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ORIGINAL ARTICLE

# Three-dimensional evaluation of soft tissue changes in the orofacial region after tooth-borne and bone-borne surgically assisted rapid maxillary expansion

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**Abstract**
*Objectives* This study seeks to three-dimensionally assess soft tissue changes in the orofacial region following tooth-borne and bone-borne surgically assisted rapid maxillary expansion (SARME).
*Materials and methods* This prospective cohort study included 40 skeletally mature patients with transverse maxillary hypoplasia. A tooth-borne distractor (Hyrax) was used for expansion in 25 patients. In the remaining 15, a bone-borne distractor (transpalatal distractor, TPD) was used. Cone beam computed tomography (CBCT) scans were acquired before treatment (T0) and 22 months later (T1). 3D models were constructed from CBCT data and superimposed using voxel-based matching. Distance maps between the superimposed 3D models were computed to evaluate the degree of skeletal and soft tissue changes in the maxillary region.
*Results* Distance maps showed negative distances (mean −1.25 (±1.5) mm) in the middle of the upper lip, indicating posterior repositioning of this area. The cheek region showed positive changes (mean 1.66 (±1.1) mm), reflecting the underlying increase in maxillary width. There was no significant difference between the two groups in all measured distances ($p>0.05$). Retro-positioning of the upper lip accompanied skeletal remodeling in the anterior alveolar region at a mean ratio of 88 %, while the cheek region followed 32 % of the alveolar expansion.
*Conclusion* Soft tissue changes following SARME include posterior repositioning of the upper lip and increased projection of the cheek area. These changes were comparable between bone-borne and tooth-borne appliances.
*Clinical relevance* This study provides clinicians with more information over the expected orofacial soft tissue changes following SARME

**Keywords** Distraction osteogenesis · Palatal expansion technique · Cone beam computed tomography · Orthodontics · 3D imaging · Facial changes

## Introduction

Surgically assisted rapid maxillary expansion (SARME) is currently used routinely for the treatment of transverse maxillary deficiency in adult patients. Transverse distraction of the surgically separated maxillary halves has been successfully achieved with either tooth-borne appliances, such as Hyrax (Dentaurum, Ispring, Germany), or bone-borne appliances, such as the transpalatal distractor (TPD; Surgi-Tec, Bruges, Belgium). The latter has been introduced to provide more skeletal expansion, less tipping of the dentition, and a more effective stabilization of the bony segments during the consolidation period [1]. The skeletal and dental response following SARME, with either tooth-borne or bone-borne expansion, is widely reported in the literature [1–5].

Despite growing attention among clinicians to the effects of various treatment modalities on the overlying soft tissues, limited information is available concerning the soft tissue facial changes following this procedure. Changes in the

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transverse and antero-posterior dimensions are particularly difficult to assess in conjunction with each other in a 2D image. Lateral cephalograms, which have been the standard view to evaluate soft and hard tissue changes, lack information about the transverse dimension. This made it difficult for previous studies to correlate skeletal changes with soft tissue changes.

Currently available volume-rendered 3D cone beam computed tomography (CBCT) models make it possible to simultaneously evaluate changes in the three planes of space for both soft and hard tissues via a single model [6]. Using these 3D CBCT models, the current investigation would be the first study to simultaneously evaluate soft and hard tissue changes following expansion. Consequently, the present study was carried out to evaluate, in 3D, the long-term soft tissue changes in the orofacial region following tooth-borne and bone-borne SARME and to correlate these soft tissue changes with the underlying hard tissue alterations.

## Patients and methods

### Subjects

This prospective study included 40 skeletally mature non-syndromic patients seeking orthodontic treatment at the Department of Orthodontics and Craniofacial Biology of the Radboud University Nijmegen Medical Centre, Nijmegen (the Netherlands). Inclusion criteria were skeletal maturity, skeletal transverse maxillary deficiency combined with another skeletal discrepancy requiring orthognathic surgical intervention, and no developmental deformity.

Exclusion criteria were presence of developmental deformity, absence of more than four teeth in the posterior maxillary arch, and lips not being in rest position during the CBCT scan acquisition. Bone-borne expansion was performed using a TPD in 15 patients (7 males, 8 females; mean age at the time of surgical intervention, 30±10 years); tooth-borne expansion was performed using a banded Hyrax in 25 patients (6 males, 19 females, mean age, 25.4±9 years).

