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ORIGINAL ARTICLE

Cephalometric and dental arch changes to Haas-type rapid maxillary expander anchored to deciduous vs permanent molars: a multicenter, randomized controlled trial

Kephalometrische Befunde und Veränderungen im Bereich des Zahnbogens nach forcierter Gaumennahterweiterung mit einer Haas-Apparatur mit Verankerung an Milch- bzw. bleibenden Molaren: Eine multizentrische, randomisierte kontrollierte Studie

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Abstract

Objective To assess radiographic changes and dental arch changes with Haas-type rapid maxillary expansion (H-RME) anchored to deciduous versus permanent molars in children with unilateral posterior crossbite.

Methods In all, 70 patients with unilateral posterior crossbite were randomly allocated to group GrE (H-RME on second deciduous molars) or Gr6 (H-RME on first permanent molars) and compared between T0 (before treatment) and T1 (at the RME removal; i.e., 10 months after the end of the activation of the screw). At T0 and T1, cephalometric head films were digitally traced, dental casts were scanned, and rotations of the upper first molars, of the upper central, and of the upper lateral incisors on the models were measured.

Results Between T0 and T1, the cephalometric analysis showed a significant decrease of the angulation of the upper central incisors to the SN line and to the palatal plane in GrE together with a significant increase of the lower incisors to the mandibular plane (IMPA). The digital dental cast analysis showed that the central and lateral incisors mesiorotated significantly more in GrE than in Gr6. Patients in GrE also showed a statistically significant distorotation of the upper first permanent molars after RME.

Conclusions GrE showed a significant and spontaneous retraction and alignment of the upper central and lateral incisors compared to Gr6. This is probably due to a more pronounced expansion in the anterior area and more accentuated pressure of the upper lip in GrE. IMPA increased significantly in GrE vs Gr6. GrE also showed a more significant distorotation of the upper first permanent molars compared to Gr6. This is probably due to the design of the H-RME in GrE, where the screw is more anteriorly positioned and the bands are absent on the upper first permanent molars which are, therefore, free to adapt to the best occlusal situation.

Trial registration ClinicalTrials.gov Identifier NCT02 798822.

Keywords Rapid maxillary expansion · Cephalometric changes · Three-dimensional · Deciduous vs permanent molars

Zusammenfassung

Zielsetzung Bestimmt werden sollten die kephalometrischen Veränderungen und die Veränderungen im Zahnbogen bei forcierter Gaumennahterweiterung (GNE; "rapid maxillary extension", RME) durch Einsatz eines RME("rapid maxillary expander")-Expanders vom Haas-Typ, verankert entweder an Milchzahnmolaren oder an bleibenden Molaren bei Kindern mit einseitigem posteriorem Kreuzbiss.

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Methoden Insgesamt 70 Patienten mit einseitigem posteriorem Kreuzbiss wurden randomisiert einer von 2 Gruppen zugeteilt: GrE (H-RME auf den zweiten Milchzahnmolaren) bzw. Gr6 (H-RME auf den ersten permanenten Molaren). Verglichen wurde jeweils zwischen T0 (vor Behandlung) und T1 (bei Entfernung der GNE-Apparatur, d.h. 10 Monate nach Beendigung der Schraubenaktivierung). Zu den Zeitpunkten T0 und T1 wurden kephalometrische Aufnahmen digital durchgezeichnet und Modelle eingescannt. Auf den Modellen vermessen wurden unter anderem die Rotation der oberen ersten Molaren sowie der oberen zentralen und lateralen Schneidezähne.

Ergebnisse Zwischen den Zeitpunkten T0 und T1 zeigten sich in der Gruppe GrE in der kephalometrischen Analyse eine erhebliche Verringerung des Winkels zwischen den oberen zentralen Schneidezähnen und der SN-Linie und der Gaumenebene und gleichzeitig eine signifikante Erhöhung des Winkels zwischen den unteren Schneidezähnen und der Unterkieferebene (IMPA). Die Analyse der digitalisierten Modelle zeigte in der Gruppe GrE an den zentralen wie an den lateralen Schneidezähnen eine signifikant stärkere Mesiorotation als in der Gruppe Gr6. Die GrE-Patienten wiesen nach forcierter GNE auch eine statistisch signifikante Distorotation der oberen ersten Molaren auf.

