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Original article

Soft tissue evaluation of functional therapy in growing patients with Class II malocclusion: a long-term study

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Summary

Objective: The objective of this study was to analyse the soft tissue changes produced by the functional treatment of mandibular advancement in growing Class II patients.

Materials: The treated group consisted of 25 Caucasian patients (12 females and 13 males) with dento-skeletal Class II malocclusion treated with functional therapy (Activator). All patients were evaluated before treatment (T1; mean age, 9.9 years), at the end of functional treatment phase (T2; mean age, 11.9 years), and at a post-pubertal follow-up observation (T3; mean age, 18.5 years). The treated group was compared with a matched control group of 25 untreated subjects (13 females, 12 males) with untreated Class II division 1 malocclusion. Statistical comparisons between the two groups were performed with independent samples *t*-tests ($P < 0.05$).

Results: Significant improvements were found during the long-term interval for mandibular sulcus (9.9°) and the profile facial angle (9.8°) in the treated group. No significant effects were found in terms of lower face percentage between the two groups.

Conclusion: Removable functional appliances induced positive effects on the soft tissue profile in Class II growing subjects with good stability in the long-term.

Introduction

Dento-skeletal Class II malocclusion is commonly associated with skeletal mandibular retrusion (1–3). Functional therapy stimulates mandibular growth by forward posturing of the mandible with the condyles in a more downward and forward position in the glenoid fossa (2–5). Several functional appliances have been specifically designed to enhance mandibular growth and forward repositioning of the mandible in order to correct Class II dento-skeletal disharmonies (5, 6). A number of authors have analyzed the effectiveness of functional appliances demonstrating that the improvement of the sagittal discrepancy consists of a combination of dental and skeletal effects on both maxilla and mandible (3, 6–8). The main modifications have been identified as an effective mandibular growth associated with a reduced maxillary forward growth and a retroinclination of the upper incisors (9). According to the results of recent meta-analyses (10–13), orthopaedic functional appliances, regardless of their type, are effective in improving overjet values to within normal limits with similar correction in terms of skeletal and dental effects on the sagittal plane. Moreover, some authors have recently highlighted the importance of treatment timing showing a significant supplementary elongation of the mandible when functional therapy is performed at the pubertal growth spurt (3, 14). Despite dento-skeletal effects have been extensively illustrated in the literature, data available concerning aesthetic improvements and soft tissue modifications are limited (3–13,15–21). Based on the few results available, it has been found that the soft-tissue facial structures are affected favourably from the functional appliances (15). A convex facial profile represents the main feature associated with mandibular retrusion. Furthermore, the malocclusion is generally characterized by specific facial traits such as pronounced upper lip associated with an acute nasolabial angle, deep mandibular sulcus, reduced projection of lower lip and chin. Among therapeutical objectives, one consists of the improvement of facial aesthetics by reducing the profile convexity and recovering a good lip projection and competence especially in growing patients (20). As a matter of fact, the influence of functional orthopaedic appliances on the skeletal components determines a more physiologic and harmonious adaptation and improvement of the soft tissues during active growth. Some studies have reported soft tissue response to fixed functional appliances in the short-term (1, 17, 19–21). A significant improvement of the facial convexity, a better relation of the upper and lower lip and more harmonious soft tissues in relation to the skeletal structures have been demonstrated (20). Pancherz in 1994 (17) examined the short- and long-term effects of Herbst appliance on facial profile highlighting the unpredictability and variability of long-term modifications. However, only a few data are available with regard to soft tissue changes following functional therapy especially in terms of long-term stability (3–13,15–21). Therefore, the purpose of the present retrospective study was to evaluate the long-term soft tissue changes determined by Class II treatment with functional therapy followed by fixed appliances, comparing them to a Class II control group.

