Patient Specific Dual Surgical Guidance for Alveolar Cleft Grafting

Ahmed Talaat Temerek , Ahmed M. Salah

Original Article

Oral and Maxillofacial surgery Dept., Faculty of Oral and Dental Medicine, South Valley University.

ABSTRACT

Objectives: To investigate the clinical and radiological outcomes of a computer guided technique using dual surgical guidance to generate a patient-specific bone graft to reconstruct unilateral alveolar cleft (AC).

Design: Prospective cohort study.

Setting: Patients with unilateral complete AC.

Participants: Out of 14 non-syndromic children with complete ACs who fulfilled the other inclusion criteria, 11 completed the follow-up period (4 males, 7 females, mean age 8.1 years).

Main Outcome Measure: Assess the dual surgical procedures using the clinical and radiographic outcomes in terms of facial expression scale (FES) to the donor site pain, cleft defect volume and bone graft volume at 6 months plus the incidence of clinical complications.

Results: Females comprised 63.6% (7) with a mean age of 8.1years (range 79.5- yrs). The mean mediolateral width of the superior iliac crests was 12.2 mm (range11.1 – 13.1 mm) and it exceeded the mean labio-palatal depth of the contra-lateral non-clefted maxilla by 3.5 mm. The mean volume of the reconstructed cleft defect was 940.9 mm3 (range 630 - 1125 mm3) which decreased after 6 months to 805.3 mm3 (range 576 – 993 mm3). FES peaked 2 days after the operation reaching 7.7 \pm 1.6, and then decreased to 2.6 \pm 0.93 at 1wk. No major complications were observed. Minor complications were labial flap dehiscence, labial cortex necrosis, hematoma, gait disturbance and neurological injury.

Conclusion: Within our selection criteria, dual computer guided bone grafting procedures from the iliac crest has a role in treating AC defects.

Key Words: computer guided surgery, reconstruction. dual surgical guidance, alveolar cleft, bone graft, iliac bone.

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Corresponding Author:Ahmed Talaat temerek ,Associate Professor at Oral and Maxillofacial surgery Dept , Faculty of Oral and Dental Medicine, South Valley University., **Mobile:** 01006652708 , **E-mail:** attemerek@dent.svu.edu.eg **ISSN:** 2090-097X, April 2024, Vol. 15, No. 2

INTRODUCTION:

ACs are congenital heterogenous soft tissue and bone defects that attain different volumes and shapes. Closure and grafting are usually addressed before canine eruption date. This will enhance health of teeth in and adjacent to the AC, confer support to the nose and lip, assures a donor site is of acceptable volume and guarantees minimal to no later maxillary growth and facial alteration.

The first bone grafting attempts in cleft patients were described by Lexer 1908 and Drachter 1914. They reported the use of the small finger as a pedicled bone transplant. ^[1] Since then, different techniques and donor sites have evolved and revised. Particulate cancellous spongy bone from the anterior iliac crest is the most used graft as it is autogenous, osteogenic and can provide generous amounts. ^[2,3] Unfortunately, in unilateral cases, the attainment of symmetry in the anterior nasal aperture and alveolar bone graft to the non-clefted side is not consistently realized.^[4] Also, a resorption potential of up to 64% was reported.^[5]

Significant advancements in computer-assisted surgery over the past several years have resulted in straightforward surgical procedures. It also guarantees a shorter surgical procedure and a lower risk of complications, all of which promote patient acceptance and satisfaction.6 In alveolar cleft defect, computer guided steps can generate a patient specific implant that provide a near normal vertical and horizontal ridge dimensions.^[7]

Dual surgical guidance is a novel protocol that employs two surgical guides designed to generate a patient specific graft. The first guide will have cutting slots that define the graft side walls contour and angles while the second one will outline the superior and inferior walls. This study was designed to investigate the clinical and radiological outcomes plus incidence of complications following dual surgical guidance in reconstruction of unilateral ACs.

METHODS

All children's guardians signed an informed consent and gave their approval for the procedure and to take part in

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the study and for publication. The research protocol was approved by the Research and Ethics Committee of the Faculty of Medicine - South Valley University – Qena (SVU-FODM-OMSD-4696-8-23-) on August 5, 2023.

Study Design

The present study is a prospective cohort clinical follow-up type. It was conducted between August 2023 and February 2024. All patients with non-syndromic complete unilateral ACs, between the ages of 7 and 9.5 years, who had not received any prior surgical treatment for their ACs, were cleared for surgery by our institution's cleft lip and palate team and had no systemic or local contraindications to surgery were invited to participate in the study. Using patient's first language, the nature of the procedures and the potential side effects were explained to the children's guardians.

For each patient computed axial and coronal tomograms (CT) of the iliac bone and maxillofacial region were included in the records. According to a standard protocol, a scan was performed from the inferior border of the orbit to the occlusal plane of the present dentition with a bony window, slice distance of 0.5 mm, slice thickness of 0.5 mm and gantry tilt of zero. The Digital Imaging and Communications in Medicine (DICOM) files of the patients were imported to Mimics software (Materialise, Leuven, Belgium).

