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Increase in Age Is Associated With Worse Outcomes in Alveolar Bone Grafting in Patients With Bilateral Complete Cleft Palate

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Abstract: This prospective study aimed at evaluating the surgical outcomes of alveolar bone grafting (ABG) in subjects with bilateral cleft lip and palate treated at the Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo, Bauru, Brazil, by means of cone-beam computed tomography. Twenty-five patients with bilateral complete cleft lip and palate, resulting in 50 clefts, were analyzed. Subjects were divided into 2 groups according to the dentition status at the time of surgery: (1) SABG group: subjects with mixed dentition operated on before or immediately after eruption of the permanent canine (10–13 years); (2) TABG group: subjects with permanent dentition (15–23 years). Cone-beam computed tomography analysis was performed in the buccal, intermediate, and palatal views, 2 and 6 to 12 months postoperatively. In the SABG group, 96% of the grafts were classified as successful, and no failure cases were observed. In the TABG group, successful cases decreased to 65%, and failures were seen in 27% of the cleft sites. In both postoperative periods, significantly better outcomes (lower mean scores) were observed for the SABG group in all the cone-beam computed tomography views ($P < 0.05$). Results show that the timing of surgery is an important factor in determining the outcomes of ABG in patients with bilateral cleft lip and palate, with increasing age being associated with the worse outcomes.

Key Words: Bilateral cleft lip and palate, alveolar bone grafting, cone-beam computed tomography

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The bilateral complete cleft lip and palate represents the most severe form of cleft lip and palate and accounts for approximately 12% to 14% of all types of orofacial clefting in Brazil.^{1–3} The residual alveolar cleft is considered the main obstacle for obtaining optimum results in the rehabilitation process.¹¹ Secondary alveolar bone grafting (SABG), performed before the eruption of the permanent canine, associated to preoperative and postoperative orthodontic treatment is considered the criterion standard procedure for stabilizing the premaxilla and the maxillary segments in bilateral cleft cases.^{4–8} The primary goal of SABG is to allow the eruption of the permanent canine into the cleft site and subsequent orthodontic movements.

Alveolar bone grafting (ABG) should have a minimum impact on maxillary growth and development of the maxillofacial complex. Previous studies suggested that better surgical outcomes are achieved when ABG is performed during the mixed dentition.^{7,9,10} However, anatomic defects determined by bilateral clefts, such as premaxillary prognathism and mobility, make ABG a more complex procedure, with a higher chance of failures, when compared with unilateral clefts.

Cone-beam computed tomography (CBCT) has been used for the outcome assessment and follow-up, especially because it allows the visualization of cross-sectional images and the measurement of depth and volume of the grafted bone. The method has proved to be effective for evaluating the surgical outcomes of ABG, as in a study of our group, which investigated ABG outcomes in unilateral patients.¹⁰

Considering that a few controlled studies have investigated the outcomes of ABG surgery in bilateral clefts^{2,7,11,12} and that the rehabilitation protocol of subjects with craniofacial anomalies should be based on scientific evidence, as recommended by the World Health Organization,¹³ this prospective study aimed at evaluating the surgical outcomes of ABG in bilateral cases performed at the Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo, Bauru, São Paulo, Brazil, by means of CBCT.

MATERIALS AND METHODS

This study was approved by the institutional ethics review board. All participants, or their parents or legal guardians, were informed about the procedures involved in the study and signed the informed consent form before the surgery and tomography were undertaken.

Twenty-eight subjects with nonsyndromic bilateral complete cleft lip and palate, who underwent ABG from November to March 2010, were analyzed preoperatively and postoperatively. Three patients



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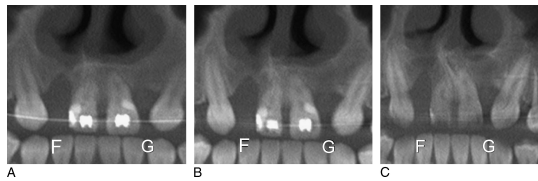


FIGURE 1. Patient with a bilateral cleft showing failure on 1 side (F) and good result on the other side (G), according to the modified Bergland Index, in the buccal (A), intermediate (B), and palatal (C) views.

were excluded because they did not return for the second or third examination, resulting in a sample size of 25 subjects (50 clefts). Cleft sites were analyzed separately, because it was anticipated that different outcomes could be observed for the 2 sites in a single subject (Fig. 1).

