

Article

Validity and Reliability of New Three-Dimensional Reference Systems for Soft Tissue Analysis Using Non-Ionizing Three-Dimensional Imaging

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Featured Application: The use of a new and valid reference system for analysis of facial scans might improve the quality of the assessment of orthodontics and orthognathic outcomes.

Abstract: Background: The aim of this study was to evaluate the accuracy and the repeatability of two reference systems for three-dimensional facial scans (FSs) compared with a reference system based on cone-beam computed tomography (CBCT). Subjects and methods: A total of sixty subjects, thirty growing participants (8–17 years old) and thirty non-growing participants (older than 21 years old), with FSs and full-field-of-view CBCT were included. Two different reference systems on the same FS were constructed. To assess validity, the two reference systems based on FSs were compared with the reference systems built using the CBCT scans. After two weeks, all of the FSs were reassessed to evaluate intra-operator repeatability. Reliability and repeatability were evaluated by means of parametric and non-parametric tests, intra-class correlation, the Dahlberg formula, and Bland–Altman plots ($p < 0.05$). Results: Both reference systems presented good reliability and showed a small difference with respect to the CBCT-based sagittal plane (Sagittal FS1 = $1.90 \pm 0.98^\circ$; Sagittal FS2 = $1.80 \pm 1.13^\circ$; $p = 0.232$). Between them, the two reference systems showed a small difference in the position of the sagittal plane (Sagittal FS1–Sagittal FS2 = $1.39 \pm 1.13^\circ$). Conclusions: Both reference systems assessed in this study showed good intra-operator repeatability and their use may be suggested as reliable reference systems for FSs.

Keywords: facial scan; CBCT; reference system; orthodontics



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1. Introduction

The assessment of soft tissues of the face has a fundamental role in the analysis and description of different patterns of craniofacial growth and growth modification. As such, orthodontists and maxillofacial surgeons have always been interested in facial changes during growth and after treatment [1]. Indeed, the main objectives of orthodontics are the correction of the occlusion as well as the improvement in the smile and facial aesthetics. Similarly, the primary concern of patients is the improvement in facial appearance, which is considered an important factor of well-being and social success [2,3]. Ackerman and co-workers have described a paradigm shift from the hard tissues toward the soft tissues; according to this revised point of view, the crucial aspect for successful treatment is the soft tissue position, which needs a reliable method for the evaluation of the effects that various orthodontic treatments and growth have on the face [4].

One method for the assessment of craniofacial changes is craniofacial anthropometry; however, albeit reliable and inexpensive, it is limited to direct measurements on subjects, it

is time consuming, and it requires the patient's compliance, which is difficult to achieve in children [5]. On the other hand, the most common technique used to evaluate cranio-facial growth and changes after treatment in orthodontics is cephalometry [6]. Although cephalometric analysis is an important diagnostic tool in orthodontics, it has some disadvantages in evaluating facial soft tissues [7]. First, the two-dimensionality creates some limitations in assessing the three-dimensional (3D) morphology and growth changes in the face. Second, the regular exposition to ionizing radiation of patients or healthy subjects for longitudinal studies is ethically questionable [8,9]. Hence, the use of alternative non-invasive and radiation-free techniques seems to be the best way to understand how the face develops and changes with time and/or after treatment [10–12]. Furthermore, it has been hypothesized that almost 50% of the variability in the shape of soft tissues might be an effect of changes in the dental and skeletal tissues underneath [13]. Three-dimensional imaging systems have benefitted from tremendous and rapid improvements over the last 20 years and now allow for detailed diagnoses of facial soft tissue, opening new opportunities in orthodontic and maxillofacial treatment planning. Among these three-dimensional techniques, such as cone-beam computed tomography (CBCT), facial surface laser scanning [14], and 3D stereophotogrammetry [15], the use of stereophotogrammetry is largely spreading in research and clinical fields because of its radiation-free characteristic. Three-dimensional facial scanning seems to be a good alternative to record and analyze facial soft tissues because it is totally free of risks, fast to use, and relatively easy to analyze [15,16]. Stereophotogrammetry involves determining the 3D coordinates of points on an object by taking measurements from two or more photographs combined with a speckle projection that are captured from different positions, possibly taken at the same time. This technique allows the system to work as a stereo pair, generating a 3D composite surface model where the texture is superimposed to the collection of points plotted on an X, Y, and Z coordinate system to create the final 3D image [17–19]. Yet, standardization of analysis and norms are needed. In the literature, longitudinal changes in soft tissues during growth have been analyzed mainly on facial photographs or on lateral cephalograms [20]. Recently, some studies have evaluated 3D facial soft tissue morphology among different populations [1,21] and cross-sectional growth changes [22]. Moreover, 3D changes after surgical [19] and nonsurgical treatments [18,23] were also analyzed. Three-dimensional stereophotogrammetry was extensively tested for its reliability and validity: high precision and accuracy were shown [12,24], and good accuracy was found when facial scans (FSs) were superimposed on CBCTs [25]. However, there is a great diversity in soft tissue analysis and FS analysis has never been compared with the analysis of CBCT. In the analysis of FSs, there is still a lack of a standardized reference system that could allow for better analysis for longitudinal studies. In 2D cephalometry, the cranial base serves as the reference structure for superimposition. However, in 3D soft tissue images, there are no stable structures available for superimpositions to measure growth. One study explored using an alternative reference frame for facial scans, utilizing the mid-pupil point as the origin, specifically applied to infants [26]. This reference system for children proved clinically applicable for soft tissue analysis but was not evaluated with respect to CBCT, stating that the mid-pupil reference point can be easily affected by the position of the pupils at the time of scanning.

