Original Article

Evaluation of Long-term Stability of Secondary Alveolar Bone Grafts in Cleft Palate Patients Using Multislice Computed Tomography and Three-Dimensional Printed Models: A Prospective Study

Venkatesh Palankar[1], Atul Sattur[2], Aditi Palankar[3], S. Raja Rajeswari[4], Srinath Thakur[5], Anil Kumar Desai[6]

[1]Department of Orthodontics and Dentofacial Orthopaedics, SDM College of Dental Sciences and Hospital, Dharwad, Karnataka, India, [2]Department of Oral Medicine and Radiology, SDM College of Dental Sciences and Hospital, Dharwad, Karnataka, India, [3]Former Hospital Administrator, SDM College of Dental Sciences and Hospital, Dharwad, Karnataka, India, SRM Institute of Science and Technology, Chennai, Tamil Nadu, India, [5]Department of Periodontics and Implantology, SDM College of Dental Sciences and Hospital, Dharwad, Karnataka, India, [6]Department of Oral and Maxillofacial Surgery, SDM College of Dental Sciences and Hospital, Dharwad, Karnataka, India

Submitted: 27-Mar-2021
Revised: 31-Apr-2021
Accepted: 01-May-2021
Published: 10-Nov-2021

ABSTRACT

Aim: Three-dimensional (3D) printed models are contemporary volumetric bone graft assessment technique for secondary alveolar bone grafting (SABG) in cleft lip and palate (CLP) patients. The study aimed at evaluation of long-term stability of iliac autograft in SABG using multislice computed tomography (CT) and 3D-printed model-based volumetric analysis. **Materials and Methods:** Twenty-eight patients were included in this prospective clinical study. CT image (T1) was taken after orthodontic maxillary expansion, correlating with the presurgical image. Furthermore, 3D-printed model was prepared, and volumetric assessment of graft needed was ascertained with water displacement technique. SABG was carried on with the anterior iliac crest autografting procedure. After 1-year follow-up, postoperative CT analysis (T2) was followed upon. **Results:** The stability of bone graft at the 1-year postoperative was found to be 43.74% with mean bone loss of 56.26% (95% confidence interval; $P < 0.005$). The moderate scale of CLP cases has shown statistically significant bone stability compared to that of severe and mild cases. Furthermore, the 3D-printed model has shown a significant difference to that of T1 CT imaging ($P < 0.005$). **Conclusion:** Within the limitations of the study, it seems appropriate to conclude that 3D-printed models serves as better reference than CT imaging in the context of planning and execution of precise bone grafting in SABG.

KEYWORDS: *Cleft lip palate, computed tomography scan, three dimensional printed model, volumetric analysis*

INTRODUCTION

One of the congenital anomaly affecting orofacial region is cleft lip and palate (CLP) occurring due to incomplete facial prominences fusion in the embryonic development.[1,2] Apart from facial deformity, alveolar bone defect, missing teeth and maxillary deformity can be seen which involves several types of treatment procedures by a specialist right from infancy until adulthood.[3,4] In CLP, a role of orthodontist is mainly concerned with maxillary arch expansion and alignment, thereby correcting crossbite and facilitating the oral surgeon for the placement of secondary alveolar bone graft (SABG).[5,6] In the process of rehabilitation, SABG is crucial in the stabilization of the cleft fragments.[7] It is usually performed at 9–11 years of age when maxillary canine is in one-third to two-third of root formation stage.[8,9] The anterior iliac crest graft is considered gold standard for SABG.[10] Hence, proper understanding regarding the defect morphology of alveolar defect and architecture is essential for diagnosis and treatment planning.[11] Initially, two dimensional (2D) radiographs were the used for diagnosing the cleft defect.[12] However, due to inherent problems such as image enlargement and distortion, superimposition of adjacent structures, there

Access this article online

Quick Response Code:

Website: www.jpbsonline.org

DOI: 10.4103/jpbs.jpbs_265_21

Address for correspondence: Dr. S. Raja Rajeswari, Senior Lecturer, Department of Periodontics, SRM Institute of Science and Technology, Kattankulathur, Tamil Nadu, India
E-mail: rajarajeswari@gmail.com

