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Dentoskeletal outcomes of a rapid maxillary expander with differential opening in patients with bilateral cleft lip and palate: A prospective clinical trial

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Abstract

Introduction—The purpose of this 2-arm parallel study was to evaluate the dentoskeletal effects of rapid maxillary expansion with differential opening (EDO) compared with the hyrax expander in patients with complete bilateral cleft lip and palate.

Methods—A sample of patients with complete bilateral cleft lip and palate was prospectively and consecutively recruited. Eligibility criteria included participants in the mixed dentition with lip and palate repair performed during early childhood and maxillary arch constriction with a need for maxillary expansion before the alveolar bone graft procedure. The participants were consecutively divided into 2 study groups. The experimental and control groups comprised patients treated with rapid maxillary expansion using EDO and the hyrax expander, respectively. Cone-beam computed tomography examinations and digital dental models of the maxillary dental arches were obtained before expansion and 6 months postexpansion. Standardized cone-beam computed tomography coronal sections were used for measuring maxillary transverse dimensions and posterior tooth inclinations. Digital dental models were used for assessing maxillary dental arch widths, arch

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perimeters, arch lengths, palatal depths, and posterior tooth inclinations. Blinding was used only during outcome assessment. The chi-square test was used to compare the sex ratios between groups (P<0.05). Intergroup comparisons were performed using independent *t* tests with the Bonferroni correction for multiple tests.

Results—Fifty patients were recruited and analyzed in their respective groups. The experimental group comprised 25 patients (mean age, 8.8 years), and the control group comprised 25 patients (mean age, 8.6 years). No intergroup significant differences were found for age, sex ratio, and dentoskeletal variables before expansion. No significant differences were found between the EDO and the hyrax expander groups regarding skeletal changes. The EDO promoted significantly greater increases of intercanine width (difference, 3.63 mm) and smaller increases in canine buccal tipping than the conventional hyrax expander. No serious harm was observed other than transitory variable pressure sensations on the maxillary alveolar process in both groups.

Conclusions—The EDO produced skeletal changes similar to the conventional hyrax expander. The differential expander is an adequate alternative to conventional rapid maxillary expanders when there is need for greater expansion in the maxillary dental arch anterior region.

Registration—This trial was not registered.

Protocol—The protocol was not published before trial commencement.

Maxillary arch constriction is a frequent clinical feature in patients with complete bilateral cleft lip and palate (BCLP).¹ Both the absence of the midpalatal bone and the soft tissue traction produced by lip and palate repair promote arch constriction.^{2,3} Although the transversal deficiency may occur in all regions of the maxillary dental arch, it is more pronounced in the canine region.^{4–7} Previous studies analyzing the maxillary arch form in patients with BCLP have demonstrated that the maxillary segments move and rotate toward the medial aspect with the fulcrum located in the maxillary tuberosity, determining an anteriorly progressive constriction.^{5–7} Thus, the intercanine distance shows a greater reduction compared with the intermolar width in these patients.⁶

Rapid maxillary expansion (RME) is an orthopedic procedure that aims to correct the maxillary arch constriction by transversal separation of the maxillary halves.^{8–10} Especially in patients with cleft lip and palate, RME can be performed in the late mixed dentition before the secondary alveolar bone graft procedure.^{1,11} The aim of the maxillary expansion is not only to treat the posterior crossbite, but also to align the maxillary segments.¹ This procedure increases the alveolar cleft width and creates room for bone graft placement.¹ Additionally, it facilitates the transoperative procedures for nasal mucosa suture before the filling of the alveolar cleft with bone graft.¹ For these reasons, the correction of the maxillary arch constriction by maxillary expansion is necessary in most patients with BCLP.¹

Currently, the appliances for RME may produce either a conventional or a fan-type expansion. Conventional expansion produces similar transversal increases in the anterior and posterior regions of the maxillary dental arch.^{8–10,12,13} On the other hand, fan-type expanders promote a transversal increase only in the anterior region of the dental arch.^{14–17} Recently, a novel maxillary expander was designed especially for achieving different

amounts of expansion in the anterior and posterior regions of the maxillary dental arch in patients with complete BCLP. 18

Specific objectives or hypotheses

The purpose of this study was to evaluate the dentoskeletal effects of the expander with differential opening (EDO) in comparison with the conventional hyrax expander. The hypothesis was that the EDO and the hyrax expander have similar effects.