Schlussfolgerungen Im Vergleich mit der Gruppe Gr6 zeigten sich in der Gruppe GrE eine signifikante, spontane Retraktion und ein Alignment der oberen zentralen und lateralen Schneidezähne. Dies liegt wahrscheinlich an einer ausgeprägteren Expansion im vorderen Bereich und einem stärker akzentuierten Druck der Oberlippe in der Gruppe GrE. In der Gruppe GrE vergrößerte sich der Winkel zwischen Mandibularlinie und Schneidezahn (IMPA) im Vergleich Zur Gruppe Gr6 deutlich. Auch die Distorotation der oberen ersten Molaren war in der Gruppe GrE stärker signifikant als in der Gruppe Gr6Dies liegt wahrscheinlich am Design der H-RME in der GrE-Gruppe, d. h. an der weiter vorne positionierten Schraube und daran, dass die oberen ersten permanenten Molaren nicht bebändert waren und sich damit frei in eine optimierte Okklusion entwickeln konnten.

Schlüsselwörter Forcierte Gaumennahterweiterung · Kephalometrische Veränderungen · Dreidimensional · Milchzahn- vs. permanente Molaren

Introduction

Posterior crossbite is a nonself-correcting common clinical malocclusion often associated with transverse maxillary deficiency and functional mandibular shift. If left untreated, it can lead to the development of craniofacial asymmetries and mandibular dysfunction [13, 21, 22]. Rapid maxillary expansion (RME) is reported to be an efficient clinical technique aiming to correct maxillary transverse deficiency and crossbite [1, 17].

The Haas appliance is a well-known device designed to expand the palate. It is a tooth- and tissue-borne appliance attached to four teeth and to the palatal vault (Fig. 1). High forces are generated during RME and they can affect the periodontal and endodontic status of the anchoring teeth [24]; therefore, some authors [4, 5, 15, 20, 23] have suggested banding the Haas-type rapid maxillary expander (H-RME) to deciduous teeth. If the roots of the upper second deciduous molars have at least the same length of their crowns at the orthopantomogram diagnostic examination, the H-RME anchored to deciduous teeth is an effective device to correct posterior crossbite [23].

The aim of the current investigation was to evaluate changes on lateral cephalometric head films and on dental cast models after rapid maxillary expansion with H-RME anchored to deciduous teeth versus H-RME anchored on upper first permanent molars.

Patients and methods

The present paper is a secondary outcome analysis based on a previous multicenter, randomized trial (trial registration: ClinicalTrials.gov Identifier NCT02798822, https://clinicaltrials.gov/ct2/show/NCT02798822). Details on the experimental design, study groups, and treatment methods were previously published [23].

Briefly, a sample of 70 consecutive children (31 boys and 39 girls; mean age 8.4 ± 1.1 years) presenting unilateral posterior crossbite were recruited at the Orthodontic Departments of the Universities of Genova, Siena, and Insubria (Varese), Italy. All the subjects exhibited a Class I or Class II dental malocclusion with ANB $<5°$ and were selected before the pubertal peak (CVM 1–3) [2]. The inclusion and exclusion criteria are shown in Tables 1 and 2.

Patients were randomly assigned (using a stratified blocked randomization) to group GrE (H-RME with bands on second deciduous molars; Fig. 1a) or Gr6 (H-RME with bands on first permanent molars; Fig. 1b). After placing of H-RME, the activation rate of the screw was one quarter turn a day (0.22 mm) until overcorrection was achieved, then the appliance was left in situ for 10 months. Pretreatment records (T0) were obtained by means of dental casts, panoramic radiographs, and lateral cephalometric head films. The same set of records was also taken at the removal of H-RME (T1), 10 months after that the device was used for retention purposes. The average treatment time was 12 ± 1.3 months.

