CBCT EVALUATION DURING SURGICAL TREATMENT OF CLEFT LIP AND PALATE

DOCTORAL THESIS

SUMMARY

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The doctoral thesis is illustrated by 77 figures and 42 tables. The research is based on 272 references.

This summary contains a limited number of figures and tables, preserving their original designation from the doctoral thesis.

**Keywords:** Cone-Beam CT, cleft lip and palate, secondary alveolar bone grafting, questionnaire.
Cleft lip and palate (CLP) represent an important problem of public health, due to their incidence and the numerous aesthetic, functional, and social modifications they cause among patients (Mossey et al., 2009; Dean, 2011).

The surgical treatment of cleft lip and palate is particularly complex and it is performed in several stages. Currently, the appropriate planning of surgical treatment is inconceivable without an accurate diagnosis based on clinical and preclinical data (Haba, 2007; Iannuci, 2012). In this context, two-dimensional imaging (2D) represented the only available resource for a long time. During the last 30 years, three-dimensional examination (3D) accessed all branches of modern medicine through computed tomography (CT) and, subsequently, through Cone Beam computed tomography (CBCT). The use of CBCT instead of the classic CT is recommended, whenever possible, as a method of radiation protection and dose reduction for the patient, thus respecting the ALARA principle (As Low As Reasonably Achievable) (Iannuci, 2012; Lauc, 2012).

In the described context, the specific goals throughout the doctoral study were:

1. Implementing a multidisciplinary approach to the management of CLP patients, in line with current trends and modern medical principles.
2. Introducing the latest imaging technology in the three-dimensional examination protocol for CLP patients, and assessing its contributions.

3. Developing a homogenous and representative group of patients presenting DLMP, to achieve further research studies.

4. Undertaking a study on the preoperative CBCT evaluation of patients presenting an alveolar cleft, for the purpose of performing secondary alveolar bone grafting.

5. Undertaking a study on the assessment of volumetric measurements of bone defects, based on preoperative CBCT examinations and on the use of a specialized software program.

6. Undertaking a study on the postoperative evaluation of CLP patients, to assess the results of the secondary alveolar bone grafting.

7. Designing and applying a questionnaire to assess knowledge on 3D imaging methods (CT and CBCT) among medical residents involved in the treatment of patients with CLP, as well as their perception on the received training in this area.

8. Constituting a CBCT scan protocol for CLP patients, that can be practically implemented for preclinical examination, after being compensated by the medical assurance system (CNAS).
CHAPTER 5
IMAGISTIC ASSESSMENT OF THE PREOPERATIVE ESTIMATIVE VOLUME OF THE BONE DEFECT IN CLEFT LIP AND PALATE PATIENTS

5.1 INTRODUCTION

Alveolar bone grafting has become an essential component in the surgical treatment of CLP patients. CBCT preoperative examination provides surgeons with valuable information about the size of the alveolar defect and the anatomical structures involved therein, allowing 2D (linear, angular) and 3D measurements (volumetric) (Pinsky et al., 2006; Zhang et al., 2012). This assessment enable an efficient planning of the surgical intervention (Linderup et al., 2015).

The present study aimed mainly to establish an appropriate protocol for the preoperative CBCT examination and the imaging assessment of the preoperative estimative volume of the alveolar bone defect, in order to provide information on the quantity of bone to be harvested for the alveolar bone grafting.

5.2 MATERIAL AND METHODS

5.2.1 Selection of patients

The study group consisted of 13 CLP patients, selected in the order of referral to treatment at the Pediatric Surgery Department, at "Saint Mary" Emergency Hospital for Children. The mean age of the subjects was 7.46 ± 2.3 years (SD) (range 5-12 years). The gender distribution was: 2 female patients (15.4%) and 11 male patients (84.6%).
5.2.2 CBCT examination

CBCT examinations were performed prior to secondary alveolar bone grafting procedure, in a private radiology clinic. A Planmeca Promax 3D Mid unit (Planmeca Oy, Finlanda) was used to collect CBCT data, while technical parameters were selected based on the patient’s age and body structure.

5.2.3 Evaluation of the preoperative estimative volume

The scans were saved as DICOM files (Digital Imaging and Communications in Medicine), and were reconstructed using three-dimensional imaging software Romexis 3.6.0.R (Planmeca, Helsinki, Finlanda). All digital measurements were performed by three independent observers, after defining the following limits of the region of interest:

- the superior limit was set to be the nasal plane, taking into consideration the position of the anterior nasal spine (ANS);
- the inferior limit was considered to be the inferior margin of the alveolar bone adjacent to the cleft;
- the lateral boundaries were represented by the limits of the alveolar bone surrounding the teeth adjacent to the cleft;
- the antero-posterior limits were set to follow the outline of the maxillary alveolar arch.

