

RESEARCH ARTICLE

Bone and soft tissue palatal morphology and potential anchorage sides in cleft palate patients

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ABSTRACT

Aim: The aim of this study was to evaluate palatal vertical bone thickness and density in relation to soft tissue on the hard palate for better selection of adequate bone regions for the insertion of orthodontic mini-implants (MIs) in cleft palate patients.

Materials and methods: Cone beam computed tomography scans (CBCT) were obtained from 60 patients (mean age range 9–12). The study population included patients with isolate right side cleft palate formation (n = 20; 6 females; 14 males), left side cleft palate formation (n = 20; 9 females; 11 males) and without cleft formation as control group (n = 20; 15 females; 5 males). Bone and soft tissue measurements were performed vertical at a 90° angle to the bone surface, on previously defined measurement points (n = 88) on the hard palate. Bone density was measured on ten vertical layers in caudo-cranial direction.

Results: In non-cleft patient the highest bone thickness was in the anterior palate and decreased significantly in posterior direction. In patients with right and left cleft palate, the highest vertical bone level could be observed at the palatal premaxillary border opposite to the cleft side. Patients in the control group showed a significantly lower vertical soft tissue thickness than patients with palatal cleft formation. The evaluation of bone density showed no significant differences in all three groups.

Conclusion: The results suggest that the favorable region for orthodontic MI placement is in the similar anatomical region compared to non-cleft patients, but differs from one side in each group. In unilateral cleft palate patients, the highest bone level was found on the anterior palate side opposite to the cleft side, indicating the most effective region for MIs placement.

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1. Introduction

Orofacial clefts are common congenital anomalies of the head. The clinical development of cleft lip and palate is very different. There are unilateral as well as bilateral clefts, but also microforms in which only the cleft lip determines the clinical appearance (Eppley et al., 2005). The clinical symptoms of patients with cleft lip and palate are usually treated by interdisciplinary collaboration of dentists, orthodontists and maxillofacial surgeons (Bergland and Semb, 1986). Depending on the extent of the cleft defect, patients require complex orthodontic treatment, including biomechanical and anchoring planning (Proff et al., 2006). Prior to secondary alve-

olar bone transplantation at the age of 10–12 years, orthodontic treatment is often required to align the teeth and correct anterior and posterior cross bites to prepare the maxillary for surgery (Chang et al., 2016). Orthodontic mini-implants (MIs) are increasingly being used to correct severe malalignments in order to ensure anchorage for planned tooth movements (Huang et al., 2012; Vachiramon et al., 2009). MIs are important for an profound skeletal anchorage in orthodontic treatments, which can be used to perform complex tooth movements without impairing side effects on adjacent teeth (Schlegel et al., 2002). Further advantages of MIs are the simple and fast insertion and removal, as well as the fact that the treatment result does not depend on the patient compliance. Added to this are the relatively low costs compared to conventional dental implants (Papadopoulos and Tarawneh, 2007). The most important prerequisite for successful treatment of MIs is that they remain stable in the bone and are not lost during treatment. In this context, the bone density and thickness of cortical bone in combination with little mucosa are significant stability