Hence, due to the importance of soft tissue variations after orthodontic treatment, the aim of this study is to evaluate the accuracy and repeatability of two reference systems for three-dimensional facial scans (FSs), compared with a reference system based on CBCT scans, that can be useful as reference systems for soft tissue analysis. The hypothesis to be assessed is that these new reference systems are valid and reproducible with respect to a CBCT reference system.

2. Materials and Methods

2.1. Ethical Approval

This protocol was approved by the Ethical Committee of University “Federico II” of Naples (protocol 30116).

2.2. Experimental Design and Procedures

Records of all of the patients of the School of Orthodontics at the University of Naples Federico II and the Section of Orthodontics at Aarhus University were screened to find patients with full-field-of-view CBCT and an FS performed at a maximum of 10 days apart in order to find a total number of 60 subjects, 30 growing subjects (8–17 years old) and 30 non-growing subjects (older than 21 years old).

The FSs were carried out in both centers (Naples and Aarhus) in a standard similar setting, which included similar lighting conditions (no light) and a fixed scanner position, with the same type of scanner (3dMD, Atlanta, GA, USA; Figure 1). The 3dMD system uses structured light and stereophotogrammetry. The system is composed of three pairs of stereo cameras, two texture cameras, and four geometric cameras with the lenses slightly convergent toward the participant's position. The capture time is 1.5 ms at the highest resolution. The usual acquisition protocol requires firstly the calibration of the system. The patient is positioned approximately 110 cm away from the scanner. Patients are seated and instructed to look straight ahead with their head held in a natural head position (NHP), with their teeth together and eyes opened. The system has algorithms that merge the pictures into one 3D model in .obj extension or “.stl” extension, which can be imported into software such as Mimics (Mimics v.19 Materialise Interactive Medical Image Control System, Leuven, Belgium) to place landmarks or perform other evaluations, such as angle and distance measurements.



Figure 1. The 3dMD system.

The CBCT examinations were conducted using the NewTom 5G machine (NewTom 5G, QR, Verona, Italy) with an 18×16 cm field of view. The image acquisition parameters included settings of 110 kV and 3–7 mA, an 18 s scanning time, a 3.6 s exposure time, and with patients in a supine position.

All CBCT scans were reconstructed with an isotropic voxel dimension of 0.3 mm. The raw data obtained from CBCT scanning were exported in DICOM format and imported into a specific software program (MIMICS 19.0, Materialise, Leuven, Belgium). The threshold level was determined for each CBCT data set individually based on a profile line and the corresponding vertical intersecting lines. With the profile line, it was possible to visualize the profile of the gray values or Hounsfield Units (HUs) along a pre-defined line. Based on the minimal and maximal threshold values, a layer of the relevant structures was defined (i.e., skeletal, soft tissues, and airways) and color-coded. This layer was called a “mask”. From the masks, the corresponding 3D surfaces could be generated. In Mimics, a new template for a 3D construction of reference planes was created. Using this template, three landmarks (Nasion N, Basion Ba, and Incisive Foramen IF) were identified for constructing the sagittal, coronal, and axial plane in adults and three landmarks (Nasion

N, Mid-Cribform MCR, and Incisive Foramen IF) were identified for children [27]. All landmarks were identified on the sagittal view of the midsagittal plane to better simulate what was normally performed on lateral cephalograms, and their position was checked on all of the orthogonal planes (Table 1). The first constructed plane was the sagittal plane passing through the three points [27]; next, the transversal plane passing through Na and Ba perpendicular to the sagittal plane was constructed, and finally, the coronal plane passing through Na and perpendicular to the other two planes was constructed.

Table 1. Face scan and CBCT landmark descriptions.