### CBCT

An initial CBCT scan was taken prior to treatment (T0) and a second scan was performed 22±7 months later after completion of the pre-surgical orthodontic treatment and prior to the second orthognathic intervention (T1). The scans were acquired using the i-CAT® 3D Imaging System (Imaging Sciences International Inc, Hatfield, PA, USA) with a field of view of 22×16 cm and a 0.4-mm voxel size. Data from the CBCT were exported in Digital Imaging and Communications in Medicine (DICOM) format.

The Medical Ethics Committee of Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands (#181/2005) approved the study protocol. All patients provided informed consent.

### Surgical procedure

Osteotomy at the level of Le Fort I with additional midline osteotomy and pterygo-maxillary disjunction was performed under general anesthesia in all patients. In patients treated with Hyrax, the tooth-borne distractor was cemented with orthodontic bands fitted on the first premolars and first molars several days before the operation. In patients treated with TPD, the device was fixed to the palatal bone during the operation by means of two screws at the level of the second premolars. All patients were operated on by the same surgeon. The choice of type of distractor was made by agreement between the orthodontist and the surgeon. Generally, the periodontal condition of the anchor teeth and the degree of palatal constriction were factors influencing this decision. Following a latency period of one week, the appliances were activated at a rate of 1 mm per day. Expansion was carried out until the palatal cusps of the maxillary teeth touched the buccal cusps of the lower dentition. When the desired amount of expansion was achieved, the distraction device was blocked by inserting a blocking screw in one of the boreholes of the TPD and left in place for a consolidation period of three months. At the end of the consolidation period, the distraction device was replaced by a transpalatal arch on the first molars. Orthodontic treatment using straight wire fixed appliances was initiated 8–10 weeks after the end of active distraction.

### Measurements on superimposed 3D CBCT models

3D models were constructed, superimposed and registered on the anterior cranial base using voxel based superimposition in Maxilim software (Medicim, Mechelen, Belgium). The accuracy of this superimposition technique was tested and thoroughly described previously by our group [7]. All measurements were performed by one observer (RN) who was not directly involved in the treatment and was blinded to the type of appliance.

Following each superimposition, color-coded distance maps were constructed to measure the amount of skeletal expansion on the maxillary alveolar level. Two reference landmarks were placed on the frontal view of the skull, defined as the most superior aspect of the concavity of the maxillary bone where it joined the zygomatic process. A line extending between these two reference points was plotted from the frontal view to represent the level of the basal bone of the maxilla [8, 9]. The maxilla was then divided into three segments: anterior segment, representing the incisor region (B-mid), right (B-right), and left (B-left) posterior segments starting from the distal aspect of the right and left canine, respectively. The distances between the 3D models at T0 and T1 were computed separately for each segment. The distances were then exported to Excel spreadsheets and the mean value for each segment was calculated.

To evaluate soft tissue changes, a modified 3D cephalometric analysis based on the 3D cephalometric soft tissue analysis of Swennen et al. [10, 11] was performed to outline the soft tissue region of interest on the superimposed models. Table 1 defines soft tissue landmarks used for this analysis. Using six vertical and two horizontal planes, the maxillary soft tissue region was divided into three subregions (Fig. 1):

- Middle region of upper lip (L-mid)
- Right and left lateral regions of upper lip (L-right and L-left)
- Right and left cheek region posterior to the angle of the mouth (C-right and C-left)

A separate distance map was computed for each subregion of the superimposed models. The distances were then exported to Excel spreadsheets and the mean distance between the two surfaces for each subregion was calculated.

## Upper incisor inclination

The change in the upper incisors inclination in relation to the palatal plane (PP; anterior nasal spine–posterior nasal spine) was measured on sagittal slices, using the most median slice showing the entire root and full crown thickness of the most protruded upper central incisor (Fig. 2).