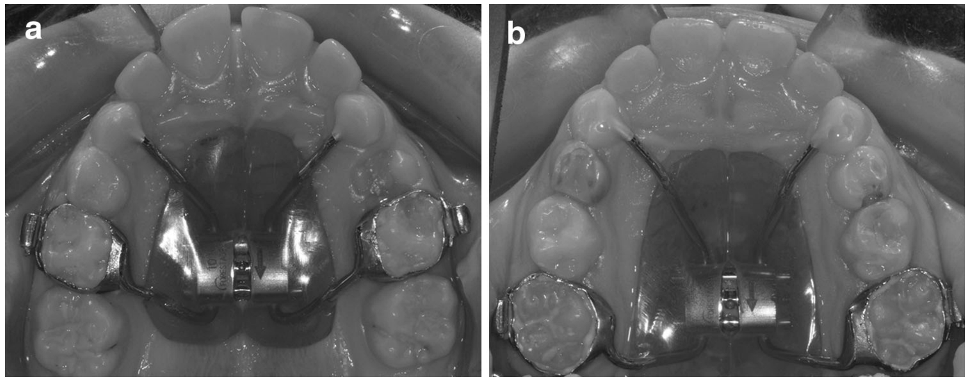

Fig. 1 **a** H-RME banded on upper second deciduous molars. **b** H-RME banded on upper first permanent molars
Abb. 1 **a** H-RME befestigt an den oberen zweiten Milchzahnmolaren. **b** H-RME befestigt an den oberen ersten bleibenden Molaren

Tab. 1 Inclusion criteria
Tab. 1 Einschlusskriterien

Patients in mixed dentition
Unilateral posterior crossbite at least of the first permanent molar
Upper deciduous second molars available as RME anchoring teeth[a]
Subjects before the pubertal peak (CVM 1–3)

[a] The deciduous molar was considered available as anchoring tooth when the root had the same length of the clinical crown at the orthopantomogram rx examination

Tab. 2 Exclusion criteria and number of patients
Tab. 2 Ausschlusskriterien und Anzahl der Patienten

Exclusion criteria and number of patients for secondary outcome analysis	No. of patients
Initial sample	70
Exclusion criteria for cephalometric analysis	
Lack of post-treatment lateral cephalometric head films	4
Poor radiographic quality	6
Final sample for cephalometric analysis	60
Exclusion criteria for cast analysis	
Breakage of one or more upper central or lateral incisor at the stone models removal from the impression	4
Poor quality impression regarding upper incisors and/or molar cusps	10
Not yet occured eruption of the upper lateral incisors at T0	4
Final sample for cast analysis (molars)	60
Final sample for cast analysis (incisors)	52

Cephalometric analysis

Cephalograms were traced digitally by a single examiner (CC) using Nemoceph 2D software (Arroyomolinos, Madrid, Spain). Each subject was appointed a random identification number so the examiner would be blinded to the subject when measuring. Landmark location and accuracy of the anatomic outlines was verified by a second senior clinician (AU). Cephalometric points selected are shown in Fig. 2 together with the angular measurements used in the present investigation. To analyze the error of the method, five randomly selected lateral cephalometric radiographs were retraced. A combined error of landmark location, tracing, measurement was determined. Intraclass correlation coefficients (ICC) were calculated to compare within-subject variability to between-subject variability. Correlation coefficients for the skeletal measures were greater than 0.94. Linear measurement errors averaged 0.3 mm [standard deviation (SD) 0.6 mm] and angular measurements averaged 0.6° (SD 0.5°).

Measurements on three-dimensional dental casts

Maxillary and mandibular casts were processed by means of a three-dimensional (3D) scanner (NextEngine, Inc., Santa Monica, CA, USA) and landmarks considered in this study were traced by means of Rhinoceros 4.0 (Robert McNeel and Associates, Seattle, WA, USA). Measurements were