Landmarks	Legend	Description
Face scan Point	Legend	Description
Endocanthion Left	EN_L	Endocanthion (EN) is the soft tissue point located at the inner commissure of each eye fissure.
Endocanthion Right	EN_R	Endocanthion (EN) is the soft tissue point located at the inner commissure of each eye fissure.
Mid-Endocanthion	MEN	The middle point between the two ENs.
Mid-Tragyon	MTR	The middle point between the two TRs.
Nasion	N	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.
Tragyon Left	TR_L	Tragyon (Tr) is the point located at the upper margin of each tragus.
Tragyon Right	TR_R	Tragyon (Tr) is the point located at the upper margin of each tragus.
Menton	M	Soft tissue menton (M) is the most inferior midpoint on the soft tissue contour of the chin located at the level of the 3D cephalometric hard tissue Menton landmark.
CBCT Point	Legend	Description
Sella	S	Sella is the center of the hypophyseal fossa (Sella turcica).
Nasion	N	Nasion is the midpoint of the frontonasal suture.
Basion	Ba	Basion is the most anterior point of the great foramen (foramen magnum).
Cribriiform Left	Cr_L	The deepest point in the cribform plate.
Cribriiform Right	Cr_R	The deepest point in the cribform plate.
Mid-Cribriiform	MCR	The midpoint between the two cribform plates.
Incisive Foramen	IF	The anteroposterior and mediolateral center of the incisive foramen as it exits the maxilla viewed from the sagittal and axial views, respectively.

The FSs were superimposed with a best-fit alignment on the CBCT data using the nasal bridge and forehead areas, which are the areas least affected by gravity and facial expression [28]. After this alignment phase, the CBCT scan was hidden, and 8 landmarks were identified on the FS (Table 2). These landmarks were used for the construction of two different reference systems.

Table 2. The Dahlberg error for the facial scan points.

Dahlberg Error			
	x	y	z
EN_L	0.101748	0.158439	0.170183
EN_R	0.293203	0.104427	0.141493
MEN	0.17231	0.101827	0.303197
MTR	0.196255	0.124968	0.074406
N	0.066723	0.706758	0.295421
TR_L	0.090969	0.107532	0.100185
TR_R	0.089091	0.136929	0.098464
M	0.240336	0.296052	0.283187

In the first one, the reference system followed these steps (FS1):

- (1) Construction of the transverse plane through three points: Tragyon Right (TR_R), Tragyon Left (TR_L), and Mid-Endocanthion (MEN, midpoint between Right and Left Endocanthion).
- (2) Construction of the coronal plane between Tragyon Right (TR_R) and Tragyon Left (TR_L) and perpendicular to the axial plane.
- (3) Construction of the sagittal plane perpendicular to the other two planes and passing through MEN.

In the second one, the reference system followed the following steps (FS2):

- (1) Construction of the transverse plane through three points: Tragyon Right (TR_R), Tragyon Left (TR_L), and Mid-Endocanthion (MEN, midpoint between Right and Left Endocanthion).
- (2) Construction of the sagittal plane perpendicular to the axial plane and passing through MEN and Mid-Tragyon point (MTR, midpoint between TR_R and TR_L).
- (3) Construction of the coronal plane perpendicular to the other two planes and passing through MEN.

The two reference systems of the FSs were built on the same image using the same landmarks. Once the CBCT scan and the FS were aligned and superimposed, the three reference systems were built, one on the CBCT scan and two on the facial scan.

2.3. Validity of the Reference Systems

As the first step of the analysis, the two reference systems based on the FSs were compared with the reference system built using the CBCT scans, considered the gold standard, to assess which of the two systems was more accurate.

Secondly, the two reference systems of the FSs were compared by measuring the differences (in degrees) shown between the two sagittal planes (Sagittal FS1^Sagittal FS2).

2.4. Reliability

The reference systems were constructed by the same operator twice for all of the FSs to assess the intra-operator repeatability for the two analyses. Finally, the repeatability was also assessed by evaluating the coordinates' variation when placing the points.

2.5. Statistical Analysis

Means, standard deviations, and 95% confidence intervals were calculated for all of the variables investigated. The Shapiro–Wilk test was used to evaluate the distribution of the angular parameters assessed. Student's paired sample *t* tests and Wilcoxon tests were used to assess differences between the two reference systems (Sagittal FS1^Sagittal CBCT vs Sagittal FS2^Sagittal CBCT; Coronal FS1^Coronal CBCT vs Coronal FS2^Coronal CBCT). For each coordinate (x-transverse; y-sagittal; z-vertical) of each point identified on the FS, the Dahlberg error was calculated and a Bland–Altman plot with relative related limits of agreement ($LoA = 1.96 \times SD$) was constructed. To assess the reliability of the analysis, intra-class correlation (ICC), Student's paired sample *t* tests, and Wilcoxon tests were used to compare the data (Sagittal FS1^Sagittal CBCT, Sagittal FS2^Sagittal CBCT, Coronal FS1^Coronal CBCT, Coronal FS2^Coronal CBCT, Sagittal FS1^Sagittal FS2) at different time points (T0 vs T1). All of the analyses were performed with commercial software (SPSS version 22.0, SPSS IBM, New York, NY, USA). The Dahlberg values were judged as good if they were smaller than 0.7 mm; ICC above 0.9 was judged as very good [29]. The level of significance was set as $p < 0.05$.

