taken. The Hyrax expansion unit was fabricated from a Snap Lock expansion screw (Forestadent) by

Table 1
Demographic and skeleto-dental characteristics of sample.

	Hybrid group		Hyrax group		P value
	Mean	SD	Mean	SD	
Age	19.2	3.64	19.3	5.01	0.96
Gender					
Male	3		6		
Female	7		4		0.37
EMW4	37.92	3.49	35.93	1.82	0.13
EMW6	62.11	2.09	62.92	8.14	0.76
ICW4	36.75	1.89	34.71	1.81	0.02*
ICW6	45.49	2.68	45.78	3.18	0.83
IAW4	29.32	1.99	27.28	3.14	0.10
IAW6	31.08	2.25	31.06	1.71	0.98
Angle4	9.23	3.25	8.92	4.08	0.85
Angle6	6.01	5.58	6.93	2.82	0.86

P > 0.05 not significant (no statistically significant change).
*Statistically significant change.

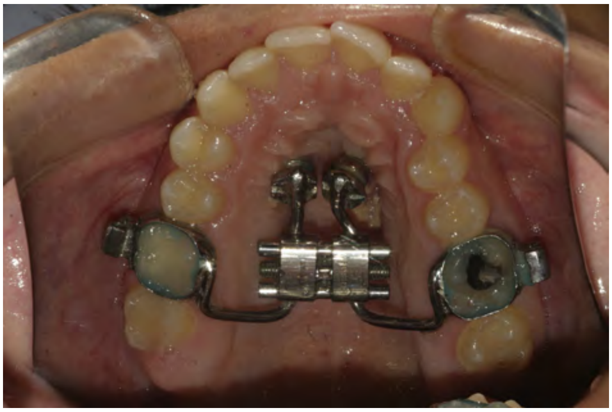

Fig. 1. Tooth- and bone-borne: hybrid rapid maxillary expansion device.

laser-welding wire segments between the screw and the upper first molar bands. To allow adequate time for installing the hybrid Hyrax, light-curing acrylic resin (Band-Lok; Reliance Orthodontic Products, Itasca, IL, USA) was used for molar band cementation.

The same surgical procedure was carried out in all of the patients by the same surgical team in the Department of Plastic, Reconstructive, and Aesthetic Surgery at the Faculty of Medicine, Istanbul University. With the patient under general anesthesia, a Le Fort I osteotomy was performed with a midline osteotomy and Glassman pterygomaxillary dysjunction (Glassman et al., 1984; Schimming et al., 2000). To verify that the osteotomy was adequate, the expansion screw was activated intraoperatively until a diastema of 1 mm could be seen.

The expansion screw was activated at 2 turns per day (0.25 mm per turn) for 14 days, reaching a total expansion of 7 mm in all patients in both groups. The expander was then kept in place on the teeth as a passive retainer for 6 months. To allow comparison of the long-term effects of the hybrid and TB appliances, no orthodontic forces were applied to the teeth during this 6-month retention period.

Cone-beam computed tomography (CBCT) scans were taken before rapid palatal expansion (T0), at the end of the active expansion phase (T1), and after the 6-month retention period, when the expander was being removed (T2). All of these examinations were carried out by a single trained radiographer at the same scanner console (Scanora 3D; Soredex, Tuusulu, Finland). Subsequent scans were taken with a voxel size of 0.25 mm, at 12.5 mA, with a field of view (FOV) of 14.5 cm, and following a low-dose protocol with 90 kVp instead of the standard CT setting of 120 kVp. Measurements were made using Mimics 16.0 (Materialise, Belgium).

2.4. Outcomes (primary and secondary) and changes after trial commencement

The primary outcome of this study was the amount of skeletal expansion with either the hybrid or the tooth-borne technique. The secondary outcomes were the amount of dental expansion and the dental and periodontal side effects (dental tipping, root resorption, and vestibuler bone resorption) of each technique.

On the scanned CBCT images, measurements were made at the skeletal (Fig. 2A, B), dental (Fig. 3A, B), and periodontal (Fig. 4) levels in accordance with the definitions provided in previous studies by Garib et al. (2005) and Podesser et al. (2007) (Table 2).

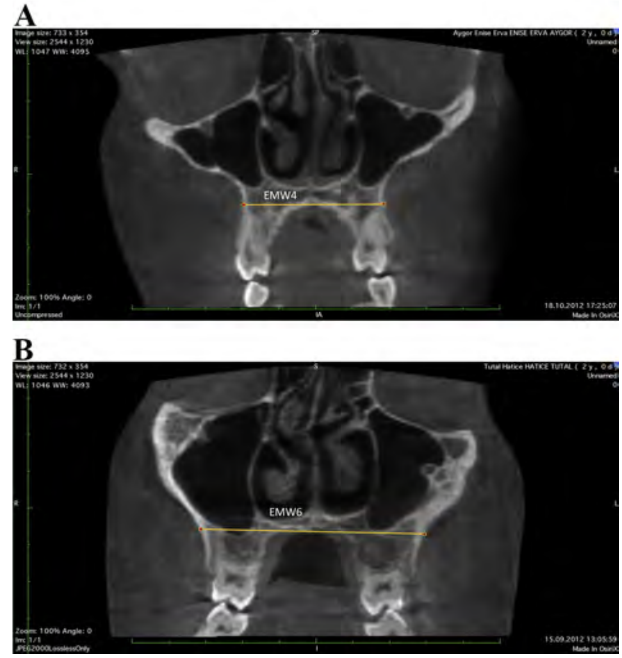

Fig. 2. Skeletal measurements on cone-beam computed tomographic images: External maxillary width (EMW) at the level of center of the right maxillary first premolar root (A) and the right maxillary first molar furcation (B).