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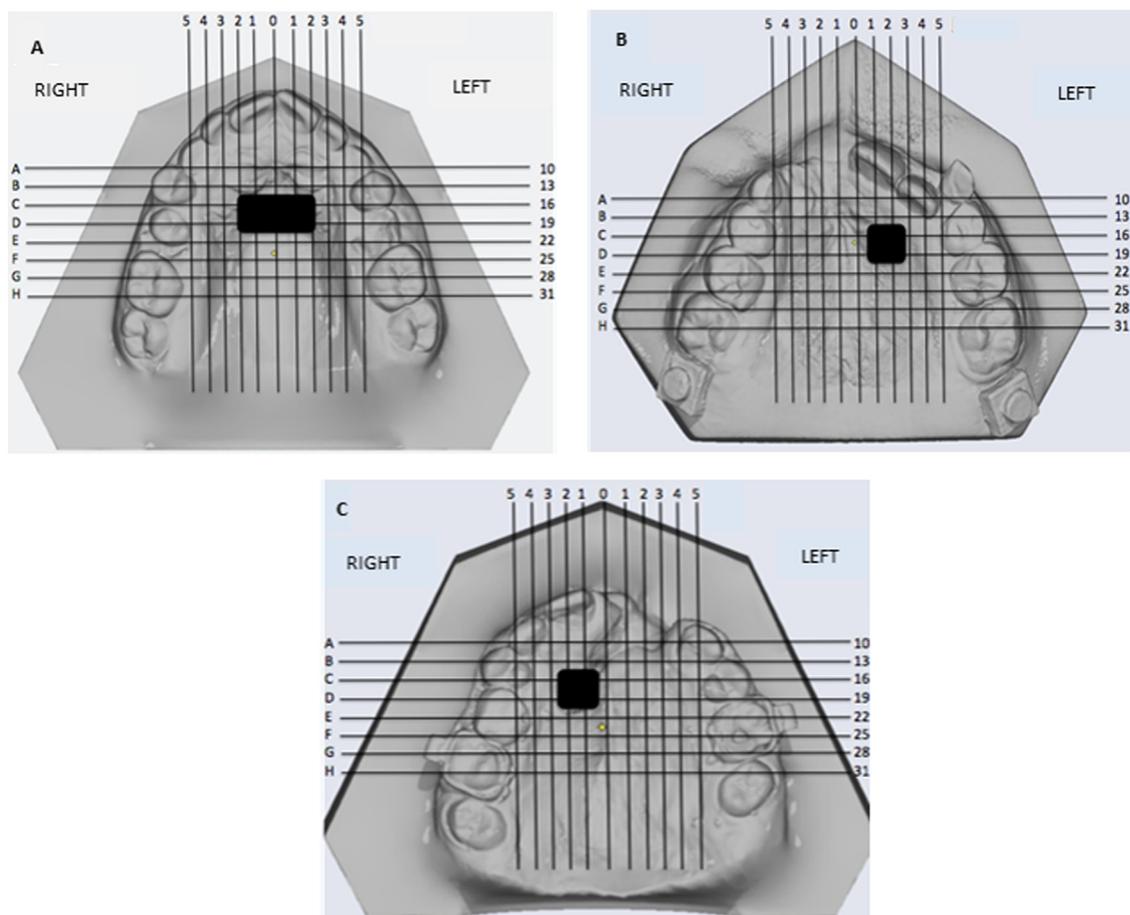


Fig. 1. Anatomical mapping of cleft formation and the most favorable region with the highest bone and soft tissue ratio within the anterior hard palate. Plaster model scans with methodical mapping of the hard palate in non-cleft (A), right (B) and left (C) palate cleft patient (x-axis: line; y-axis: anterior-posterior reference line). The marking zone points to the region with the highest bone and lowest soft tissue relation. In cleft palate patients this region is located in the central palate within the non-clefts side. This region can be recommended for orthodontic bone anchorage implantation (black bar: Zone of high bone/soft tissue ratio). (A) Marking zone with most favorable region for the implantation of orthodontic mini-implants in non-cleft patients. (B) Marking zone with most favorable region for the implantation of orthodontic mini-implants in right cleft patients. (C) Marking zone with most favorable region for the implantation of orthodontic mini-implants in left cleft patients.

factors (Holm et al., 2012; Motoyoshi et al., 2009). The paramedian region of the anterior maxilla is well suited for insertion of MIs (King et al., 2007; Ohiomoba et al., 2017) due to the low mucosal thickness (Kim et al., 2006), the sufficient bone and the low risk of damaging anatomical structures such as tooth roots (Hourfar et al., 2015; Wehrbein, 2008). Several studies have already proven the best insertion region for MIs in non-cleft anatomical conditions (Hourfar et al., 2015; Schlegel et al., 2002; Wehrbein, 2008). For cleft lip and palate patients, where the need for correct anchorage planning is even greater, no corresponding data are yet available. It is difficult to find a suitable region for the insertion of MIs in these patients due to unpredictable bone conditions and cleft-dependent soft tissue morphologies. In current literature there are hardly any studies providing information on bone and mucosal thickness as well as on bone density in patients with unilateral cleft lip and palate for potential insertion sites of orthodontic MIs.