MATERIAL AND METHODS

Trial design and any changes after trial commencement

This study was a nonrandomized controlled clinical trial, in which the participants of each group were prospectively recruited and consecutively divided into 2 study groups. No changes in methods occurred after trial commencement.

Participants, eligibility criteria, and settings

A sample of orthodontic patients with complete BCLP was recruited prospectively from August 2010 to June 2014, in the Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo, in Bauru, Brazil. Inclusion criteria were patients in the mixed dentition with lip and palate repair performed during early childhood and maxillary arch constriction with a need for maxillary expansion before the alveolar bone graft procedure. Exclusion criteria were syndromes, previous orthodontic treatment, and periodontal disease.

This study was approved by the research institutional board of the Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo (protocol number 60/2010), before trial commencement. Parents signed the informed consent form before intervention if the patients were minors.

Interventions

The participants were consecutively divided into 2 groups. The experimental group was recruited from August 2010 to July 2012 and comprised patients treated with the EDO (Fig 1, *A*).¹⁸ Because the participants were in the mixed dentition, appliance anchorage was provided by bands adapted on either the maxillary permanent first molars or the deciduous second molars, and circumferential clamps were bonded to the maxillary deciduous canines. When the maxillary deciduous second molars were banded, a lingual extension wire was placed in the partially erupted maxillary permanent first molars. Both anterior and posterior screws were activated with a complete turn a day (approximately 0.8 mm) until achieving an overcorrection at the molar region, with the palatal cusp tip of the maxillary posterior teeth contacting the buccal cusp tip of the mandibular posterior teeth. During the following days, only the anterior screw was activated until achieving a slight overcorrection of 2 mm in the intercanine distance. The amount of expansion was determined individually, depending on the severity of the maxillary arch constriction. Mean activations were 5 mm (SD, 1.77) and 7 mm (SD, 1.99) with the posterior and anterior screws, respectively. After the active period of

RME, the screws were fixed with acrylic resin, and the appliances were kept as retainer for 6 months (Fig 1, *B*).

The control group was recruited from August 2012 to June 2014 and comprised patients treated with a conventional hyrax expander. Bands were adapted on either the maxillary permanent first molars or the deciduous second molars, and circumferential clamps were bonded to the maxillary deciduous canines. Similarly to the experimental group, a lingual extension wire was placed on the partially erupted maxillary permanent first molars when the maxillary deciduous second molars were banded. The expander screw (Dentaurum, Ispringen, Germany) was activated with a complete turn a day (approximately 0.8 mm) until achieving an overcorrection in the molar region where the palatal cusp tip of the maxillary posterior teeth contacted the buccal cusp tip of the mandibular posterior teeth. The mean expansion amount was 5 mm (SD, 2.79). After the expansion active phase, the screw was fixed with acrylic resin, and the appliances were kept in the dental arch as retainers for 6 months.

Cone beam computed tomography (CBCT) and dental models of the maxillary arch were obtained before expansion and 6 months postexpansion, after appliance removal.

CBCT examinations were performed using the i-CAT New Generation System (Imaging Sciences International, Hatfield, Pa). The technical parameters for image acquisition were 120 kVp, 8 mA, 26.9 seconds, field of view of 13 cm, and voxel size of 0.25 mm. CBCT examinations replaced conventional radiographs for orthodontic treatment planning, before expansion and for bone graft planning after expansion.

CBCT images were measured by 1 examiner (R.C.M.C.L.) using the Nemoscan software (Nemotec, Madrid, Spain). Before measurement, the head image position was standardized with the Frankfort plane and the infraorbital line parallel to the horizontal plane in the lateral and frontal views, respectively. In the axial plane, the ethmoidal septum was positioned in the vertical plane.

The dental models were digitized using a scanner (R700 3D; 3Shape, Copenhagen, Denmark). OrthoAnalyzer 3D software (3Shape) was used by 1 examiner (L.R.C.) to measure the complementary primary outcomes.