3. Results

Both of the two new FS analyses presented good reliability when compared to the reference system built on CBCT, without any difference between growing or non-growing patients. Both reference systems showed a small difference with respect to the CBCT sagittal plane (Sagittal FS1 = $1.90 \pm 0.98^\circ$; Sagittal FS2 = $1.80 \pm 1.13^\circ$) but did not show any statistically significant difference ($p = 0.232$). Between them, the two reference sys-

tems showed a small difference in the position of the sagittal plane (Sagittal FS1^Sagittal FS2 = $1.39 \pm 1.13^\circ$). Both reference systems showed a stable difference with respect to the CBCT coronal plane (Coronal FS1 = $25.82 \pm 4.97^\circ$; Coronal FS2 = $25.80 \pm 4.91^\circ$; $p = 0.770$; Table 2). Finally, no differences were found for any of the assessed variables between T0 and T1.

All of the landmarks investigated in this study presented good repeatability, with a Dahlberg error ranging between 0.07 mm and 0.71 mm (Table 3). All of the Bland–Altman plots showed good intra-operator repeatability of the points (Figures 1–4 and Table 4). According to the Dahlberg formula, the landmark that showed the best repeatability on the X-axis was the Nasion (N, 0.07 mm), the landmarks that showed the best repeatability on the Y-axis were the Endocanthions (EN_L and EN_R, 0.10 mm), the landmark that showed the best repeatability on the Z-axis was the Nasion (N, 0.07 mm). All of the landmarks showed a Dahlberg value lower than 0.7 mm, except for the N on the Y-axis.

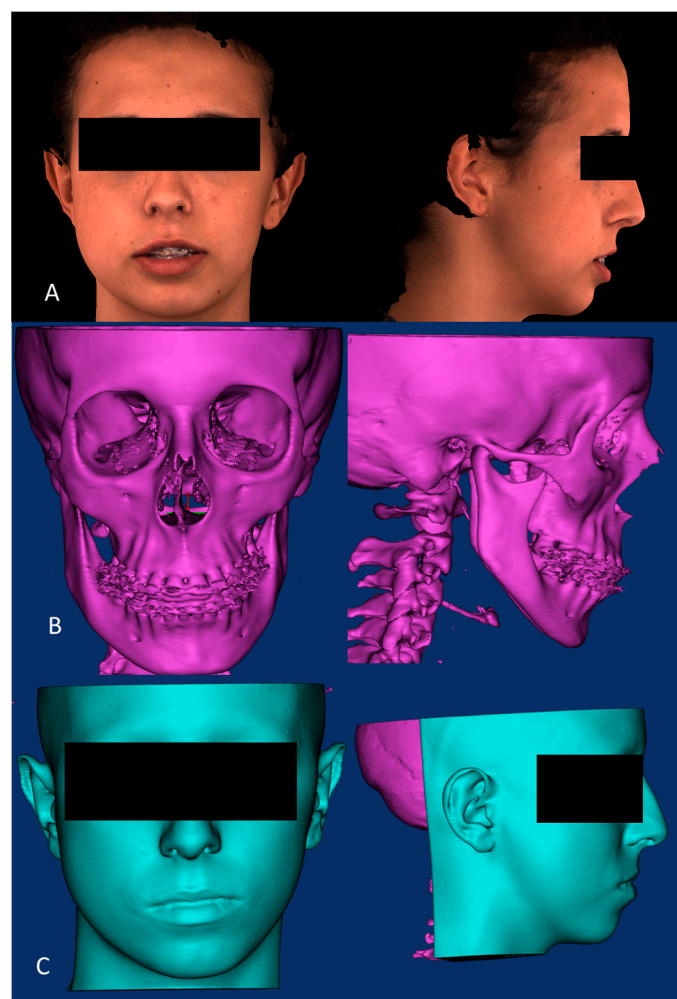


Figure 2. (A) Facial scan acquisition with 3dMD with soft tissue landmarks: Endocanthion Left and Right (EN_L-EN_R), Mid-Endocanthion (MEN), Mid-Tragyon (MTR), Nasion (N), Tragyon Left and Right (TR_L-TR_R), and Menton (M). (B) Three-dimensional reconstruction of a CBCT full-FOV scan; (C) Reconstruction of soft tissue of a CBCT full-FOV scan.