At this stage, the mediolateral width of the iliac crest and the labio-palatal dimension of the contra-lateral non-clefted maxilla at the level of the nasal floor were measured. The anatomical boundaries and geometry were evaluated.

Following the methodology outlined by Phienwej et al, definition and measurements of the bony cleft defect was done by a conversion process of acquired DICOM files. ^[8] The regions of maxilla in the DICOM files were segmented and converted into 3D virtual models. Superior and inferior borders of alveolar cleft were created using 3 reference points for each of them. The inferior and superior borders were merged into the 3D virtual model of cleft. The cleft borders on the axial cuts were made to follow the buccal and palatal walls contour and curvature and to spare minor irregularities up to 2mm. The volume of the 3D image of the cleft defect was obtained using the software tool (properties) and this was considered the preoperative defect volume (Fig.1a,1b).

Then the cleft 3D defect and the iliac 3D model were exported to the 3 Matic software. Following this step, the first surgical guide fabrication started by seating the reconstructed defect virtually with the labial, nasal and palatal surfaces of the defect facing the lateral, superior and medial surfaces of the ilium bone, respectively.

The iliac bone's medial cortex naturally has a medial concavity when viewed from a coronal aspect, so to maintain an adequate insertion path without breaking, the guide covering area was not extended beyond 2-3 mm. With reference to the second bone cutting guide,

its purpose was to hold the bone segment that was created in the preceding step and to use superior and inferior circumferential cutting slots to shape these bony walls to mimic the nasal floor and the inciso-palatal curvature and dimensions (Fig.1c,1d).

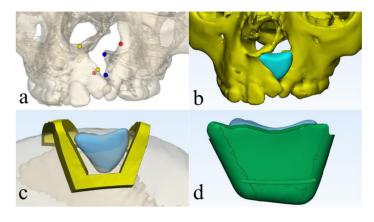


Figure 1

To be used intraoperatively, the two guides and the clefted maxilla were exported as STL files and printed. The path of insertion, need for fine trimming, need for spongy bone to fill a cortical gap, fitness, and stability of the cut bone graft are all checked using the printed maxillary cleft.

Surgical Technique

A full thickness labial and palatal flaps were performed, including any residual anterior palatal defect, while the patient was under general anesthesia. The nasal mucosa from the palatal and labial mucosae were cut using sharp dissection along the cleft walls. The nasal floor was then repaired.

The iliac crest bone graft was obtained through a standard apophyseal splitting approach. In all cases a cartilaginous cap was found before reaching the iliac crest. It was left attached to the periosteum and split at the midline. The cut cartilage, the periosteum and abdominal muscles were mobilized as a unit. Then, the first and second surgical guides were used to harvest and contour the iliac bone graft. Next, it was checked with the printed maxillary cleft. Then, A bone hammer covered in Teflon inserts was used to gently tap the iliac bone block into the bony cleft (Fig.2).

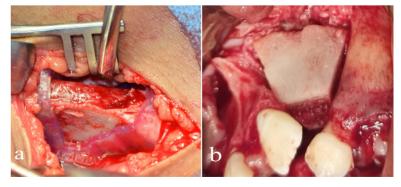


Figure 2

Finally, the mucosal walls of the palatal and labial regions were completely sealed off. Palatal splints were not used in any of the cases. Iliac approach and cleft repair procedures were done simultaneously.

Postoperative protocol

Following the surgery, patients received analgesics and antibiotic medications for a 5-day period. They were discharged from the hospital 3 days after surgery. Skin stitches were removed after 10 days. On the first day after the operation, patients were advised to start moving around, while they were asked to avoid school for 3 weeks and refrain from participating in sports for 2 months.

Clinical outcomes were assessed using both the Wong-Baker Facial Expression Scale (FES) for the iliac graft donor site pain 9, and the incidence of complications. FES assessment was done just before surgery, 2 days after and at 1wk. The scale ranges from 0 = no pain at all to 10 =worst pain ever. By the end of the follow-up period, the donor site and cleft area related minor and major complications were reported using a questionnaire and physician evaluation. Minor complications included superficial sensory nerve injury, temporary claudication, superficial hematoma, infection and donor-site contour defect.

Major complications comprised deep hematoma requiring operative drainage, incisional hernia, permanent neurological injury, vascular injury, sacroiliac joint injury, permanent Trendelenburg gait, donor-site fracture and deep infection. Patients were closely monitored for complications during follow-up appointments at 1 week, 2 weeks, 6 weeks, 3 months, and 6 months post-surgery in the outpatient clinic. These assessments involved both a questionnaire and physician evaluation. Radiological outcomes were assessed by measuring the graft volumetric changes found at 6months follow-up compared to the preoperative defect volume (Fig.3).

Other reported variables of interest were age, sex, involved side and surgical time.