Outcomes (primary and secondary) and any changes after trial commencement

CBCT primary outcomes were maxillary transverse dimensions and posterior tooth inclinations. Transverse dimensions of the maxilla were measured in 2 coronal images perpendicular to the midsagittal plane, one passing through the center of the palatal root of the maxillary right permanent first molar (molar region), and other displaced 15 mm anteriorly (premolar region). Figure 2 illustrates the linear variables obtained in the coronal images before and after expansion. Posterior tooth inclination was measured only in the molar coronal image (Fig 2, *B*).

Digital dental model primary outcomes included maxillary dental arch widths (at the deciduous canines, first molars or permanent first premolars, second molars or permanent second premolars, and permanent first molars), arch perimeters, arch lengths, palatal depths,

Sample size calculation

Calculation of the sample size was based on the ability to detect a difference in maxillary width of 1.0 mm (SD, 1.10), with an alpha error of 5% and a test power of 80%.¹⁰ Twenty participants were required in each group.

Interim analyses and stopping guidelines

Not applicable.

Randomization

Randomization was not performed in this study. Patients were treated consecutively starting with the experimental group.

Blinding

Blinding of both patient and operator was not possible in this study. However, the outcome assessment was blinded.

Statistical analyses

All measurements were made twice by the same examiner with a month interval. Statistical analysis was performed, taking into account the means of the 2 measurements. The mean and standard deviation of each variable were calculated before and after expansion, as well as the changes between these stages. The Shapiro-Wilk normality test, followed by the Levene test for equality of variances, showed a normal distribution of the variables, and parametric tests were used.

Random and systematic errors were calculated by comparing the first and second measurements with the Bland-Altman¹⁹ analysis and the intraclass coefficient correlation.²⁰

Chi-square and independent *t* tests were respectively used to compare sex ratios and initial ages between groups (P<0.05). Intergroup comparisons were performed using independent *t* tests with the Bonferroni correction for multiple tests (*t* tests on a set of 9 CBCT measurements and 10 digital dental model measurements). Associated 95% confidence intervals (CIs) were calculated.

Multiple linear regression analysis was used to verify whether banded molars were a confounding factor for inclination changes.

RESULTS

Participant flow

Fifty patients with a mean age of 8.7 years (SD, 1.21) were prospectively recruited and consecutively allocated to the experimental or control group. Patient recruitment

commenced in August 2010 and ended in June 2014. No participant was lost during the follow-up (Fig 5).

Baseline data

Participants of both groups showed comparability regarding initial age and sex ratio (Table I).

Numbers analyzed for each outcome, estimation and precision, subgroup analysis

Since no patient was lost during the follow-up period, all 50 participants received an intervention. Appliance anchorage varied between patients in both study groups. In the experimental group, 9 (36%) patients had bands on the maxillary deciduous second molars, and 16 (64%) patients had bands adapted on the maxillary permanent first molars. In the control group, these corresponded to 12 (48%) and 13 (52%) patients, respectively. All patients were properly analyzed in their respective groups.

Intraexaminer reliabilities were considered excellent; intraclass correlation coefficients for the CBCT and digital dental model measurements ranged from 0.990 to 0.999 and 0.900 to 0.993, respectively (Table II).²⁰ Additionally, the Bland-Altman¹⁹ charts showed low degrees of dispersions for most repeated measures (Figs 6 and 7).

No significant intergroup differences were found for dentoskeletal measurements before expansion, showing adequate intergroup comparability (Table III).

No significant intergroup differences were observed for changes in CBCT variables (Table IV). The mean increase in the lower third of the nasal cavity (1.99 mm) at the molar region corresponded to approximately 33% of the amount of expansion of the arch width (5.91 mm) for the EDO (Table IV). The EDO group showed a significantly greater increase in intercanine width (mean difference, 3.63 mm) and a significantly smaller increase in canine buccal tipping (mean difference, 2.88°) than did the control group (Table IV).

The multiple linear regression analysis showed no significant correlation between banded molars and inclination changes of the deciduous second molars (P = 0.892) and the permanent first molars (P = 0.674).

Harms

No serious harm was observed other than transitory variable pressure sensations on the maxillary alveolar process, on the maxillary posterior teeth, and at the nasal area during the active period of expansion in both groups.