## Statistical analysis

Statistical analysis was performed using SPSS (Statistical Package Social Sciences 16.0, SPSS Company, Chicago, IL). Descriptive statistics were first calculated to give a rough outline of the results. The two groups were compared using the independent *t* test (significance at $p<0.05$). Pearson correlation coefficient was used to test the relationship between the alveolar changes in the maxillary region and the overlying soft tissue changes. Backward regression analysis was used to determine the

**Table 1** Definitions of landmarks and planes based on 3D cephalometric soft-tissue analysis

| Landmarks and planes | Abbreviation | Description |
|---|---|---|
| Landmarks | | |
| Cheilion (left) | ch(l) | Left cheilion, point located at the left labial commissure. |
| Cheilion (right) | ch(r) | Right cheilion, point located at the right labial commissure. |
| Endocanthion (left) | en(l) | Left endocanthion, soft tissue point located at the inner commissure of the left eye fissure. |
| Endocanthion (right) | en(r) | Right endocanthion, soft tissue point located at the inner commissure of the right eye fissure. |
| Exocanthion (left) | ex(l) | Left exocanthion, soft tissue point located at the outer commissure of the left eye fissure. |
| Exocanthion (right) | ex(r) | Right exocanthion, soft tissue point located at the outer commissure of the right eye fissure. |
| nostril base (left) | nb(l) | Lowest point of the left nostril |
| nostril base (right) | nb(r) | Lowest point of the right nostril |
| Pupil reconstructed | p′ | Pupil reconstructed point, midpoint between the endocanthi and pupils, located on the level of the exocanthi. |
| Subnasale | sn | Subnasale, midpoint on the nasolabial soft tissue contour between the columella crest and the upper lip. |
| Planes | | |
| Horizontal plane | | The horizontal (*x*) 3D Reference Plane is automatically computed as a plane 6.6 degrees below the Cantion - Superaurale line, along the horizontal direction of the natural head position and through the Pupil Reconstructed Point translated 77.2 mm more posteriorly. |
| Vertical plane | | The vertical (*y*) 3D Reference Plane is computed as a plane perpendicular to the Horizontal (*x*) 3D Reference Plane and along the horizontal direction of the natural head position. |
| Subnasal plane | | A plane through landmark sn and parallel to the horizontal plane. |
| Upper lip plane | | A plane through landmarks ch(r) and ch(l) and perpendicular to the vertical plane. |
| P1 right | | A plane through landmark nb(r) and perpendicular to the upper lip plane. |
| P1 left | | A plane through landmark nb(l) and perpendicular to the upper lip plane. |
| P2 right | | A plane through landmarks en(r) and ch(r) and perpendicular to the vertical plane. |
| P2 left | | A plane through landmarks en(l) and ch(l) and perpendicular to the vertical plane. |
| P3 right | | A plane through landmark ex(r) and perpendicular to the upper lip plane. |
| P3 left | | A plane through landmark ex(l) and perpendicular to the upper lip plane. |

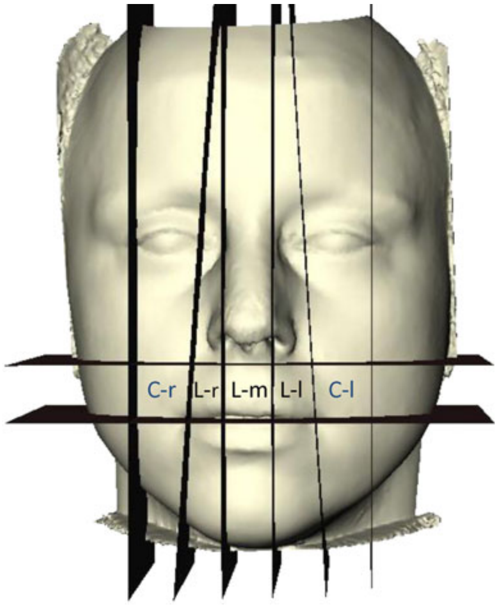


**Fig. 1** Six vertical and two horizontal planes used to divide the maxillary soft tissues into three subregions. *L-m* middle region of upper lip (L-mid), *L-r* and *L-l* right and left lateral regions of upper lip (L-right and L-left ), *C-r* and *C-l* right and left cheek region posterior to the angle of the mouth (C-right and C-left)

best combination of variables that could predict the soft tissue changes. A $p$ value ≥0.1 was used as the threshold for removing a variable from the model. The change in the middle part of the upper lip was used as the dependent variable (L-mid) and six independent variables were initially included in the analysis: change in the middle alveolar region (B-mid), age, gender, type of expansion device, total amount of lateral alveolar expansion (B-right + B-left), and change in upper incisor

