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Assessment of Soft Tissue Changes on Facial Scans After Functional Treatment in Class II Malocclusion Patients

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Abstract

Background: The aim of this prospective longitudinal study was to evaluate three-dimensional facial soft tissue changes following treatment with the Sander Bite Jumping Appliance (BJA) in growing patients with skeletal class II malocclusion. Methods: Seventeen consecutive growing patients (14 males and 3 females; mean age of 11.7 ± 1.1 years) with skeletal class II malocclusion due to mandibular retrusion were treated with the Sander BJA. Three-dimensional facial scans were acquired before treatment (T0) and after completion of active treatment (T1) using a 3dMD stereophotogrammetric system. Twelve angular soft tissue variables were measured after image superimposition using stable facial reference regions. Changes between T0 and T1 were analysed using paired Student's *t*-tests ($p < 0.05$). Results: The facial convexity angle increased significantly from 155.49 ± 4.12° at T0 to 157.21 ± 3.84° at T1, corresponding to a mean change of 1.72° (95% CI: 0.06–3.39; $p = 0.044$) and a moderate effect size (Cohen's dz = 0.53). Among the secondary outcomes, significant changes were observed for the SS-N-SL angle (mean change: −1.29°; $p = 0.002$; dz = −0.89), upper lip position (−1.09°; $p = 0.006$; dz = −0.77), LS-N-LI angle (−0.69°; $p = 0.042$; dz = −0.54), and submental angle (+13.86°; $p < 0.001$; dz = 1.10). No significant changes were observed for the remaining angular measurements. Conclusions: Treatment with the Sander BJA was associated with measurable three-dimensional soft tissue changes predominantly involving the lower facial region. The observed modifications included mainly profile straightening and changes in lip position. Because of the absence of an untreated control group, these findings should be interpreted as treatment-associated soft tissue changes in growing patients.

Keywords: class II malocclusion; functional treatment; soft tissue analysis; three-dimensional analysis

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1. Introduction

Class II malocclusion is one of the most common orthodontic problems in children and adolescents, with a mean prevalence of approximately 24–25% worldwide and about 25% in European populations [1,2]. Class II malocclusion may result from a true skeletal discrepancy, most commonly mandibular retrusion, or from predominantly dentoalveolar alterations, with a relatively normal sagittal relationship between the maxillary and mandibular bases. Of these class II malocclusions, 15% have true skeletal discrepancy such as mandibular retrusion [3], while 27% affect only the dento-alveolar region, with a good relationship between the upper and lower jaws [4].

The dentoalveolar and skeletal characteristics of class II malocclusions affect the aesthetic of the patients. Indeed, patients might present high degrees of facial convexity, decreased mentolabial angles, normal or decreased nasolabial angles, lip incompetence with small and retro-positioned lower lips, and short chin-to-neck lengths [5]. Alterations in facial profile imbalances can adversely affect a patient's dental and facial aesthetics [6,7].

Class II malocclusion can also affect the psychological sphere of the patients. Prior studies have shown that such malocclusions can negatively impact self-esteem and mental health, influencing social behaviour and emotional well-being. Adolescents with pronounced class II profiles often perceive their appearance negatively, which can affect their self-confidence [8,9]. Correction of the facial imbalance may therefore improve not only occlusal function but also patients' self-perception and psychosocial well-being. The treatment of class II malocclusion depends on the underlying aetiology. In growing patients with mandibular retrusion (skeletal class II), functional orthopaedic appliances are used to stimulate mandibular growth producing a combination of skeletal, dentoalveolar, and soft tissue effects, whereas extraoral traction (headgear) can be used if the maxilla is protrusive. Skeletally, functional appliances can enhance mandibular growth and length, while dentoalveolar effects typically include forward proclination of the lower incisors, with mesialisation of the lower molars and loss of inclination of the upper incisors with reduction in the overjet [10]. However, the soft tissue effects of functional appliance therapy have not been as extensively studied as the skeletal and dental effects [11,12].

Functional treatment of mandibular retrognathia is expected to induce adaptive changes in the overlying facial soft tissues. Previous two-dimensional cephalometric studies have consistently reported improvements in facial profiles, particularly in the chin and lower lip regions. However, the magnitude and distribution of these soft tissue changes remain controversial because of differences in appliance design, study methodology, and outcome measurements. [13]. For example, Varlik et al. (2008) [13] reported that functional treatment outcomes in such patients include a decrease in facial convexity and improvements in the mentolabial region. Nevertheless, the evidence on soft tissue outcomes has been mixed, and differences in appliance types and measurement methods have led to variable results in the literature. Few studies, instead, used conventional lateral radiograph in patients treated with removable functional appliances [13–21], with variable results. Flores-Mir and Major analysed three types of functional devices, fixed and mobile, and found that the Twin Block has positive effects with regard to facial convexity, but without movements of the lower lip and soft tissue menton [21,22]. D'Antò et al. found, in a systematic review of systematic reviews, that there is insufficient evidence to determine if functional appliances influence soft tissue [10]. However, most of these studies presented a two-dimensional evaluation via cephalometric analysis of a three-dimensional and radiotransparent tissue (facial soft tissue); hence, due to the difficulties and the few analyses of the soft tissue valuation, a new way to analyse facial parameters could be three-dimensional stereo photogrammetry.