Materials and methods

This retrospective study was approved by the Ethical Committee at the University of Rome 'Tor Vergata' (201/16), and informed consent was obtained from the subjects' parents. The sample size was calculated considering an effect size for the primary outcome variable Facial profile angle (G'-SubN-Pg') of 1.0, an alpha value of 0.05 and a power of 0.80. At least 17 subjects were required for each group. A sample of 25 consecutively treated patients (12 females and 13 males) with dento-skeletal Class II malocclusion treated with functional therapy (Activator) at the Department of Orthodontics, University of Rome " Tor Vergata" was collected. Inclusion criteria consisted of subjects of Caucasian origin, an overjet greater than 5 mm, full Class II or end-to-end molar relationships, ANB angle greater than 4°, and an improvement in facial profile when the lower jaw was postured in a forward position (22). Subjects with facial asymmetry, craniofacial syndromes, previous orthodontic treatment were excluded. No permanent teeth were congenitally missing or extracted before or during treatment. The non-extraction treatment protocol consisted of an acrylic monobloc attached to the upper arch by Adams clasps and with the capping of the upper and lower incisors (3). All patients were instructed to wear the appliance 16 h a day until the end of treatment. Treatment with functional appliances ended up with the achievement of Class I molar relationships. Then a second phase with fixed appliance was performed in permanent dentition. Lateral cephalograms at three time points were selected for all patients included in the study: T1, at the start of treatment (mean age: 9.9 ± 1.3 years; CS1 = 6, CS2 = 14, CS3 = 5 according to the cervical vertebral maturation, CVM, method) (23); T2, at the end of functional treatment phase and before fixed appliance (mean age: 11.9 ± 1.2 years; CS2 = 5, CS3 = 10, CS4 = 7, CS5 = 3); and T3, at long-term observation after completion of growth (mean age: 18.5 ± 2.2 years; CS5 = 8, CS6 = 17). The T3 observations were collected and evaluated regardless of the treatment outcomes in terms of correction of Class II malocclusion in single patients. A group of 25 subjects (13 females, 12 males) with untreated Class II division 1 malocclusion was selected from the American Association of Orthodontists Foundation (AAOF) Craniofacial Growth Legacy Collection (http://www.aaoflegacycollection.org, Bolton–Brush Growth Study, Michigan Growth Study, Denver Growth Study, Oregon Growth Study, and Iowa Growth Study). Cephalograms from the AAOF legacy were obtained at high resolution. The magnification factor of each collection was retrieved from the AAOF legacy website. The inclusion criteria of the control group were the same as those of the treated sample.

Cephalometric analysis

Lateral cephalograms for both treated and untreated subjects were scanned at the same resolution (150 dpi). A customized digitization regimen and cephalometric analysis provided by Viewbox (version 3.0; dHAL Software, Kifissia, Greece) were used for all cephalograms selected. The customized cephalometric analysis, containing measurements from the analysis of Bergman (24), generated seven variables, four angular and two linear, and one percentage value. All the soft tissue cephalometric measurements are summarized in Supplementary Table 1. Also, eight additional cephalometric variables were digitized for each patient at T1, T2, and T3 in order to provide data on the dento-skeletal correction obtained (Figures 1

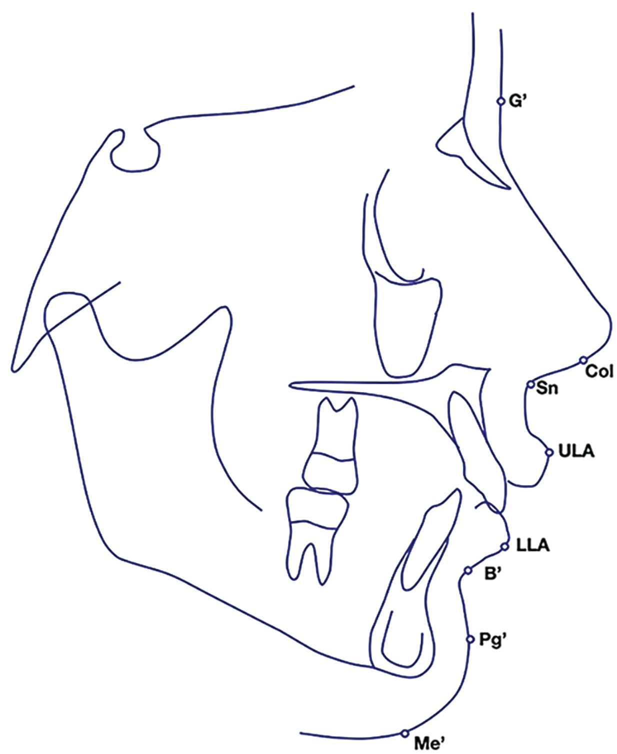

Figure 1. Soft tissue landmarks used in analysis: G′ (soft tissue Glabella), Col (Colummella), Sn (Subnasale), ULA (upper lip anterior point), LLA (lower lip anterior point), B′ (soft tissue B point), Pg′ (soft tissue Pogonion), Me′ (soft tissue Menton).

and 2). All lateral cephalograms of both groups at T1, T2, and T3 were standardized to life size (0% enlargement).

