Assessment of alveolar defect volume in unilateral cleft lip and palate patients using a free software program

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ABSTRACT

The purpose of this study was to assess the alveolar defect volume in unilateral cleft lip and palate (UCLP) subjects using computed tomography (CT) and a free software program to evaluate the intra- and inter-rater measurements, and to compare the cleft volume between age and affected side. The sample of this retrospective study consisted of 20 UCLP individuals, 12 boys and 8 girls, mean age 10.3 ± 2.4 years at the beginning of orthodontic treatment. All subjects required alveolar bone grafting. CT scans of the cleft area were obtained prior to secondary bone grafting, and were analyzed using Image J. software program. The cleft volume was calculated based on axial cross-sectional CT images by two raters (orthodontist and radiologist) and by the same rater (orthodontist) at two different moments. Linear mixed model, Bland-Altman, Pearson's and intraclass correlation coefficient (ICC) were used. The mean cleft volume was $7.53 ± 1.55 \text{ mm}^3$. The intra- and inter-rater measurements were reproducible (ICC = 0.976 and 0.963, respectively) with no significant difference between them. There were no statistically significant differences in the cleft volume related to age or cleft location. The assessment of cleft volume in UCLP using CT images and a free software program was a reproducible method. There was no significant relation between alveolar defect volume and age or cleft location.

1. INTRODUCTION

Secondary bone grafting is considered the gold standard for repairing the cleft region [1]. It is indicated for most patients with an alveolar cleft, the best stage for this procedure is in the mixed dentition when the canine adjacent to the cleft has completed half to three quarters of its root formation [2]. Its major benefit is to restore alveolar integrity to induce spontaneous migration of permanent teeth adjacent to the cleft in the newly formed bone [3,4]. The outcome of the surgery is considered satisfactory when sufficient volume of normally remodeled bone tissue is obtained [5]. Secondary bone grafting enhances the dental alveolus for eruption and periodontal support of the teeth adjacent to the cleft, usually the canine and the lateral incisor [2,6,7]. This allows, through orthodontic treatment, the closing of the residual space, and in many cases it does not require rehabilitation with prosthesis or implants. Furthermore, the alveolar bone graft bridges the cleft defect with bone, providing an alar base support and allowing closure of the communication between the oral and nasal cavities [5,8,9].

Fresh autogenous bone is the ideal bone graft material because it supplies living immunocompatible bone cells essential to osteogenesis [10,11]. For optimum osteoconductive, osteoinductive and osteogenic properties, autogenous cancellous bone from the ilium is preferred [12] due to the easy access and the large amount of bone tissue that can be obtained from this area [11,13]. However, even though the iliac crest can produce an abundant amount of bone tissue for grafting [14], it is important to obtain an accurate estimation of the alveolar cleft volume and its architecture to determine the quantity of bone to be collected prior to the surgery and thus, to avoid inadequate bone harvesting (reduced or excessive) as well as to reduce the postoperative morbidity of the donor

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region [10]. Another material, such as allogeneic bone, can present an advantage in terms of reduced morbidity, and can be used during alveolar bone grafting, but it is not as beneficial as autogenous bone [11,15]. Favorable results using bone morphogenetic protein 2 (BMP-2) for reconstruction of the alveolar cleft have been reported in the literature, but more studies are necessary to assess the bone quality in the long term [16].

Loss of the bone graft, reopening of the oronasal fistula, or both can happen, although secondary bone graft failures are considered uncommon [17]. Besides the ilium, the literature has reported high rates of success with other donor sources as tibia, mandibular symphysis and calvarial bone [17,18].

Progress related to Computed Tomography (CT) has contributed to the virtual representation of craniofacial anatomy and provides visualization of bone defects and measurements of dentoalveolar areas [15]. Although conventional X-rays allow 2-dimensional (2D) assessment, the inability to assess the volume, buccolingual morphology and architecture of the cleft are the main disadvantages inherent to this method [19]. The use of CT images enables the creation of three-dimensional (3D) virtual models of anatomical structures. These images allow better accuracy as well as segmentation of structures for 3D analysis [20,21]. Therefore, the estimation of the bone amount required for grafting in the alveolar cleft area can be predicted by using surgical simulation software programs based on 3D CT images [10]. The CT images are stored by using *Digital Imaging and Communications in Medicine* (DICOM) format, and there is a wide range of software packages and applications available, even freeware, dedicated to managing and analyzing the DICOM images, working on them, and exporting sections of images in other formats [22-24], therefore those images can be used for various measurements [24,25].