Given the limitations of lateral cephalograms for soft tissue analysis, three-dimensional imaging techniques have gained popularity in orthodontics [23,24]. Three-dimensional stereophotogrammetry has become one of the most reliable noninvasive methods for quantitative assessment of facial soft tissues, offering high accuracy, excellent reproducibility, and the absence of ionizing radiation. Previous studies have demonstrated that 3D facial scanning systems (such as the 3dMD system) are highly reproducible and precise for measuring facial distances and angles, with errors of about 0.2–0.5 mm. In particular, the 3dMD stereophotogrammetry system has been validated for craniofacial measurements, showing excellent accuracy in landmark identification and superimposition [25–28]. Using 3D soft tissue imaging allows clinicians and researchers to evaluate treatment-induced changes

in facial morphology without exposing patients to ionizing radiation. This is a significant advantage for longitudinal studies in growing patients, where repeated radiographs would raise ethical concerns. A few recent investigations have combined cone beam computed tomography (CBCT) with stereophotogrammetry or have used 3D optical scans alone to assess soft tissue changes after class II functional therapy. These studies reported positive soft tissue improvements, such as forward movement of the chin and lips, following functional appliance treatment (particularly with Twin Block appliances). For example, Güler and Malkoç [29] and Yıldırım et al. [30] found that Twin Block therapy led to a more forward chin position and improved facial convexity in their class II patients, as measured in 3D scans. Moreover, a recent systematic review that focused exclusively on 3D soft tissue analyses [31] concluded that functional appliance therapy has a generally positive influence on the facial soft tissues in class II patients.

One functional appliance commonly used in Europe for class II correction is the Sander Bite Jumping Appliance (BJA). This removable appliance postures the mandible forward via interlocking acrylic bite blocks and metal prongs, thereby stimulating mandibular growth during peak pubertal development. The Sander BJA's effectiveness in correcting the class II occlusion and its skeletal dental effects have been previously documented. In particular, a randomised controlled trial by Martina et al. [32] demonstrated that the BJA produced significant improvements in mandibular position and dental occlusion in growing patients. Additionally, a short-term study by Rongo et al. [33] showed that the BJA induced some changes in pharyngeal airway dimensions (and in tongue and soft palate position), although the clinical relevance of those airway changes was debatable. Furthermore, in recent paper, D'Antò supported the hypothesis that some morphological characteristics of the patient, such as the CoGoMe angle and IMPA angle, influence the treatment outcome [34]. To date, however, there have been no studies specifically examining the 3D facial soft tissue changes resulting from Sander BJA treatment.

Given this background, the aim of this prospective longitudinal study was to evaluate three-dimensional facial soft tissue changes associated with treatment using the Sander BJA in growing patients with skeletal class II malocclusion. We hypothesised that treatment would be associated predominantly with modifications of the lower facial soft tissues, while changes in the upper facial region would be limited.

2. Materials and Methods

This prospective longitudinal single-group clinical study was conducted at the Section of Orthodontics in the Department of Neurosciences, Reproductive Sciences and Oral Sciences at the University of Naples Federico II between April 2021 and June 2022.

Seventeen consecutive growing patients with skeletal class II malocclusion due to mandibular retrusion were consecutively recruited. The patients were between 9 and 13 years old at T0 (mean age: 11.7 $\pm$ 1.06 years), and they were between 10 and 14 years old at T1 (mean age: 12.8 $\pm$ 1.34 years), with a T1–T0 mean interval of 1.2 $\pm$ 0.44 years. Before taking part in the study, the participants received an oral explanation outlining the study details, and the parents or legal guardians of all patients provided informed consent. The study protocol was approved by the Ethical Committee of the University "Federico II" of Naples (protocol no. 22616), in compliance with the Code of Ethics of the World Medical Association (Declaration of Helsinki) for research involving human subjects.

2.1. Inclusion and Exclusion Criteria

The inclusion criteria were the following: the presence of at least an edge-to-edge class II molar relationship (angle class II malocclusion), an overjet $\geq$6 mm (pronounced horizontal overlap of incisors), negative response to the Frankel maneuver (indicating a

true mandibular deficiency, i.e., the class II malocclusion could not be posture-corrected by guiding the mandible forward), and cervical vertebral maturation stage (CVMS) II or III (i.e., prepubertal or early pubertal growth, indicating the patient was at or before the peak growth spurt).

Patients were excluded if they had any of the following: congenital craniofacial anomalies or endocrine disorders affecting growth (which could influence treatment outcomes), skeletal discrepancies in other planes, severe facial asymmetries, or a vertical growth pattern with an extremely high mandibular plane angle (Sella–Nasion to mandibular plane angle > 38°).

2.2. Appliance

The Sander BJA [35] consists of two removable acrylic plates connected by interlocking bite-jumping mechanisms. The appliance advances the mandible into a therapeutic position during functioning. The patients were instructed to wear the appliance for at least 14 h per day, including nighttime. When maxillary transverse deficiency was diagnosed, the expansion screw was activated by 0.25 mm per week until the transverse discrepancy had been corrected.

2.3. Acquisition Process

Three-dimensional facial images were acquired using a 3dMD stereophotogrammetric system (3dMD LLC, Atlanta, GA, USA), characterised by an acquisition accuracy of approximately 0.2 mm and an image capture time of 1.5 ms.

All recordings were performed in a dedicated room without any ambient illumination, either natural or artificial, with the scanner maintained in a fixed position. The system configuration comprised three stereo camera pairs, two texture cameras, and four geometric cameras equipped with slightly convergent lenses, in addition to two projectors and three LED panels placed bilaterally. The scanner was calibrated before each acquisition session according to the manufacturer's recommendations. The participants were positioned in a natural head position, looking straight ahead with the teeth in maximum intercuspation and the lips relaxed. Each participant was positioned at a standardised distance of 90 cm from the scanner, and a video sequence was captured using the six-camera system. This procedure was performed at two time points: before the start of BJA treatment (T0) and after its completion (T1), defined by the achievement of a class I molar and canine relationship. During acquisition, the patients were asked to maintain their habitual occlusion. From each video, two 3D images were subsequently extracted and exported as .obj files. These datasets were analysed using 3dMDvultus (3dMD LLC, Atlanta, GA, USA), and all files were securely archived on institutional computers at the University of Naples Federico II.

2.4. 3D Soft Tissue Analysis

The images were registered, superimposed, and analysed using 3dMDVultus Software 2.4 (3dMD LLC, Atlanta, GA, USA). The T0 and T1 facial scans were first manually aligned in the sagittal, coronal, and axial planes. Surface-based registration was subsequently performed using the periorbital and nasal regions, which were selected as relatively stable anatomical reference areas during the observation period. Following image registration, 12 predefined soft tissue landmarks were identified (Figure 1), and 12 angular variables (Table 1) were calculated for quantitative analysis. All landmark identification and angular measurements were performed by a single calibrated examiner who was blinded to the measurement session during the reliability assessment.