Statistical analysis

Firstly, descriptive statistics and statistical between-group comparisons (treated group versus control group) were calculated for the craniofacial starting forms at T1 and for the T1–T3 changes. The Fisher Exact test was used to compare gender distribution and the distribution of the CVM stages at T1, T2, and T3. After having checked the normal distribution of the data (Kolmogorov–Smirnov test), statistical between-group comparisons for the T1–T3 changes were performed with independent samples *t*-tests. With data not normally distributed, statistical between-group comparisons were carried out with the Mann–Whitney test. Moreover, descriptive statistics and between-group comparisons for the T1–T2 and T2–T3 changes were performed. The primary aim of this study was to evaluate the long-term soft tissue changes determined by Class II treatment with functional therapy followed by fixed appliances. In order to apply a correction for multiple testing, the Holm–Bonferroni sequential correction (25) was applied for all the between-group comparisons for the seven soft-tissue variables and for the eight dento-skeletal variables.

Fifteen lateral cephalograms were randomly selected. Then, they were traced and measured again within 2 weeks by the same operator (FG). The intra-observer reproducibility was analysed with the intraclass correlation coefficient (ICC). Method of moments' estimator was used to calculate measurements errors (26).

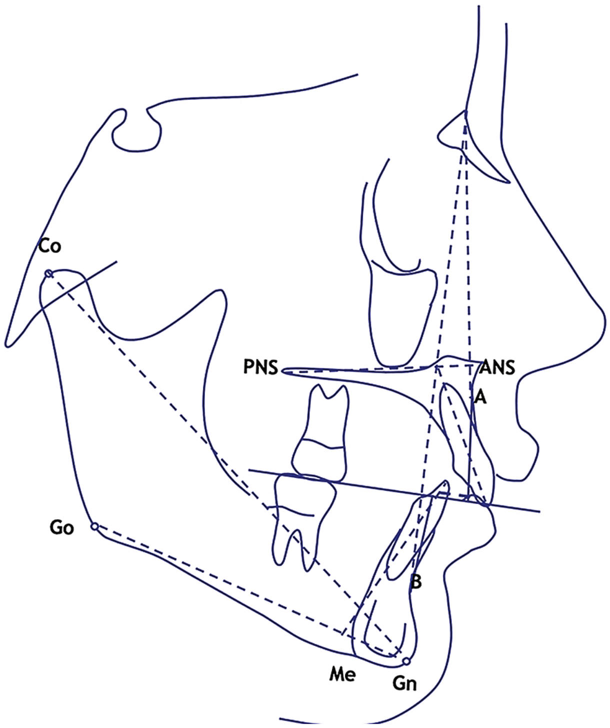

Figure 2. Cephalometric points, lines, and angles used in the analysis: SNA angle (maxillary sagittal position), SNB angle (mandibular sagittal position), ANB angle (maxillomandibular sagittal discrepancy), Wits appraisal (maxillomandibular sagittal discrepancy), Co–Gn (mandibular total length), Pal. Pl to Mand. Pl. angle (palatal plane to mandibular plane), Upper Inc. to Pal. Pl. angle (upper incisors to the palatal plane, upper incisors inclination), Lower Inc. to Mand. Pl. angle (lower incisors to mandibular plane, lower incisors inclination).

Results

The demographic data of the treated and the control groups are reported in Table 1. No significant between-group differences were found either for chronologic age at T1 (P = 0.333) and for gender distribution (P = 1.000). The control group matched the treated group as to skeletal maturation at the various times; chronologic age at T1 (mean age: 10.2 ± 1.1 years; CS1 = 4, CS2 = 9, CS3 =12), T2 (mean age: 12.0 ± 1.3 years; CS2 = 2, CS3 =10, CS4 = 9, CS5 = 4), and T3 (mean age: 17.7 ± 1.9 years; CS4 = 1, CS5 = 7, CS6 = 17); and observation intervals. As for the observation periods, only the T2–T1 interval was significantly longer in the treated group compared to the controls (2.1 and 1.8 years, respectively). The intra-observer reproducibility, evaluated with the ICCs, indicated a high level of intraobserver agreement (ICCs varied between 0.897 and 0.999). As for the measurement errors they varied from 0.2° to 0.4° for the angular measurements and from 0.4 to 0.5 mm for the linear measurements. No significant between-group differences were found in any of the variables at T1 (Table 2). The statistical comparisons of the T1–T3 changes between the treated and control groups (Table 3) showed significant modifications produced by