DISCUSSION

Main findings in the context of the existing evidence, interpretation

We assessed RME outcomes in patients with complete CBLP using a novel RME appliance that promotes differential expansions in the anterior and posterior regions of the maxillary arch. The need for differential expansions is justified because when using conventional RME expanders in patients with BCLP, there is the risk of overexpanding the intermolar distance

to correct the extreme constriction in the intercanine distance. Overexpansion of the intermolar distance is undesirable and can cause negative periodontal repercussions on the buccal aspects such as bone dehicences and gingival recessions in the long term.^{21,22} To prevent these side effects with RME, currently 2 expanders would be necessary. First, the conventional rapid maxillary expander would be used to correct the intermolar width. After 6 months of retention, a fan-type expander would achieve adequate intercanine expansion. RME using 2 appliances is effective but not efficient. To avoid or minimize the burden of care, the World Health Organization recommends reducing the number of interventions during the rehabilitation process of patients with cleft lip and palate.²³

Intergroup comparisons showed no significant differences between the experimental and control groups for the skeletal changes (Table IV). These findings suggest that the EDO might be an acceptable alternative to the conventional hyrax expander to orthopedically expand the maxillary segments in patients with BCLP. Additionally, the EDO produced a greater increase of intercanine width than the hyrax expander (Table IV). This intergroup difference of approximately 4 mm is clinically relevant and is related to the greater screw activation in the anterior region of the maxillary dental arch in the experimental group compared with the control group. This finding was expected since the EDO was originally designed to achieve greater expansion in the anterior region of the maxillary dental arch in patients with CBLP.

The EDO also showed a statistically significant smaller buccal inclination of the maxillary canines compared with the hyrax expander (Table IV). One possible explanation for these differences is that the anterior divergent opening of the EDO determines a combined buccal and distal movement of the canines, decreasing the buccal tipping changes. However, this intergroup difference of approximately 3° is not clinically relevant.

Limitations

A methodologic limitation of this study was the lack of randomization of patients before the trial. However, because the participants were recruited consecutively and impartially, the risks of potential biases can be considered acceptable. Additionally, the absence of intergroup significant differences observed for initial age, sex ratio, and dentoskeletal characteristics before expansion confirms the homogeneity of the study sample even without randomization (Table III). Another speculated limitation was the variation in posterior anchorage teeth. These variations of band locations should have influenced the outcomes observed for molar buccal inclination. The molars preferentially banded were the permanent first molars because patients were in the late mixed dentition and could show varying degrees of root resorption of the deciduous second molars. Only when patients still had the distal aspect of the permanent first molars covered by gingivae were the deciduous second molars banded. However, the multiple linear regression analysis did not show that anchorage variation had a significant influence on the appliance outcomes.

Generalizability

The generalizability of these results might be limited to patients with complete BCLP in the mixed dentition because expansion effects differ according to age and presence of the

midpalatal suture. Additionally, these results should not be generalized to different types of expanders or to the same expanders used with different activation protocols.

CONCLUSIONS

The null hypothesis was rejected. Although no significant differences were found between the EDO and the conventional hyrax expander for skeletal changes, the EDO promoted a greater expansion in the anterior region of the maxillary dental arch. The EDO is an adequate alternative to conventional RME expanders when a greater amount of expansion is required in the maxillary dental arch anterior region.

Acknowledgments

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Fig. 2.

A, CBCT transversal dimensions in the molar region; **B**, maxillary permanent first molar inclination. *NCW*, Nasal cavity width: width of the nasal cavity measured at the level of the intersection between the nasal cavity and the maxillary sinus floor; when the right and left intersections were not leveled, and only the right side was used as the reference for a measurement parallel to the horizontal plane. MxW, Maxillary width: maxillary width at the level of the hard palate. *CW*, Cleft width was measured from the right cleft border to the left cleft border parallel to the horizontal plane. ACW, Alveolar crest width: maxillary width at the level of the interpalatal alveolar crest. *AW*, Arch width: dental arch width measured at the level of the palatal cusp points. *I*, Tooth Inclination: the angle between lines passing through the buccal and lingual cusp tips of the first molars.



Fig. 3.