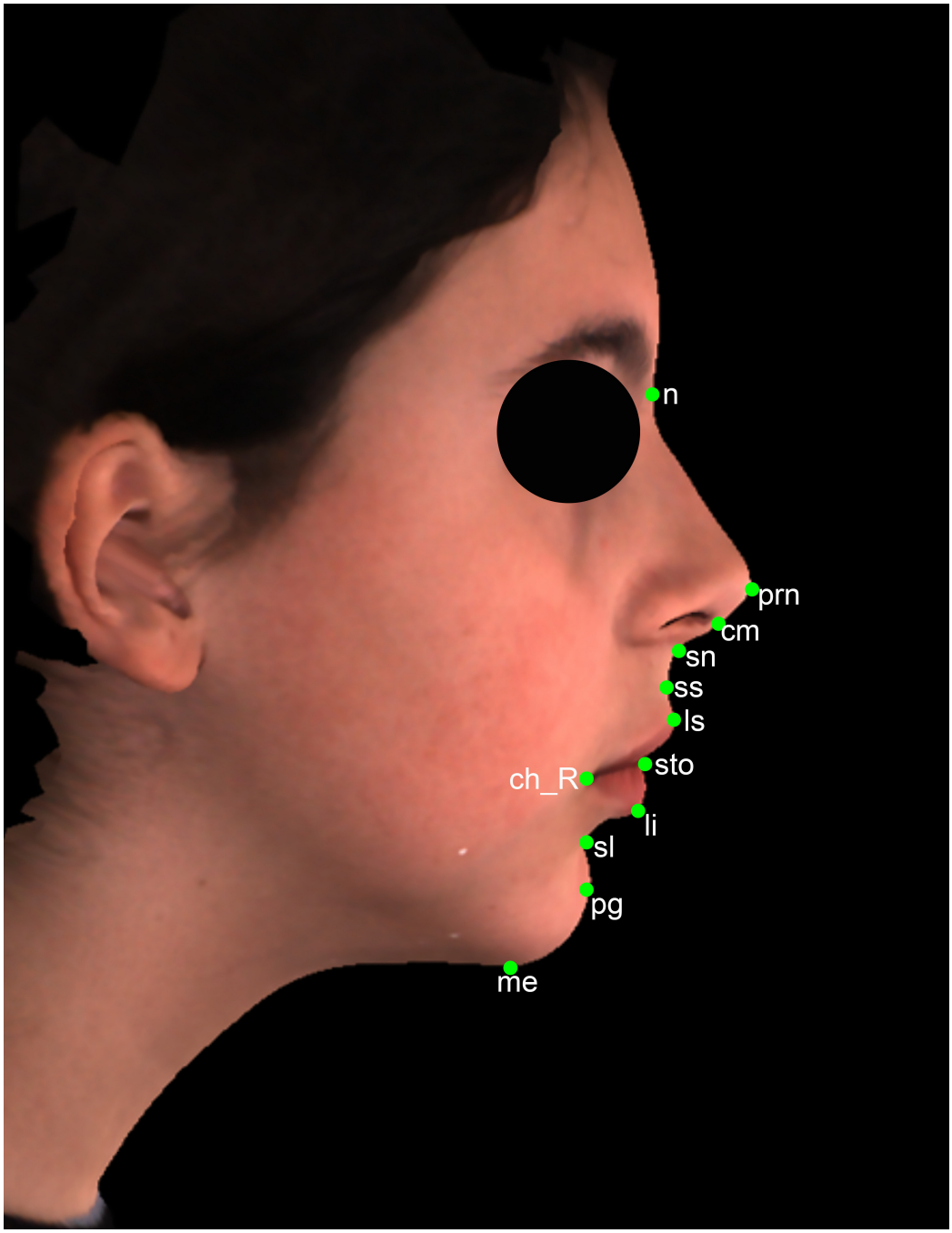


Figure 1. Illustration of the used 3D soft tissue landmarks. The soft tissue nasion (n) is the midpoint on the soft tissue contour of the base of the nasal root at the level of the frontonasal suture. The pronasale (prn) is the most anterior midpoint of the nasal tip. The columella (cm) is the midpoint of the columella crest at the level of the nostril top points. The subnasale (sn) is the midpoint on the nasolabial soft tissue contour between the columella crest and the upper lip. The subspinale (ss) is the most posterior midpoint of the philtrum. The labiale superius (ls) is the midpoint of the vermilion line of the upper lip. The stomion (sto) is the midpoint of the horizontal labial fissure. The chelion (ch_R+L) is the point located at each labial commissure on or at the right (R) and left (L) side of the face. The labiale inferius (li) is the midpoint of the vermilion line of the lower lip. The sublabiale (sl) is the most posterior midpoint on the labiomental soft tissue contour that defines the border between the lower lip and the chin. The pogonion (pg) soft tissue pogonion is the most anterior midpoint of the chin. The soft tissue menton (me) the most inferior midpoint on the soft tissue contour of the chin.

Table 1. List of variables assessed of facial scans.

