Quantitative Assessment of Oral Orbicular Muscle Deformation After Cleft Lip Reconstruction:
An Ultrasound Elastography Study

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Abstract—Reconstruction of a cleft lip leads inevitably to scar tissue formation. Scar tissue within the restored oral orbicular muscle might be assessed by quantification of the local contractility of this muscle. Furthermore, information about the contraction capability of the oral orbicular muscle is crucial for planning the revision surgery of an individual patient. We used ultrasound elastography to determine the local deformation (strain) of the upper lip and to differentiate contracting muscle from passive scar tissue. Raw ultrasound data (radio-frequency format; rf-) were acquired, while the lips were brought from normal state into a pout condition and back in normal state, in three patients and three normal individuals. During this movement, the oral orbicular muscle contracts and, consequently, thickens in contrast to scar tissue that will not contract, or even expand. An iterative coarse-to-fine strain estimation method was used to calculate the local tissue strain. Analysis of the raw ultrasound data allows estimation of tissue strain with a high precision. The minimum strain that can be assessed reproducibly is 0.1%. In normal individuals, strain of the orbicular oral muscle was in the order of 20%. Also, a uniform strain distribution in the oral orbicular muscle was found. However, in patients deviating values were found in the region of the reconstruction and the muscle tissue surrounding that. In two patients with a successful reconstruction, strain was reduced by 6% in the reconstructed region with respect to the normal parts of the muscle (from 22% to 16% and from 25% to 19%). In a patient with severe esthetical and functional disability, strain decreased from 30% in the normal region to 5% in the reconstructed region. With ultrasound elastography, the strain of the oral orbicular muscle can be quantified. In healthy subjects, the strain profiles and maximum strain values in all parts of the muscle were similar. The maximum strain of the muscle during pout was 20% ± 1%. In surgically repaired cleft lips, decreased deformation was observed.

Index Terms—Cleft lip, elastography, muscle deformation, muscle function, muscle geometry, noninvasive ultrasound, oral orbicular muscle, strain.

I. INTRODUCTION

ONE out of 500–1000 babies is born with a facial cleft [1]. Cleft lip, with or without cleft palate, is the most common congenital malformation among facial clefts. The reconstruction of the upper lip and the restoration of the continuity of the circular muscle in the lip (oral orbicular muscle), which is performed at two to six months of age, is an important step in the treatment of these children. However, every surgical intervention leads inevitably to scar formation. The amount, position, and appearance of the scar tissue strongly compromise the functional and esthetic outcome of the primary lip repair. For this reason one or more revision operations are often necessary to improve esthetics and function of the upper lip. Residual deformities may vary from small esthetic irregularities such as slight asymmetry or scarring of the philtral area to major stigmata as shortening and flattening of the upper lip [2]. Furthermore, even residual malformation leading to functional disability may remain [3]. The esthetic outcome of lip repair is usually judged clinically by visual inspection, while it is semi-quantitatively assessed using standardized photos in outcome studies [4]. Lip function is usually assessed subjectively by inspection, a method that has considerable drawbacks, since the extent of visible scarring influences the perception of impaired lip movement considerably [5]. The need for more objective measures to assess lip function is supported by a recent study, which showed poor agreement among surgeons in judging the need for revision surgery of the cleft lip using photographs and videotapes [6]. Mishima et al. [7] and Trotman et al. [8] developed systems for 3-D assessment of lip movements. However, these methods use information obtained from the outside of the lip and cannot give insight on the specific anatomical problem of the lip tissues. Therefore, a simple, convenient, and cost effective method to establish the quality of the reconstruction is required.

Ultrasound imaging, enables the visualization of different tissues in the healthy and reconstructed upper lip [9]. The superficial epidermal layer yields a clear thin echo border and the loose connective tissue of the lip returns relatively bright echo values, whereas the deeper lying muscles are characterized by low echo levels. However, the characterization of the scar region and functionality of the muscle remains limited [10], since the analysis is based on normal echograms. In particular, distinction between scar tissue and connective tissue or muscular tissue often remains difficult. The thickness of the muscle can be determined in both relaxed and contracted states, but published data show large variance in thickness increase and muscle size [11]–[14].