2.5. Sample size calculation

The sample size for this clinical trial was calculated according to previous reports that used CT images to evaluate RME (Ballanti et al., 2009; Lagravere et al., 2010). The number of patients was 10 per group.

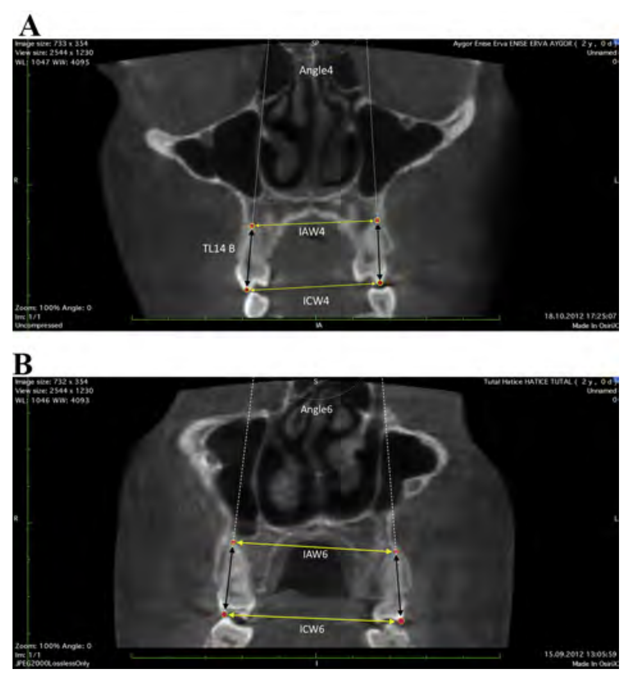

Fig. 3. Dental measurements on cone-beam computed tomographic images at the level of maxillary first premolars (A) and the first molars (B).

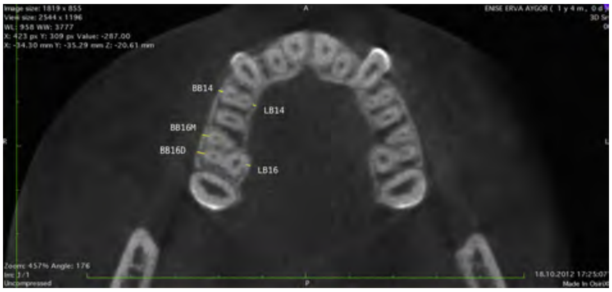

Fig. 4. Periodontal measurements on cone-beam computed tomographic images at the level of the right maxillary first molar furcation: lingual bone (LB) and buccal bone plate (BB) thicknesses.

errors were calculated by comparing the first and second measurements using paired *t*-tests and the Dahlberg formula, respectively (Houston, 1983). No statistically significant differences ($P > 0.05$) were found between the first and second measurements for any of the variables analyzed; the range for random errors was 0.01–0.19 mm. The correlation between the first and second readings was calculated using Spearman correlation analysis and represented with the *r* value. All measurement error coefficients were found to be close to 1.00 and within acceptable limits (range 0.89–0.99). The mean differences in measurements at T0, T1, and T2 were contrasted using Friedman analysis of variance (ANOVA) for repeated measures. The significance level was set at $P < 0.05$.

Table 2
Measurements on cone beam computed tomographic scan.

Skeletal measurement: (Fig. 2A, B)
EMW4 (External maxillary width-anterior): the maxillary width tangent to the hard palate at the level of the right maxillary first molar furcation.
EMW6 (External maxillary width-posterior): the maxillary width tangent to the hard palate at the center of the right maxillary first premolar root.

Dental measurements: (Fig. 3A, B)

ICW4 (Interpremolar Crown Width): the width between the buccal cusp tips of the first premolars.
ICW6 (Intermolar Crown Width): the width between the mesiobuccal cusp tips of the first molars.
IAW4 (Inter-premolar Root Apex Width): the width between the palatal apex of the first premolars.
IAW6 (Inter-molar Root Apex Width): the width between the palatal apex of the first molars.
Angle4 (Interpremolar Angle): the angulation of the first premolars.
Angle6 (Intermolar Angle): the angulation of the mesiobuccal root of the first molars.
TL 14B (Buccal Tooth Length of first premolar): the distance between the buccal cusp and the buccal apex of the first premolars.
TL 14L (Lingual Tooth Length of first premolar): the distance between the lingual cusp and the lingual apex of the first premolars.
RL 16 MB (Mesio-Buccal Root Lenght of first molar): the width between the trifurcation and the mesiobuccal apices of the first molars.
RL 16DB (Disto-Buccal Root Lenght of first molar): the width between the trifurcation and the distobuccal apices of the first molars.
RL 16L (Lingual Root Lenght of first molar): the width between the trifurcation and the lingual apices of the first molars.