Digital dental model measurements: **A**, maxillary arch widths were measured at the cervical level of the deciduous canines (*C3-3*), deciduous first molars or first premolars (*C4-4*), deciduous second molars or second premolars (*C5-5*), and permanent first molars (*C6-6*); **B**, arch perimeter was measured in 4 segments from the mesial aspect of the right permanent first molar to the mesial surface of the contralateral tooth; **C**, arch length was measured from the incisive papilla to the mesial aspect of the permanent first molars in the horizontal plane; **D**, palatal depth was measured from a line passing through the mesial gingival papilla of the permanent first molars to the deepest point on the palate, perpendicular to the line representing arch length.



Fig. 4.

Posterior tooth inclination measurements between the crown long axis and the occlusal plane. The occlusal plane was defined as a plane passing bilaterally through the mesiobuccal cusp tip of the maxillary first molars and the mesioincisal point of the left central incisor. **A**–**F**, On a buccal view of each posterior tooth, the arrows was mesiodistally manipulated to represent tooth angulation (**A**, **C**, and **E**), according to facial axis point of Andrews.²⁴ On the mesial view of each tooth, the *arrow* was buccolingually manipulated, representing crown torque (**B**, **D**, and **F**) according to Andrews. The variable was expressed as the external angle. After expansion, increasing values of the angle meant buccal inclination of the teeth.





CONSORT diagram showing patient flow during the trial.

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Fig. 7.

Dispersion chart for all repeated measurements on the digital dental models (Bland-Altman¹⁹ test).

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	Experimental	group (n =25)	Control gro	up (n =25)	
Variable	Mean	SD	Mean	SD	Ч
Initial age (y)	8.8	1.08	8.6	1.28	0.442*
Sex					0.851°
Male	19		18		
Female	9		7		
* t test;					
$r_{\rm chi-square test.}$					

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Table II

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Method error analysis (intraclass correlation coefficient)

	First measu	Irement	Second meas	arement	
Variable	Mean	SD	Mean	SD	L
CBCT analysis					
Molar region (mm)					
Nasal cavity width	26.75	3.94	26.52	4.04	066.0
Maxillary width	60.53	4.43	60.54	4.28	0.995
Cleft width	9.41	4.14	9.57	4.17	0.999
Alveolar crest width	31.44	4.68	31.38	4.68	0.998
Arch width	39.50	5.23	39.56	5.19	0.999
Tooth inclination	149.95	9.97	150.13	10.03	0.996
Premolar region (mm)					
Nasal cavity width	26.54	4.19	26.31	4.13	0.997
Maxillary width	42.85	5.75	42.81	5.72	0.999
Cleft width	9.42	3.40	9.35	3.45	0.998
Digital dental model analys	is (mm)				
C3-3	19.58	3.83	19.74	3.85	0.974
C4-4	24.08	2.87	24.03	2.87	0.900
C5-5	29.24	2.67	29.22	2.65	0.992
C6-6	35.15	3.84	35.26	3.81	0.950
Arch perimeter	69.68	10.47	70.90	13.07	0.993

-		
0.970		
0.944		

3.24

3.30

SD

Mean 23.97

SD

Mean 24.07

Second measurement

First measurement

3.44

10.03

3.48

10.12

Palatal depth

Arch length

Variable

C Cervical; 3, deciduous canines; 4, deciduous first molars or permanent first premolars; 5, deciduous second molars or permanent second premolars; 6, permanent first molars.

0.993

4.45

75.72

4.52

76.02

Tipping 6

0.976

2.77

72.93

2.74

73.25

Tipping 5

0.954

4.24

66.72

4.22

66.45

Tipping 3

Table III

Intergroup comparability at before expansion (independent *t* tests)