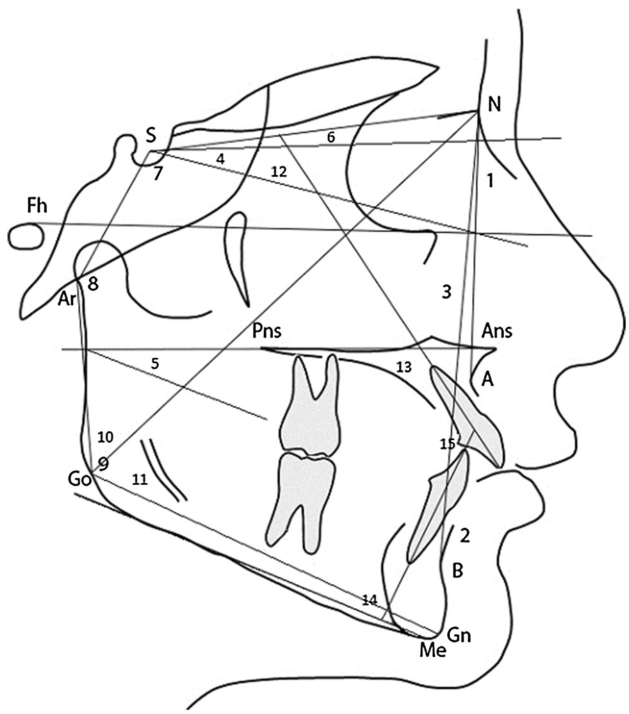

Fig. 2 Angular measurements analyzed. *1* SNA, *2* SNB, *3* ANB, *4* Sn/GoGn, *5* AnsPns/GoGn, *6* Sn/AnsPns, *7* NSAr, *8* SArGo, *9* ArGoGn, *10* ArGoN, *11* NGoGn, *12* U1/Sn, *13* U1/AnsPns, *14* IMPA, *15* U1/L1

Abb. 2 Analysierte Winkelmessungen: *1* SNA, *2* SNB, *3* ANB, *4* Sn/GoGn, *5* AnsPns/GoGn, *6* Sn/AnsPns, *7* NSAr, *8* SArGo, *9* ArGoGn, *10* ArGoN, *11* NGoGn, *12* U1/Sn, *13* U1/AnsPns, *14* IMPA, *15* U1/L1

subsequently calculated directly on scanned dental casts by means of an ad hoc software, and first maxillary molars and central and lateral upper incisors rotations were assessed. Each subject was appointed with a random identification number so that the examiner would be blinded to the subject when measuring.

The reference points on the scanned dental casts were the mesiopalatal and the distobuccal cusps of the first upper right and left molars. A line connecting the tips of these two cusps of each molar was used to assess the mesiorotation of each upper permanent molar, as stated by Ricketts [19]. The software traced these lines and also measured the angle formed by their intersections (molar rotation angle, MRA; Fig. 3). The same protocol was also applied to assess the rotation of the right and left central incisor (upper central rotation angle, U1RA) and of the right and left lateral incisors (upper lateral rotation angle, U2RA), taking as a reference the most distal and mesial points of the incisal edge of the central and lateral incisors. The angular measurements formed by the intersections of these lines running on the incisal edges were also calculated.

In order to assess the angular error of methods, ten maxillary casts were randomly selected and retraced. Intraclass correlation coefficients (ICCs) were calculated to compare within-subject variability to between-subject variability. Correlation coefficients for the angular measures were greater than 0.91 with measurement errors averaged 0.7° (SD 0.6°).

Statistical analysis

Descriptive statistics were computed for all analyzed variables. Shapiro–Wilks test showed that data were normally distributed ($W = 0.93$). GrE and Gr6 changes at T0 and at T1 were compared using Student's *t* tests for independent samples. Probabilities less than 0.05 were accepted as significant in all statistical analyses ($p < 0.05$). The effect size (ES) coefficient (d) was also calculated [3]. An ES of 0.2–0.3 might be a "small" effect and, thus, have a small clinically significant difference, 0.5 had a "medium" effect, and 0.8 to infinity a "large" effect.

Results

Cephalometric measurements of the two groups reported at T0 and T1 are summarized in Table 3. At T0, none of the skeletal cephalometric variables were significantly different between GrE and Gr6. At T1, no statistically significant skeletal differences were found between the two groups.

Between T0 and T1, both groups exhibited a decrease of the upper central incisors angulation on SN line and on the palatal plane; that decrease was found to be statistically significant in GrE when compared to Gr6 (U1/SN −3.1°, $p = 0.022$; U1/AnsPns −2.8°, $p = 0.028$). Conversely, lower central incisor angulation on the mandibular plane tended to increase in both groups between T0 and T1, and GrE reported a statistically significant increase of the IMPA when compared to Gr6 (IMPA +2.5, $p = 0.029$).

The ES result was medium ($0.5 < \text{ES} > 0.6$) for all of the three statistically significant variables (Table 4).

Dental cast analysis at T0 showed no statistically significant differences between groups regarding MRA, U1RA, and U2RA. Between T0 and T1, MRA decreased in both groups, more in GrE than in Gr6 (−16.1° vs −6.6°). The difference between the groups was statistically significant ($p < 0.00$) with a very large effect size (ES = 2.4). Moreover, U1RA and U2RA increased in both groups, more in GrE than Gr6 (central 13.4° vs 8.9°, and lateral 18.2° vs 11.5°). The difference between the groups was statistically significant ($p = 0.002$ for U1RA; $p = 0.008$ for U2RA) with a ES for incisor changes (ES > 0.75; Table 5).