Periodontal measurements: The scanning plane was parallel to the palatal plane at the level of the right and left maxillary first molar furcation (Fig. 4)

BB 14 (Buccal alveolar bone thickness of first premolar): the width between the external aspect of the buccal cortical plate and the center of the buccal roots of the first premolars.
LB 14 (Lingual alveolar bone thickness of first premolar): the width between the external aspect of the palatal cortical plate and the center of the palatal roots of the first premolars.
BB 16M (Mesio-Buccal alveolar bone thickness of first molar): the width between the external aspect of the buccal cortical plate and the center of the mesiobuccal roots of the first molars.
BB 16D (Disto-Buccal alveolar bone thickness of first molar): the width between the external aspect of the buccal cortical plate and the center of the distobuccal roots of the first molars.
LB 16 (Lingual alveolar bone thickness of first molar): the width between the external aspect of the palatal cortical plate and the center of the palatal aspect of the root of the first molar.

2.6. *Interim analyses and stopping rules*

There were no interim analyses or stopping rules.

2.7. *Randomization*

A total of 33 patients with a transverse maxillary discrepancies were evaluated, of whom 20 patients fulfilled the inclusion criteria. Randomization was performed using computer-generated tables; allocation was concealed using sequentially numbered opaque and sealed envelopes. A total of 20 consecutive skeletally mature non-syndromic patients (9 male and 11 female) were prospectively included in the study (Table 1). They were randomly distributed into 2 groups with 10 patients in each group. Hybrid devices were inserted in the first group and TB (Hyrax) devices in the second.

2.8. *Statistical analysis*

All of the measurements were made by 2 operators (E.K. and M.S.) at the same scanner console, and were repeated after 1 month at the same console by 1 operator (E.K.). Systematic and random

3. Results

3.1. *Participant flow*

A total of 33 consecutive patients were assessed for eligibility. Ten patients did not fulfill the inclusion criteria (6 had periodontal problems, 3 had missing first molars, and 1 had genetic disease), and 3 patients declined to participate. Thus 20 patients were randomized to either the hybrid devices or the tooth-borne devices group. The study began in December 2012 and ended in January 2014.

3.2. *Baseline data*

Table 2 lists the demographic and skeletal–dental characteristics of the 2 groups. The participants' average age was 19.37 ± 4.18 years (range 18–35 years). The patients who received the hybrid device had an increased interpremolar crown width in comparison with the TB group ($P = 0.02$). The other parameters were similar between the 2 groups ($P > 0.05$).

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3.3. Numbers analyzed

Skeletal, dental, and periodontal changes in the group with hybrid devices are presented in Table 3, and those for the group with TB devices in Table 4. Intergroup comparisons are presented in Table 5.

When the treatment changes in TB and hybrid devices groups were compared, significant differences were found in the anterior dental expansion, first molar dental inclination, buccal and lingual alveolar bone thickness, and tooth length of first premolars.

There was significantly less anterior dental expansion in the hybrid devices during the active expansion period (T0–T1: 4.74 mm vs. 6.13 mm; $P = 0.019$) and retention period (T0–T2: 4.03 mm vs. 6.29 mm; $P = 0.001$). However, posterior dental expansion at the first molars was comparable in the 2 groups ($P > 0.05$) (Table 5).

The first molars tipped buccally more in the group with TB devices during the active expansion phase (T0–T1; $P = 0.029$) and moved upright more than those in the group with hybrid devices during the retention phase (T1–T2; $P = 0.035$) (Table 5).

Buccal alveolar bone thickness (BB14) decreased during both the T0–T1 ($P = 0.036$) and T1–T2 ($P = 0.022$) periods in the group with TB devices. There was a statistically significant decrease of -0.55 ± 0.38 mm in the buccal alveolar bone thickness in the TB device group in T0–T2 ($P = 0.001$) (Table 5). The mean value for the BB14 parameter was 0.08 ± 0.17 at the end of the observation period (T2). No statistically significant changes in BB14 were observed in the hybrid devices at any period ($P > 0.05$) (Table 3). Differences in the buccal (BB14) and lingual (LB14) alveolar bone thickness were found to be significant between the 2 groups during both the T0–T2 and T1–T2 periods ($P < 0.01$) (Table 5).

A significantly smaller decrease in palatal tooth length in the first premolars (TL 14L) was observed in the group with hybrid devices during both the T0–T2 ($P = 0.036$) and T1–T2 ($P = 0.011$) periods (Table 5).

3.4. Adverse effects

No serious adverse effects were observed during the whole study period.