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Ultrasound elastography is a technique to quantify relative deformation of tissue using ultrasound and was first described in 1991 [15]; [16]. Although, in the first 10 years this technique was mainly used for tumor detection, a tendency towards cardiac, vascular, and smooth muscular applications can be observed in the last decade [17]–[22]. Elastography is based on acquiring multiple images of tissue while it is deforming. First the displacement is determined from subsequently acquired echo images. Next, the difference between two displacement estimates at different echo depths divided by the distance between these two depths is calculated for assessment of the strain (relative deformation). For an accurate estimation of the displacement, the raw ultrasound data containing both phase and amplitude information are used. The phase information is especially sensitive for minute displacements. A drawback of using the phase information is that only low deformation values can be measured. The maximum strain value that can be determined depends on the used frequency and required resolution, but is typically in the order of 2% between successive echo frames [23]. Consequently, temporal resolution is an important issue. To properly track the tissue while it is contracting a frame rate of 30–100 images per second is required, depending on the rate of contraction. In contrast to most other diagnostic techniques, ultrasound offers this temporal resolution.

In this study, ultrasound elastography is used to assess the strain of lip tissue, especially of the oral orbicular muscle. The hypothesis is that scar tissue in surgically repaired cleft lips has a different strain pattern than the oral orbicular muscle of healthy subjects. Using elastography, the absence of active contraction in parts of the oral orbicular muscle in reconstructed cleft lips, as well as reduced functionality of the muscle might be quantified.

II. SUBJECTS

Ultrasound data were acquired in three healthy volunteers (age range 24–30) and in three patients that underwent a surgical reconstruction of a unilateral (one patient) or bilateral (two patients) cleft lip. The patient with the reconstructed unilateral cleft had no functional disability and almost no esthetical malformation. One of the patients with the bilateral cleft had a successful repair with only moderate disability. The other patient had severe disability even after repeated surgical reconstruction procedures. All volunteers and patients signed an informed consent and the study was approved by the Ethical Committee of the Radboud University Nijmegen Medical Center.

III. METHODS

Ultrasound data were acquired using a SONOS 7500 live 3D ultrasound system (Philips Medical Systems, Best, The Netherlands), equipped with an L3-11 (3–11 MHz) linear array transducer. The transmitted ultrasound pulse bandwidth was set at 7–11 MHz. The upper lip of the subjects was prepared by extruding approximately a one-centimeter layer of commercial ultrasound coupling gel (Kendall Meditec, Mirandola (MO), Italy) over the full width of the upper lip. The transducer was carefully applied to this layer for making a transversal scanning plane while avoiding inclusion of air bubbles between transducer surface and gel (Fig. 1). In this way, the ultrasound beams are almost perpendicular to the muscle direction. The gel layer acted as an acoustic window and prevented direct contact between the lip and the ultrasound transducer.

The acquisition of ultrasound data started with the lip in a noncontracted state. During the acquisition, the subject was asked to slowly contract the lips by smoothly moving them into a pout condition and from this condition back to the initial noncontracted state without moving the lips forward or backward. A full acquisition took 3 s. The deformation of the lip is caused by contraction of the oral orbicular muscle, which is positioned in the upper and lower lip as a circular structure. Due to the contraction, this muscle will change its length and thickness. This deformation of the muscle and surrounding tissue is determined using ultrasound elastography.

The raw (rf-) ultrasound data were sampled at 39 MHz in the ultrasound machine and transmitted using a USB 2.0 interface to a workstation using a custom made module (AFLINK, Philips Medical Systems). The frame rate while acquiring the ultrasound data was 40 images per second.