The objective of the present study was therefore to evaluate bone and soft tissue morphology in unilateral cleft palate patients and compare it with non-cleft palate patients to obtain further information on possible orthodontic palatal anchoring sites for orthodontic MIs and to make further recommendations for their clinical use.

2. Material and methods

2.1. Patients

The present study was designed according to the Declaration of Helsinki. CBCT scans of 60 patients (female: 30; male: 30) at the age of nine to twelve years were collected retrospectively in the period from 2015 to 2018. The study population included patients with isolate right side cleft formation ($n=20$; 6 females; 14 males), left side cleft palate formation ($n=20$; 9 females; 11 males) and without cleft formation as control group ($n=20$; 15 females; 5 males) were analyzed for linear measurements and for measurements of bone density. The chosen study size was based on the study by Gracco et al. (2006) in which a similar study size was chosen. Due to a lack of basic data, this study was carried out as a pilot study.

All CBCT scans were performed for clinical examination and treatment planning only. In cleft palate patients, CBCT scans were performed for surgical treatment planning for osteoplasty.

Exclusion criteria were: (1) Presence of other craniofacial abnormalities; (2) Refusal to participate in the study. Non cleft CBCT scans resulted from treatment planning of interradicular canine retention and vestibular displacement cases, i.e. retention or displacement was outside the analyzed range. In non-cleft CBCT scans, palatal tooth retention and the presence of other craniofacial abnormalities were considered exclusion criteria. All subjects were

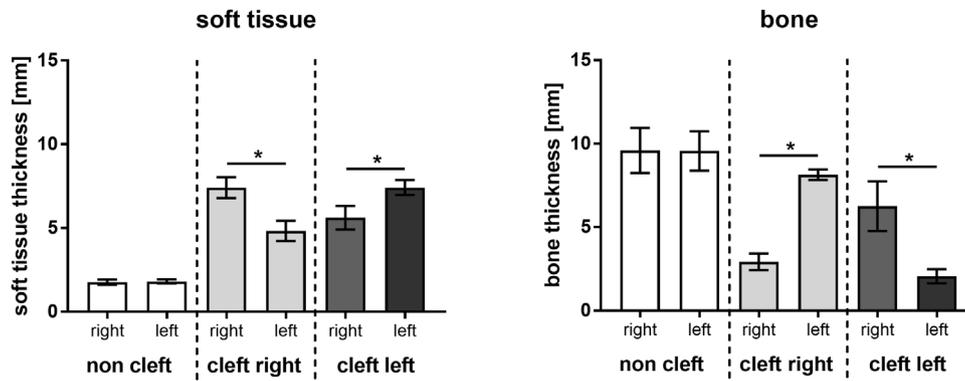


Fig. 2. Evaluation of hard and soft tissue thickness. The graph shows measurements of bone (A) and soft tissue (B) thickness of the hard palate in non-cleft, right and left palate cleft patients. Cleft palate patients show significant reduction in bone thickness and increase in soft tissue especially on the cleft side. Each value represents the mean \pm SD of regions C1, C2, D1, D2 in the grid per group. *p-value \leq n005 right vs. left side. Means of each regions were calculated from values of 20 patients.

selected according to the following inclusion criteria: (1) Diagnosed with non-syndromic, single continuous right or left cleft formation (LAHS— or —SHAL according to the official LASHAL classification of Kriens (1989) or intact maxilla without palatal canine retention; (2) Cleft palate patients undergoing cheiloplasty at the age of 3 to 6 months and palatoplasty at the age of 9 to 18 months of age.