4. Discussion

The most reliable and stable procedure for correcting maxillary skeletal transverse problems in adults is the SARME procedure (Graber et al., 2005). However, there is no consensus in the literature regarding the type of distractor (tooth-borne or bone-borne) that should be used for SARME to provide the best dental and skeletal results and stability (Koudstaal et al., 2005; Suri and Taneja, 2008; Verstraaten et al., 2010; Vilani et al., 2012). Both tooth-borne and bone-borne devices have been used successfully for SARME, and each has some advantages and disadvantages. Tooth-borne devices transmit the expansion force to the anchoring teeth and may cause buccal tipping of the anchoring teeth, maxillary dentoalveolar tipping, and several complications including periodontal problems, root resorption, tooth extrusion, cortical bone resorption and fenestration, speech problems, and relapse. It has been claimed that bone-borne devices, which deliver the expansion force directly to the palatal bone, produce parallel expansion of the palatal halves, keeping segmental and tooth tipping and associated complications to a minimum (Gerlach and Zahl, 2003; Harzer et al., 2006; Suri and Taneja, 2008; Koudstaal et al., 2009; Verstraaten et al., 2010). However, studies evaluating dental and skeletal changes following either tooth-borne or bone-borne SARME have produced divergent results (Landes et al., 2009; Nada et al., 2012; Zandi et al., 2014). Some studies have reported that bone-borne devices are associated with a risk of root lesions or infections, asymmetric maxillary expansion, periodontal damage, and loss of the distractor modules. In addition, insertion and removal of bone-borne devices are invasive, as they require flap preparation (Neyt et al., 2002; Seitz et al., 2008; Koudstaal et al., 2009; Verlinden et al., 2011). To minimize the surgical invasiveness of such techniques, Wilmes et al. (2010) introduced the hybrid Hyrax, using mini-implants in the palate for anterior skeletal anchorage and the first molars for posterior dental anchorage. The skeletal, dental, and periodontal effects of tooth-borne (TB) and hybrid devices in SARME were compared in the present study.

The mean skeletal maxillary widening was found to be similar in the hybrid and TB groups during the active expansion phase (T0–T1) (Table 5), and changes during the retention period (T1–T2) did not differ significantly between the 2 groups (Tables 3 and 4).

Table 3
Skeletal, dental, and periodontal changes in hybrid devices group.

	T0	T1	T2	T0-T1	T0–T2	T1–T2	T0–T1	T0–T2	T1–T2
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	[a]p	[a]p	[a]p
EMW4	37.92 ± 3.49	41.67 ± 3.78	41.94 ± 3.21	3.75 ± 1.15	4.02 ± 1.42	0.27 ± 0.94	**0.001****	**0.001****	0.391
EMW6	62.11 ± 2.09	64.04 ± 2.08	63.74 ± 1.77	1.93 ± 2.92	1.63 ± 2.76	−0.3 ± 1	0.067	0.095	0.369
ICW4	36.75 ± 1.89	41.49 ± 1.99	40.78 ± 2.16	4.74 ± 0.79	4.03 ± 0.84	−0.7 ± 0.48	**0.001****	**0.001****	**0.001****
ICW6	45.49 ± 2.68	51.63 ± 3.19	51.73 ± 2.95	6.13 ± 1.62	6.24 ± 2.46	0.11 ± 1.95	**0.001****	**0.001****	0.864
IAW4	29.32 ± 1.99	32.85 ± 2.19	33.17 ± 2.60	3.53 ± 1.34	3.85 ± 1.43	0.32 ± 0.81	**0.001***	**0.001****	0.246
IAW6	31.08 ± 2.25	33.29 ± 2.22	35.70 ± 2.87	1.99 ± 1.10	4.16 ± 1.89	2.16 ± 1.44	**0.001****	**0.001****	**0.001****
IA4	9.23 ± 3.25	11.26 ± 3.81	8.6 ± 4.36	2.03 ± 2.05	−0.63 ± 3.35	−2.66 ± 2.12	**0.012***	0.569	**0.003****
IA6	6.01 ± 5.58	9.65 ± 6.05	9.12 ± 3.25	3.64 ± 10.72	3.11 ± 8.66	−0.53 ± 5.81	0.031*	**0.014***	0.315
BB 14	0.98 ± 0.49	1.01 ± 0.55	1.18 ± 0.69	0.03 ± 0.2	0.2 ± 0.35	0.17 ± 0.24	0.646	0.121	0.066
LB 14	1.1 ± 0.47	1.22 ± 0.48	1.05 ± 0.62	0.12 ± 0.13	−0.05 ± 0.26	−0.17 ± 0.28	**0.027***	0.553	0.102
BB 16B	1.02 ± 0.32	0.53 ± 0.39	0.49 ± 0.55	−0.49 ± 0.48	−0.53 ± 0.4	−0.04 ± 0.62	**0.016***	**0.004****	0.834
BB 16D	1.59 ± 0.47	0.89 ± 0.45	0.85 ± 0.42	−0.7 ± 0.59	−0.75 ± 0.6	−0.05 ± 0.75	**0.007****	**0.006****	0.856
LB 16	0.92 ± 0.18	1.33 ± 0.26	1.72 ± 0.4	0.41 ± 0.23	0.8 ± 0.48	0.39 ± 0.43	**0.001****	**0.001****	**0.025***
TL 14B	20.73 ± 1.33	20.45 ± 1.49	20.37 ± 1.69	−0.28 ± 0.57	−0.36 ± 0.65	−0.08 ± 0.23	0.15	0.114	0.308
TL 14L	19.82 ± 2.17	19.49 ± 2.09	19.32 ± 2.23	−0.32 ± 0.32	−0.5 ± 0.45	−0.17 ± 0.28	**0.011***	**0.007****	0.081
RL 16MB	9.79 ± 1.21	9.61 ± 1.21	9.26 ± 1.23	−0.18 ± 0.21	−0.54 ± 0.41	−0.36 ± 0.28	**0.024***	**0.002****	**0.003****
RL 16DB	10.42 ± 1.05	10.17 ± 1.24	9.84 ± 1.17	−0.25 ± 0.21	−0.57 ± 0.38	−0.33 ± 0.39	**0.004****	**0.001****	**0.027***
RL 16L	11.45 ± 0.5	11.23 ± 0.5	11.06 ± 0.47	−0.22 ± 0.17	−0.39 ± 0.22	−0.17 ± 0.21	**0.003****	**0.001****	**0.030***

*p < 0.05.
**p < 0.01.
Bold values denote statistically significant changes.
[a] Paired sample t test.