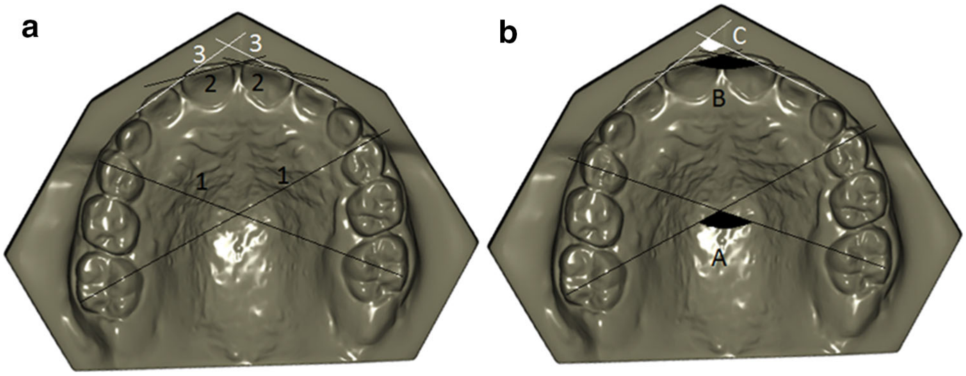

Fig. 3 **a** *Line 1* connects the distovestibular cusp and the mesiopalatal cusp of the *upper right* and of the *upper left* first molar; *line 2* represents the incisal edge of the *upper right* and of the *upper left* central incisor; *line 3* represents the incisal edge of the *upper right* and of the *upper left* lateral incisor. **b** *Angle A* MRA: the inferior angle originated from the intersection of both *lines 1*; *angle B* U1RA: the inferior angle originated from the intersection of both *lines 2*; *angle C* U2RA: the inferior angle originated from the intersection of both *lines 3*

Abb. 3 **a** *Linie 1* verbindet den distovestibulären und mesiopalatinalen Höcker des oberen rechten und des oberen linken ersten Molaren; *Linie 2* repräsentiert die Schneidezahnkanten des oberen rechten und des oberen linken zentralen Inzisivus; *Linie 3* repräsentiert die Schneidezahnkanten des oberen rechten und des oberen linken lateralen Inzisivus. **b** *Winkel A* = MRA: unterer Winkel, Ursprung in der Schnittstelle beider Linien 1; *Winkel B* = U1RA: unterer Winkel, Ursprung in der Schnittstelle beider Linien 2; *Winkel C* = U2RA: unterer Winkel, Ursprung in der Schnittstelle beider Linien 3

Discussion

In the present study, after RME treatment, GrE showed a major significant spontaneous retraction (U1/SN −3.1°, $p = 0.022$; U1/AnsPns −2.8°, $p = 0.028$) and alignment of the upper incisors (central 13.4° vs 8.9°, $p = 0.002$ and lateral 18.2° vs 11.5°, $p = 0.008$) compared to Gr6. This finding is in accordance with Habeeb et al. [9] who reported significant posterior movement of the upper incisors following RME therapy. The effect size found was medium ($0.5 < ES > 0.6$) for the dental retraction of the upper incisors on the lateral head film evaluation and large ($ES > 0.75$) for the U1RA and U2RA in the scanned model analysis. These variations are probably due to the significantly greater increase of the intercanine width in GrE versus Gr6 at the end of treatment [23]. As already reported in our previous investigation [23], this effect, in turn, is probably due to the design of the RME in GrE that comprises a more anterior positioned screw.

The major expansion in the anterior area may guarantee for more space for the upper central and lateral incisors that are therefore free to align themselves and mesiorotate spontaneously, also under the influence of the upper lip.

Halazonetis et al. [10] found a three-times increase of buccal pressure on the maxillary first molars after RME. The authors also reported no return to the pretreatment level of pressure regarding the soft tissues during the 3–4 month retention period. Küçükkeleş and Ceylanoğlu [11] showed that the pressure values of the upper lip on the buccal side of upper first molar and incisors increased significantly right after expansion but started decreasing during retention. On the other hand, tongue pressure on the lingual side of the upper first molar and upper incisor decreased significantly with expansion but started increasing after the expansion procedure. This is in accordance with the theory of equilibrium of Proffit [18] that can explain the spontaneous retraction and alignment of the upper incisors. In our study, we can therefore speculate that the lip pressure on the upper incisors could be more present in GrE rather than Gr6 because of the major intercanine width obtained in GrE after expansion and at the end of the retention period. Also Mew [14] and later Mutinelli et al. [16] reported an associated improvement in dental alignment following RME by means of the Little irregularity index measured in the upper arch.