Table 1. Demographics of the treated and control groups.[a]

Variables	Age at T1 (years) Mean	SD	CVM stages at T1	Age at T2 (years) Mean	SD	CVM stages at T2	Age at T3 (years) Mean	SD	CVM stages at T3	T1-T2 interval (years) Mean	SD	T2-T3 interval (years) Mean	SD	T1-T3 interval (years) Mean	SD
Treated group (n = 25, 12 f, 13 m)	9.9	1.3	6 CS1 14 CS2 5 CS3	11.9	1.2	5 CS2 10 CS3 7 CS4 3 CS5	18.5	2.2	8 CS5 17 CS6	2.1	0.7	6.4	2.2	8.6	2.2
Control group (n = 25, 13 f, 12 m)	10.2	1.1	4 CS1 9 CS2 12 CS3	12.0	1.3	2 CS2 10 CS3 9 CS4 4 CS5	17.7	1.9	1 CS4 7 CS5 17 CS6	1.8	0.4	5.7	1.8	7.6	1.8
***P* value**	0.333		0.132	0.880		0.655	0.182		0.881	**0.042**		0.247		0.078	

Descriptive statistics and statistical comparisons at T1, T2, and T3 (independent-samples *t*-tests); CVM distribution at T1, T2, and T3 (Fisher Exact test).
f, female; m, male; y, years; SD, standard deviation; NS, not significant.
[a] T1 indicates before treatment; T2 immediately after removal of the functional appliances; T3 follow-up observation.

functional therapy. In particular, both mandibular sulcus and profile facial angle (G'-SubN-Pg') exhibited a significant increase (9.9° and 9.8°, respectively). In the short-term T1-T2 interval (Supplementary Table 2), mandibular sulcus and profile facial angle showed significant increases in the treated group with the respect to control group (9.2° and 6.9°, respectively) who presented a decrease for these variables (−0.8° and −0.8°, respectively). Only the upper lip protrusion showed a significantly greater decrease in the treated group (−1.2 mm) than in the control group (−0.1 mm). During the T2–T3 period, only one cephalometric variable showed statistically significant changes, with an increase of the profile facial angle in the treated group versus the control sample (2.5°) (Supplementary Table 3). As for the dento-skeletal changes observed during the T1–T3 interval, the treated group showed a significant decrease in Wits measurements (−4.0 mm). This favourable change was associated with a significantly higher increase in total mandibular length (Co–Gn + 3.3 mm). No significant changes in vertical relationship were revealed in the treated group.

Table 2. Descriptive statistics and statistical comparisons (independent-samples *t* tests) of the starting forms (cephalometric values at T1). The *P* values were adjusted according to the Holm–Bonferroni sequential correction and they appear in bold character if statistically significant.

	Treated Group (*n* = 25)		Control Group(n=25)				95% CI of the difference	
Variables	Mean *median*	SD *IQR*	Mean *median*	SD *IQR*	Diff.	*P* value	Lower	Upper
Upper Lip-SubN/Pg' (mm)	3.1	1.5	3.7	1.9	−0.6	0.165	−1.7	0.3
Nasolabial (°)	131.1	10.1	128.3	9.7	2.8	0.312	−2.8	8.5
Maxillary Sulcus (°)	158.1	5.4	160.2	5.4	−2.1	0.180	−5.1	−1.0
Mandibular sulcus (deg)	125.2	10.5	123.7	13.1	1.5	0.667	−5.3	8.2
LowerLip-SubN/Pg' (mm)	1.5	1.8	2.0	2.6	−0.5	0.504	−1.7	0.8
Lower face (%)	51.6	2.1	50.6	2.2	1.0	0.103	−0.2	2.2
G'-SubN-Pg' (°)	139.7	3.9	140.6	3.0	−0.9	0.341	−2.9	1.0
SNA (°)	81.9	3.0	80.6	3.0	1.3	0.108	−0.3	3.1
SNB (°)	74.9	3.1	74.6	2.4	0.3	0.715	−1.3	1.9
ANB (°)	7.0	1.6	5.9	1.6	1.1	0.018	0.2	2.0
Wits (mm)	3.0	2.9	2.0	3.0	1.0	0.212	−0.6	2.7
Co–Gn (mm)	104.8	7.0	105.4	5.3	−0.6	0.718	−4.2	2.9
Pal. Pl. to Mand. Pl. (deg)	*26.2*	*6.7*	*27.0*	*6.0*	−0.8	0.554		
Upper Inc. to Pal. Pl. (°)	*110.8*	*4.3*	*111.1*	*6.7*	−0.3	0.467		
Lower Inc. to Mand. Pl. (°)	96.5	6.4	96.3	6.3	0.2	0.942	−3.5	3.7