After reorienting the CBCT scans and verifying the limits in all three plans (coronal, sagittal, and axial), volumetric measurements were performed using a semi-automated method and an elliptical tool. After 10 days, all three observers repeated the volumetric measurements on all CLP patients. The arithmetic mean
of the measurements made by all examiners was used to represent the preoperative estimative volume (PEV) of the bone defect for each patient.

**Fig.5.2** C Patient A.E.R., 6 years old, presenting nonsindromic right UCLP; axial sections.

### 5.2.4 Secondary alveolar bone grafting

All alveolar bone grafting interventions were performed by the same surgeon, following the same surgical protocol. After harvesting autogenous bone from the iliac crest, it was placed in a 5 ml sterile syringe, recording the intra-operative measured volume (IV) for each patient.

### 5.3 RESULTS

#### 5.3.1 CBCT volumetric assessment of the alveolar bone defect

The presence of right unilateral CLP (UCLP) was observed in 46% of patients, left UCLP in 38%, and bilateral CLP (BCLP) only in 16% of the patients. The evaluation of the alveolar defect volume, yielded the following mean values for PEV: \(1.449 \pm 0.28\, \text{cm}^3\) (range 0.865-1.913cm\(^3\)) for the entire study group; \(1.367 \pm 0.22\, \text{cm}^3\) (range 0.865-1.702cm\(^3\)) in patients with UCLP;
1.900± 0.02cm³ (range 1.888-1.913cm³) in patients with BCLP.

Statistical analysis was performed using SPSS version 20.0 (SPSS Inc, Chicago, IL), revealing a fairly good to strong intra-observer reliability (ICC=0.638-0.774 and coefficient Pearson=0.732-0.861) and a strong inter-observer reliability (ICC=0.820-0.870 and coefficient Pearson=0.686-0.781). Dispersion diagrams and Bland-Altman charts supported these results.

### 5.3.2 Intra-operative volumetric assessment of the alveolar bone defect

The mean intra-operative volume (IV) was 1.615±0.47cm³ (range 1.000-3.000cm³) for the whole study group; 1.473± 0.23cm³ (range 1.000-1.900cm³) in patients with UCLP; 2.400±0.85cm³ (range 1.800-3.000 cm³) in patients with BCLP.

### 5.3.3 Comparative evaluation between PEV and IV

The average difference PEV-IV was: -0.166 ± 0.39cm³ (range 1087-0.043cm³) for the whole study group; -0.106 ± 0.30cm³ (range -0.602-0.432cm³) in patients with UCLP; -0.500 ± 0.83cm³ (range -1.087-0.088cm³) in patients with BCLP.

Statistical analysis of the correlation PEV-IV for all participating patients (ICC=0.634; Pearson=0.557) showed a moderate concordance between them.

### 5.4 DISCUSSION

Several previous studies have reported the benefits of 3D imaging (CT, CBCT) for the evaluation of the preoperative estimative volume of the alveolar bone
defect (Shirota et al., 2010; Choi et al., 2012; Linderup et al., 2015). However, in Romania, a clear protocol has not yet been established for the 3D analysis of the bone defect taking place before alveolar bone grafting.

As indicated by the experience of surgeons involved in the CLP treatment at "Saint Mary" Emergency Hospital for Children in Iasi, preoperative volumetric evaluation of the alveolar bone defect based on CBCT data, was firstly introduced in the management of CLP patients in the North Eastern region of Romania. Also, research in the specialty literature in Romania did not reveal similar studies conducted with CLP patients. PEV values obtained from three-dimensional analysis matched the results reported by most previous studies, included in the range 1.1 – 2.1 cm³ (Bradrick et al., 1990; Botel et al., 1993; Boyne et al., 1993; Feichtinger et al., 2006; Feichtinger et al., 2008; Choi et al., 2012; Nagashima et al., 2014). Other studies have reported lower volumetric values than our results for patients with UCLP (0.210-0.934 cm³) and BCLP patients (0.820 cm³) (Tai et al., 2000; Oberoi et al. 2009; Quereshy et al., 2012; Linderup et al., 2014). One study, conducted by Shirota et al. in 2010, reported higher values compared to the present study, included in the range 1.9 - 5.2 cm³. The difference PEV-IV (mean value -0.166 ± 0.39 cm³ for the entire study group) is almost insignificant when taking into account that the mean IV value for the entire study group was 1.615 ± 0.47 cm³ (SD).

Greater PEV-IV differences were observed in BCLP patients (m= -0.500 cm³) compared to UCLP patients (m= -0.106 cm³). The examiners’ experience supports these results, by finding that setting precise limits of the
alveolar defect is more complicated in patients with BCLP, due to the bigger bone defects involving more periodontal dental units, as well as due to the position and orientation of the premaxilla segment. These issues could influence preoperative volumetric assessment results.