2.2. Three-dimensional CBCT scan

All CBCT scans were obtained by an experienced technician with a CBCT device (Galileos ComfortSirona, Germany, using the default technical parameters 85 kV, 28 mA, FOV $512 \times 512 \times 512$, voxel 0.25 mm; Whitefox Satelec, Acteon group, Germany, using the default technical parameters 105 kV, 6–10 mA, voxel 0,1–0,3 mm) at the department of Maxillofacial Surgery, University of Aachen, Cologne and Essen, Germany.

Routine calibration and system quality assurance tests of the machine were performed regularly. The examined subjects were positioned in the sagittal plane perpendicular to the floor, which was parallel to the Frankfort plane. All CBCT data were exported to digital imaging and communications in medicine (DICOM) format. The 3D images were imported into Osirix[®] imaging software (Version 2.0.1, 64 Bit, Pixmeo, Bernex, Switzerland for MacOS (Apple, Cupertino, California, USA).

2.3. Reproducible CBCT scan orientation for palatal measurements

According to the protocol of Medea and coworkers for facial analyses, CBCT scans were orientated on anatomical landmarks. Based on the most vestibular upper incisor a scatter pattern with 88 defined measurement points was applied (Fig. 1).

2.4. Palatal soft and hard tissue measurement

Soft and hard tissue analyses were performed consecutively at each previously defined measurement point ($n = 88$) vertical to palatal bone according to the similar previous published protocol of Hourfar et al. (2015) (Fig. 1). Briefly, all measurements were recorded in mm and recorded for each analyzed subject. Measurement points within the cleft region showing non soft/hard tissue combination have been excluded. Mean values of all measuring points of the non-cleft patients as well as the patients with isolated right and left side cleft were calculated (Hourfar et al., 2015).

2.5. Bone density measurements

Palatal bone density analyses were performed consecutively according to the modified protocol of Moon et al. (2010). Based on initial results indicating the region of greatest bone thickness (line “C” and “D” in the grid), a bone density analysis of the right and left palatal bone was performed at line 1 with a distance of 16–19 mm in anterior-posterior direction to the anterior enamel cement margin in the grid. The measurements of the bone density were recorded in ten layers of the CBCT. Measurements of the enamel density served as a reference with the highest density. Bone density is normally determined by the use of Hounsfield units, which can be estimated from multidetector CT (MDCT) data sets. However, there are significant differences between MDCT and CBCT between what makes the use of Hounsfield units for CBCT more difficult (Pauwels et al., 2015). For this reason, we have not described bone density in Hounsfield Units but in relation to enamel density.

2.6. Statistical analyses

Data were analyzed using the statistical software Graph Path Prism (SPSS Version 22.0 for Windows; IBM Corporation, Armonk, NY, USA). Since the data is not normally distributed (D’Agostino & Pearson) a non-parametric test (Mann-Whitney-U test) was performed to compare the soft and hard tissue measurements between the groups. A p-value of, or below, 0.05 was considered to be statistically significant and marked with an asterix.

3. Results

3.1. Anatomical orientation and palate analysis

Orientation to anatomical landmarks (dens axis, sella, nasion) allowed a reproducible orientation of cbct scans with and without cleft palate formation. Based on cbct orientation, an individual anatomical and non-tooth depend evaluation of maxillary complex and anterior palate was possible. Referring to these landmarks, a previous established orientation map for palatal anchorage planning could be transferred to cleft palate situations (Hourfar et al., 2015). Landmarks and points of analyses were orientated in relation to the upper central incisors in both, cleft and non-cleft palate patients.