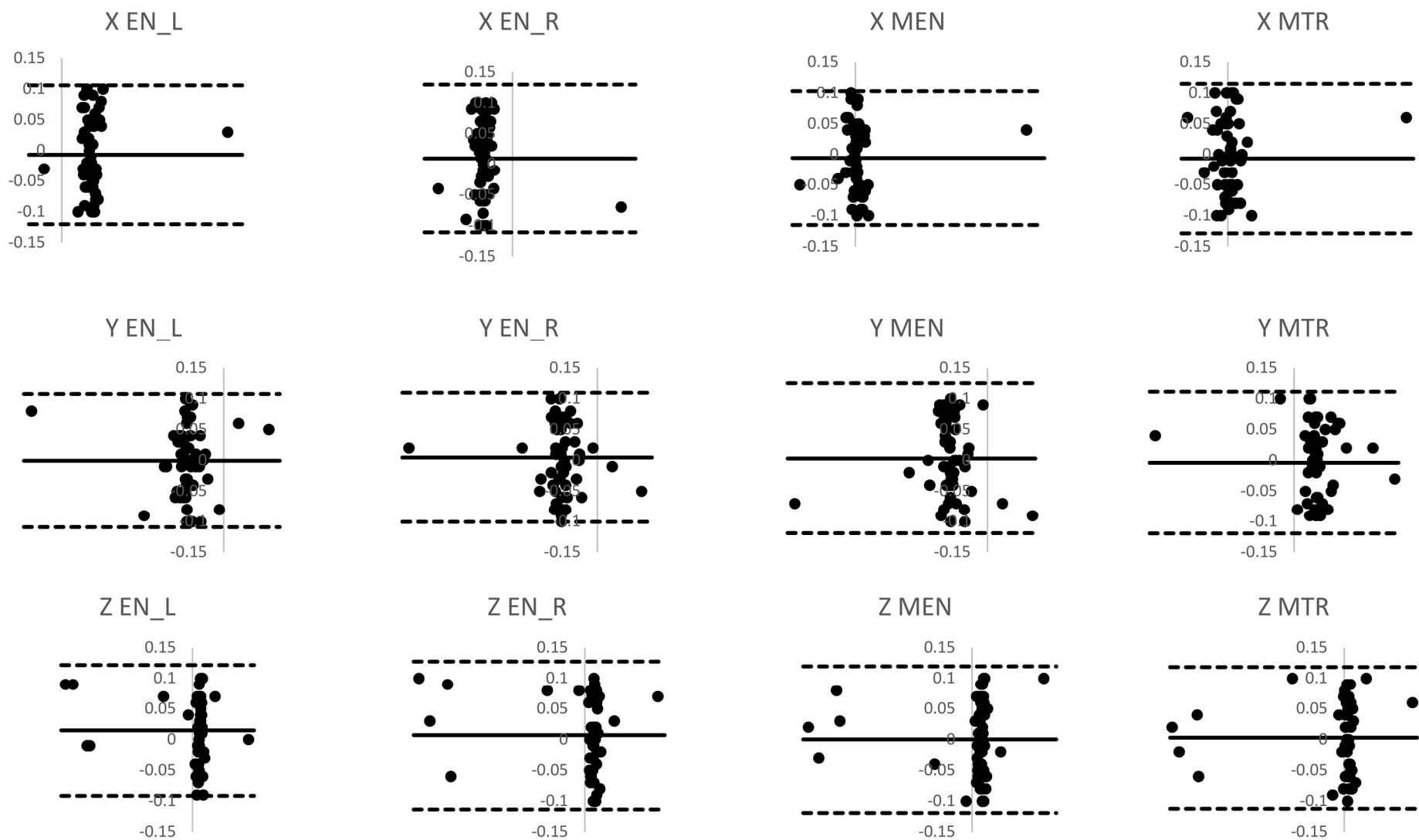


Figure 3. Bland-Altman plots of X, Y, and Z coordinates for EN_L, EN_R, MEN, and MTR.