**Fig. 5.12** (D) Patient G.M.M., 11 years old, with complete BCLP; introducing the bone graft into the alveolar left defect (green arrow).

Also, the existing connection between alveolar bone defect and the palatal defect in some patients, determined the surgeon's decision to introduce a greater amount of bone grafting, exceeding the limits of the alveolar defect. Nonetheless, digital volumetric measurements were made strictly to the alveolar defect, not including the palatal defect. It is considered that this factor influenced the differences observed between PEV and IV.

**5.5 CONCLUSIONS**

Three-dimensional imaging methods represent a qualitative leap in the radiological examination of the neck and head region, and they constitute essential
imaging techniques during the surgical treatment of CLP patients.

The study reveals that CBCT examination and 3D analysis using Romexis software (Planmeca, Helsinki, Finland), represents an appropriate and reproducible method for the volumetric assessment of bone defect in CLP patients. Establishing the correct and accurate 3D limits of the alveolar defect constitutes an essential step to achieve optimal volumetric results.

The mean volumetric value of the alveolar defect (PEV) in UCLP patients was $1.367 \pm 0.22 \text{cm}^3$, and $1.900 \pm 0.02 \text{cm}^3$ for BCLP patients, with a mean value of $1.449 \pm 0.28 \text{cm}^3$ for the entire study group. The average volume of the harvested bone (IV), used for alveolar reconstruction was $1.473 \pm 0.23 \text{cm}^3$ for UCLP patients and $2.400 \pm 0.85 \text{cm}^3$ for BCLP patients, with a mean of $1.615 \pm 0.47 \text{cm}^3$ for the entire study group.

Establishing a protocol for the estimative volumetric evaluation of the alveolar bone defect in CLP, provides the surgeon with valuable information about the required amount of cancellous bone to be harvested, the choice of the donor region and effective planning of the surgery, bringing benefits for the secondary alveolar bone grafting procedure.
CHAPTER 6
COMPARATIVE VOLUMETRIC EVALUATION OF THE ALVEOLAR BONE DEFECT AMONG CLP PATIENTS, USING TWO VERSIONS OF ROMEXIS SOFTWARE PROGRAM

6.1 INTRODUCTION
When planning a surgical intervention for alveolar bone grafting of the alveolar cleft, 3D imaging examination offers essential information regarding the size and extension of the bone defect, and the position of the teeth that are not yet erupted in the region of interest (Oberoi et al., 2010; Shirota et al., 2010). These information contribute to diminishing the length of the surgical intervention, but also to reduce costs and morbidity risks.

Specialized software programs used for the 3D analysis of CBCT scans, represent helpful tools for the physicians involved in CLP management. Currently, a series of specialized programs are available for processing DICOM files, generated by CBCT examinations. The aim of the present study was to achieve a comparative evaluation of two distinct versions of the Romexis software (Planmeca, Helsinki, Finlansa), which utilize two different methods for volumetric measurements of the bone defect.

6.2 MATERIAL AND METHODS

6.2.1 Selection of patients
Selection lead to a study group of 25 CLP patients presenting an alveolar cleft. The gender distribution of the participating subjects was 6 female patients and 19
male patients, with an approximate ratio F / M = 1/3. Patients were included within the age range 5-22 years, and the mean age was 9.24 ± 4.2 years old (SD).

6.2.2 CBCT volumetric evaluation of the alveolar bone defect

CBCT scans were analyzed using two versions of the software program Romexis (Planmeca, Helsinki, Finland) - 3.6.0.R and 4.0.0.R. Romexis 3.6.0.R enables volumetric measurements through a semi-automatic method, by drawing an ellipsoid in order to cover all the edges of the alveolar defect. The more recent version of the software, Romexis 4.0.0.R, allows digital volumetric measurements by using a manual method, drawing point by point the region of interest, based on the sections visualized in one of the three planes (coronal, sagittal, or axial).

![Volumetric measurements with Romexis 4.0.0.R](image)

Fig. 6.6 (D) Volumetric measurements (blue) with Romexis 4.0.0.R, illustrated on the volume rendering of a patient presenting left UCLP.

CBCT scans of the participating patients were analyzed by a trained observer (dentist, Radiology PhD student). After 10 days, all measurements were repeated
with every version of the software program, among 10 randomly selected patients.

6.2.3 Volumetric evaluation of simulated bone defects

By taking into consideration that volumetric measurements performed in CLP patients can not offer real values (or as close to reality) of the alveolar bone defect, the study team resorted to the reproduction of measurements on simulated bone defects. Molar teeth were extracted from four sheep hemimandibles, thus simulating bone defects by using postextractional alveolar cavities. The hemimandibles were examined with a CBCT imaging device (Promax 3D Mid, Planmeca Oy, Finland) and volumetric measurements of the 10 bone defects were made with both versions of the Romexis program (3.6.0.R and 4.0.0.R), following the exact same conditions as used among CLP patients. The measurements were repeated on all simulated bone defects after 10 days from the first session of measurements.