Subjects were divided into 2 groups according to the dentition status at the time of surgery: (1) SABG group (n = 24): children with mixed dentition, aged 10 to 13 years, who underwent surgery before or immediately after eruption of the permanent canine; (2) TABG group (n = 26): adolescents and adults, aged 15 to 23 years, who underwent tertiary ABG, that is, surgery performed in the permanent dentition. All surgical procedures were performed according to the Boyne and Sands protocol,⁴ using particulate bone from the iliac crest.

Patients were submitted to rapid maxillary expansion before surgery, for the repositioning and stabilization of the maxillary segments, and for providing better access for the graft placement and soft tissue closure. Patients submitted to ABG using iliac cortical blocks, regrafting or repositioning of the premaxilla were not included in this study.

For preoperative planning purposes and the postoperative evaluation of the bone graft, CBCT scans with 0.2-mm slices were obtained using the Isi-Icat Imaging System–Cone Beam (Imaging Sciences International, Hatfield, IN). Postoperative assessments were done 2 and 6 to 12 months after surgery. Three trained and blinded examiners (2 maxillofacial surgeons and 1 postdoctoral fellow) separately classified the surgical outcomes of all images using the modified Bergland Index.¹¹ If a disagreement occurred, a consensus was reached. The interexaminer agreement was calculated using the κ statistics.

Axial images of the graft were obtained and then reformatted into 3 periapical images with different depths: buccal, intermediate, and palatal, as done in our first study.¹⁰ Periapical images were classified into 5 types based on the analysis of the bone septum height: E (excellent: septum with a normal height), G (good: septum with minor deficiency of the interdental bone), R (regular: graft with sufficient bone for the canine eruption but tooth movement potentially unsuccessful or a marginal defect of >25% of root length), B (bad: bone deficiency on the nasal aspect preventing tooth movement), or F (failure: complete resorption of the bone graft). Types E, G, and R could occur in association with the B type.¹¹ The 3 periapical images were classified individually, thus forming a triple rating (eg, EGG, GRR, or FFF), allowing for the analysis of the bone graft in different depths and not only in a single two-dimensional view, as in conventional periapical radiographs.^{10,14}

For the descriptive analysis, clefts were distributed into the 5 outcome types previously described, and the data were expressed as percentage. For statistical purposes, scores of neoformed bone septum were graded as follows: E = 1, G = 2, R = 3, B = 4, and F = 5, meaning that the lower the value, the better the surgical outcome. The Mann-Whitney *U* test was used to compare groups (SABG × TABG). The Wilcoxon matched-pairs test was used to compare the same views at the 2 postoperative periods (2 months × 6–12 months). *P* < 0.05 was considered significant.

RESULTS

Table 1 shows the consensus results observed for the SABG and TABG groups, assessed at 2 and 6 to 12 months postoperatively,

TABLE 1. Distribution of Cleft Sites From Subjects Who Underwent SABG and TABG, According to Surgery Outcomes (Consensus of 3 Examiners) Assessed by the Modified Bergland Index, 2 and 6 to 12 Months Postoperatively (PO)

Timing	PO, mo	Excellent/Good, n (%)	Regular, n (%)	Bad/Failure, n (%)	Total, n (%)
SABG (10–13 y)	2	23 (96)	1 (4)	0 (0)	24 (100)
	6–12	23 (96)	1 (4)	0 (0)	24 (100)
TABG (15–23 y)	2	17 (65)	2 (8)	7 (27)	26 (100)
	6–12	17 (65)	2 (8)	7 (27)	26 (100)

by the 3 examiners. The κ statistical analysis showed a moderate to good agreement among them (*P* < 0.001), according to Landis and Koch.¹⁵ The great majority of cleft sites (96%) submitted to SABG were classified as E/G, 4% as R, and no cleft site was classified as B/F. On the other hand, in the TABG group, 65% of the cleft sites were classified as E/G (Fig. 2), 8% as R, and 27% as B/F.

Table 2 shows the mean values of the neoformed bone septum height scores in both groups, in the buccal, intermediate, and palatal views, assessed 2 and 6 to 12 months postoperatively. The lower the values, the better the surgical outcomes, that is, the higher the neoformed septum. Significantly better outcomes (lower mean scores) were observed for the SABG group, in the buccal, intermediate, and palatal views, in both periods analyzed (*P* < 0.05). Differences between periods of assessment (2 vs 6–12 months) in the same group were not statistically significant.