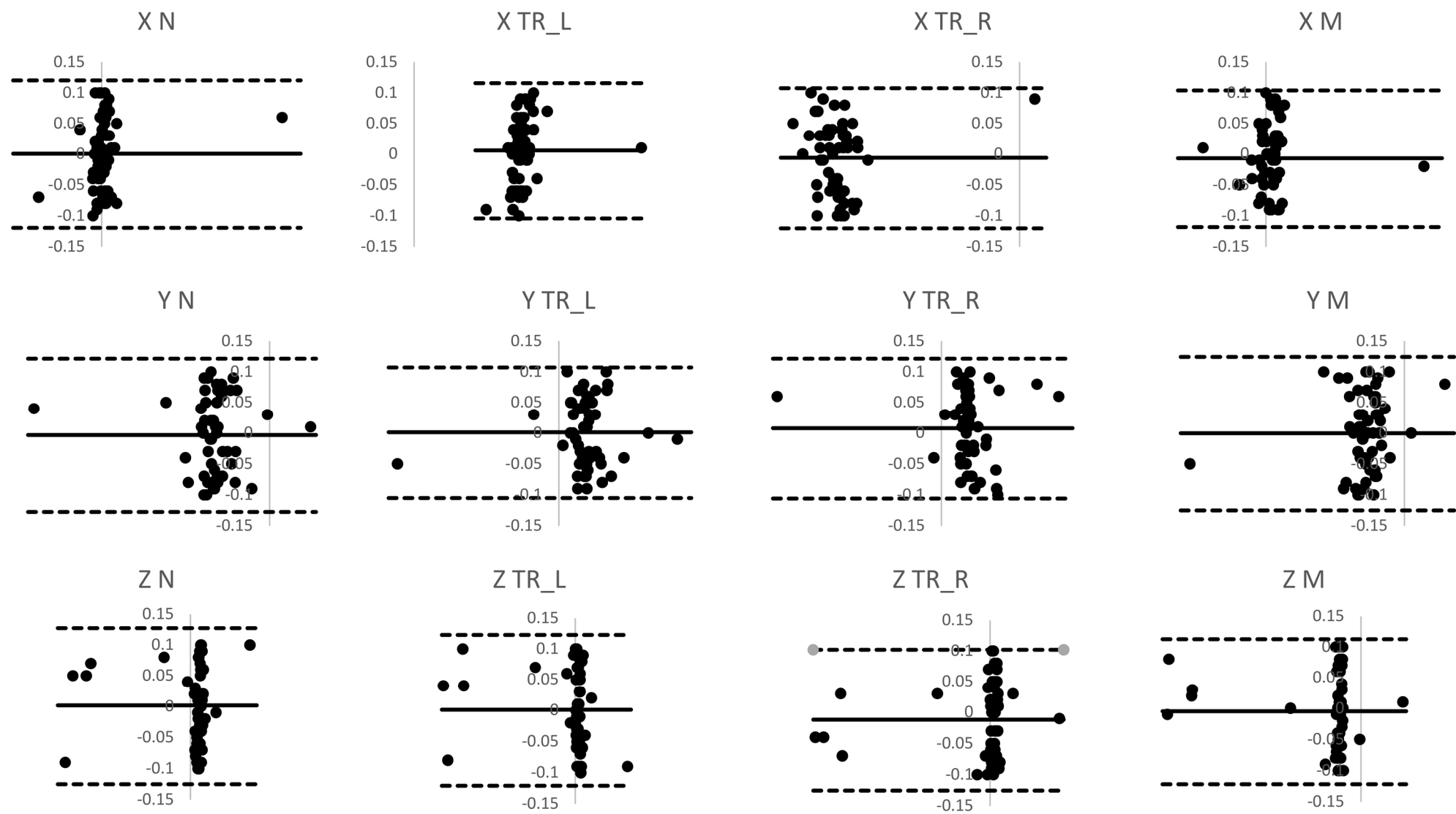


Figure 4. Bland-Altman plots of X, Y, and Z coordinates for N, TR_L, TR_R, and M.

Table 3. Bias and limits of agreement (LoA) for Bland–Altman plots.

	X Axis				Y-Axis				Z-Axis			
	Bias	SD	Lower LoA	Upper LoA	Bias	SD	Lower LoA	Upper LoA	Bias	SD	Lower LoA	Upper LoA
EN_L	−0.02	0.14	−0.31	0.26	−0.03	0.22	−0.47	0.41	−0.04	0.24	−0.51	0.43
EN_R	−0.07	0.41	−0.88	0.75	0.02	0.15	−0.27	0.31	−0.07	0.19	−0.44	0.30
MEN	−0.05	0.24	−0.52	0.42	−0.02	0.14	−0.30	0.27	−0.11	0.42	−0.93	0.71
MTR	0.02	0.28	−0.52	0.57	0.03	0.18	−0.32	0.37	0.02	0.10	−0.18	0.23
N	−0.10	0.37	−0.82	0.62	0.25	0.98	−1.67	2.16	−0.08	1.85	−3.70	3.54
TR_L	0.01	0.13	−0.25	0.26	0.04	0.29	−0.54	0.61	0.00	0.14	−0.28	0.28
TR_R	−0.04	0.12	−0.27	0.20	0.02	0.19	−0.36	0.40	0.03	0.14	−0.24	0.30
M	−0.02	0.34	−0.69	0.65	0.09	0.41	−0.90	0.72	0.07	0.40	−0.71	0.85

Table 4. The two reference systems were compared by means of Wilcoxon tests (*) and paired sample *t* tests (**); intra-operator reliability was assessed by means of Wilcoxon tests (§), paired sample *t* tests (§§), and intra-class correlation (ICC). Abbreviations: 95% CI (LL): lower limit 95% confidence interval; 95% CI (UL): upper limit 95% confidence interval.