**Fig.6.9** D Volumetric assessment (red) using Romexis 3.6.0.R, on a simulated bone defect; 3D volume rendering.

**Fig.6.12** B Measuring cylinder used to evaluate the volume of the silicone impressions.
After isolating the alveolar walls with vaseline, each cavity was filled with the silicone material under pressure, and after 24 hours, the mass was removed in the form of rubber, resistant and elastic. The volume of silicon impression obtained was measured using a graduated cylinder, ISO 4788 standard (error ± 0.25 ml), filled with a known quantity of distilled water. After being submerged in water, the volume of water displaced for each impression was noted, this value representing the volume of the simulated defect.

**6.3 RESULTS**

In the study group, 7 patients (28%) presented BCLP, and 18 patients (72%) presented UCLP. Out of the UCLP patients, in 10 patients (56%) the cleft was localized in the left side, and in 8 patients (44%) on the right side.

The absence of the lateral maxillary incisor was observed at 14 patients (56%). Whenever the lateral maxillary incisor was present, there were observed isolated anomalies of position or/and form.

**6.3.1 Volumetric measurements among CLP patients**

From the volumetric assessment of the alveolar bone defect with Romexis 3.6.0.R, the mean values of the alveolar cleft volume were obtained: 1.460±0.40cm³ (range 0.784-2.423cm³) for the entire study group; 1.274±0.26cm³ (range 0.784-1.747cm³) for UCLP patients, and 1.937±0.30cm³ (range 1.676-2.423cm³) for BCLP patients.
After volumetric measurements made with Romexis 4.0.0.R the mean value of the alveolar bone defect for the entire study group was 1.508±0.43cm$^3$ (range 0.856-2.658cm$^3$); 1.367±0.35cm$^3$ (range 0.856-1.909cm$^3$) in UCLP patients; 1.871±0.42cm$^3$ (range 1.398-2.658cm$^3$) in BCLP patients.

Pearson coefficient values (0.747; 0.954) and ICC values (0.859; 0.969) showed a strong degree of intra-examiner concordance for each version of Romexis (3.6.0.R and 4.0.0.R). It was also shown a strong concordance and lack of significant differences between the measurements made with the two distinct versions of the software (Pearson=0.735; ICC=0.848). Dispersion diagrams and Bland-Altman charts confirmed these results.

Statistical analysis (Spearman test) of the relationship between the volumetric measurement results and a series of variables (age, sex, CLP type) showed a positive correlation statistically significant only between the variable CLP type and volumetric measurement results obtained with both Romexis 3.6.0.R (p = 0.000), and the version 4.0.0.R (p = 0.012).

### 6.3.2 Volumetric measurements on simulated bone defects

After volumetric measurements of simulated bone defects, done with Romexis 3.6.0.R, the mean value of the volume of the bone defects was 1.449±0.92cm$^3$ (range 0.337-2.711cm$^3$); and with Romexis 4.0.0.R version, the mean value was 1.766±0.98cm$^3$ (range 0.497-3.135cm$^3$).
After the assessment of the volume of silicone impressions, the mean volumetric value was 2.08±1.13cm$^3$ (SD), range 0.500-3.600cm$^3$.

Pearson coefficient values (0.990-0.998) and ICC values (0.957-0.998) revealed an excellent agreement for measurements made with both versions of Romexis program, and also for the repeated measurements made by using the same version of the software program.

### 6.3.3 Comparative evaluation between Romexis 3.6.0.R and Romexis 4.0.0.R

Comparative evaluation between volumetric values obtained with the two versions of the software program, showed that the mean value of differences Romexis 3.6.0.R - Romexis 4.0.0.R was -0.05±0.31cm$^3$ (SD) (range -0.847 - 0.396cm$^3$) for the entire study group; 0.093±0.32cm$^3$ (SD) (range -0.847 – 0.288cm$^3$) for UCLP patients; 0.07±0.26cm$^3$ (SD) (range -0.023 – 0.396cm$^3$) for BCLP patients.

Comparative evaluation of volumetric values of the simulated bone defects, measured with both versions of the software program, showed that differences Romexis 3.6.0.R - Romexis 4.0.0.R were included in the range -0.141 - -0.562cm$^3$, with the mean value of -0.317±0.14cm$^3$ (DS).

In both study groups, measurements made with the manual method (Romexis 4.0.0.R) showed higher volumetric values than the results achieved with the semi-automatic method (Romexis 3.6.0.R) (52% of cases in CLP patients, 100% of the simulated bone defects).
Comparative evaluation between the volumetric values of the simulated bone defects obtained with both versions of the Romexis program, and the volumetric values of the silicone impressions, highlighted differences between Romexis 3.6.0.R-impressions with the mean value of -0.631±0.28cm³ (DS) (range -0.986 – - 0.144cm³) and differences between Romexis 4.0.0.R and impressions’ volume showing the mean value of -0.314±0.24cm³ (DS) (range -0.650 - -0.003cm³).