How to cite this article: Palankar V, Sattur A, Palankar A, Rajeswari SR, Thakur S, Desai AK. Evaluation of long-term stability of secondary alveolar bone grafts in cleft palate patients using multislice computed tomography and three-dimensional printed models: A prospective study. J Pharm Bioall Sci 2021;13:S1496-500.

was change of focus from 2D to three-dimensional (2D to 3D) approach with incorporation of computed tomography (CT) images in diagnosing and treating CLP patients.[13] Various software products are available for volumetric digital analysis, and studies report variation in the degree of accuracy of different software programs.[14] Recently, there has been wide application of 3D printing in the field of medicine for preoperative planning; however, its accuracy is yet to be fully validated.[15,16] Therefore, the aim of our study was to evaluate the long-term stability of the bone graft with an orthodontic-surgical protocol and volumetric assessment of bone grafts in CLP patients using multislice CT scan and 3D-printed models.

Materials and Methods

The ethical clearance for the given study was obtained from SDM Dental College and hospital, Dharwad (IRB. No: 2017/S/ORTH/43), and all the subjects have given written consent. The study comprised nonsyndromic CLP patients in the age group of 8–15 years, requiring alveolar bone grafting. The alveolar bone defect was classified using Bergland scale into mild, moderate, and severe. Exclusion criteria included patients with syndromic CLP; the previous history of SABG and cone-beam computed tomography (CBCT) scans with excessive scattering and motion artifacts; medically compromised patients. All the included patients underwent orthodontic maxillary arch expansion, prior the bone grafting. In most of the cases, SABG was undertaken before permanent canine tooth eruption.

Data acquisition

All the patients underwent CT scan pretreatment (T0), preoperatively (T1), and 1-year postsurgery (T2). Digital Imaging and Communications in Medicine (DICOM) data from the CT image were processed by the imaging software Sidexis (SIRONA, GERMANY) [Figure 1]. The CT images were reconstructed as 3D images and stored as standard triangulated language format (STL). The region of interest with alveolar defect was selected, and STL data were processed in a 3D printer (MEDIAPT3D PRINTER, INDIA). The printing resolution was 300 × 450 dots per inch. The model was formed together with an automatically generated base, which was removed following 3D printing. The 3D-printed models were then presented to two clinicians. Rubber base material was used to fill the defects of the 3D-printed models to simulate alveolar bone grafts. Water-displacement technique was employed to measure the volume of simulated graft [Figure 2].

Autologous bone harvesting from anterior iliac crest and grafting into alveolar crest was executed by a single experienced oral surgeon. A wide-based full thickness flap was elevated to completely cover the graft on the nasal, buccal, and lingual sides according to the technique described by Bergland *et al*. (1986b). Bio-Guide® resorbable bilayer membrane was utilized to cover the graft.

Results

T2 DICOM image analysis exhibited that all the patients have achieved bridging of the grafted tissue with the adjacent bone and showed good maturation, with regular bony architecture. The mean and standard deviation of volume of defect T1 and 3D model were tabulated and statistically analyzed with Mann–Whitney U-test [Table 1], thereby concluding that T1 differs significantly from 3D model. Paired *t*-test between 3D model and T2 [Table 2] signifies statistical difference between both. In our study, the stability of bone graft at the 1-year postoperative was found to be 43.74% with mean bone loss of 56.26% (95% confidence interval; $P < 0.005$). Furthermore, in order to ascertain the influence of defect severity (minor, moderate, and severe) on the long-term success of graft, paired *t*-test was used to test the significant difference between T1 and T2 status wise [Table 3]. The moderate scale of CLP cases has shown statistically significant bone stability compared to that of severe and mild cases. 75% of cases were in canine eruption stage and showed significant bone support.