	Sagittal FS1*Sagittal CBCT				Sagittal FS2*Sagittal CBCT				<i>p</i> Value *	Sagittal FS1*Sagittal FS2			
	Mean	SD	95% CI (LL)	95% CI (UL)	Mean	SD	95% CI (LL)	95% CI (UL)		Mean	SD	95% CI (LL)	95% CI (UL)
Growing T0°	1.94	0.93	1.57	2.30	1.71	0.79	1.40	2.01	0.232	1.42	1.08	0.99	1.83
Growing T1°	1.92	0.91	1.57	2.28	1.79	0.84	1.46	2.11	0.564	1.47	1.15	1.03	1.92
<i>p</i> Value §	0.407				0.923					0.608			
ICC	0.998				0.923					0.926			
Non-growing T0°	1.87	1.05	1.44	2.30	1.91	1.41	1.33	2.48	0.438	1.37	1.22	0.88	1.87
Non-growing T1°	1.76	1.04	1.34	2.18	1.90	1.04	1.48	2.32	0.684	1.22	1.02	0.81	1.63
<i>p</i> Value §	0.161				0.692					0.936			
ICC	0.997				0.920					0.850			
Total T0°	1.90	0.98	1.63	2.17	1.80	1.13	1.50	2.11	0.753	1.39	1.13	1.08	1.71
Total T1°	1.91	0.97	1.65	2.18	1.78	0.93	1.52	2.03	0.476	1.35	1.08	1.05	1.65
<i>p</i> Value §	0.660				0.724					0.777			
ICC	0.997				0.918					0.888			

	Coronal FS1*Coronal CBCT				Coronal FS2*Coronal CBCT				<i>p</i> value **
	Mean	SD	95% CI (LL)	95% CI (UL)	Mean	SD	95% CI (LL)	95% CI (UL)	
Growing T0°	28.14	4.40	26.44	29.85	28.13	4.40	26.42	29.84	0.372
Growing T1°	28.07	4.39	26.37	29.78	28.05	4.39	26.35	29.76	0.401
<i>p</i> Value §	0.143				0.125				
ICC	0.999				0.999				
Non-growing T0°	23.31	4.33	21.57	25.07	23.29	4.40	21.60	24.98	0.863
Non-growing T1°	23.18	4.33	21.42	24.93	23.18	4.35	21.43	24.94	0.837
<i>p</i> Value §§	0.328				0.177				
ICC	0.993				0.998				
Total T0°	25.82	4.97	24.46	27.18	25.80	4.91	24.46	27.14	0.770
Total T1°	25.71	4.98	24.35	27.07	25.71	4.97	24.35	27.07	0.599
<i>p</i> Value §§	0.137				0.132				
ICC	0.997				0.999				

All of the landmarks used in this analysis showed good intra-operator repeatability.

4. Discussion

Understanding the soft tissue changes achieved with orthopedic/orthodontic treatments is of utmost importance in orthodontics. However, the assessment of these changes based on two-dimensional radiological analysis has limitations. Indeed, there is a need for an analysis method able to overcome the limitations of linear and angular measurements that could allow for reliable registration and superimposition of two (or more) three-dimensional facial scans based on a stable reference system.

In this study, two new reference systems were compared with one created using CBCT scans as the gold standard. Both reference systems were found to be valid and reliable, and without any difference between growing and non-growing subjects. Indeed, the sagittal plane of both FS reference systems, although not coincident, present a deviation of less than 2 degrees with respect to the CBCT-derived sagittal plane. This difference is similar between the two reference systems at both time points, and between non-growing and growing

subjects; hence, the analyses are reliable. In the study of Brons et al., a new reference system for the analysis of infants was introduced [26]. This reference system was found to be clinically applicable for soft tissue analysis in growing individuals, and thus, it could be used to superimpose 3D soft tissue pictures of growing individuals. However, one of the limits of this system was the use of the mid-pupil point, which could easily be affected by pupil position at scanning time. Instead, in our study, by using the Mid-Endocanthion point, which has been shown to be the most stable point during growth in patients assessed by facial scans, it was possible to base the origin of the reference system on a more stable and reliable landmark [30]. Interestingly, although two different methods to construct the sagittal plane in the FS were used, the differences between the two methods were very small and not statistically significant. Both methods started by the same transversal plane (TR_R-TR_L-N) based on two bilateral points (TR_R and TR_L) and on the Nasion (N). When a good scan is performed, and an ear-to-ear image is present, the TR points and the N point present good repeatability, as shown also in this study, and then, the transversal plane is deemed reliable. Furthermore, the Nasion was the most repeatable sagittal landmark in the X-axis, and this also affected the accuracy and the reliability of the sagittal landmark of the FS with respect to the sagittal landmark of the CBCT scan. Indeed, the subsequent construction of the coronal plane first, or the sagittal plane first, did not affect the reliability of the reference system, as highlighted by the fact that the differences found with respect to CBCT used as the gold standard were not statistically significant. The coronal CBCT plane and the two coronal FS planes differed by almost 30° in both growing and non-growing subjects at both time points. On the other hand, this discrepancy was anticipated due to the different inclination of the CBCT and FS axial planes. The most important aspect was the stability of the differences in all of the variables assessed that confirmed good reliability of the reference system. The choice of the following reference system was based on the high reproducibility of the identification of N, EN, and TR and the high stability of MEN during growth [30,31].