Name	Description
LS-N-LI	The angle assesses the relation between points ls, n, and li
LS-N-SN	The angle assesses the position of the ls to the maxillary structure (n and sn)
LI-N-SN	The angle assesses the position of the li to the maxillary structure (n and sn)
UPPER LIP POSITION	The angle assesses the relation among the upper lip (ls) with respect to n and pg
LOWER LIP POSITION	The angle assesses the relation among the lower lip (li) with respect to n and pg
SS-N- SL	The angle assesses the relation between points ss, n, and sl
SS-N-SN	The angle assesses the relation between points ss, n, and sn
SL-N-SN	The angle assesses the relation between points sl, n, and sn
SL-N-PG	The angle assesses the relation between points sl, n, and pg
Nasolabial angle	The angle between points cm, sn, and ls
Submental angle	The angle between points li, sl, and pg
Facial convexity	The angle between points n, sn, and pg

2.5. Sample Size

The facial convexity angle (n-sn-pog) was selected as the principal outcome for the sample size calculation. Based on the three-dimensional study by Güler and Malkoç [29], which reported a minimum standardized paired effect size (Cohen's dz) of 0.87 with a fixed functional appliance, a slightly more conservative effect size of dz = 0.80 was assumed for the present study. An a priori power analysis was performed using G*Power (version 3.1; Heinrich Heine University Düsseldorf, Düsseldorf, Germany), considering a two-tailed paired-samples *t*-test, an α level of 0.05, and a statistical power of 80%. The analysis indicated that a minimum sample size of 15 subjects was required. To compensate for potential dropouts, the sample size was increased by approximately 10%, resulting in the inclusion of 17 patients.

2.6. Statistical Analysis

Statistical analyses were performed using SPSS Statistics version 22.0 (IBM Corp., Armonk, NY, USA). Normality of the data distribution was assessed using the Shapiro–Wilk test. As all variables showed an approximately normal distribution, differences between the pre-treatment (T0) and post-treatment (T1) measurements were evaluated using paired-samples Student's *t*-tests.

The facial convexity angle represented the principal outcome of the study and was used a priori for the sample size calculation. The remaining angular variables were considered secondary exploratory outcomes. Given the exploratory nature of these secondary analyses, no formal adjustment for multiple comparisons was applied; therefore, their *p* values should be interpreted accordingly.

The results are reported as the mean ± standard deviation (SD). The mean paired differences (T1 − T0) are presented together with their 95% confidence intervals (CIs). Cohen's dz, calculated as the mean paired difference divided by the standard deviation of the paired differences, was used to quantify the standardized effect size for paired comparisons, and it is reported with its 95% CI. Statistical significance was set at $p < 0.05$.

2.7. Intra-Observer Reliability

Intra-observer reliability was assessed by comparing duplicate measurements on eight 3D images performed by a single investigator, with at least a two-week interval between

the first and second evaluations. Differences between measurements were analysed using a paired *t*-test. The error of the method was calculated using Dahlberg's formula.

3. Results

The method error ranged from 0.28° for SLNPG to 2.8° for the nasolabial angle, while that for facial convexity was 0.65°. No statistically significant systematic error was detected for any variable (Student's *t*-test; $p > 0.05$), supporting the overall reliability of the measurement protocol. Nevertheless, the magnitude of the measurement error was considered when interpreting variables showing relatively small changes.

The statistical analysis of the class II group at T0 and T1 is shown in Table 2.

Table 2. Data are presented as mean ± standard deviation (SD). Mean changes were calculated as T1−T0 and are reported with their 95% confidence intervals (CI). T0 and T1 measurements were compared using paired-samples Student's *t*-tests. Cohen's dz represents the standardized mean paired difference and is reported with its 95% CI. Statistical significance was set at $p < 0.05$. † Facial convexity angle was the principal outcome used for the a priori sample size calculation. Secondary outcomes were considered exploratory and were not adjusted for multiple comparisons.

Variable	T0 Mean ± SD (°)	T1 Mean ± SD (°)	Mean Change T1−T0 (°)	95% CI	*p* Value	Cohen's dz	95% CI of dz
LS-N-LI	5.61 ± 1.34	4.92 ± 1.69	−0.69	−1.35 to −0.03	0.042	−0.54	−1.04 to −0.02
LS-N-SN	2.33 ± 1.53	2.42 ± 1.53	+0.08	−0.80 to 0.97	0.845	+0.05	−0.43 to 0.52
LI-N-SN	7.72 ± 1.88	7.19 ± 1.80	−0.53	−1.82 to 0.76	0.395	−0.21	−0.69 to 0.27
SS-N-SL	10.48 ± 1.81	9.19 ± 1.96	−1.29	−2.02 to −0.55	0.002	−0.89	−1.45 to −0.32
SS-N-SN	2.76 ± 1.41	2.94 ± 1.47	+0.18	−0.64 to 0.99	0.650	+0.11	−0.37 to 0.59
SL-N-SN	13.18 ± 2.00	12.06 ± 2.08	−1.12	−2.32 to 0.08	0.065	−0.48	−0.98 to 0.03
SL-N-Pg	1.16 ± 0.76	1.14 ± 0.66	−0.02	−0.43 to 0.40	0.937	−0.02	−0.50 to 0.46
Nasolabial angle	121.73 ± 6.12	121.68 ± 4.80	−0.05	−2.08 to 1.97	0.957	−0.01	−0.49 to 0.46
Submental angle	120.39 ± 12.06	134.25 ± 13.81	+13.86	7.39 to 20.33	<0.001	+1.10	+0.48 to +1.70
Facial convexity †	155.49 ± 4.12	157.21 ± 3.84	+1.72	0.06 to 3.39	0.044	+0.53	+0.02 to +1.03
Upper lip position	10.39 ± 2.04	9.30 ± 2.55	−1.09	−1.82 to −0.36	0.006	−0.77	−1.30 to −0.22
Lower lip position	4.82 ± 1.38	4.41 ± 1.73	−0.41	−0.97 to 0.15	0.138	−0.38	−0.87 to +0.12

The facial convexity angle, which represented the principal outcome of the study, increased by 1.72° from T0 to T1 (95% CI: 0.06 to 3.39; $p = 0.044$), corresponding to a moderate standardised effect size (Cohen's dz = 0.53; 95% CI: 0.02 to 1.03). An increase in this angle indicates a reduction in profile convexity and, consequently, a straighter facial profile.