The purpose of this study was to determine the bone defect volume in a group of patients with unilateral complete cleft lip and palate (UCLP), prior to secondary bone grafting, using CT images and a free software program, to analyze the reproducibility of intra- and interraters measurements and to compare the cleft volume between age and the affected side.

2. MATERIALS AND METHODS

2.1. Sample Characteristics

The sample of this retrospective study using multi-slice spiral CT scans consisted of twenty patients with UCLP seeking care in the Cleft Lip and Palate Rehabilitation Center (CERLAP) at Pontifical Catholic University of Rio Grande do Sul (PUCRS). The patients included 12 boys and 8 girls, with no previous orthodontic and or-

thopedic treatment. The mean age at the beginning of the treatment was 10.3 years (SD = 2.49 years). The cleft location was on the right side in 12 patients and 8 showed left-sided clefts (**Table 1**). Patients with congenital malformations, syndromes, periodontal disease or those aged 15 years or older were excluded from the study. An informed consent for research, approved by the PUCRS Scientific Research Ethics Committee, was obtained (08/04364).

2.2. CT Data Acquisition and Measurements

Selected acquisition parameters in the command console of the spiral CT Elscint (Elscint Ltd., Haifa, Israel) were the following: gantry zero degree with laser-guide coinciding with the Frankfurt plane of the patients, 120 kVp tube voltage and 150 mA tube current, 14 cm field-of-view (FOV), 512×512 of matrix. CT image protocol consisted of axial cross-sectional slices of the region of interest (from the nasal cavity to the occlusal plane) with 0.5 mm slice thickness. The DICOM CT images were assessed and the alveolar cleft volumes were measured using the Image J. software program (version 1.38, available at http://rsbweb.nih.gov/ij/).

The alveolar bone defect was free-handedly traced on each of the axial cross-sectional images. The first slice that allowed the visualization of the alveolar margin surrounding the cleft was considered the lower limit; this was followed by the delimitation of the alveolar cleft in all slices, until the image of the floor of the nostril (considered the upper limit). The measurement of the bounded area on each slice provided a sequence of individualized measures. The sum of these measures resulted in the total area of the bone defect. The region of interest was then analyzed in accordance to the method proposed by Feichtinger *et al.* [26]. All procedures of delineation and measurement of the cleft area were performed twice by the same examiner (an orthodontist, P.P.), and a minimum interval of thirty days elapsed between measurements to assess the differences between intra-rater (orthodontist 1st and 2nd measurements). A second examiner (a radiologist, M.B.) performed the measure-

Table 1. Patient characteristics.

Characteristics	n = 20
Age (years), mean ± SD (minimum to maximum)	10.30 ± 2.49 (7 to 14)
Gender, no. (%) Male Female	12 (60.0) 8 (40.0)
Cleft location, no. (%) Right Left	12 (60.0) 8 (40.0)
Cleft volume (mm³), mean ± SD (minimum to maximum)	7.53 ± 1.55 (4.77 to 10.20)

ments once and differences between inter-rater (orthodontist and radiologist) were evaluated. The examiners were blinded to perform the measurements.

2.3. Statistical Analysis

Continuous data were described using mean, standard deviation, minimum and maximum values. Categorical data were presented as counts and percentages. To evaluate observer agreement (within and between components) it was initially calculated the Pearson's correlation coefficient. This approach was followed by the intraclass correlation coefficient (ICC) and Bland-Altman's plot with difference bias and 95% limits of agreement. The influence of selected factors (age and affected side) on cleft volume was explored using a linear mixed model considering all three measurements available for each patient. Significance level was set at α = 0.05. Data were analyzed using SPSS version 18.0.