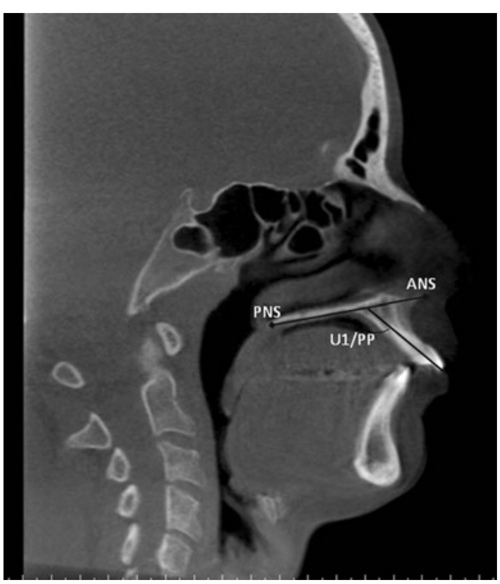


**Fig. 2** Upper incisor inclination in relation to the palatal plane, U1/PP. *ANS* anterior nasal spine, *PNS* posterior nasal spine

inclination relative to the palatal plane (U1/pp). For changes in the cheek region, the left cheek region was used as dependent variable and six independent variables were included in the initial analysis: change in the left alveolar region (B-left), age, gender, type of expansion device, total amount of alveolar expansion, and the middle part of the upper lip (L-mid).

## Results

### Surface change superimposed models

Table 2 shows the mean distances between the superimposed models for the three maxillary alveolar segments and the five soft tissue subregions in both groups. The distance maps of the superimposed models showed positive distances on the right and left posterior alveolar segments of the maxilla, indicating lateral displacement of these segments or alveolar expansion. The anterior maxillary region showed negative distances, indicating posterior displacement of the anterior alveolar region following transversal expansion (Fig. 3a). The mean difference between the two groups ranged from −0.22 to −0.06 mm. This difference was not statistically significant between TPD and Hyrax groups at the three alveolar segments ($p$ values, 0.53–0.84).

The soft tissue changes seen on the superimposed models reflected the underlying dento-alveolar changes (Fig. 3b). The distance maps of the superimposed soft tissues showed positive distances at the C-right and C-Left regions, indicating increased projection of the cheeks with a mean surface change of 1.13±1.2 mm for the Hyrax group and 1.48±1.6 mm for the TPD group; again, this change was not significantly different between groups ($p$ value, 0.47). The middle part of the upper lip (L-mid) showed negative distances, indicating retro-positioning of the central part of the lip. Mean surface change was −1.11 ±1.3 mm for the Hyrax group and −1.6±1.9 mm for the TPD group. The mean difference between the two groups was 0.45 mm ($p$ value, 0.43). The lateral regions of the upper lip (L-right, L-left) showed less surface changes, ranging from 0.002±1.4 to −0.48±1.8 mm. Although the magnitude of changes varied between patients, the soft tissue changes followed the same pattern in 39 patients: retropositioning of the central part of the upper lip, a transitional zone with minimal changes in the lateral parts of the upper lip, and increased projection of the cheek region lateral to angle of the mouth.

Given the fact that there was no significant difference between the Hyrax and TPD groups in the independent sample $t$ test, the data for both groups were combined for further statistical analysis.

**Table 2** Comparison between TPD and hyrax. Mean (SD) surface changes between T0 and T1 in mm and upper incisor inclination (in degrees)