Among the secondary outcomes, statistically significant changes were observed for the LS-N-LI angle (mean change: −0.69°; 95% CI: from −1.35 to −0.03; $p = 0.042$; Cohen's dz = −0.54), SS-N-SL angle (−1.29°; 95% CI: from −2.02 to −0.55; $p = 0.002$; Cohen's dz = −0.89), upper lip position (−1.09°; 95% CI: from −1.82 to −0.36; $p = 0.006$; Cohen's dz = −0.77), and submental angle (+13.86°; 95% CI: 7.39–20.33; $p < 0.001$; Cohen's dz = 1.10). These findings were associated with moderate-to-large standardised effect sizes. As these variables represented secondary exploratory outcomes, their *p* values were not adjusted for multiple comparisons and should be interpreted accordingly.

No statistically significant changes were observed for the LS-N-SN, LI-N-SN, SS-N-SN, SL-N-SN, SL-N-Pg, nasolabial angle, or lower lip position (all $p > 0.05$), suggesting that treatment had little influence on the upper facial soft tissues.

4. Discussion

The present prospective longitudinal study evaluated three-dimensional facial soft tissue changes associated with treatment using the Sander BJA in growing patients with skeletal class II malocclusion. The principal finding was a small increase in the facial convexity angle, corresponding to a reduction in profile convexity. Changes were also observed in several secondary variables describing the lower facial region, whereas the

upper facial region remained substantially unchanged. However, given the absence of an untreated control group, the observed modifications cannot be attributed exclusively to treatment and should be interpreted within the context of physiological craniofacial growth. Nevertheless, the direction and distribution of the observed changes are consistent with previously reported soft tissue adaptations following functional treatment [10].

The facial convexity angle, which represented the principal outcome used for the sample size calculation, increased by 1.72° (95% CI: 0.06–3.39; $p = 0.044$). Because an increase in this angle corresponds geometrically to a less convex profile, this finding suggests a tendency toward profile straightening during the observation period. The standardised effect size was moderate (Cohen's dz = 0.53), although its relatively wide 95% CI (0.02–1.03) indicates considerable uncertainty regarding the magnitude of the effect. Therefore, although the change was statistically significant, its clinical and aesthetic relevance cannot be established from the present data alone. Among the secondary outcomes, the largest standardised changes were observed for the submental angle (dz = 1.10), SS-N-SL (dz = −0.89), and upper lip position (dz = −0.77). A moderate change was observed for the LS-N-LI (dz = −0.54). These findings suggest that the most evident soft tissue modifications occurred in the lower facial region. Nevertheless, these variables were secondary exploratory outcomes, and no multiplicity adjustment was applied; consequently, individual p values should be interpreted cautiously, and the pattern of the findings may be more informative than isolated statistically significant comparisons.

The absence of an untreated control group is particularly relevant when interpreting these results, as physiological craniofacial development may contribute to changes in facial profile during adolescence. Longitudinal studies on untreated class II subjects indicate that the class II skeletal pattern generally does not undergo spontaneous correction during growth [36,37]. Bishara et al. (1997) reported persistence of greater skeletal and soft tissue convexity in untreated class II division 1 subjects compared with subjects with normal occlusion, despite some catch-up in mandibular growth [36]. Similarly, Stahl et al. (2008), following untreated class II division 1 subjects from prepubertal to postpubertal stages, found that the class II dentoskeletal discrepancy did not tend to self-correct, and that mandibular length increments during the pubertal growth spurt were smaller than those observed in the class I subjects [37]. Nevertheless, physiological growth of the facial soft tissues should also be considered. Three-dimensional investigations of healthy children and adolescents have demonstrated significant age- and sex-related changes in facial soft tissue morphology during growth [38,39]. Therefore, although the persistence of the untreated class II pattern suggests that the observed profile changes may not simply represent spontaneous correction of the malocclusion, some contribution from normal craniofacial and soft tissue growth cannot be excluded. To our knowledge, longitudinal three-dimensional normative data for untreated adolescents with class II malocclusion using the same stereophotogrammetric variables are not available. Consequently, the observed 1.72° increase in facial convexity angle cannot be attributed exclusively to treatment and should be interpreted as a treatment-associated change occurring during active craniofacial growth. The findings of this study are consistent with recent three-dimensional investigations reporting improvements in chin projection and facial profile following functional treatment. Güler and Malkoç, Yıldırım et al., and the recent systematic review by Luyten et al. similarly described favourable modifications of the lower facial soft tissues after functional appliance therapy [29–31].

Comparable findings have also been reported in conventional cephalometric studies evaluating the Sander BJA and other removable functional appliances. Although the measurement techniques differ substantially, both two-dimensional and three-dimensional investigations consistently suggest that the most evident soft tissue changes occur in the

lower facial region. Tepedino et al. reported a significant improvement in facial convexity after treatment with the Sander BJA [16]. Similarly, Idris et al. observed a greater increase in the facial convexity angle following Activator treatment [17].

Regarding the upper facial region, previous three-dimensional studies reported no significant changes in the nasolabial angle [29–31], contrary to Varlik's study, in which Twin Block treatment increased the nasolabial angle (increases of 6.23 ± 3.10°, $p < 0.05$) [13]. No significant modifications were observed for variables describing the upper facial region, suggesting that the treatment had limited influence on the maxillary soft tissues [10].

Moreover, in our results, there was a reduction in upper lip position. The slight reduction in upper lip prominence is likely multifactorial and may reflect both dentoalveolar adaptations and changes in the spatial relationship between the upper and lower lips following correction of the sagittal discrepancy [11]. Similarly, Gazzani et al. reported a significantly greater reduction in upper lip protrusion in the treated group (−1.2 mm) than in the untreated control group (−0.1 mm) [14]. These studies consistently reported an improvement in perceived facial profile following treatment.

An increase in the submental angle was also observed. This finding may reflect changes in the relationship between the lower lip, chin, and cervical soft tissues following treatment. This change in the submental area is also present with other appliances such as the Herbst Miniscope appliance, in which a statistically significant greater increase in sulcus protrusion ($p = 0.002$) and a greater lower lip protrusion ($p = 0.029$) than the controls was found, probably due also to the proclination of the lower incisors [15].