3.2. Soft tissue morphology

Systematic soft tissue evaluation of maxillary palatal soft tissue morphology in non-cleft and single side cleft palate patients

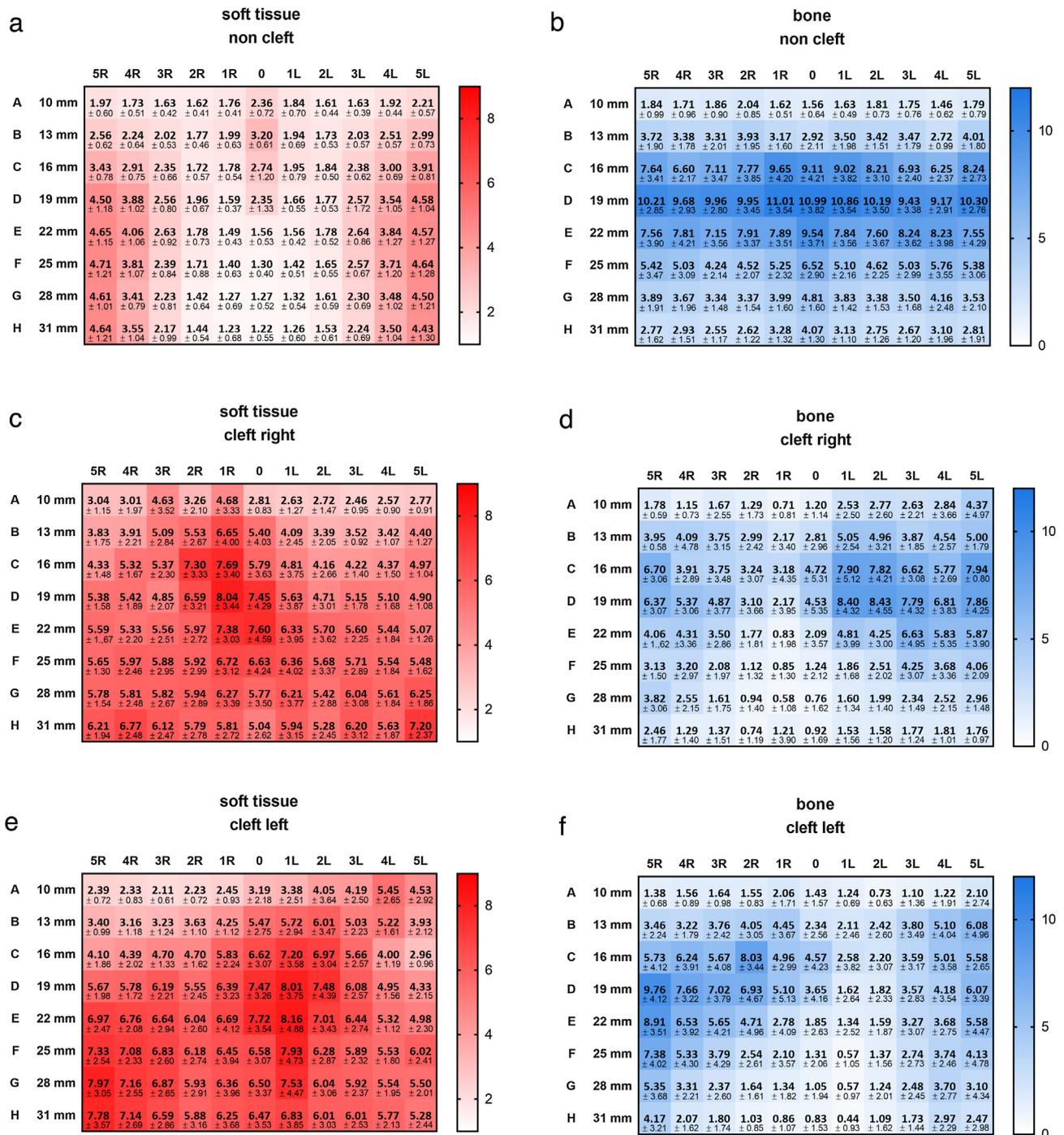


Fig. 3. Graphical evaluation of soft and hard tissue distribution. Structural mapping of average bone and soft tissue thickness of the hard palate in non-cleft, right and left palate cleft patient. Graphs show colored signature measurements in each patient group. Areas of significant soft tissue increase and reduced vertical bone thickness within the central palate can be observed in cleft palate patients. A correlation to the patients side can be observed (light color: low tissue/bone thickness; dark color: high tissue/bone thickness). Each value represents the mean \pm SD (mm) of a total of 20 independent patients in each group.