The strain was calculated between subsequent echo frames to prevent strain values larger than 2%. In this way, the decorrelation was kept low. For calculating the strain, the ultrasound data were divided into windows. In conventional strain estimation algorithms, first the displacement of tissue is determined from the time shift between two congruent ultrasound data window pairs taken from consecutive echo images and additionally the strain is calculated using these displacement estimates [16]. This time shift can be calculated by using cross-correlation analysis. The position of the peak of the cross-correlation function represents the shift between the two windowed data. In this study, the displacement of the tissue was determined using...
a coarse-to-fine strain estimation method [24]. This method is based on initially calculating the displacement using a large window (2.5 mm). For an rf-based technique, an accurate displacement estimate using a relatively large window can only be determined if the strain is in the order of 1%–2%, depending on the window size and ultrasound frequency used [23]. However, by using the envelope of the ultrasound data, a reliable displacement estimate for larger strain values can be calculated [25]. Therefore, initially, an envelope based correlation is applied using a relatively large window. In this way, the chance is minimized that the wrong peak of the cross-correlation function is taken, a problem frequently occurring using this technique. This coarse estimate is used as input for a displacement estimate using a smaller window and an rf-based technique. Since the tissue is not only moving along the ultrasound beams (axial direction) but also perpendicular to that (lateral direction), the displacement is determined in axial as well as in lateral direction (2-D). Although no lateral strain is calculated in this study, the lateral displacement estimate is used to improve the axial strain estimate [24]. The resolution of the coarse displacement estimate is increased by interpolating the peak of the correlation function with a parabola. By iteratively repeating this step in which the window size is decreased, a final window size of 0.6 mm is obtained with an error of the displacement estimate of 15 μm [24]. Since the overlap between windows was taken 50%, a strain estimate for each 300 μm was determined. Strain was calculated from the final displacement estimate using a least squares strain estimation (LSQSE) algorithm [26]. Finally, the deformation of tissue over the full cycle was constructed by cumulatively summing the strain data determined from subsequent echo images.

Quantitative analysis of the relative muscle deformation was performed by manually selecting the left, middle, and right part. The average accumulated strain in these regions was plotted as a curve as function of time.

### IV. RESULTS

The cumulative strain images acquired over the full cycle show positive strain values in the oral orbicular muscle from initial state to pout condition and strain values returning to zero after release of the pout condition and going back to initial state (Fig. 2). Positive strain values represent a thickness increase and this increase is related to the contracting oral orbicular muscle. While contracting, the muscle is getting shorter, and as a consequence, becoming thicker.

Initially, the surrounding tissue is almost not deforming as illustrated by the low strain values [Fig. 2(b)]. However, the pout

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**Fig. 2.** A–D: Strain images of a healthy lip during a contraction-relaxation sequence. The strain is color coded from zero (yellow) to 30% thickening (blue), and to 20% thinning (red). The thickening of the muscle is clearly visible. E: On the echogram three regions-of-interest (red, green, and blue) are selected within the orbicular oral muscle. F: The strain versus time curves show similar thickening (up to 20%) for all three regions.

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**TABLE I**

<table>
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<tr>
<th>Region</th>
<th>Normal 1</th>
<th>Normal 2</th>
<th>Normal 3</th>
<th>Unilateral 1</th>
<th>Bilateral 1</th>
<th>Bilateral 2</th>
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<td>17.7</td>
<td>21.8</td>
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<td>25.1</td>
</tr>
<tr>
<td>middle</td>
<td>19.6</td>
<td>22.3</td>
<td>17.8</td>
<td>22.0</td>
<td>19.7</td>
<td>5.7</td>
</tr>
<tr>
<td>right</td>
<td>18.2</td>
<td>23.1</td>
<td>19.6</td>
<td>16.3</td>
<td>19.1</td>
<td>6.4</td>
</tr>
<tr>
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<td>23.7</td>
<td>18.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>1.1</td>
<td></td>
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</tbody>
</table>