The efficacy of functional treatment on soft tissue was also evaluated in studies that analysed patients' profiles after fixed or removable functional appliances using profile silhouettes, not providing for a quantitative evaluation of changes and only assessing the perception of these changes by a group of different examiners [40–42]. In all the studies, an improvement in the profiles due to the treatments was found.

The speed acquisition and the safety of stereophotogrammetry allow analysing children during growth without any radiation exposure [43]. In fact, performing radiographies to longitudinally assess growth in children raises serious ethical issues for multiple radiation exposure, and today, it is almost impossible to carry out a similar study [44]. Moreover, simple lateral cephalograms are not sufficient if we are interested in three-dimensional change evaluation. Alternative approaches to three-dimensionally assessing changes due to orthodontic treatment of the soft tissues are CT-CBCT or anthropometry. CT-CBCT cannot be used longitudinally in children for ethical reasons and can suffer of some artefacts during soft tissue acquisition [44]. Anthropometry is time-consuming and requires subject compliance, which is not always possible in children. On the other hand, facial scanning, even if it cannot allow a direct measure of hard tissue changes, provides information on the soft tissue without exposing the patient to additional risks [43].

Due to these considerations, the advantages of this system are the ease in the use, the absence of risks for the patient (in terms of ionizing radiation), and the chance to follow longitudinally a subject or patient without any health problems. Hence, this innovative approach to stereophotogrammetry looks promising for investigating modifications in soft tissue without any exposure to radiation and with extremely short acquisition times [43].

The present study has several limitations that should be considered when interpreting the findings. First, the absence of an untreated control group prevents complete separation of treatment-related changes from physiological craniofacial growth. However, recruiting untreated growing patients with skeletal class II malocclusion for a prospective longitudinal study raises important ethical concerns, particularly when treatment is clinically indicated. Therefore, treatment-associated changes were assessed through within-subject comparison of pretreatment and post-treatment facial scans. Nonetheless, the absence of an untreated

control group prevents separation of treatment-associated changes from physiological craniofacial growth. Although longitudinal class II studies suggest that the underlying malocclusion does not generally self-correct during adolescence, directly comparable three-dimensional normative data are currently lacking. Future studies could consider a control group or use regional superimposition on stable structures (like the midface) to distinguish growth from treatment effects; our superimposition on the upper face attempted this to an extent. Second, the relatively small sample size and the predominance of male participants limit the generalisability of the findings. Although the sample size satisfied the predefined power calculation, and all patients were treated during comparable stages of skeletal maturation, we can speculate that the present findings predominantly reflect the response of male growing patients, and future multicenter studies with larger and more balanced samples are required to confirm the present observations. Third, only immediate post-treatment outcomes were evaluated. Long-term follow-up is necessary to determine the stability of the observed soft tissue changes after the completion of craniofacial growth. Finally, the present investigation evaluated only soft tissue changes. Integration of stereophotogrammetry with skeletal imaging techniques could provide a more comprehensive understanding of the relationship between skeletal adaptation and facial soft tissue response following functional treatment.

5. Conclusions

Within the limitations of this prospective longitudinal study, treatment with the Sander BJA was associated with measurable three-dimensional changes in facial soft tissues in growing patients with skeletal class II malocclusion. The facial convexity angle, which represented the principal outcome, showed a small statistically significant increase corresponding to a reduction in profile convexity, with a moderate standardised effect size. Secondary analyses suggested that additional changes predominantly involved the lower facial region, whereas the upper facial soft tissues remained substantially unchanged.

Because the study did not include an untreated control group, these changes cannot be attributed exclusively to functional treatment. Three-dimensional stereophotogrammetry represents a useful noninvasive approach for longitudinal assessment of facial soft tissues; however, larger controlled studies are required to distinguish treatment-related effects from physiological growth and to determine the clinical relevance and long-term stability of the observed changes.