SD = standard deviations; Diff. = differences; IQR = interquartile range; CI = confidence interval; G = Gonion; SubN = subnasale; Pg = Pogonion; Gn = Gnation; Pal.= palatal; Pl.= plane; Mand. = mandibular; Inc.= incisor; mm = millimetres

Table 3. Descriptive statistics and statistical comparisons (independent-samples *t* tests or Mann–Whitney *U* test) of the T3–T1 changes. The *P* values were adjusted according to the Holm–Bonferroni sequential correction and they appear in bold character if statistically significant.

	Treated Group (*n* = 25)		Control group(*n* = 25)				95% CI of the difference	
Variables	Mean *median*	SD *IQR*	Mean *median*	SD *IQR*	Diff.	*P* value	Lower	Upper
UpperLip-SubN/Pg' (mm)	−1.7	1.1	−0.7	1.9	−1.0	0.031	−1.9	−0.1
Nasolabial (°)	−0.1	6.9	0.4	7.8	−0.5	0.802	−4.7	3.7
Maxillary Sulcus (°)	−1.3	6.6	−2.8	6.2	1.5	0.414	−2.1	5.1
Mandibular Sulcus (°)	11.6	5.2	1.7	12.0	9.9	**0.000**	4.6	15.2
LowerLip-SubN/Pg' (mm)	−0.7	1.7	−0.3	1.9	−0.4	0.410	−1.5	0.6
Lower Face (%)	−0.2	3.1	0.1	2.5	−0.3	0.688	−1.9	1.3
G'-SubN-Pg' (°)	*9.0*	*0.3*	*−0.8*	*4.7*	*9.8*	**0.000**		
SNA (°)	−0.3	1.9	−0.2	1.8	−0.1	0.800	−1.2	0.9
SNB (°)	2.0	1.8	1.5	1.7	0.5	0.289	−0.5	1.5
ANB (°)	−2.3	1.7	−1.7	1.3	−0.6	0.130	−1.5	0.2
Wits (mm)	−2.2	3.3	1.8	3.8	−4.0	**0.000**	−6.0	−2.0
Co–Gn (mm)	18.9	4.7	15.6	3.1	3.3	**0.006**	1.0	5.5
Pal. Pl. to Mand. Pl. (°)	−2.4	2.8	−3.0	1.9	0.6	0.445	−0.9	1.9
Upper Inc. to Pal. Pl. (deg)	−3.9	7.3	−0.4	5.7	−3.5	0.066	−7.2	0.2
Lower Inc. to Mand. Pl. (°)	−0.6	4.8	2.3	4.3	−2.9	0.032	−5.4	−0.3

SD = standard deviations; Diff. = differences; IQR = interquartile range; CI = confidence interval; G = Gonion; SubN = Subnasale; Pg = Pogonion; Gn = Gnation; Pal. = palatal; Pl. = plane; Mand. = mandibular; Inc.= incisor; mm= millimetres.