3. RESULTS

The intra- and inter-rater measurements were reproducible (ICC = 0.976 and 0.963, respectively) and comparesons showed a strong association with no significant difference among measurements (**Figure 1**).

The mean volume corresponding to the initial alveolar defect of the cleft in this study was 7.53 ± 1.55 mm³, ranging from 4.77 to 10.20 mm³ (**Table 1**).

Although no statistically significant, the age presented a borderline significance (p = 0.097), and it could be an influent factor in the alveolar cleft volume. There was no statistically significant impact of the cleft side (right or left) on the cleft volume (p = 0.687).

4. DISCUSSION

Secondary bone grafting is an essential step in alveolar deformity reconstruction in cleft lip and palate (CLP) patients [17]. In addition to the benefits recognized in creating bone support for tooth eruption [15,27], secondary bone grafting allows the elimination of oronasal fistulae, improves oral hygiene by separating the dental and nasal cavities, rebuilds the hypoplastic pyriform aperture [17] and the soft tissue of the nasal base support [28], and stabilizes the maxillary arch [29], thus providing a suitable volume of bone to allow dental movement and subsequent residual space closure in the cleft region [30]. The recognition of the initial size of the alveolar defect and the use of reproducible measurement methods are essential factors in studies that evaluate the stability of alveolar grafting [16].

The measurements in this study presented excellent examiner repeatability (**Figure 1**), and the mean volume corresponding to the preoperative alveolar defect was 7.53 ± 1.55 mm³ (**Table 1**). Other studies reported higher

mean volumes of the alveolar defects (11.0 to 38.0 mm³) [10,26,30-32]. However, previous orthopedic procedures were not mentioned in those researches. In the present study, the sample consisted of patients with no previous orthodontic and orthopedic procedures when the CT scans were taken. Therefore, the difference among cleft volume values could be explained by the maxillary expansion and orthopedic protraction performed to correct the sagittal and transverse deficiency [33,34], usually performed before the secondary bone graft [35].

In a study based on radiographs, Aurouze *et al.* [36] reported that there was no correlation between the alveolar cleft size and the success in secondary alveolar grafting. However, van der Meij *et al.* [37] evaluating this topic on CT scans, indicated that there could be a positive correlation (*i.e.*, bigger clefts would be more prone to have alveolar graft resorption due to insufficient vascularization of progenitor cells in the center of the bone graft) [38]. According to Shirota *et al.* [10] it is important to understand the architecture of the alveolar defect in the cleft area and to assess its volume using CT images prior to the surgical procedure to obtain the correct volume necessary for bone grafting. Although CT is still used in situations when 3D information is required, dosimetry studies demonstrated that the absorbed and effective doses of spiral and conventional CT were higher than that using cone beam CT (CBCT) [39-41]. Furthermore, the CBCT technology has other advantages over CT such as lower cost, shorter acquisition time, better resolution, greater detail, being more appropriate for dentistry [42-47]. However, spiral CT was used in this retrospective study because the access to CBCT scanners in the early 2000's (when the cleft patients' data were acquired) was difficult.