We also have to underline that the values concerning U1RA and U2RA are only analyzed in terms of net difference between the two groups instead of considering the mean value. We considered the mean value less important in this case, considering also that the significant increase of U1RA and U2RA at T2 in GrE was not always represented by a symmetrical movement between the right and the left correspondent incisor. Further analyses are still needed in order to clarify the asymmetrical response of mesiorotation of the right and left upper incisors.

IMPA increased also significantly more between T0 and T1 in GrE compared to Gr6. The retraction of the upper incisors could have reduced an eventual lip interposition between the upper and lower incisors, therefore, creating the lip bumper effect [23]. Nevertheless, the lip interposition was not recorded in our study; therefore, further analysis regarding this parameter needs to be done in order to clarify this event.

Tab. 3 Cephalometric measurements of the two groups reported at T0 and T1 and T test analyses at baseline
Tab. 3 Kephalometrische Messungen der beiden Gruppen zu den Zeitpunkten T0 und T1 sowie t-Test-Analysen zum Zeitpunkt T1

	SNA	SNB	ANB	SN/GoGn	AnsPns/GoGn	SN/AnsPns	NSAr	SarGo	ArGoGn	ArGoN	NgoGn	Jarabak's sum	U1/SN	U1/AnsPns	IMPA	U1/L1
T0																
Gr6 ($n = 31$)																
Mean	81.2	76.8	4.4	35.6	26.1	8.8	125.7	139.2	132.0	57.4	74.6	397.2	103.9	113.3	93.5	126.5
SD	4.4	3.6	3.0	5.7	5.9	3.9	7.4	8.0	5.5	3.6	5.6	6.1	6.7	6.4	6.6	7.4
GrE ($n = 29$)																
Mean	82.7	78.4	4.3	33.6	26.5	7.3	122.9	141.6	129.9	55.9	74.2	394.6	105.4	113.0	92.0	128.0
SD	4.7	4.1	3.0	5.7	5.3	2.5	4.3	6.6	5.0	3.7	4.7	5.6	9.8	10.2	7.1	9.8
p value at baseline	0.212	0.132	0.922	0.174	0.790	0.085	0.076	0.206	0.128	0.118	0.725	0.090	0.483	0.897	0.397	0.532
T1																
Gr6 ($n = 31$)																
Mean	82.6	77.7	4.8	35.7	27.0	8.6	125.3	141.0	131.0	55.4	75.6	397.0	103.0	112.5	94.3	127.7
SD	3.5	3.2	3.1	5.6	6.4	3.2	6.3	8.4	5.0	3.9	4.4	6.6	5.5	6.2	6.2	7.0
GrE ($n = 29$)																
Mean	83.1	78.5	4.6	34.2	27.1	7.4	123.1	144.1	128.7	54.0	74.7	395.9	101.4	109.4	95.2	126.8
SD	5.3	3.8	3.1	4.8	5.4	3.9	5.7	7.6	6.1	5.1	4.6	5.7	9.2	9.2	8.3	8.1

Tab. 4 Unpaired *t* tests for the net difference T1–T0 regarding the cephalometric variables
Tab. 4 Ungepaarte t-Tests für die "Nettounterschiede" zwischen T1 und T0 hinsichtlich der kephalometrischen Variablen

Net difference T1–T0	SNA	SNB	ANB	SN/GoGn	AnsPns/GoGn	SN/AnsPns	NSAr	SarGo	ArGoGn	ArGoN	NgoGn	Jarabak's sum	U1/SN	U1/AnsPns	IMPA	U1/L1
Gr6 ($n = 31$)																
Mean	1.3	0.9	0.5	0.1	0.8	−0.2	−0.5	1.8	−1.0	−2.0	0.9	−0.3	−0.9	−0.8	0.7	1.2
SD	2.3	2.1	2.0	2.2	3.7	3.8	3.5	6.2	4.6	3.2	3.1	2.8	3.8	3.3	3.2	6.0
GrE ($n = 29$)																
Mean	−1.4	0.1	0.3	0.7	0.6	0.1	0.2	2.5	−1.2	−1.9	0.6	1.2	−4.0	−3.6	3.2	−1.1
SD	1.8	1.6	2.2	2.4	2.9	2.8	5.4	7.4	4.8	5.1	2.9	4.0	6.1	5.4	5.0	5.3
Net difference	−2.7	−0.8	−0.2	0.6	−0.3	0.3	0.7	0.7	−0.2	0.0	−0.4	1.5	−3.1	−2.8	2.5	−2.3
p value	0.1	0.1	0.7	0.3	0.8	0.7	0.6	0.7	0.9	1.0	0.6	0.1	0.022**	0.028**	0.029**	0.1
												Cohen's effect size	0.6	0.5	0.6	
													Medium	Medium	Medium	