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condition also results in a smaller circumference of the mouth. This shortening of the tissue in the direction perpendicular to the strain estimate results in thickening of the tissue in the direction parallel to the strain estimate. This is visualized by the positive strain values in later stages of the cycle [Fig. 2(c)]. Especially in the central part of the lip these positive strain values are found. In normal lips, similar deformation patterns and levels in the left, middle and right part of the muscle were observed [Fig. 2(e)]. The strain profile and the maximum value of strain values were similar. In all normal subjects, a maximum strain value of around 20% was found in all three parts of the lip (Table I). The high correspondence between the three curves is demonstrated by the similarity of the shape [Fig. 2(e)] and by the low standard deviation of the maximum strain value (Table I).

In patients, strain patterns different from the normal strain patterns were obtained, depending on the rate of success of the surgical procedure. In a patient with a successful repair of a unilateral cleft lip, only a small deviation of the strain pattern was observed (Fig. 3). The region where this deviation was found was co-localized with a region with different echogenicity in the conventional echogram. However, in a patient with a surgically repaired bilateral cleft lip (bilateral 1), different strain patterns were found. The left side of the lip showed strain values of the oral orbicular muscle similar to normal patients. However, it is clear that the middle and right part have lower strain values with respect to the left part. Although the repair seems to have succeeded in creating a united oral orbicular in this patient, the functionality of the muscle in these regions appears to be decreased.

In a patient with residual deformities and reduced functional properties (bilateral 2), no strain was observed in the middle and right side of the lip (Fig. 4). The left part showed a properly functioning oral orbicular muscle: strain values up to 25% were found. However, the middle and right part of the muscle showed no deformation at all, except from a small drift up to 6% strain.

V. DISCUSSION

In this study, an image of the strain of a cross section of the lip was made. Using ultrasound elastography, the strain of the oral orbicular muscle was quantitatively determined. Contrary to conventional, standardized photographs and films, information of the structures within the lip was obtained instead of information from the outside only. The principal findings of this study are as follows.

1) Ultrasound elastography provides local quantitative information of the different parts of the oral orbicular muscle. In healthy volunteers, the strain profiles are similar for all areas and the maximum strain was found to be around 20%.

2) In patients with a reconstructed cleft lip, different strain profiles and different maximum strain values were found. In this pilot study, the deviation and the size of the area in which these deviating strain values were measured seemed related to the quality of the reconstruction.

Local quantitative strain information of the oral orbicular muscle was previously not available. Using conventional ultrasonography, changes in the thickness of the various tissues could be measured. In our previous study based on conventional ultrasound data [13], the thickness of the oral orbicular muscle changed by 50% (from 2 to 3 mm). However, the standard deviation of the increase was 0.7 mm, indicating a large variance in the thickness estimate between subjects. Also, in other studies in which the thickness change of the muscle during contraction...
Fig. 4. A–D: Strain images of a repaired cleft lip (bilateral 2) during a contraction–relaxation sequence. The strain is color coded from zero (yellow) to 30% thickening (blue), and to 20% thinning (red). E: On the echogram three regions-of-interest (red, green, and blue) are selected within the orbicular oral muscle. F: The strain versus time curves show thickening (up to 30%) in the left part (red) of the lip, whereas reduced thickening (5%) is found in the middle and right part (green and blue) of the lip.

was investigated using conventional ultrasound, values ranging from $-2\%$ [11] to 37% [12] and even 50% [14] were reported. In all these studies, different methods for deformation of the muscle were used in subjects with different malformations. In the present study, all normal volunteers showed maximum strain values around 20% in the right, left, and middle part of the muscle, although this number is based on a limited number of subjects. The small standard deviation ranging from 0.7% to 1.7% strain illustrates the high quality of the estimate and the potential of ultrasound elastography to quantitatively determine the relative deformation. A thickness measurement is based on the outline of the muscle that can be easily obscured by out of plane motion and echo pattern changes, whereas the deformation of the whole cross section of the muscle is used in elastography. Because a 2-D imaging technique was used in this study, special care was taken to prevent out of plane motion during contraction and relaxation of the lip. In acquisitions of the volunteers with large in plane motion, strain images were deteriorated. In these acquisitions, the position of the different tissues was not stable and consequently the cumulative strain values did not correspond to a particular region but a region composed of muscle and connective tissue. This problem can be solved by automatically tracking the tissue over the deformation cycle. Since displacement is already estimated, this information can be used to automatically track the tissue. The current progress in 3-D echography allows even to compensate for out of plane motion.