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Table 4
Skeletal, dental, and periodontal changes in tooth-borne (TB) devices group.

	T0	T1	T2	T0–T1	T0–T2	T1–T2	T0–T1	T0–T2	T1–T2
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	[a]p	[a]p	[a]p
EMW4	35.93 ± 1.82	40.51 ± 1.97	40.26 ± 2.54	4.58 ± 1.8	4.33 ± 1.85	−0.25 ± 1.9	**0.001****	**0.001****	0.689
EMW6	62.92 ± 8.14	63.94 ± 7.97	64.05 ± 8.04	1.02 ± 2.1	1.13 ± 2.2	0.1 ± 0.21	0.157	0.14	0.148
ICW4	34.71 ± 1.81	40.84 ± 1.55	41 ± 1.51	6.13 ± 1.47	6.29 ± 0.51	0.16 ± 1.33	**0.001****	**0.001****	0.708
ICW6	45.78 ± 3.18	52.91 ± 2.65	52.59 ± 2.67	7.12 ± 1.75	6.81 ± 0.83	−0.32 ± 1.31	**0.001****	**0.001****	0.463
IAW4	27.28 ± 3.14	30.48 ± 2.71	31.91 ± 2.99	3.20 ± 1.71	4.63 ± 2.34	1.43 ± 1.52	**0.001****	**0.001****	**0.016***
IAW6	31.06 ± 1.71	32.68 ± 1.70	34.30 ± 2.38	1.62 ± 0.94	3.24 ± 1.78	1.62 ± 1.03	**0.001****	**0.001****	**0.001****
Angle4	8.92 ± 4.08	13.02 ± 7.01	10.93 ± 6.59	4.1 ± 4.48	2.01 ± 5.35	−2.08 ± 3.62	**0.018***	**0.043***	0.102
Angle6	6.93 ± 2.82	16.39 ± 7.8	10.71 ± 6.72	9.46 ± 7.38	3.77 ± 6.58	−5.68 ± 4.43	**0.003****	**0.045***	**0.003****
BB 14	0.63 ± 0.41	0.49 ± 0.48	0.08 ± 0.17	−0.15 ± 0.19	−0.55 ± 0.38	−0.4 ± 0.46	**0.036***	**0.001****	**0.022***
LB 14	0.81 ± 0.27	1.21 ± 0.5	1.83 ± 0.53	0.4 ± 0.57	1.02 ± 0.58	0.62 ± 0.53	0.055	**0.001****	**0.005****
BB 16B	0.94 ± 0.57	0.66 ± 0.62	0.39 ± 0.38	−0.28 ± 0.19	−0.54 ± 0.31	−0.27 ± 0.31	**0.001****	**0.001****	**0.022***
BB 16D	1.43 ± 0.55	0.92 ± 0.67	0.75 ± 0.54	−0.51 ± 0.36	−0.68 ± 0.35	−0.17 ± 0.19	**0.002****	**0.001****	**0.021***
LB 16	0.47 ± 0.34	0.94 ± 0.45	1.61 ± 0.59	0.47 ± 0.46	1.14 ± 0.47	0.67 ± 0.45	**0.011***	**0.001****	**0.001****
TL 14B	21.18 ± 1.36	21.08 ± 1.51	20.88 ± 1.35	−0.1 ± 0.28	−0.3 ± 0.36	−0.2 ± 0.49	0.289	**0.027***	0.231
TL 14L	20 ± 1.65	19.71 ± 1.65	18.93 ± 1.17	−0.28 ± 0.28	−1.06 ± 0.65	−0.78 ± 0.6	**0.011***	**0.001****	**0.003****
RL 16MB	10.34 ± 0.88	10.22 ± 1.01	10.03 ± 0.96	−0.12 ± 0.26	−0.3 ± 0.25	−0.18 ± 0.28	0.178	**0.004****	0.068
RL 16DB	11.13 ± 0.98	10.93 ± 0.91	10.48 ± 1.22	−0.2 ± 0.32	−0.65 ± 0.65	−0.45 ± 0.67	0.073	**0.012***	0.063
RL 16L	11.81 ± 1.22	11.62 ± 1.16	11.39 ± 1.28	−0.19 ± 0.25	−0.42 ± 0.35	−0.22 ± 0.25	**0.035***	**0.001****	**0.018***

$^{*}p < 0.05$.
$^{**}p < 0.01$.
Bold values denote statistically significant changes.
[a] Paired Sample t test.

Thus, both hybrid and TB devices can be used successfully for SARME procedures.

Anterior skeletal maxillary widening of 4 mm was successful in both groups and was comparable with findings from other studies (Glassman et al., 1984; Koudstaal et al., 2005). The amount of posterior skeletal maxillary widening was, however, minimal.