* $p < 0.05$; ** $p < 0.01$

In our study, the first maxillary molars distorotated significantly more in GrE than in Gr6 with a very large effect size (ES = 2.4). This could be explained by the triangular opening of the palatal suture due to the position of the center of resistance of the maxilla with respect to the screw position [6, 7, 15, 25]. Moreover, in GrE the upper first molars are free to adapt to the best occlusal situation, since they are not banded.

Our investigation lacks a control group; however, Mutinelli et al. [16] reported that the intercanine width and the intermolar width of the patients who had undergone expansion were significantly higher than the values measured for an untreated control group exhibiting lateral crossbite in the same dental period. Moreover, when compared to the treated group, the control group showed a higher irregularity index in the area of the upper incisors. All these findings indicate that crossbite and upper incisor misalignment do not improve spontaneously with growth in the control groups exhibiting the same characteristics as the treated group before the expansion procedure is performed.

Clinically, the secondary outcome of early treatment of posterior crossbite regarding the spontaneous upper incisors alignment may induce a better arrangement of the transeptal fibers, thus, reducing the probabilities of severely rotated incisors [12]. The spontaneous distorotation of the upper first molars was also detected in our study, in accordance with the literature [15]. Clinically, this result implies a significant increase of the upper arch length [15], a possible improvement of a class II malocclusion [8], and a less invasive and less difficult second phase of treatment.

Conclusions

- There was an improvement of the anterior crowding and spontaneous retraction of the upper incisor after RME, significantly more in GrE compared to Gr6. This is probably due to more pronounced expansion in the anterior area and a more accentuated pressure of the upper lip in GrE.
- GrE showed a more significant distorotation of the upper first permanent molars compared to Gr6. This is probably due to the design of the H-RME in GrE, where the screw is more anteriorly positioned and the bands are absent on the upper first permanent molars which are, therefore, free to adapt to the best occlusal situation.
- Apart from the dental variables measured in the lateral cephalometric head films, GrE and Gr6 did not show

Tab. 5 Unpaired *t* tests regarding the net difference T1–T0 for the variables MRA (molar rotation angle), U1RA (upper central rotation angle U1RA), U2RA (upper lateral rotation angle)

Tab. 5 Ungepaarte t-Tests für die "Nettounterschiede" zwischen T1 und T0 für die Variablen Rotation der Molaren (*MRA*), Rotation der oberen zentralen Schneidezähne (*U1RA*) und Rotation der oberen zweiten Schneidezähne (*U2RA*)

Net difference T1–T0	MRA (°)	Net difference T1–T0	U1RA (°)	U2RA (°)
Gr6 ($n = 31$)		Gr6 (U1RA $n = 30$; U2RA $n = 27$)		
Mean	−6.6	Mean	8.9	11.5
SD	2.6	SD	4.5	9.1
GrE ($n = 29$)		GrE (U1RA $n = 28$; U2RA $n = 25$)		
Mean	−16.1	Mean	13.4	18.2
SD	4.8	SD	6.3	8.6
p value	<0.000**	*p* value	0.002**	0.008**
Cohen's effect size	2.4	Cohen's effect size	0.82	0.75
	Very large		Large	Large

* $p < 0.05$; ** $p < 0.01$

any statistical significant difference concerning the skeletal variables.

Compliance with ethical standards

Conflict of interest C. Cerruto, A. Ugolini, L. Di Vece, T. Doldo, A. Caprioglio, and A. Silvestrini-Biavati state that there are no conflicts of interest.

Ethical statement All studies on humans described in the present manuscript were carried out with the approval of the responsible ethics committee and in accordance with national law and the Helsinki Declaration of 1975 (in its current, revised form).

Informed consent Informed consent was obtained from all patients included in studies.

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