| Region | Mean (SD) | | Sig. (2-tailed) | Mean diff. | 95 % Confidence Interval of Diff. | |
|---|---|---|---|---|---|---|
| | Hyrax $n$=25 | TPD $n$=15 | | | Lower | Upper |
| Soft tissue | | | | | | |
| L-mid | −1.11 (1.3) | −1.6 (1.9) | 0.43 | 0.45 | −0.69 | 1.58 |
| L-right | 0.002 (1.4) | −0.45 (2.3) | 0.49 | 0.45 | −0.87 | 1.77 |
| L-left | −0.24 (1.4) | −0.48 (1.8) | 0.67 | 0.24 | −0.91 | 1.39 |
| C-right | 1.13(1.2) | 1.48 (1.6) | 0.47 | −0.35 | −1.35 | 0.65 |
| C-left | 1.12 (1.2) | 0.82 (1.6) | 0.55 | 0.29 | −0.71 | 1.29 |
| Hard tissue | | | | | | |
| B-mid | −1.24 (1.2) | −1.12 (1.5) | 0.79 | −0.12 | −1.12 | 0.87 |
| B-right | 1.91(1.1) | 1.97 (0.9) | 0.84 | −0.06 | −0.72 | 0.60 |
| B-left | 1.6 (1.2) | 1.82 (0.9) | 0.53 | −0.22 | −0.92 | 0.48 |
| Upper incisor | | | | | | |
| U1/pp pre (°) | 109.97 (7.9) | 112.01 (7.1) | 0.52 | −2.04 | −8.40 | 4.32 |
| U1/pp post (°) | 107.34 (11.7) | 102.72 (7.6) | 0.07 | 4.62 | −0.31 | 9.56 |

*TPD* transpalatal distractor, *SD* standard deviation, *Diff* difference, *U1/pp* upper incisor angulation to palatal plane

### Correlations and backward linear regression

Pearson's correlation showed significant positive correlations between alveolar and soft tissue changes (Table 3). While significant, the correlation between the amount of lateral skeletal expansion and the projection of the cheek regions ($r$=0.34, $r$=0.5) was not as strong as that of the anterior alveolar region and the upper lip ($r$=0.79). On the other hand, there was no significant correlation between changes in the upper lip and changes in the upper central incisor inclination ($r$=0.28).

Table 4 shows the final backward regression models aiming to predict soft tissue changes. For the upper lip changes, four out of the six initially-included independent variables remained in the model. The amount of upper lip retraction could be explained by the amount of remodeling in the middle alveolar region, the type of device, the change in the upper incisor inclination, and the age of the patient, with 79 % contribution ratio. For every 1 mm of retraction or remodeling in the middle alveolar region of the maxilla, a 0.88 mm retraction of the central part of the upper lip would be expected. Regarding the type of device, TPD would be expected to result in less retraction of the upper lip. For the cheek region, only two variables remained in the model. Change in the cheek region could be explained by the

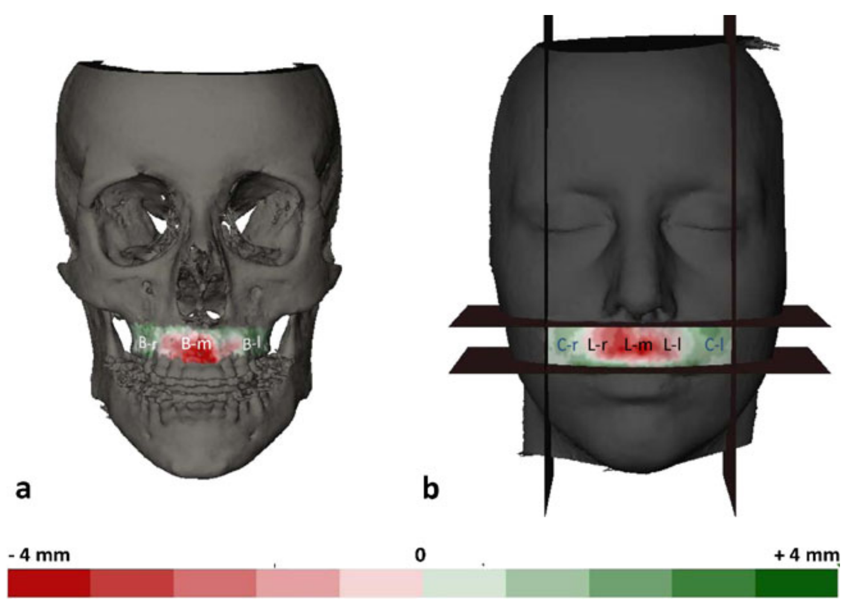


**Fig. 3** Color coded distance maps to visualize the direction and magnitude of changes between the superimposed models. The *green color* indicates that the superimposed model is in front of the original model and *red color* indicates the opposite; each color graduation is 0.8 mm. **a** The distance maps at the three maxillary dentoalveolar segments. *B-m* B-mid, *B-r* B-right, *B-l* B-left. **b** The distance maps at the three soft tissue subregions for the same patient. *L-m* L-mid, *L-r* L-right, *L-l* L-left, *C-r* C-right, *C-l* C-left