The widening of the maxilla with both the TB and hybrid devices was therefore V-shaped in the frontal and in the horizontal planes. Bone-borne devices are expected to distract ideally in parallel, reducing the tipping of the maxillary halves (Koudstaal et al., 2009). However, several authors have reported greater anterior expansion, converging at the posterior (Braun et al., 2000; Pinto et al., 2001; Hansen et al., 2007; Tausche et al., 2007; Gunbay et al., 2008; Landes et al., 2009). These findings are in agreement with previous studies on TB expansion (Haas, 1965; Haas, 1970, 1980; Wertz, 1970). Despite surgical assistance, the maxilla continued to be fixed in the pterygoid process area, as a down-fracture was not carried out, in contrast to complete Le Fort I osteotomies (Haas, 1961; Bell, 1982).

Although dental expansion was significantly smaller anteriorly in the hybrid group (4.03 mm vs. 6.29 mm), posterior dental expansion at the first molars was comparable in the 2 groups. The dental arch widened more in parallel in the TB group in the present study than in the hybrid RME device group posteroanteriorly (viewed from the occlusal aspect). Similarly, Chamberland and Proffit (2008) and Koudstaal et al. (2009) found that tooth-borne devices caused parallel expansion of the dental arch on an anteroposterior plane. However, Kilic et al. (2013) reported greater expansion in the first premolar area than in the molar area following tooth-borne SARME. Factors that may affect the pattern

Table 5
Intergroup comparison between tooth-borne (TB) and hybrid devices.

	T0–T1			T0–T2			T1–T2		
	Hybrid	TB	[a]p	Hybrid	TB	[a]p	Hybrid	TB	[a]p
	Mean ± SD	Mean ± SD		Mean ± SD	Mean ± SD		Mean ± SD	Mean ± SD	
EMW4	3.75 ± 1.15	4.58 ± 1.8	0.236	4.02 ± 1.42	4.33 ± 1.85	0.677	0.27 ± 0.94	−0.25 ± 1.9	0.451
EMW6	1.93 ± 2.92	1.02 ± 2.1	0.436	1.63 ± 2.76	1.13 ± 2.2	0.658	−0.3 ± 1	0.1 ± 0.21	0.240
ICW4	4.74 ± 0.79	6.13 ± 1.47	**0.019***	4.03 ± 0.84	6.29 ± 0.51	**0.001****	−0.7 ± 0.48	0.16 ± 1.33	0.077
ICW6	6.13 ± 1.62	7.12 ± 1.75	0.205	6.24 ± 2.46	6.81 ± 0.83	0.507	0.11 ± 1.95	−0.32 ± 1.31	0.573
IAW4	3.53 ± 1.34	3.20 ± 1.71	0.640	3.85 ± 1.43	4.63 ± 2.34	0.377	0.32 ± 0.81	1.43 ± 1.52	0.056
IAW6	1.99 ± 1.10	1.62 ± 0.94	0.431	4.16 ± 1.89	3.24 ± 1.78	0.281	2.16 ± 1.44	1.62 ± 1.03	0.345
IA4	2.03 ± 2.05	4.1 ± 4.48	0.208	−0.63 ± 3.35	2.01 ± 5.35	0.202	−2.66 ± 2.12	−2.08 ± 3.62	0.671
IA6	3.64 ± 10.72	9.46 ± 7.38	**0.029***	3.11 ± 8.66	3.77 ± 6.58	0.714	−0.53 ± 5.81	−5.68 ± 4.43	**0.035***
BB 14	0.03 ± 0.2	−0.15 ± 0.19	0.061	0.2 ± 0.35	−0.55 ± 0.38	**0.001****	0.17 ± 0.24	−0.4 ± 0.46	**0.004****
LB 14	0.12 ± 0.13	0.4 ± 0.57	0.162	−0.05 ± 0.26	1.02 ± 0.58	**0.001****	−0.17 ± 0.28	0.62 ± 0.53	**0.001****
BB 16B	−0.49 ± 0.48	−0.28 ± 0.19	0.221	−0.53 ± 0.4	−0.54 ± 0.31	0.935	−0.04 ± 0.62	−0.27 ± 0.31	0.327
BB 16D	−0.7 ± 0.59	−0.51 ± 0.36	0.394	−0.75 ± 0.6	−0.68 ± 0.35	0.760	−0.05 ± 0.75	−0.17 ± 0.19	0.638
LB 16	0.41 ± 0.23	0.47 ± 0.46	0.706	0.8 ± 0.48	1.14 ± 0.47	0.135	0.39 ± 0.43	0.67 ± 0.45	0.188
TL 14B	−0.28 ± 0.57	−0.1 ± 0.28	0.377	−0.36 ± 0.65	−0.3 ± 0.36	0.791	−0.08 ± 0.23	−0.2 ± 0.49	0.502
TL 14L	−0.32 ± 0.32	−0.28 ± 0.28	0.780	−0.5 ± 0.45	−1.06 ± 0.65	**0.036***	−0.17 ± 0.28	−0.78 ± 0.6	**0.011***
RL 16MB	−0.18 ± 0.21	−0.12 ± 0.26	0.607	−0.54 ± 0.41	−0.3 ± 0.25	0.145	−0.39 ± 0.22	−0.42 ± 0.35	0.820
RL 16DB	−0.25 ± 0.21	−0.2 ± 0.32	0.731	−0.57 ± 0.38	−0.65 ± 0.65	0.753	−0.33 ± 0.39	−0.45 ± 0.67	0.635
RL 16L	−0.22 ± 0.17	−0.19 ± 0.25	0.821	−0.39 ± 0.22	−0.42 ± 0.35	0.820	−0.17 ± 0.21	−0.22 ± 0.25	0.616

$^{*}p < 0.05$.
$^{**}p < 0.01$.
Bold values denote statistically significant changes.
[a] Student t test.