DISCUSSION

Few studies have evaluated the surgical outcomes of ABG in patients with bilateral clefting, probably due to its lower prevalence comparatively to other cleft types and hence difficulty in composing a significant sample size. In the current study, ABG surgeries in subjects with bilateral complete cleft lip and palate, performed at optimal age (mixed dentition), and in delayed ages (permanent dentition), were evaluated prospectively.

The most relevant finding of the current study is that almost all cases (96%) of the SABG group had excellent/good results, with no failure cases observed. On the other hand, the success rate in patients operated on in later ages decreased to 65%, with failure cases being observed in 27% of the sample analyzed. Other centers have shown similar rates of success, between 85% and 98%, for secondary bone grafting of bilateral clefts, before the eruption of the permanent canine.^{11,12,16} In addition, Bergland et al¹¹ reported successful results in 80% of the cleft sites grafted after the eruption of the permanent canines in patients with bilateral cleft. To our knowledge, no other studies assessing the outcomes of ABG in bilateral patients were published in the literature.

The better results observed for the SABG as compared with the TABG were probably due to the irruptive stimulus of the permanent canine through the graft, and in cases of recently erupted canine, successful results could be due to the stimuli of the orthodontic movement on the neoformed bone septum. However, in the cases of later intervention (TABG), orthodontic mechanics was directed to open

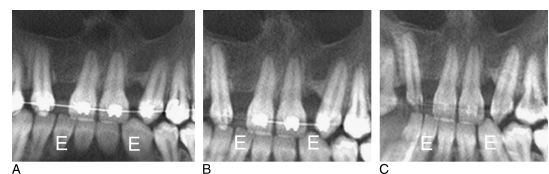


FIGURE 2. Patient with a bilateral cleft who underwent tertiary ABG, showing excellent results (E) for both sides, according to the modified Bergland Index, in the buccal (A), intermediate (B), and palatal (C) views.

TABLE 2. Mean (SD) Scores of Neoformed Bone Septum Resulting From the Consensus of 3 Examiners, 2 and 6 to 12 Months Postoperatively, in SABG and TABG Groups, in the Buccal, Intermediate, and Palatal Views

	Scores					
	Buccal		Intermediate		Palatal	
	2 mo	6–12 mo	2 mo	6–12 mo	2 mo	6–12 mo
SABG	1.08 (0.16) ^a	1.08 (0.16) ^b	1.08 (0.16) ^c	1.08 (0.16) ^d	1.08 (0.16) ^e	1.08 (0.16) ^f
TABG	2.23 (1.65) ^a	2.11 (1.70) ^b	2.34 (1.74) ^c	2.00 (1.62) ^d	2.23 (1.79) ^e	2.15 (1.71) ^f

P < 0.05; same letters represent significant difference.

space for further implant placement, which implies no stimuli on the grafted tissue. In other words, the authors’ interpretation is that, once again, the graft success is directly related to the stimulus to which it is submitted in the immediate postoperative period.

An unexpected finding of the current study was that the percentages of successful results obtained in bilateral clefts, 96% and 65% for the SABG and TABG, respectively, were higher than those in unilateral clefts analyzed in a previous study (75% and 53%, respectively).¹⁰ Our initial hypothesis was that the worse outcomes should be expected for bilateral cases because of premaxillary mobility, considered a crucial factor for grafting success. The reasons why better surgical outcomes were observed for bilateral clefts remain unclear and should be further investigated.

In addition, when comparing the scores assigned to the different evaluation periods (2 vs 6–12 months), no significant differences were detected, for both groups analyzed. The same was observed for the unilateral clefts in the previous study of Trindade-Suedam et al.¹⁰ Clinically, this reflects a dimensional stability of the graft over time. Considering that a minimal resorption should always be expected, individual cases were reviewed, and it was observed that some of them were classified as excellent at the 2-month assessment and were reclassified as good, 6 to 12 months after surgery, meaning that resorption occurred, but without clinical significance. No graft classified as good became regular, bad, or failure cases.

In summary, apart from the success rates, this study shows that the timing in which ABG is performed in bilateral clefts is a determinant for the success of the procedure, as demonstrated for unilateral clefts.¹⁰ In other words, the later the surgery is performed, the worse the results, regardless of the cleft type to be grafted. Therefore, teams involved in the rehabilitation of patients with bilateral clefts must ensure that the ABG surgery is performed before the eruption of the permanent canine for achieving good outcomes.

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