**Table 3** Pearson's correlation coefficients between hard and soft tissue changes

| | Mean | SD |
|---|---|---|
| L-mid | −1.25 | 1.55 |
| B-mid | −1.01 | 1.49 |
| correlation | $r$=0.79** | $p$=0.0001 |
| C-right | 1.27 | 1.34 |
| B-right | 1.91 | 1.01 |
| correlation | $r$=0.34* | $p$=0.042 |
| C-left | 1.01 | 1.39 |
| B-left | 1.66 | 1.11 |
| correlation | $r$=0.5** | $p$=0.001 |
| Change U1/pp | −5.03 | 9.20 |
| L-mid | −1.25 | 1.55 |
| correlation | $r$=0.28 | $p$=0.08 |

*SD* standard deviation, *U1/pp* upper incisor inclination to palatal plane

amount of changes in the lip and the underlying alveolar expansion.

## Discussion

The objective of this prospective cohort study was to perform 3D evaluation of the orofacial soft tissue changes following SARME and to correlate these changes with the underlying dento-alveolar changes. Berger et al. [12] used serial frontal photographs to measure changes in facial dimensions following orthopedic and surgically assisted rapid maxillary expansion. Due to the inherent limitation of conventional 2D photographs, their study was limited to evaluation of transverse and vertical changes in the soft tissues only. Moreover, some of the changes measured from the skeletal landmarks on postero-anterior radiographs did not coincide with changes measured from corresponding soft tissue landmarks on the frontal photographs. Therefore, they were unable to correlate some of these soft tissue changes with the underlying skeletal expansion.

**Table 4** Prediction of soft-tissue changes with backward regression analysis

| | | *B* | Sig. | 95 % CI for B | |
|---|---|---|---|---|---|
| | | | | Lower | Upper |
| Model ($R^2$=0.79) | | | | | |
| Dependent variable | L-mid | | | | |
| Independent variables | (Constant) | −0.94 | 0.04 | −1.82 | −0.05 |
| | B-mid | 0.88 | 0.00 | 0.69 | 1.07 |
| | Device | −0.78 | 0.02 | −1.44 | −0.13 |
| | Change U1/pp | 0.04 | 0.01 | 0.01 | 0.08 |
| | Age | 0.04 | 0.02 | 0.01 | 0.07 |
| Model ($R^2$=0.72) | | | | | |
| Dependent variable | C-left | | | | |
| Independent variables | (Constant) | 1.32 | 0.0010 | 0.59 | 2.06 |
| | L-mid | 0.66 | 0.0001 | 0.45 | 0.86 |
| | B-left | 0.32 | 0.03 | 0.03 | 0.61 |

*CI* confidence interval, *Sig.* significance, *U1/pp* upper incisor inclination to palatal plane

Ramieri et al. [13] investigated 3D facial soft-tissue responses to bone-borne SARME using laser scanned facial surfaces, 2D lateral cephalograms, and dental plaster models. While their study provided 3D descriptions of the soft tissue changes, it provided limited information about the underlying skeletal alterations as only dental casts were used to evaluate transverse movements.

Voxel based superimposition of 3D surface models constructed from CBCT scans has become a widely used tool to assess treatment effects and their stability over time in three dimensions [14–17]. Quantifying changes on color-coded distance maps gives a complete overview of the direction and magnitude of changes in the various anatomical structures. The numbers exported from the distance maps describe the direction and the mean change of all surface points located on the defined hard and soft tissue regions. The soft tissue regions evaluated in the present study were limited to the upper lip and cheek region adjacent to the angle of the mouth. The remaining parts of the cheeks were avoided, as these regions might be influenced by changes in patients' weight over the 2-year treatment period [18]. Ideally, we would have liked to include changes in the nose as well. Unfortunately due to a technical problem in the acquisition of earlier CBCT scans, the tip of nose was cut off in many scans, preventing us from evaluating changes in the nose.