6.4 DISCUSSION

The study group was bigger than the one in the previous study (Chapter 5), as the only inclusion criteria was the presence of the alveolar defect, which qualifies any CLP patient to undergo alveolary bone grafting (Vander Kolk, 2000). The absence of the lateral incisor was observed in 14 patients (56% of the study group), and these results are consistent with data reported by previous studies (Ranta, 1986; Lourenço Ribeiro et al., 2003; Răducanu et al., 2015).

The results indicate minimal differences of reliability, reproducibility (intra-observer concordance) and precision (SD, SE) between the two methods used to perform the digital measurements of the estimative volume of the alveolar defect. However, the fact that results obtained with the semi-automatic method presented a greater difference relative to the control values used in the simulated bone defects group (volume of silicone impressions) compared to the manual method, leads to the conclusion that there could be a systematic error associated with the semi-automatic method.
6.5 CONCLUSIONS

The study reveals that the volumetric assessment of bone defects based on the CBCT scans, using both versions of the software program (Romexis, Planmeca, Finland) consists in a reproducible and accurate method. After performing the three-dimensional imaging analysis with the semi-automatic method (Romexis 3.6.0.R) and the manual method (Romexis 4.0.0.R), the mean volume of the alveolar defect was 1.274±0.26cm³ (SD) and, respectively, 1.367±0.35cm³ (SD) in UCLP patients, and 1.937±0.30cm³ (SD) and, respectively, 1.871±0.42cm³ (SD) in BCLP patients. The mean estimative volume of the alveolar defect for the entire study group was 1.460±0.40cm³ (DS) for the semi-automated method (Romexis 3.6.0.R), and 1.507±0.43cm³ (DS) for the manual method (Romexis 4.0.0.R).

Statistical analysis showed that the volumetric results obtained by the two versions of the software program have a strong positive correlation, and between them there is any significant difference. However, the volumetric assessment of simulated bone defects in sheep hemimandibles showed that the results measured by the manual method (Romexis 4.0.0.R) are closer to the control values (volume of silicon impressions) compared to the results obtained using the semi-automatic method (Romexis 3.6.0.R).
CHAPTER 7
THE USE OF CBCT IN THE POSTOPERATIVE QUALITATIVE EVALUATION OF SECONDARY ALVEOLAR BONE GRAFTING RESULTS AMONG CLP PATIENTS

8.1 INTRODUCTION

The results of the secondary alveolar bone grafting in CLP patients were evaluated over time by a series of different methods. Studies conducted using 3D imaging have reported higher rates of resorption compared to those assessed on 2D radiographs (Tai et al., 2000; Hamada et al., 2005; Feichtinger et al., 2006; Feichtinger et al., 2008; Oberoi et al., 2009). The present study aimed to evaluate the quality of the alveolar bone after a certain period since the secondary alveolar bone grafting, using preoperative and postoperative CBCT scans of CLP patients.

7.2 MATERIAL AND METHODS

7.2.1 Selection of patients

This study was based on the collaboration between the Radiology Department, Faculty of Dental Medicine, "Grigore T. Popa" University of Medicine and Pharmacy, a private imaging center in Iasi, and the Department of Pediatric Surgery, "Saint Mary" Emergency Hospital for Children in Iaşi.

It was intended to involve in the study group all subjects who participated in the previous study (Chapter 5), in order to obtain a uniform group of CLP patients and to avoid any errors or uncontrollable variables. Out of the 13 patients involved in the previous study, only 8
presented for CBCT re-examination, after a period of 5-5 months since the secondary alveolar bone grafting. The gender distribution of the participating subjects was 75% male and 25% female. Patients were within the age range of 5-13 years, mean age 3.02 ± 8.37 years (SD).

7.2.2 CBCT examination
All patients underwent postoperative CBCT examination (Promax 3D Mid, Planmeca Oy, Finlanda), following the same protocol as for the preoperative CBCT examinations.

7.2.3 Evaluation of the postoperative CBCT examinations
After reorienting all CBCT scans according to the reference plans, after achieving a panoramic reconstruction and selecting the region of interest, establishing the section parameters (1 mm thickness, 1 mm interval), 2D densiometric measurements were performed for each axial section.

The limits, set in all three plans, were:
- superior – nasal floor, taking into consideration the position of the anterior nasal spine –ANS;
- inferior – enamel-cement junction of the adjacent teeth to the cleft;
- medial – midline;
- lateral – lateral surface of the adjacent tooth;
- antero-posterior – following the outline of the maxillary alveolar arch.