ſ							
EXP	perimental gro	up $(n = 25)$	Control group	(n = 25)			
Variable	Mean	SD	Mean	SD	95% CI	Р	Significance
CBCT analysis							
Molar region (mm)							
Nasal cavity width	26.19	3.59	26.60	4.16	-2.82, 2.00	0.733	NS
Maxillary width	60.51	4.28	59.83	3.99	-1.90, 3.25	0.600	NS
Cleft width	7.02	3.74	7.79	4.34	-3.64, 1.56	0.550	NS
Alveolar crest width	30.04	3.32	30.17	3.43	-2.19, 1.97	0.895	NS
Arch width	37.52	3.69	38.86	3.83	-3.63, 1.13	0.272	NS
Tooth inclination	155.04	9.80	149.93	11.89	-1.21, 12.78	0.151	NS
Premolar region (mm)							
Nasal cavity width	26.06	3.84	26.81	3.62	-3.09, 1.67	0.306	NS
Maxillary width	42.09	5.19	42.84	5.02	-4.02, 2.60	0.283	NS
Cleft width	7.69	2.86	7.95	2.83	-2.12, 1.64	0.740	NS
Digital dental model analysis (m	m)						
C3-3	18.57	3.62	18.69	4.05	-2.45, 2.21	0.917	NS
C4-4	23.08	3.18	23.47	2.85	-2.24, 1.47	0.679	NS
C5-5	29.17	2.67	28.40	3.32	-1.02, 2.57	0.390	NS
C6-6	33.65	3.41	34.79	4.07	-3.29, 1.02	0.294	NS
Arch perimeter	70.40	8.57	68.52	7.03	-2.64, 6.39	0.408	NS

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	Experimental gr 0	oup (n = 25)	Control group ((n = 25)			
Variable	Mean	SD	Mean	SD	95% CI	Ч	Significance
Arch length	25.23	5.71	24.43	3.43	-2.01, 3.62	0.567	NS
Palatal depth	9.58	1.73	8.79	2.72	-0.51, 2.08	0.229	NS
Tipping 3	67.05	4.82	69.49	6.15	-5.94, 0.26	0.037	NS
Tipping 5	73.78	6.00	74.94	5.03	-6.50, 1.51	0.369	NS
Tipping 6	74.58	4.98	75.40	5.00	-7.45, 1.33	0.459	NS

NS, Nonsignificant; C, cervical; 3, deciduous canines; 4, deciduous first molars or permanent first molars; 5, deciduous second molars or permanent second premolars; 6, permanent first molars.

Table IV

Intergroup comparisons of the expansion changes (independent t tests)

EXI	<u>perimental grou</u>	ıp (n = 25)	Control grou	p (n = 25)			
Variable	Mean	SD	Mean	SD	95% CI	Ρ	Significance
CBCT analysis							
Molar region (mm)							
Nasal cavity width	1.99	1.42	1.02	1.62	0.00, 1.90	0.048	NS
Maxillary width	1.31	2.14	1.59	1.23	-1.35, 0.79	0.601	NS
Cleft width	1.95	1.47	1.13	1.14	-0.02, 1.66	0.045	NS
Alveolar crest width	4.79	1.98	3.89	1.67	-0.26, 2.05	0.126	NS
Arch width	5.91	2.35	5.33	2.18	-5.2, 2.71	0.432	NS
Tooth inclination	-3.04	10.88	-6.89	8.40	-2.48, 10.18	0.226	NS
Premolar region (mm)							
Nasal cavity width	1.87	1.60	1.13	0.84	-0.07, 1.54	0.074	NS
Maxillary width	1.44	3.29	1.54	1.64	-1.82, 1.63	0.911	NS
Cleft width	2.17	1.26	1.24	1.31	0.05, 1.80	0.037	NS
Digital dental model analysis (m	(m						
C3-3	7.68	1.99	4.05	1.72	2.49, 4.78	0.000	*
C4-4	6.12	2.65	5.35	2.60	-0.85, 2.38	0.344	NS
C5-5	5.38	2.14	5.66	2.90	-1.80, 1.24	0.714	NS
C6-6	5.57	1.77	4.30	2.78	-0.06, 2.61	0.061	NS
Arch perimeter	7.66	6.13	4.58	3.97	0.10, 6.05	0.042	NS

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	Experimental grou	p (n = 25)	Control grou	<u>p (n = 25)</u>			
Variable	Mean	SD	Mean	SD	95% CI	Ъ	Significance
Arch length	-0.01	1.25	-0.88	1.61	-0.96, 0.71	0.767	NS
Palatal depth	-1.66	1.34	-1.42	1.49	-1.04, 0.57	0.558	NS
Tipping 3	2.17	2.46	5.05	3.69	-4.91, -0.86	0.000	*
Tipping 5	1.53	6.77	1.43	4.83	-4.34, 4.01	0.944	NS
Tipping 6	0.67	4.55	0.74	5.61	-2.18, 2.85	0.951	NS

* Statistically significant at P < 0.005 with the Bonferroni correction for digital dental model measurements.