The strain values are dependent on the angle between muscle fiber orientation and ultrasound beam direction. However, in this study no difference between the left, middle, and right regions of the muscle was found in healthy lips. A large scale prospective study currently performed will provide data on the difference between these regions and the necessity to correct for this.

The strain images provide information on the presence and absence of a thickening oral orbicular muscle. Where in the normal volunteers, the oral orbicular muscle can be identified throughout the lip from left though right, this pattern is not always apparent in patients with a reconstructed cleft lip. Although this study is a feasibility study based on a limited amount of patients, a relation between the severity of disability and the deviation of strain pattern from the normal situation is found. In a patient with a very successful unilateral cleft lip reconstruction, only a small deviation is present. In a small part, a less deforming region is present. So, although the repair of the muscle was successful and a closed structure was obtained, full recovery of the function was not achieved. In the patient with the repaired bilateral cleft, larger areas with reduced functionality were found. The right and middle parts of the oral orbicular muscle showed reduced deformation. However, also in this patient, partial recovery of the functionality of the muscle was achieved. This is in contradiction to the patient with severe malformations who had reduced function of the lip even after repeated surgeries to correct esthetic malformations.

Our results explain the findings of Trotman et al. [6] who showed, using a video-based tracking system, that patients with a cleft lip exhibit less upper lip movements and greater asymmetry of mean upper lip movements relative to non-cleft individuals. The decreased strain locally observed in our cleft patients might be also associated with the greater contraction instability of the upper cleft lip measured by Trotman et al. [27]. Using standardized photos or films, the effect of the reduced muscle function was measured previously [6], but no informa-
tion on the actual function of the oral orbicular muscle was provided. In a follow up of this study, the force generated by the upper and lower lips was measured [27]. Although reduced force was found in cleft lip patients, it is hard to determine the location with the reduced function. Using elastography, the absence of muscle function can be directly related to a specific region. In the study by Trotman et al. [27] a compensatory force from the lower lip was found in cleft lip patients. In our study also a compensated increased deformation of the nondiseased side of the lip was found in the patient with almost no deformation in the diseased side.

Elastography of the lip may contribute to the objective assessment of treatment outcome as well as in the decision making procedure of the surgeon who is confronted with a compromised lip repair. Currently, the esthetic and functional outcome of lip repair is usually judged clinically by visual inspection, a method that has considerable drawbacks, since the extent of visible scarring influences the perception of impaired lip movement considerably [5]. Because elastography yields information about the nonvisible part of the lip, it will allow the surgeon to identify the in-depth location and the amount of the scar and it can give an objective picture of local tissue deformation. This information will help the surgeon to decide whether a lip revision might improve lip function, as well as to choose the least invasive operation technique for the specific patient. Since this study only describes the technique and first evaluation in a relative small number of people, larger scale prospective and retrospective studies are required to assess the full potential of the ultrasound elastography technique to aid the physician in evaluating the reconstruction and to improve the surgical technique.

VI. CONCLUSION

With ultrasound elastography the local relative deformation of the oral orbicular muscle can be quantified. In healthy subjects, the strain profiles in all parts of the muscle are similar. The maximum strain of the muscle is 20% ± 1%. In surgically repaired cleft lips decreased strain was locally observed relative to 20% strain in healthy parts. In this preliminary study, the decreased strain values were related to the success of the reconstruction.

REFERENCES