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References

1. Lombardo, G.; Vena, F.; Negri, P.; Pagano, S.; Barilotti, C.; Paglia, L.; Colombo, S.; Orso, M.; Cianetti, S. Worldwide prevalence of malocclusion in the different stages of dentition: A systematic review and meta-analysis. *Eur. J. Paediatr. Dent.* **2020**, *21*, 115–122. [CrossRef] [PubMed]
2. Kalinowska, J.; Suligowska, K.; Racka-Pilszak, B.; Kusiak, A.; Kisała, M. Prevalence of malocclusion and assessment of orthodontic treatment needs in an urban population in Poland: The SOPKARD-Junior program. *Dent. Med. Probl.* **2025**, *62*, 1017–1025. [CrossRef] [PubMed]
3. Rongo, R.; Bucci, R.; Adaimo, R.; Amato, M.; Martina, S.; Valletta, R.; D'Antò, V. Two-dimensional versus three-dimensional Fränkel Manoeuvre: A reproducibility study. *Eur. J. Orthod.* **2020**, *42*, 157–162. [CrossRef] [PubMed]
4. McNamara, J.A. Components of class II malocclusion in children 8–10 years of age. *Angle Orthod.* **1981**, *51*, 177–202. [CrossRef] [PubMed]
5. do Rego, M.V.N.N.; Thiesen, G.; Marchioro, E.M.; da Silva Filho, O.G.; Rizzatto, S.M.D. Cephalometric study of the early treatment of Class II division 1 malocclusion with the Herbst appliance: Sagittal skeletal alterations. *Rev. Dent. Press Ortod. E Ortop. Facial* **2005**, *10*, 120–140.
6. Pace, M.; Cioffi, I.; D'Antò, V.; Valletta, A.; Valletta, R.; Amato, M. Facial attractiveness of skeletal class I and class II malocclusion as perceived by laypeople, patients and clinicians. *Minerva Stomatol.* **2018**, *67*, 77–85. [CrossRef] [PubMed]
7. Asgharlou, M.A.; Esfehani, M.; Tofangchiha, M.; Javadi, A.; Sheikhdavoodi, N.; Yousefi, Z.; Reda, R.; Testarelli, L. Comparison of facial soft tissue thickness in subjects with different malocclusions according to the lateral cephalograms of an Iranian adult population. *Dent. Med. Probl.* **2025**, *62*, 255–263. [CrossRef] [PubMed]
8. de Almeida-Pedrin, R.R.; Henriques, J.F.C.; de Almeida, R.R.; de Almeida, M.R.; McNamara, J.A. Effects of the pendulum appliance, cervical headgear, and 2 premolar extractions followed by fixed appliances in patients with Class II malocclusion. *Am. J. Orthod. Dentofac. Orthop.* **2009**, *136*, 833–842. [CrossRef] [PubMed]
9. Mejia-Maidl, M.; Evans, C.A.; Viana, G.; Anderson, N.K.; Giddon, D.B. Preferences for facial profiles between Mexican Americans and Caucasians. *Angle Orthod.* **2005**, *75*, 953–958. [CrossRef]
10. D'Antò, V.; Bucci, R.; Franchi, L.; Rongo, R.; Michelotti, A.; Martina, R. Class II functional orthopaedic treatment: A systematic review of systematic reviews. *J. Oral Rehabil.* **2015**, *42*, 624–642. [CrossRef] [PubMed]
11. Zymperdikas, V.F.; Koretsi, V.; Papageorgiou, S.N.; Papadopoulos, M.A. Treatment effects of fixed functional appliances in patients with Class II malocclusion: A systematic review and meta-analysis. *Eur. J. Orthod.* **2016**, *38*, 113–126. [CrossRef] [PubMed]
12. Almrayati, D.M.; Hajeer, M.Y.; Almusawi, A.O.A.; Jaber, S.T.; Baba, M.O.; Ajaj, M.A. Evaluation of the External Soft Tissue Changes Following the Correction of Class II Skeletal Malocclusion in the Adolescence Period Using Removable and Fixed Functional Appliances: A Systematic Review and Meta-Analysis. *Cureus* **2024**, *16*, e57070. [CrossRef] [PubMed]
13. Varlik, S.K.; Gültan, A.; Tümer, N. Comparison of the effects of Twin Block and activator treatment on the soft tissue profile. *Eur. J. Orthod.* **2008**, *30*, 128–134. [CrossRef] [PubMed]
14. Gazzani, F.; Franchi, L.; Lione, R.; Cozza, P.; Pavoni, C. Soft tissue evaluation of functional therapy in growing patients with Class II malocclusion: A long-term study. *Eur. J. Orthod.* **2022**, *44*, 37–42. [CrossRef] [PubMed]
15. Martina, S.; Di Stefano, M.L.; Paduano, F.P.; Aiello, D.; Valletta, R.; Paduano, S. Evaluation of profile changes in class II individuals treated by means of herbst miniscope appliance. *Dent. J.* **2020**, *8*, 27. [CrossRef] [PubMed]
16. Tepedino, M.; Dellanoce, M.V.; Ciavarella, D.; Gallenzi, P.; Cordaro, M.; Chimenti, C. Soft-tissue changes after Class II malocclusion treatment using the Sander bite-jumping appliance: A retrospective study. *Minerva Stomatol.* **2019**, *68*, 118–125. [CrossRef] [PubMed]
17. Idris, G.; Hajeer, M.Y.; Al-Jundi, A. Soft- and hard-tissue changes following treatment of Class II division 1 malocclusion with Activator versus Trainer: A randomized controlled trial. *Eur. J. Orthod.* **2019**, *41*, 21–28. [CrossRef] [PubMed]
18. Stamenković, Z.; Raičković, V.; Ristić, V. Changes in soft tissue profile using functional appliances in the treatment of skeletal class II malocclusion. *Srp. Arh. Celok. Lek.* **2015**, *143*, 12–15. [CrossRef] [PubMed]
19. Lisson, J.A.; Mokrys, K.; Kinzinger, G.S.M.; Glasl, B.; Ludwig, B. Changes in soft-tissue profiles after treatment of class II/1 patients with bite-jumping appliances. *J. Orofac. Orthop.* **2013**, *74*, 113–123. [CrossRef] [PubMed]
20. Quintão, C.; Brunharo, I.H.V.P.; Menezes, R.C.; Almeida, M.A.O. Soft tissue facial profile changes following functional appliance therapy. *Eur. J. Orthod.* **2006**, *28*, 35–41. [CrossRef] [PubMed]
21. Flores-Mir, C.; Major, M.P.; Major, P.W. Soft tissue changes with fixed functional appliances in class II division 1: A systematic review. *Angle Orthod.* **2006**, *76*, 712–720. [CrossRef]
22. Flores-Mir, C.; Major, P.W. A systematic review of cephalometric facial soft tissue changes with the Activator and Bionator appliances in Class II division 1 subjects. *Eur. J. Orthod.* **2006**, *28*, 586–593. [CrossRef] [PubMed]