Table 1: Comparison of preoperative computed tomography image and three-dimensional model

	Mean±SD	Difference	*P*
T1	2.08±0.49	1.20	0.00
3D model	0.88±0.25		

3D: Three dimensional, SD: Standard deviation, T1: Computed tomography image

Table 2: Comparison of preoperative computed tomography image and postoperative computed tomography image

	Mean±SD	Difference	*P*
T1	1.29±0.27	0.41	0.00
T2	0.88±0.25		

SD: Standard deviation, CT: Computed tomography, T1: CT image, T2: CT analysis

Table 3: Comparison of different grades of defect

Grade	T1	T2
Minor	1.10±0.19	0.79±0.22
Moderate	1.29±0.17	1.00±0.25
Severe	1.60±0.22	0.88±0.25
Total	1.29±0.27	0.88±0.25

CT: Computed tomography, T1: CT image, T2: CT analysis

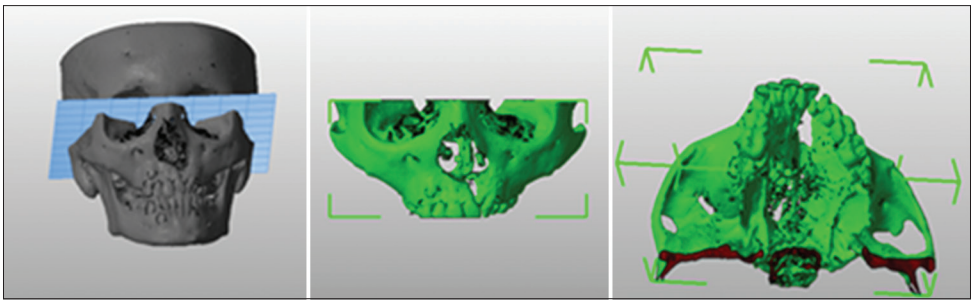

Figure 1: CT image analysis

Figure 2: Three-dimensional model and defect filling with rubber base material

Discussion

Traditionally, 2D methods such as occlusal, periapical, or OPG were used to evaluate the alveolar bone graft needed in CLP cases, with a reportedly higher success rate.[17,18] However, dental literature has been shown that success rate can be overestimated with 2D measurement methodology. A study has compared 2D and 3D measurement of graft metrics and had 21% overestimation and 18% underestimation with traditional radiographs.[12] Moreover, with 2D metrics, it is difficult to determine volumetric measurements.[19] When compared to that of 2D radiographic methods, CT scan images provide following advantages: Volume of the defect being accurately determined; provide 3D image of erupting teeth; assess bone extension with existing maxillary bone.[18]

Establishing the ideal time period for follow-up of SABG is crucial in determining the success rate. The complete graft remodeling and replacement with new bone have been reported between 3 and 12 months.[17] Feichtinger *et al*. conducted 3-year follow-up study, with 95.2% mean bone loss after 1 year in cases with no orthodontic gap closure.[4] While comparing different clinical studies, caution needs to exercised, since different measurement methods and follow-up time may influence the outcome.[20] In view of the reports, a follow-up period of year was selected in the present study as new bone volume estimation after 1 year of bone grafting was found to be more reliable than early estimation because then the new bone showed complete maturation and incorporation.[2] In our study, the stability of bone graft at the 1-year postoperative was found to be 56.26% ($P < 0.005$) with mean bone loss of 43.74%. The moderate scale of CLP cases has shown statistically significant bone stability compared to that of severe and mild cases.

Several software products are available for digital volumetric analysis and manipulation. Threshold setting is one of the software-related factor-influencing results.[11] Chen *et al*. conducted a volumetric analysis of defect of alveolar cleft prior surgery and had found difficulty in determining the boundaries of the cleft defect as well as volumetric measurement in bilateral alveolar cleft.[13] In the present study, CT scans with a slice thickness of 0.6 mm was used for fabrication of physical 3D-printed models which is more accurate than another study where 1.5mm slice thickness was used.[7] 3D models are advantageous as overcome the previously mentioned drawbacks of the software programs; evaluating the irregular nature of cleft defect; to perform simulated surgery.[15]

Rubber base material was used to fill the defects of the 3D-printed models and the volume of each simulated graft was measured by water-displacement technique. The bone wax impressions were later converted to resin models and immersed in water to indirectly determine the volume of the clefts.[18] Linderup, *et al*. 2015 conducted a study on dry skulls, comparing the volumes of simulated bone grafts obtained by water displacement technique with that of CBCT scan derived volumes has confirmed the accuracy and reliability of CBCT for this particular

purpose.[11] In our study, the 3D-printed model accuracy has shown to be have high significant difference compared to that of T1 CT imaging ($P < 0.005$). Thus, our study results emphasize the importance of 3D model technique in volume determination.