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of dental expansion on the posteroanterior plane are the pterygomaxillary suture osteotomy and the location and direction of the expansion screw (Pereira et al., 2012).

In the hybrid device group, the interpremolar angle (Angle4) increased by 2° during the active expansion phase (T0–T1) (Table 3). Although no force was applied directly to the premolars by the hybrid devices, this angulation change might be caused by segmental inclination changes in the maxillary halves. After the retention period of 6 months (T1–T2), Angle4 decreased by −2.66°. During this period, the interapex width in the first premolars was nearly stable, but the intercrown width decreased statistically significantly. Thus, the premolars were tipping palatally, while the retention period in hybrid SARME was associated with forces provided by the palatal mucoperiosteum resistance or the surrounding bucco-oral muscles. Landes et al. (2009) found that bone-borne devices provoke inward dental rotation. The present study showed that the dental effects of hybrid devices in the premolar region were similar to those of bone-borne devices, because of the anterior mini-implants. No statistically significant changes in the interpremolar angles were observed during the whole study period (T0–T2) in the hybrid device group.

In the TB group, the interpremolar angle increased by 4° in the T0–T1 period and decreased by −2° in the T1–T2 period. The supporting teeth were expanded using bands firmly attached to the TB (Hyrax) device. As the screw was activated, the premolars were tipped buccally and the bands provided resistance to inclination, leading to uprighting of the supporting teeth during the retention period. This is illustrated by the changes in width between the tooth apices shown in Table 4. After the retention phase had ended (T1–T2), the interapex width of the first premolars increased significantly, but their crown tips remained nearly stable with the premolar bands. However, there was a statistically significant change in Angle4 of 2° over the whole study period (T0–T2) in the TB group. These findings are in agreement with those of previous studies comparing tooth-borne and bone-borne expansion (Landes et al., 2009; Zandi et al., 2014).

As the premolars showed significant buccal tipping in the TB group, the increase in the interpremolar width was significantly greater in the TB group than in the group with hybrid devices during the T0–T1 and T0–T2 periods. There were some significant side effects of buccal tipping movement, such as buccal bone and root resorption, in the TB group (Table 4).

It has been demonstrated that the orthodontic and orthopedic forces applied by the TB devices cause histological modifications such as activation of osteoclastic cells in the direction of the periodontal ligament and hyalinization on the pressure side, and that tipping movement in the anchoring teeth may cause bone resorption at the dentoalveolar level (da Silva Filho et al., 1995; Ballanti et al., 2009). In the present study, reductions of 0.55 mm were found in the buccal bone plate thickness of the first premolars at the end of the overall observation period (T0–T2). The remaining buccal alveolar bone thickness was at critical levels in the TB group, at 0.08 mm at T2, in comparison with 1.18 mm in the hybrid device group. A change of 0.08 mm cannot be clearly shown on CBCT images with the voxel size used in this study. Such a low mean value was calculated because some total bone resorptions were found in the TB group. These findings with the TB device are consistent with those reported in previous studies (Garib et al., 2006; Rungcharassaeng et al., 2007; Ballanti et al., 2009; Landes et al., 2009). More palatal root resorption was also observed in the first premolars with the TB devices, since with Hyrax devices the anchoring teeth are subject to the forces acting on them. As the transverse forces are transferred to the maxillary bone in hybrid devices, there are no dental or periodontal side effects involving dental tipping in the first premolar area.

In this study, the dental movement pattern of expansion following TB and hybrid SARME differed significantly between the 2 groups (Fig. 5). Although the first molars were used as the posterior anchorage unit in both the hybrid and TB devices, a different movement pattern was observed in the first molars between the 2 groups during the active expansion (T0–T1) and retention (T1–T2) phases. In TB group, the first molars tipped buccally by 9.5° in T0–T1, significantly more than in the hybrid group, and moved upright again significantly by 5.7° in T1–T2. The final angulation change in the first molars (T0–T2) was 3.8° in the TB group. In the hybrid group, the intermolar angle increased significantly less than in the TB group during the T0–T1 period, at 3.6°, and the angulation change did not differ significantly in the T1–T2 period. These findings may show that the movement occurred via excessive buccal tipping during the active phase, followed by slight uprighting during the retention phase, even though the angulation changes were similar in the 2 groups at the end of the study period. The hybrid devices led to buccal movement in the first molars with more physical translation during T0–T1, and the first molars remained stable during the retention phase (which might be explained by the mini-implant anchorage). The dental and periodontal health of the first molars was reasonable at the end of the active and retention phases, with more physical translation being applied by the hybrid devices.