All obtained values were automatically reported in Hounsfield units (HU). The mean value was calculated for all sections, and then compared to the mean value
obtained from the same patient in the analysis of the preoperative CBCT scan.

7.2.4 Evaluation of the preoperative CBCT examinations
All the steps described in the above section were followed, in order to compare values in HU, generated by CBCT examination.

7.2.5 Repetition of the densimetric measurements
The reproducibility of the densimetric measurements was assessed by repeating all measurements by the same observer, after a period of 7 days, by randomly selecting half of the CLP patients included in the study group.

7.3 RESULTS

7.3.1 Reproductibility of the evaluation method
ICC values (0.924-0.995), obtained by comparing the density values (HU) of each section of the same patient scans, based on preoperative and postoperative CBCT examinations, have indicated an excellent agreement, stating the fidelity of the evaluation method used in this study.

7.3.2 Assessment of the relation between results and some variables
The Spearman correlation test (95% confidence interval) did not reveal any statistically significant relationship between the evaluation densimetric results and other variables: age, sex, PEV, and IV.

7.3.3 Densimetric evaluation of alveolar bone grafting
The mean value for each axial section was calculated in each patient’s preoperative CBCT examination (Vpre) and postoperative CBCT examination (Vpost). Subsequently, in order to analyze the difference between preoperative and postoperative mean values, it was calculated: the absolute difference value (Da = Vpost-Vpre) (HU) and the relative difference value (Dr = Vpost / Vpre x 100 -100) (%). The mean Dr value showed an increase in the average density per section 93.73% on postoperative CBCT scans compared to preoperative examinations, for the entire study group.

![Figure 7.5](image)

**Fig. 7.5** Volume rendering, patient presenting right UCLP, after performing densimetric measurements (red). The comparison of the preoperative scan (A) to the postoperative scan (B), shows the presence of a thin bone bridge.

### 7.4 DISCUSSION

The study group, consisting of 8 CLP (9 alveolar bone defects) was characterized by a small size, which leads to a cautious interpretation of the statistical results. All clinical cases showed no signs of postoperative complications, as the presence of infection or oro-nasal fistula. The time period chosen to perform the postoperative CBCT examination allowed to distinguish imaging changes of the bone, and corresponds to the
time period reported by previous studies (Zhang et al., 2012; Seiki et al., 2012; Yoshida et al., 2013; Suomalainen et al., 2014).

Fig. 7.8 B Axial sections of a patient presenting right UCLP, after performing densimetric measurements (red) using Romexis 3.6.0.R software (Planmeca, Helsinki, Finland); postoperative CBCT examination.

When evaluating bone density, the Grey Values (GV) obtained from classic CT examination are quantified in Hounsfield units, according to the scale introduced by Sir Godfrey Hounsfield, in 1972. Although Hounsfield units are always used to express the relative density when the patient is being investigated by CT classic, the use of gray values obtained by CBCT scans and translated in Hounsfield units is still ambiguous.

Although the arithmetic mean value of the results seems satisfactory, indicating an average increase of approximately 93.73% of the postoperative density as compared to the preoperative scans, the analysis of individual measurements show major differences between CLP patients. These data indicate the need to assess the factors that influence bone graft integration into the alveolar defect, in order to improve results. It
should be noted that the evaluation results of the study group are not definitive. It is suggested to follow the postoperative development through CBCT examination after a longer period since the surgical intervention. This requires, however, a close collaboration with the patient and the parents, who must be present to the postoperative control, based on an appropriate protocol.

7.5 CONCLUSIONS

The study reveals that the proposed method for achieving densitometry measurements using CBCT and Romexis 3.6.0.R software (Planmeca, Finland) is accurate and reproducible (ICC≥0.924).

Three-dimensional imaging analysis based on CBCT scans at 4-5 months after the alveolar bone grafting, revealed that the density of the region of interest has grown on average by 93.73% per section, for the entire study group.

Postoperative outcome of alveolar bone graft reconstruction was not influenced by age, gender, CLP type, or by the preoperative estimated volume of the alveolar defect (p>0.05).

Using Hounsfield units generated by CBCT examination (Promax 3D Mid, Planmeca Oy, Finland), relatively comparing preoperative and postoperative scans, is beneficial in evaluating the results of secondary alveolar bone grafting in CLP patients.
CHAPTER 8
EVALUAREA CUNOŞTINŢELOR DESPRE EXAMINAREA IMAGISTICĂ LA MEDICII REZIDENŢI IMPLICAŢI ÎN TRATAMENTUL PACIENTILOR CU DLMP

8.1 INTRODUCTION
A majority of specialized physicians, involved in the multidisciplinary management of CLP patients, indicate multiple imaging modalities. During the last decades, three-dimensional imaging modalities have continually contributed to diagnostic purposes and treatment planning of various head and neck pathologies, providing non-distorted an non-overlapping visualisation of the anatomy, at high resolution (Damman et al., 2014). CBCT offers a lower dosage of radiation exposure compared to the classic CT, and lower costs (Wortche et al., 2006; Silva et al., 2008; Ludlow şi Ivanovic, 2008). The availability of new technology requires physicians to be aware of its applications and potential, but also benefits and possible risks, impacting the quality of medical care they offer to their patients.