revealed significant differences (Fig. 2). Regular control patient's demonstrated significant less vertical soft tissue thickness compared to patients with palatal cleft formation. Soft tissue thickness revealed significant higher measurements on the anterior palatal side in analyzed cleft palatal patients. A difference in patients with right or left cleft formation side was not observed (Fig. 3).

3.3. Bone morphology

To evaluate bone thickness of the palatal bone in right or left side cleft palate patients and to compare these data with bone thick-

ness values from healthy control patients, analyses and mapping of vertical bone dimension was performed. Comparison of the investigated groups demonstrated significant differences within bone dimension and morphology. Cleft palate deformation was associated with reduced bone levels compared to non-affected controls (Fig. 2). A difference on cleft formation on right palate or left palate did not show any difference. Interestingly, in both groups the highest vertical bone level could be observed on the palatal/premaxilla border opposite to the cleft sides. Patients with right side cleft formation showed the highest vertical bone volume on the left palatal/premaxilla border. Patients with left side cleft formation

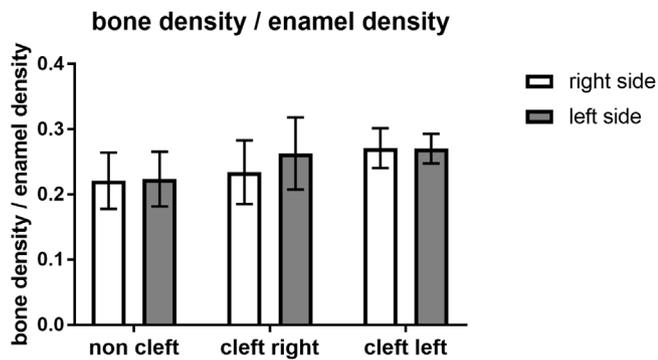


Fig. 4. Analysis of bone density. Evaluation of bone density in the central hard palate in non-cleft, right and left palate cleft patients did not reveal any significant difference within each group. Each value represents the mean \pm SD for 20 independent patients. Bone density is described in relation to enamel density.

showed highest vertical bone volume on right palatal/premaxilla border (Fig. 3).

3.4. Bone density analysis

The evaluation of bone density showed no significant differences in all three groups. The bone quality of the palatal bone in right or left side cleft palate patients was similar to the bone density of the palatal bone in non-cleft patients (Fig. 4).

3.5. Localisation of anchorage insertion side

Based on the bone and soft tissue measurements and bone density analysis of both right/left cleft palate patients and controls, a systematic map of potential anchorage insertion sides could be established (Fig. 1). According to the present data, high bone volume and bone/soft tissue relation can be expected close to the region of the premaxilla/palate border in cleft and non-cleft palate patients. In cleft palate patients a better soft/hard tissue relation was observed on the contralateral side of the cleft formation. This region showed an average of 1.8 mm increased soft tissue thickness compared to the control group.

4. Discussion

The aim of this study was to measure vertical bone and soft tissue thickness and bone density on the hard palate in cleft palate patients, to identify areas with sufficient bone for the insertion of orthodontic MIs, and provide guidelines for identification of these areas. The Osirix[®] software was used in this study. The validity of the measurements performed with this software has been demonstrated in several previous studies (Hourfar et al., 2015; Jalbert and Paoli, 2008; Kim et al., 2012; Sierra-Martinez et al., 2009). Yamauchi et al. (2010) evaluated the Osirix[®] software and other commercial software for anatomical facial CBCT analysis could provide evidence for their valuable use.