23. Kau, C.H.; Richmond, S.; Incrapera, A.; English, J.; Xia, J.J. Three-dimensional surface acquisition systems for the study of facial morphology and their application to maxillofacial surgery. *Int. J. Med. Robot. Comput Assist Surg.* **2007**, *3*, 97–110. [CrossRef] [PubMed]
24. Baik, H.S.; Kim, S.Y. Facial soft-tissue changes in skeletal Class III orthognathic surgery patients analyzed with 3-dimensional laser scanning. *Am. J. Orthod. Dentofac. Orthop.* **2010**, *138*, 167–178. [CrossRef] [PubMed]
25. Aynechi, N.; Larson, B.E.; Leon-Salazar, V.; Beiraghi, S. Accuracy and precision of a 3D anthropometric facial analysis with and without landmark labeling before image acquisition. *Angle Orthod.* **2011**, *81*, 245–252. [CrossRef] [PubMed]
26. Plooij, J.M.; Swennen, G.R.J.; Rangel, F.A.; Maal, T.J.J.; Schutyser, F.A.C.; Bronkhorst, E.M.; Kuijpers-Jagtman, A.M.; Bergé, S.J. Evaluation of reproducibility and reliability of 3D soft tissue analysis using 3D stereophotogrammetry. *Int. J. Oral Maxillofac. Surg.* **2009**, *38*, 267–273. [CrossRef] [PubMed]
27. De Menezes, M.; Rosati, R.; Ferrario, V.F.; Sforza, C. Accuracy and reproducibility of a 3-dimensional stereophotogrammetric imaging system. *J. Oral Maxillofac. Surg.* **2010**, *68*, 2129–2135. [CrossRef] [PubMed]
28. Lübbers, H.T.; Medinger, L.; Kruse, A.; Grätz, K.W.; Matthews, F. Precision and accuracy of the 3dmd photogrammetric system in craniomaxillofacial application. *J. Craniofac. Surg.* **2010**, *21*, 763–767. [CrossRef] [PubMed]
29. Güler, Ö.Ç.; Malkoç, S. Comparison of facial soft tissue changes after treatment with 3 different functional appliances. *Am. J. Orthod. Dentofac. Orthop.* **2020**, *158*, 518–526. [CrossRef] [PubMed]
30. Yildirim, E.; Karaçay, Ş.; Tekin, D. Three-Dimensional Evaluation of Soft Tissue Changes after Functional Therapy. *Scanning* **2021**, *2021*, 9928101. [CrossRef] [PubMed]
31. Luyten, J.; Vierendeel, M.; De Roo, N.M.C.; Temmerman, L.; De Pauw, G.A.M. A non-cephalometric three-dimensional appraisal of soft tissue changes by functional appliances in orthodontics: A systematic review and meta-analysis. *Eur. J. Orthod.* **2022**, *44*, 458–467. [CrossRef] [PubMed]
32. Martina, R.; Cioffi, I.; Galeotti, A.; Tagliaferri, R.; Cimino, R.; Michelotti, A.; Valletta, R.; Farella, M.; Paduano, S. Efficacy of the Sander bite-jumping appliance in growing patients with mandibular retrusion: A randomized controlled trial. *Orthod. Craniofacial Res.* **2013**, *16*, 116–126. [CrossRef] [PubMed]
33. Rongo, R.; Martina, S.; Bucci, R.; Festa, P.; Galeotti, A.; Alessandri Bonetti, G.; Michelotti, A.; D'Antò, V. Short-term effects of the Sander bite-jumping appliance on the pharyngeal airways in subjects with skeletal Class II malocclusion: A retrospective case-control study. *J. Oral Rehabil.* **2020**, *47*, 1337–1345. [CrossRef] [PubMed]
34. D'Antò, V.; Oliva, G.; Rongo, R.; Bucci, R.; Martina, S.; Franchi, L.; Valletta, R. Morphologic predictors of mandibular changes induced by Sander's Bite Jumping Appliance. *Orthod. Craniofac. Res.* **2025**, *28*, 67–74. [CrossRef] [PubMed]
35. Sander, F.G.; Weinreich, A. The bite-jumping-appliance. *Dtsch. Stomatol.* **1991**, *41*, 195–198. [PubMed]
36. Bishara, S.E.; Jakobsen, J.R.; Vorhies, B.; Bayati, P. Changes in dentofacial structures in untreated Class II division 1 and normal subjects: A longitudinal study. *Angle Orthod.* **1997**, *67*, 55–66. [CrossRef] [PubMed]
37. Stahl, F.; Baccetti, T.; Franchi, L.; McNamara, J.A. Longitudinal growth changes in untreated subjects with Class II Division 1 malocclusion. *Am. J. Orthod. Dentofac. Orthop.* **2008**, *134*, 125–137. [CrossRef] [PubMed]
38. Ferrario, V.F.; Sforza, C.; Poggio, C.E.; Schmitz, J.H. Craniofacial growth: A three-dimensional soft-tissue study from 6 years to adulthood. *J. Craniofac. Genet. Dev. Biol.* **1998**, *18*, 138–149. [PubMed]
39. Ferrario, V.F.; Sforza, C.; Serrao, G.; Colombo, A.; Ciusa, V. Soft tissue facial growth and development as assessed by the three-dimensional computerized mesh diagram analysis. *Am. J. Orthod. Dentofac. Orthop.* **1999**, *116*, 215–228. [CrossRef] [PubMed]
40. Sloss, E.A.C.; Southard, K.A.; Qian, F.; Stock, S.E.; Mann, K.R.; Meyer, D.L.; Southard, T.E. Comparison of soft-tissue profiles after treatment with headgear or Herbst appliance. *Am. J. Orthod. Dentofac. Orthop.* **2008**, *133*, 509–514. [CrossRef] [PubMed]
41. Molina de Paula, E.C.; de Castro Ferreira Conti, A.C.; Siqueira, D.F.; Valarelli, D.P.; de Almeida-Pedrin, R.R. Esthetic perceptions of facial silhouettes after treatment with a mandibular protraction appliance. *Am. J. Orthod. Dentofac. Orthop.* **2017**, *151*, 311–316. [CrossRef] [PubMed]
42. Paduano, S.; Rongo, R.; Bucci, R.; Carvelli, G.; Cioffi, I. Impact of functional orthodontic treatment on facial attractiveness of children with Class II division 1 malocclusion. *Eur. J. Orthod.* **2020**, *42*, 144–150. [CrossRef] [PubMed]
43. Hong, C.; Choi, K.; Kachroo, Y.; Kwon, T.; Nguyen, A.; McComb, R.; Moon, W. Evaluation of the 3dMDface system as a tool for soft tissue analysis. *Orthod. Craniofacial Res.* **2017**, *20*, 119–124. [CrossRef] [PubMed]
44. Oenning, A.C.; Jacobs, R.; Pauwels, R.; Stratis, A.; Hedesiu, M.; Salmon, B. Cone-beam CT in paediatric dentistry: DIMITRA project position statement. *Pediatr. Radiol.* **2018**, *48*, 308–316. [CrossRef] [PubMed]

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