The superimposed CBCT scans were taken before treatment and at 22±7 months post-SARME, at the end of presurgical orthodontics. The CBCT scans acquired at the end of the presurgical orthodontic stage were indicated for further treatment procedures and for the planning of the second orthognathic intervention and thus did not result in additional radiation exposure for sole research purposes. The soft tissue changes reported in this study were therefore the long term results of the combined effects of SARME and orthodontic treatment. Every surgical procedure causes post surgical swelling, and generally it takes a minimum of 4–6 months to eliminate this effect [19]. In clinical practice all patients receive fixed appliance therapy 8–10 weeks following SARME, which made it difficult to exclusively evaluate the soft tissue changes at the end of active expansion.

The distance maps calculated on the superimposed CBCT scans showed posterior displacement and remodeling in the anterior maxillary region for both expansion types. This remodeling observed in the anterior maxillary region could be attributed to changes in the dental arch form and alveolar remodeling to close the created midline space. There was, however, no correlation between this remodeling and the amount of lateral alveolar expansion. A more detailed evaluation of the amount of occlusal expansion and it's correlation with skeletal changes has been thoroughly described in a previous study involving the same patients [9].

A recurring and comparable pattern of soft tissue orofacial changes was seen in both groups. These changes were characterized by slight retropositioning of the central part of the upper lip and increased projection of the check region. The correlation between the changes in the anterior alveolar region and the central part of the upper lip was greater than that seen for the right and left alveolar expansion and the increased cheek projection ($r$=0.79, compared with $r$=0.34–0.5). These findings partially agree with those reported by Ramieri et al. [13]. While they also reported increased projection of the cheek area, they found no evident change of the upper lip. On the other hand, Filho et al.[20] reported a similar tendency for retropositioning of the upper lip following SARME with conventional suturing when compared with SARME with simple V–Y suture. Differences in surgical techniques might explain variations in results between studies.

Retroclination of upper incisors following SARME had been reported in various studies [21, 22]. In the present study, both groups showed increased retroclination of the upper incisors at the end of orthodontic treatment. This change in inclination of the upper incisor, however, did not correlate significantly with changes in the upper lip. Gungor et al. [22] attributed this retroclination to stretching of the gingival fibers between left and right central incisors during expansion. Based on results of the current study, alveolar remodeling in the anterior maxillary region to close the midline gap could also be a contributing factor.

When backward linear regression was applied to our analysis, gender and amount of transverse alveolar expansion did not seem to significantly influence changes in the upper lip. Moreover, patient age and inclination of the upper incisor appeared to have very small effects. While the central part of the lip closely followed the anterior alveolar changes, the soft tissues in the cheek region only followed 32 % of the underlying transverse alveolar expansion. Based on results of regression analysis, the type of device (TPD or Hyrax) did not seem to significantly influence the amount of changes in the cheek region. The use of TPD would be expected to result in less retraction of the upper lip. This might be an effect of the ratio between the amount of anterior and posterior expansion. The position of the distractor and pterygoid disjunction has been shown to affect the ratio between the amount of anterior and posterior expansion, especially with bone-borne expansion [23]. Previous studies reported increased anterior expansion following bone-borne expansion [1, 24]. This might explain differences between the two expansion devices. Since CBCT scans included in the present study were acquired at the end of fixed appliance therapy, it is impossible to evaluate the effect of this ratio on the soft tissue response.

Clinicians currently desire more precise information about the effects of various treatment modalities on the overlying soft tissues. With the increasing popularity of computer-assisted surgical planning, quantifying and predicting changes in the soft tissues has become an essential component of these programs. The results of the present study could be used to validate these computer prediction models.

## Conclusion

Orofacial soft tissue changes following SARME with tooth-borne or bone-borne expansion were comparable. Following SARME, slight retro-positioning of the upper lip and increased projection of the cheeks is to be expected. Retraction of the upper lip accompanied the remodeling in the anterior alveolar region at a mean ratio of 88 %.

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**Conflict of interest** The authors declare that they have no conflict of interest.

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