8.2 MATERIAL AND METHODS
The study group consisted of 104 medical residents in 4 specialties: Pediatric surgery, Plastic surgery and reconstructive microsurgery, Oral and maxillofacial surgery, Orthodontics and dento-facial orthopedics. The questionnaire application comprised three stages (Stone, 1993; Krosnick and Pressner, 2010): pre-testing (20 medical residents from a distinct medical specialty), testing (55 respondents) and re-testing (33 respondents).
8.3 RESULTS

8.3.1 Validation of the questionnaire

The results of the statistical analysis (McNemar test, Spearman test, and Marginal homogeneity test) have confirmed test-retest reliability, attesting to the reproducibility and validity of the questionnaire used.

8.3.2 First section of the questionnaire

Fifty-five medical residents agreed to participate in the present study, achieving a response rate of 52.88%. The participants’ age varied from 21 to 41 years old, with a mean value 28.85±3.21 years (DS). The distribution by sex variable reveals a balanced male / female report, of approximately 8/10.

8.3.3 Second section of the questionnaire

Asked to choose the imaging methods they deemed as necessary to be indicated during surgery or orthodontic treatment of CLP (I4), the majority of the participants chose CT, and CBCT OPT.

When questioned about the imaging method which they consider to be the most useful during orthodontic or surgical treatment (I5), 58.2% of the subjects chose CT and CBCT chose 29.1%.

During clinical practice with patients DLMP (I6), 63.6% of the resident doctors indicate 2-3 simultaneous imaging methods - of which at least one is a 3D method (80% of cases). In the 2D methods, they found no statistically significant differences between subjectives’ preferences for digital and conventional methods (t test, 95% confidence interval). Most respondents (74.5%) stated that they indicate patients CT examination. A
significant smaller fraction of the participants (32.7%) stated that they indicate CBCT examination.

Within the study group, the most important factors motivating the resident doctors choosing to indicate a particular imaging method in current medical practice with patients DLMP (I7) are the quality (72.7%) and the quantity (47.3%) of information provided by the imaging method.

The main source of information on the use of 3D imaging methods (I8) was electronic literature (52.7%).

8.3.4 Third section of the questionnaire
A significant percentage of medical resident considered (I9 and I12) that they did not interpret correctly CT (78.2%) and CBCT examinations (83.6%). More than half of respondents believe that their level of knowledge on the interpretation of the results obtained by a 3D imaging method (I10 and I13) is very low / low (54.6% for CT, and 74.5% for CBCT).

Tabel 8.VIII Level of knowledge on the interpretation of the results – mean values on a 5 level scale

<table>
<thead>
<tr>
<th></th>
<th>CT</th>
<th>CBCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valid no.</td>
<td>55</td>
<td>55</td>
</tr>
<tr>
<td><strong>Mean</strong></td>
<td>2.29*</td>
<td>1.82</td>
</tr>
<tr>
<td>Minimal value</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>(Very low)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximal value</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>(Very high)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DS.</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

*significantly higher than the value obtained for CBCT (95% confidence interval)
A significant number of respondents consider that the level of training offered by the residency program on the interpretation of CT and CBCT scans is very low (49.1% for CT, and 60.0% for CBCT).

8.4 DISCUSSION

Because there is no mention of a validated similar questionnaire in the specialty literature in Romania, the instrument used during the present study was designed at the Radiology Department, Faculty of Dental Medicine, „Grigore T. Popa” University of Medicine and Pharmacy, in Iasi.

It was observed the physicians’ preference to indicate CT scan (74.5%) more frequently than CBCT examination (32.7%). The reason for this preference can be explained by the results from the third section of the questionnaire, indicating precarious knowledge on both 3D imaging methods; however, a lower level was observed for CBCT compared with CT. Another possible explanation may consist in a wider availability of CT equipment compared with CBCT.

CBCT exploration costs are not compensated by the health insurance program in Romania, and this may represent another factor that influences the physicians’ decision to indicate a certain imaging method, given that most CLP patients come from vulnerable families. However, in terms of radiation protection, professional organizations (Romanian Society of Radiology and Medical Imaging, Romanian Association of Dental and Maxillofacial Radiology, and the Romanian Society of Otolaryngology) considers that to indicate a CBCT examination instead of classic CT scans whenever it is
possible, represents a strategy to help reduce radiation exposure for patients with CLP or other pathologies the oro-maxillofacial region.