In the present study, reductions of between 0.5 and 0.75 mm were observed in the buccal alveolar bone thickness of the first molars at the end of the whole observation period (T0–T2) in both groups. The remaining buccal alveolar bone thickness after expansion and retention (between 0.4 and 0.9 mm) showed that neither the hybrid nor the TB devices involved any risk of periodontal damage to the molars. This may be associated with the

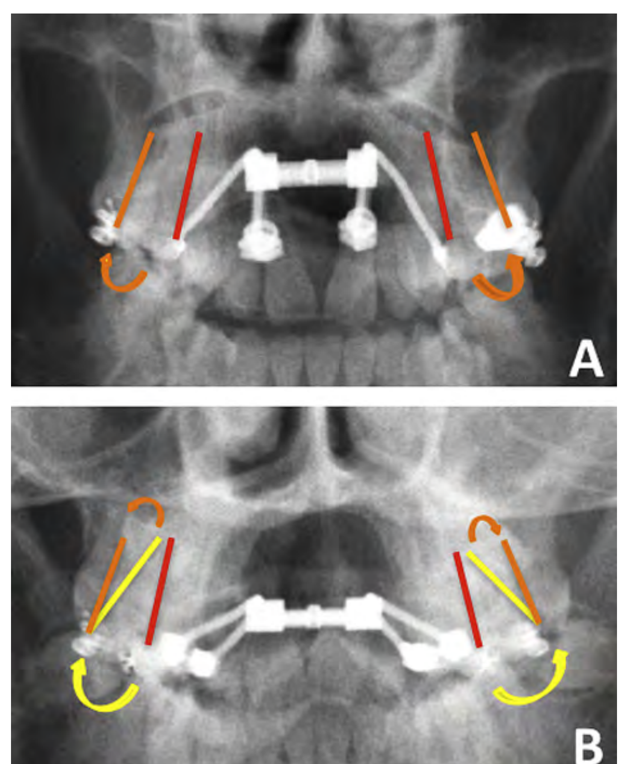

Fig. 5. Different dental movement patterns between the 2 devices in expansion and retention phases. More bodily movement of teeth effected by hybrid devices (A), and excessive tipping–uprighting movement by tooth-borne devices (B).

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anatomic location, or thicker alveolar bone in the first molars (Garib et al., 2006; Ballanti et al., 2009; Landes et al., 2009).

The relationship between the longevity of the teeth and root resorption is generally associated with root shortening. Heavy expansion forces are transmitted to the maxilla by the anchoring teeth with the TB devices. In the present study, root shortening of between 0.3 and 1 mm was observed in all of the anchorage teeth in the TB group during the T0–T2 period (Table 4), a finding that is in agreement with previous histological and CBCT studies (Langford and Sims, 1982; Erverdi et al., 1994; Baysal et al., 2012). The hybrid devices did not lead to significant root resorption in the buccal roots of the first premolars (Table 3), and there was significantly less shortening of the palatal roots of the first premolars than with the TB devices.

The mean root resorption findings in the first molars were similar with the hybrid and TB devices, at 0.3–0.65 mm. Zachrisson (1975) reported that 2 mm of apical root shortening was not detrimental to the function of the dentition. All of the root shortening findings in the present study were less than 2 mm. However, the resorptive effects of RME should be kept to a minimum level, as root resorption may be seen following orthodontic treatment. The present study showed that the resorptive effects of hybrid devices were minimal in the first premolars and were comparable with those of TB devices in the first molars.

Although hybrid devices require additional steps due to the need for mini-implants in the anterior palate, they appear to have significant benefits in terms of less tipping and reduced bone resorption and tooth resorption, particularly in the premolar area. According to Wilmes et al., the reported side effects of RME in relation to the transverse direction can be minimized using hybrid RME in growing children. Hybrid devices may also be useful for reducing unwanted side effects during SARME treatment in adults.

4.1. Study limitations

This study was limited to immediate expansion and post-retention changes after SARME, without assessment of long-term stability and relapse, and was based on a relatively small sample size. The present study had the following strengths: a randomized clinical trial study design; treatment of all patients by the same surgical team using the same surgical technique, expansion protocol, and expansion device (in each group); and use of an advanced imaging technique (CBCT) for assessment of the treatment outcomes.

4.2. Generalizability

The generalizability of these results might be limited because this investigation was performed in 1 center and with a small group of participants. The hybrid devices showed better performance in comparison to conventional devices in the study. However, randomized controlled clinical trials based on larger study groups and with long-term follow-up will be needed in the future to confirm these findings.

5. Conclusion

In conclusion, both Hybrid and TB devices were effective for SARME with similar V-shaped opening of the suture, and the skeletal results remained stable at the retention period.

The transverse forces were applied anteriorly to mini-implants in Hybrid devices, with less risk of periodontal and dental damages to the premolars. TB devices expanded more the first premolars, but led to more dental tipping, root resorption and buccal alveolar bone resorption.

Different dental movement patterns of first molars were found between both devices: TB devices led to excessive tipping-uprighting movement in expansion and retention phases, whereas Hybrid devices moved the first molars more bodily in the expansion phase.

Minimally invasive Hybrid devices, with similar skeletal effects and less dental–periodontal side effects, might be a beneficial alternative to TB devices in SARME procedures.

Conflict of interest

None declared.

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