Anterior iliac crest is considered as the gold standard for SABG, exhibiting good success rate.[10,20] Our treatment protocol included presurgical orthodontic expansion, followed by harvesting the alveolar bone defect with iliac crest graft with a well-vascularized, tension-free gingival flap. Among the several factors that influence the outcome of alveolar bone grafting, the absence of physiologic stress such as eruption of the cleft-adjacent teeth, implant placement, and orthodontic tooth movement (orthodontic gap closure) were conducive for formation of bony bridge.[4,21,22] In some cases which need orthodontic gap closure, the rate of resorption was lower than in cases which needed replacement of teeth due to severe cleft defect. Abovementioned results were in accordance with another study, with orthodontic gap closure exhibiting lower resorption rate compared to that of gap openings.[4]

Furthermore, in general, surgical success rate has been shown to be improved, when the SABG procedure was timed when two-thirds or three-fourths of the canine root is formed, or before canine eruption.[18] 8–15 years were selected in our study with 75% of cases in canine erupting stage, since an erupting tooth is considered as osteogenic.[23]

The primary limitation of the present study was reduction in the sample size. To begin with 50 cases were planned for but due to the COVID-19 pandemic, of which only 28 cases could be followed up. Within the limitations of the study, 3D model in combination with CT imaging is an accurate method of the volumetric prediction of alveolar bone graft needed for SABG, thereby reducing the surgical mortality.

Conclusion

The present study has confirmed the efficiency of volumetric assessment of graft in CLP using water displacement method with 3D printed model, compared to that of expensive software analysis. The operating surgeon and orthodontist can acquire valuable presurgical information regarding the defect morphology in a predictable way.

Acknowledgment

The study was conducted with the research grant by Rajiv Gandhi University of Health Science, Bangalore, Karnataka, India.

Financial support and sponsorship

This prospective clinical research project (D035) was funded by Rajiv Gandhi University of Health Sciences (RGUHS), Karnataka, India, for the year 2017-18.

Conflicts of interest

There are no conflicts of interest.