The available data showed the highest bone-soft tissue ratio in the anterior palatal region in non-cleft patients (Fig. 3). These measurements are consistent with the results to other studies (Baumgaertel, 2009; Kim et al., 2014; Stockmann et al., 2009) and show no significant differences (Baumgaertel, 2009; Hourfar et al., 2015). Retention was outside the analyzed palatal region, as it could be assumed that retained teeth could possibly influence bone thickness and configuration in the palatal bone region.

In accordance with previous studies, the region with the highest hard tissue values could be described by the region “C1,D1” in the anatomical map used in the present study (Figs. 1,3) (Stockmann et al., 2009). Based on these results, the insertion of orthodontic

MIs in non-cleft patients in this palate region is strongly recommended (Bernhart et al., 2001; Fayed et al., 2010; Gracco et al., 2006) (Fig. 1), as bone thickness is of high importance to the retention of orthodontic MIs (Stockmann et al., 2009). Besides the defined area values of bone thickness decrease and might reduce the needed anchorage for the insertion of orthodontic MIs (Baumgaertel, 2009; Bernhart et al., 2001; Fayed et al., 2010; Stockmann et al., 2009). There is currently a lack of reliable data on favorable palatal regions and structures that are suitable for the insertion of orthodontic anchoring implants in unilateral cleft patients. Therefore, the purpose of this study aimed to analyze bone and soft tissue values in unilateral cleft palates and to compare these results with the available data from non-cleft patients. Based on the measurements performed, the objective was to adapt the existing anatomical orientation maps for MI insertion planning from non-cleft patients to cleft patients in order to provide data for clinical treatment planning.

In this study, the results of the unilateral cleft patient showed a reduced bone fraction compared to the control group and the patient data available in the literature. In addition, the thickness of the soft tissue mucosa over the bone is higher than in patients without cleft formation. According to the available findings, the bone is partially completely missing at the cleft site and the mucous membrane is significantly thicker. On the contralateral side of the cleft there was also a lower bone supply and an average greater mucosal thickness than in the control group without cleft (Fig. 3). The highest bone level and thus the most favorable region for a possible MI insertion in patients with left cleft palate was found on the right side between lines 1–2 with a reading of 16–19 mm on the reference line anterior to posterior. In patients with a right cleft palate, the largest bone supply with the smallest mucosal thickness above average was measured on lines 1–2 on the left side with a reading of 16–19 mm in the anterior - posterior reference line (Fig. 3).

Analyzing the vertical soft tissue thickness, it can be determined that cleft palate patients have a significantly increased vertical soft tissue thickness compared to non-cleft patients, which may lead to longer MI application and consideration of the associated mechanical effects.

In a second appraisal, bone density as an important factor for implant stability was analysed. Interestingly cleft palate and non cleft patients demonstrated similar bone density within the recommended anchorage region. There was no difference between the left or right side cleft group. This goes along with reports from other groups which did not find any difference between right or left palatal sides in non cleft patients (Moon et al., 2010). According to this data, significant reduction in bone density was observed in lateral and posterior regions. Based on findings of the current study and published data, it can be suggested that there is no difference in bone density between cleft and non cleft patients.

As the study group represents only a small number of patients (20 per group) the results have to be discussed critically concerning representative aspects. Therefore, further prospective, multicenter, double-blind studies are required.

Altogether the present study provides information on vertical bone and soft tissue dimensions in unilateral cleft palatal patients. In single side cleft palate patients, the highest bone level was on the opposite side of the cleft. Therefore, the use of orthodontic MIs in unilateral cleft palate patients can be recommended on the opposite side of the cleft.

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manuscript belong to the PhD thesis of J.Scholz. The authors declare no conflict of interest.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.aanat.2019.02.005>.

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