For alveolar defect repair, autogenous bone can be harvested from intraoral sites (limited to the amount of bone available), such as the mandibular symphysis, retromolar pad, mandibular ramus, tuberosity and zygomatic buttress, and from extraoral sites, such as the tibia, and iliac crest [48]. Although the iliac crest can provide an abundant bone amount for grafting [14], the preoperative computer simulation and assessment of the 3D alveolar cleft volume using CT images can avoid the inadequate harvest of bone as well as reducing the postoperative morbidity of the donor region [10]. This can prevent some of the possible surgical complications such as excessive blood loss, delayed wound healing, pain and hypoesthesia [49]. The mandibular symphysis, an intraoral donor site with a reduced morbidity, is not a donor area that provides sufficient volume of cancellous bone [48] to fill in all kinds of alveolar cleft defects. Thus, it is essential to assess the cleft dimensions to select the adequate donor site and harvest the needed amount of bone for the alveolar graft [50].
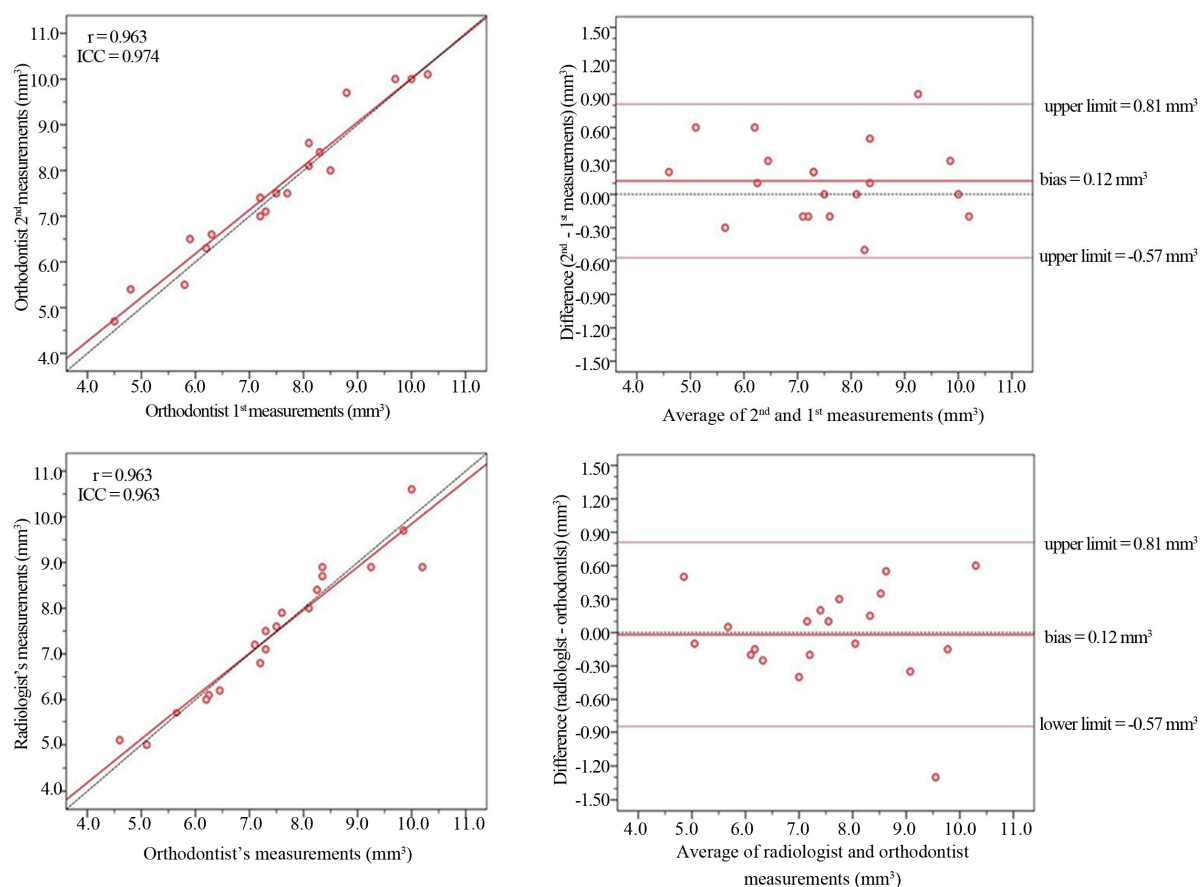
Figure 1. Linear scatter and Bland-Altman plots for the comparison among observers.

Due to the popularization of 3D imaging as a means to assist in dental diagnosis, this study assessed its clinical applicability using a public domain software program. It was possible to delimitate the alveolar bone defect in the cleft region, as well as to obtain its respective measurements in CT slices [51-53]. Considering the lack of specific researches in the literature regarding the applicability of free software programs for the evaluation of bone deformity in cleft patients, this study showed a reproducible method to assess and measure the alveolar cleft volume.

5. CONCLUSIONS

In this study, the assessment as well as measurements in cleft patients using CT images and a free software program was a reproducible method.

There was no significant relation between the alveolar defect volume with age or cleft location in UCLP.

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