References

1. Ercan E, Celikoglu M, Buyuk SK, Sekerci AE. Assessment of the alveolar bone support of patients with unilateral cleft lip and palate: A cone-beam computed tomography study. Angle Orthod 2015;85:1003-8.
2. Liu B, Li BH, Chen SX, Xiao R, Wang YQ. A novel accurate volumetric analysis protocol for evaluating secondary alveolar cleft reconstruction. J Craniomaxillofac Surg 2020;48:632-7.
3. Farronato G, Kairyte L, Giannini L, Galbiati G, Maspero C. How various surgical protocols of the unilateral cleft lip and palate influence the facial growth and possible orthodontic problems? Which is the best timing of lip, palate and alveolus repair? literature review. Stomatologija 2014;16:53-60.
4. Feichtinger M, Mossböck R, Kärcher H. Assessment of bone resorption after secondary alveolar bone grafting using three-dimensional computed tomography: A three-year study. Cleft Palate Craniofac J 2007;44:142-8.
5. Khojasteh A, Kheiri L, Motamedian SR, Nadjmi N. Regenerative medicine in the treatment of alveolar cleft defect: A systematic review of the literature. J Craniomaxillofac Surg 2015;43:1608-13.
6. Kuijpers MA, Chiu YT, Nada RM, Carels CE, Fudalej PS. Three-dimensional imaging methods for quantitative analysis of facial soft tissues and skeletal morphology in patients with orofacial clefts: A systematic review. PLoS One 2014;9:e93442.
7. Moreau JL, Caccamese JF, Coletti DP, Sauk JJ, Fisher JP. Tissue engineering solutions for cleft palates. J Oral Maxillofac Surg 2007;65:2503-11.
8. Toscano D, Baciliero U, Gracco A, Siciliani G. Long-term stability of alveolar bone grafts in cleft palate patients. Am J Orthod Dentofacial Orthop 2012;142:289-99.
9. Seo J, Kim S, Yang IH, Baek SH. Effect of secondary alveolar bone grafting on the maxillary growth: Unilateral versus bilateral cleft lip and palate patients. J Craniofac Surg 2015;26:2128-32.
10. Baqain ZH, Anabtawi M, Karaky AA, Malkawi Z. Morbidity from anterior iliac crest bone harvesting for secondary alveolar bone grafting: An outcome assessment study. J Oral Maxillofac Surg 2009;67:570-5.
11. Linderup BW, Küseler A, Jensen J, Cattaneo PM. A novel semiautomatic technique for volumetric assessment of the alveolar bone defect using cone beam computed tomography. Cleft Palate Craniofac J 2015;52:e47-55.
12. de Rezende Barbosa GL, Wood JS, Pimenta LA, Maria de Almeida S, Tyndall DA. Comparison of different methods to assess alveolar cleft defects in cone beam CT images. Dentomaxillofac Radiol 2016;45:20150332.
13. Chen GC, Sun M, Yin NB, Li HD. A novel method to calculate the volume of alveolar cleft defect before surgery. J Craniofac Surg 2018;29:342-6.
14. Blessmann Weber JB, de Macedo Menezes L, Azeredo F, Lessa Filho LS. Volumetric assessment of alveolar clefts: A literature review. J Oral Pathol Med 2017;46:569-73.
15. Du F, Li B, Yin N, Cao Y, Wang Y. Volumetric analysis

of alveolar bone defect using three-dimensional-printed models versus computer-aided engineering. J Craniofac Surg 2017;28:383-6.

16. Janssen NG, Schreurs R, Bittermann GK, Borstlap WA, Koole R, Meijer GJ, *et al*. A novel semi-automatic segmentation protocol for volumetric assessment of alveolar cleft grafting procedures. J Craniomaxillofac Surg 2017;45:685-9.
17. Feichtinger M, Mossböck R, Kärcher H. Evaluation of bone volume following bone grafting in patients with unilateral clefts of lip, alveolus and palate using a CT-guided three-dimensional navigation system. J Craniomaxillofac Surg 2006;34:144-9.
18. Tai CC, Sutherland IS, McFadden L. Prospective analysis of secondary alveolar bone grafting using computed tomography. J Oral Maxillofac Surg 2000;58:1241-9.
19. Chang CS, Wallace CG, Hsiao YC, Chiu YT, Pai BC, Chen IJ, *et al*. Difference in the surgical outcome of unilateral cleft lip and palate patients with and without pre-alveolar bone graft orthodontic treatment. Sci Rep 2016;6:23597.
20. Feng B, Jiang M, Xu X, Li J. A new method of volumetric assessment of alveolar bone grafting for cleft patients using cone beam computed tomography. Oral Surg Oral Med Oral Pathol Oral Radiol 2017;124:e171-82.
21. Zhou WN, Xu YB, Jiang HB, Wan L, Du YF. Accurate evaluation of cone-beam computed tomography to volumetrically assess bone grafting in alveolar cleft patients. J Craniofac Surg 2015;26:e535-9.
22. Kim KR, Kim S, Baek SH. Change in grafted secondary alveolar bone in patients with UCLP and UCLA. A three-dimensional computed tomography study. Angle Orthod 2008;78:631-40.
23. Wriedt S, Al-Nawas B, Schmidtmann I, Eletr S, Wehrbein H, Moergel M, *et al*. Analyzing the teeth next to the alveolar cleft: Examination and treatment proposal prior to bone grafting based on three-dimensional versus two-dimensional diagnosis-A diagnostic study. J Craniomaxillofac Surg 2017;45:1272-7.