Discussion

Functional therapy affects not only skeletal and dentoalveolar morphology, but also soft tissue arrangements, resulting in a more harmonious and acceptable facial profile with craniofacial structures (18–20). The aim of this study was to evaluate the long-term effects of functional therapy induced on soft tissue facial profile in growing Class II patients compared to an untreated Class II control group by means of Bergman soft tissue analysis (24, 27). Facial aesthetics' improvement has been recognized as one of the main reasons for seeking orthodontic treatment (19). The aesthetic factor takes on greater consideration in growing patients. As matter of fact, interceptive orthopaedic treatment modifies the growing pattern with a consequent improvement of dento-skeletal morphology and thus, of facial profile and perception of facial beauty (16, 28). Despite a number of authors (2–4, 6) extensively analyzed the dento-skeletal effects of functional therapy and their stability in the short and long-term, soft tissue changes have been less thoroughly investigated (9, 16–21). Overall T1–T3 results showed a significantly more harmonious facial profile in the treated group (Table 3). Facial profile angle significantly increased in the treated group with respect to the control group (+9.8°). This can be related to a corresponding skeletal improvement of sagittal relationship (−4 mm Wits) and thus, to a significant mandibular growth stimulation (3.3 mm Co–Gn) during the long-term interval. According to several authors (4, 9), functional appliances induce a significant elongation of the mandible during the pubertal growth spurt that is maintained in the long term. Despite a number of previous systematic reviews reported the effects of functional appliances in both short and long-term demonstrating the improvement of maxillo-mandibular relationship, however mandibular skeletal effects remain a controversial topic in orthodontics (11, 12). Mandibular position can be considered negligible, whereas the anteroposterior relationship influences more notably the treatment effects (11). Thus, clinical success should be measured not only by mandibular length but also in consideration of sagittal relationship, dental changes, facial profile outcomes and changes (12). The herein results are in line with Bock *et al.* (29) who showed a more straightened facial profile and an improvement of the lips' sagittal and vertical position after Herbst treatment in a group of Class II division 2 patients. Moreover, the mandibular sulcus significantly increased by 9.9° in the treated subjects compared with the controls. The straightening of mandibular sulcus appears to be mainly a consequence of mandibular advancement. The lack of significant increase in lower incisor inclination suggested that there was no dentoalveolar compensation in the skeletal correction of Class II malocclusion (3, 8). Also, Hourfar *et al.* (19) found a significant improvement of lower lip thickness following treatment with both FMA and Herbst appliances that can be interpreted as a further aesthetic effect related to the lack of lower incisor proclination. Upper lip protrusion was lower in the treated group than in the controls (−1.0 mm), though not statistically significant. This favourable result was due to the greater lingual inclination of the upper incisors observed in the long-term, although not statistically significant. In agreement with this result, Pavoni *et al.* (14) concluded that long-term dentoalveolar improvements might have been primarily sustained by favourable sagittal skeletal changes, with no significant modifications in the inclinations of either upper or lower incisors.

All the profile modifications were mainly determined during the functional active treatment phase (Supplementary Table 2), and they have been maintained during the post-treatment period (Supplementary Table 3). A significant normalization of soft tissues could be observed during the short-term in terms of facial profile angle (7.7°), mandibular sulcus (10°), and upper lip protrusion (−1.1 mm). During the T2–T3 interval, all values remained stable with no significant changes. Only the facial profile angle showed a significant increase of 2.5 mm. The results obtained should be supported and corroborated by further investigations to be conducted by means of long-term observation and possibly on larger Class II samples.

The limitations of the present study are its retrospective nature, the use of historical controls, and the relatively small sample size. Ideally, a contemporary control sample should have been used because it has been shown that our face and its changes are influenced by secular trends (30). However, it would be unethical to leave a contemporary Class II sample without any treatment in the long term. Moreover, another limitation is represented by a significant between-group difference in the duration of the T1–T2 interval.

Conclusions

Treatment with removable functional appliances at puberty induced a reduction in the convexity of the soft tissue facial profile with good stability in the long term. All modifications observed were mainly sustained by significant sagittal skeletal changes. In particular, the treated group showed a significant normalization of the Class II convex profile associated with a more harmonious position of the lips due mainly to a straightened mandibular sulcus.

Supplementary material

Supplementary material is available at *European Journal of Orthodontics* online.

Table 1. Descriptive statistics and statistical comparisons at T1, T2, and T3 of the treated and control groups

Table 2. Descriptive statistics and statistical comparisons (independent-samples *t* tests) of the starting forms (cephalometric values at T1).

Table 3. Descriptive statistics and statistical comparisons (independent-samples *t* tests or Mann–Whitney *U* test) of the T3–T1 changes.

Supplementary Table 1. Soft tissue cephalometric variables and their definition

Supplementary Table 2. Descriptive statistics and statistical comparisons (independent-samples *t* tests or Mann–Whitney *U* test) of the T2–T1 changes

Supplementary Table 3. Descriptive statistics and statistical comparisons (independent-samples t tests) of the T3–T2 changes

Conflict of interest

All the authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

Data availability

The data underlying this article will be shared on a reasonable request to the corresponding author.

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