Stereophotogrammetry, or in general, three dimensional facial scanning, has been indicated to be as valid as CBCT, with the differences between the two acquisition methods being clinically insignificant for soft tissue analysis [32]; hence, the authors suggested stereophotogrammetry as a non-invasive, accurate, and reliable method for imaging and analyzing facial soft tissue [33]. Furthermore, using 3D imaging for cephalometric analysis could enhance the quality of the diagnosis in the orthodontic field [34]. Several authors have assessed the reliability and reproducibility of 3D landmarks on facial scans [31,35–37], and due to the absence of ionizing radiation associated with this acquisition method, this has been considered ideal for growth studies [11,30,38].

One of the main advantages of stereophotogrammetry is the presence of facial texture on the 3D photo, which helps the clinician in landmark identification, increases the information available to the specialist regarding planned treatment, and makes it easier and more effective to communicate the findings between patients and clinicians [35].

On the other hand, there is still a lack of normative values, as present for 2D cephalometry, for assessing the soft tissues, and this often leaves soft tissue analysis on the side compared to skeletal analysis [39]. Another drawback of this new technology is the mere magnum of software and hardware available; this demotivates some clinicians in approaching new trails preferring the old lateral cephalogram [40]. Even though normative values of 3D facial soft tissue are not available, some proposals have been made [31], but certainly, more studies are needed to improve their reliability. The validity and reproducibility of 3D scans and 3D soft tissue landmarks were widely investigated in several studies. Some of them were more focused on the validity of the method with respect to landmarks obtained from a coordinate measuring machine on facial plaster casts [41], while others were more focused on the intra-operator and inter-operator reproducibility and repeatability of 3D soft tissue points [31,35,37,42].

The validity of 3D soft tissue analysis was investigated by Khambay et al. [41] and Ma et al. [43] using a coordinate measuring machine compared with the 3D positions of land-

marks on the 3D images. The studies found an extremely low system error ($\sim 0.2\text{--}0.93$ mm) and a high accuracy in landmark placing ($\sim 0.07\text{--}0.79$ mm).

Regarding the repeatability of 3D landmarks, few differences were found between 3D stereophotogrammetry and laser scans. Similarly, studies performed on 3D stereophotogrammetry and laser scans found, on average, an intra-operator and inter-operator reproducibility of around 1 mm [31,35,37,42]. The most repeatable landmarks were the ones located on the midline plane [31] and landmarks with well-defined borders or edges [37,42]. Indeed, also in this study, the landmark characterized by the best repeatability was Nasion, a midline point, which displayed the best repeatability along the X-axis, and good repeatability along the Z-axis. In fact, usually, on face scans, it has to be considered that landmarks on the X- and Z-axis are found to have better repeatability than landmarks on the Y-axis [37]. On the other hand, bilateral points without any bone references (such as zygion or gonion) are more difficult to find and thus were excluded from our analysis [35,44]. Some bilateral landmarks such as TR_L, TR_R, EN_L, and EN_R displayed particularly good intra-operator repeatability in this study. The good repeatability of EN_L and EN_R was probably related to the possibility to work with color images: thanks to this feature, it was easier to identify the eyes and the inner commissure of the eye fissure due to the contrast between the sclera and the skin. This simple identification would not have been so clear using monochromatic scans. TR_L and TR_R also presented exceptionally good repeatability because they present clear anatomical definition, and this improves the reliability of the reference systems that were introduced in this study.

Establishing a new analysis technique for soft tissue changes could be useful for example to assess the effects of Class II and Class III orthopedic treatments or of extractive treatments on soft tissues. As with all orthodontic treatment modalities, the primary goals of growth modification are both to correct the skeletal discrepancy and to achieve optimal facial esthetics. The variation in facial soft tissues during orthodontic treatment has been the subject of numerous studies, mainly based on cephalometry [45–48]. However, given the low resolution of radiographic images, the lack of 3D visualization, and the overlapping of skeletal structures, soft tissues cannot be adequately assessed [49]. As such, soft tissue 3D outcome analysis after Class II and Class III orthopedic treatments based on FSs has not been performed before. Future studies will be conducted to assess the reliability of this analysis in the superimposition of the assessed plane to evaluate facial growth in subjects treated and not treated with orthopedic appliances. The limitations of this study were the cross-sectional nature of the study and the lack of an inter-observer agreement.

5. Conclusions

Both analyses assessed in this study showed good reliability and their use can be suggested as reference systems for FSs. This study produced two different reliable reference systems that should be further evaluated for the assessment of facial soft tissue changes in orthodontics.

In this study, the intra-operator repeatability of the used cephalometric soft tissue landmarks was good.

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