The relatively small size of the study group and the provenience of the participating medical residents from only one educational institution, constitute arguments that lead us to suggest that the findings may be representative only locally. Assessment at national level, involving several universities and the formation of a large study group, may constitute the subject of further research.

The assessment of the use of 3D imaging methods in clinical practice in Romania had not been achieved out to date. The research literature revealed no previous similar studies, preventing us from comparing our results with other similar studies. The questions included in the questionnaire led to a specific assessment of the use of 3D imaging methods among CLP patients with DLMP imaging investigations, but also allowed the general evaluation of the use, interpretation and knowledge of 3D imaging in all pathologies in the oro-maxillo-facial territory. The survey also highlighted the need to adapt the present residency program to the novelties and innovations in imaging, by assessing the medical residents’ perception about the training and preparation they receive in this field.

8.5 CONCLUSIONS

Statistical analysis demonstrated the validation and the reproducibility of the questionnaire used in this study.
The results indicate that the medical residents involved in the complex CLP treatment recognize the necessity to use 3D imaging methods, emphasizing the quality and the quantity of information these methods bring to their medical practice.

The respondents’ self-evaluation highlighted a low level of knowledge regarding the correct interpretation of CT and CBCT scans. The residents’ perceptions on the quality of their training on the use of 3D imaging, as well as on their knowledge in this field, indicate the need to improve their training, by including the application and interpretation of this new imaging method (CBCT).
CHAPTER 9
GENERAL CONCLUSIONS

The doctoral thesis represents a clinical and imaging research, which analyzes the importance and contributions of CBCT examination during surgical treatment of CLP patients, and also evaluates imaging knowledge of physicians involved in this field. During the doctoral research, there were conducted four separate studies:

- A prospective study that investigated the contribution of CBCT examinations and of the volumetric analysis of the alveolar bone defect, for the benefit of the surgeons involved in the secondary alveolar bone grafting in CLP patients.
- A retrospective study, which included CLP patients selected from the database of the Department of Radiology and a private imaging center in Iasi, to assess the volumetric analysis of bone defects in these patients, using two distinct versions of the Romesi software (Planmeca, Finland).
- A prospective study, including patients who required postoperative examination control at a certain interval after the secondary alveolar bone grafting, in order to assess the results of the surgical intervention.
- A study realized by designing and applying a questionnaire to medical residents involved in the complex treatment of CLP patients, in order to assess their perceptions and knowledge about 3D imaging methods (CT and CBCT) and the importance of their use.
2. Results of the conducted studies attest that 3D imaging methods (CBCT) bring considerable contributions for the surgical treatment of CLP patients, by allowing the complete and complex examination for these patients.

3. The volumetric analysis of the alveolar bone defect, based on CBCT scans, constitutes an appropriate method for estimating the quantity of bone to be harvested for the reconstruction of the alveolar ridge with autogenous bone graft.

4. Implementing a multidisciplinary collaboration and establishing an appropriate protocol for volumetric assessment of the alveolar bone defect, contribute to a reduced time spent for alveolar bone grafting, and provides the surgeon with valuable information about the required amount of bone to be harvested, choosing donor region and decrease the risk of morbidity in this region.

5. Volumetric evaluation of bone defects based on CBCT scans and the specialized Romexis program, represent an accurate and reproducible modality when performed as a semi-automatic method, and when carried out manually, relying on experience and knowledge.

6. Results of secondary alveolar bone grafting in CLP patients can be assessed qualitatively by performing comparative measurements, based on preoperative and postoperative CBCT examination.

7. The relative use of Housnfield units, generated by CBCT scans, is beneficial for assessing the results of alveolar bone grafting.

8. Medical residents involved in the complex treatment of DLMP, recognize the necessity for 3D imaging
methods, focusing on quality and quantity of information brought into medical practice.

9. Medical residents evaluation of themselves, indicates a low level of knowledge of CT and CBCT.

10. The perception of medical residents on their residency training program on 3D imaging, indicates the need to improve their teaching and practical training.
CHAPTER 10
FUTURE PERSPECTIVES OF THE DOCTORAL STUDY

The doctoral research may be furtherly developed by following a series of goals:

1. The main perspective consists in the introduction of orthodontics in the interdisciplinary management of CLP patients that has been realized out to date, in order to improve the management of CLP patients.

2. Another objective is to evaluate, for the first time in Romania, the role of growth factors and of platelet rich fibrin (PRF) membranes on the integration of autologous bone graft in the alveolar cleft defect, and also their combined role.

3. Opening new potential research directions, by providing a significant group of CLP patients DLMP patients who have followed a uniform treatment (surgery and orthodontics) and who have been examined using the same modern imaging methods.

4. Establishing a uniform protocol for CLP patients, with a multidisciplinary approach, and publishing a guide for medical residents involved in the CLP management.

5. Collaboration with other research university centers in the country and beyond, in order to achieve all future perspectives and goals.
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