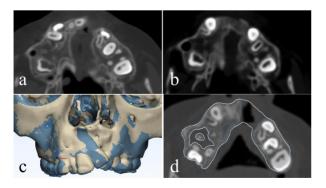


Figure 3

Statistical Analysis The collected data were recorded, fed to the computer, and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Data were presented as mean, standard deviation (SD) and range values (table 1,2). A paired t-test was used. Fisher Exact correction test was applied when more than 20% of the cells have expected count less than 5. The significance level was $P \le 0.05$. A Pearson correlation coefficient was used to study the correlation between different variables (table 2,3).

Table (1). Different parameters data analysis (n = 11)

Table (1). Different parameters data analysis $(n = 11)$				
	No. (%)			
Sex				
Male	4 (36.4%)			
Female	7 (63.6%)			
Age (years)				
Mean ± SD.	8.1 ± 0.78			
Median (Min. – Max.)	8 (7 – 9.5)			
Side				
Right	4 (36.4%)			
Left	7 (63.6%)			
Surgical time (min)				
Mean ± SD.	74.6 ± 10.3			
Median (Min. – Max.)	74 (54 – 93)			
Width of the iliac bone crest				
Mean ± SD.	12.2 ± 0.74			
Median (Min. – Max.)	12.4 (11.1 – 13.1)			
labio-palatal depth of the non-clefted maxilla				
Mean \pm SD.	8.7 ± 1.1			
Median (Min. – Max.)	8.9 (7.3 – 11.1)			
Preoperative defect volume (mm3)				
Mean \pm SD.	940.9 ± 162.4			
Median (Min. – Max.)	977 (630 – 1125)			
Graft volume at 6m (mm3)				
Mean ± SD.	805.3 ± 149.9			
Median (Min. – Max.)	839 (576 - 993)			

Table (2):	FES	at 2days	s and	1 week
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	2days	1week	t	р
FES				
Mean \pm SD.	7.7 ± 1.6	2.6 ± 0.93	12.941*	<0.001*
Median (Min. – Max.)	8 (5 – 10)	2 (1-4)		

SD: Standard deviation t: Paired t-test *: Statisfically significant at $p \le 0.05$

Table (3): Correlation between Preoperative defect volume and Graft volume at 6m (n = 11)

	Preoperative	defect volume	(mm3)
	R	Р	
Graft volume at 6m (mm3)	0.649*	0.031*	
r: Pearson coefficient			

*: Statistically significant at $p \leq 0.05$

RESULTS

Between August 2023 and February 2024, 14 patients suffering from unilateral complete AC were treated using dual surgical guidance for bony reconstruction using iliac graft. Six months were the minimum followup period that only four male and seven female patients committed. The mean age at the time of surgery was 8.1 years old and ranged from 7 years old to 9.5 years old. Seven patients (63.6%) had a left side maxillary cleft. Operative time ranged from 54 to 93 minutes (mean 74.6 minutes, SD 10.3 minutes) (table. 1). All cases show adequate fitness and primary stability of the graft requiring no further fixation. The iliac crest width ranged from 11.1 to13.1 mm (mean 12.2 mm, SD 0.7 mm) and it was wider than the labiopalatal depth of the non-clefted maxilla measured at the level of the nasal floor which ranged from 7.3 to 11.1 mm (mean 8.7 mm, SD 1.1 mm). Harvested graft in all cases included the lateral and medial cortices of the iliac bone. The preoperative defect volume ranged from 630 to 1125 mm3 (mean 940.9 mm3, SD 162.4 mm3) and it decreased after 6 months to a volume ranged from 576 - 993 mm3 (mean 805.3 mm3, SD 149.9 mm3) as calculated from the DICOM files accounting for 14.4 % resorption rate with no complete graft loss (table. 1). All cases were discharged 3 days after surgery with a postoperative follow-up period of 6 months. Except in one case, orthodontic treatment was regained by the end of 6m follow-up. Over the follow-up period, reported minor complications were labial flap dehiscence in 2 cases, labial cortex necrosis in one case, subcutaneous hematoma after iliac bone graft harvesting and only one patient had numbness over the lateral aspect of the thigh, in keeping with lateral femoral cutaneous nerve (LFCN) injury that resolved after 3 months. Gait disturbance was reported in 2 cases and it resolved at 1wk follow-up. No major complications were observed. Labial flap dehiscence occurred in two cases. One discovered 2wks after repair and the other discovered 4wks after surgery with labial cortex necrosis. Both were repaired under local anesthesia by a local flap. In the second case, bone volume decreased from 1125 mm3 to 630 mm3 by the end of the follow-up period accounting for 44 % loss.

Iliac bone graft donor-site pain

Regarding pain intensity, the FES score increased from baseline, peaked 2 days after the operation reaching 7.7 ± 1.6 , and then decreased to 2.6 ± 0.93 at 1wk. The mean FES score at 7 days postoperative was significantly lower than that reported at 2 days (P<0.001)(table 2) On data analysis, a significant correlation was found between the preoperative defect volume and the graft volume (p= 0.031) and the preoperative defect volume and FES at 2days (p=<0.001). also, no correlation was found between incidence of complications and other parameters like age, sex, surgical time and preoperative defect volume.

DISCUSSION:

About 75% of people with cleft lip and palate have ACs, a congenital defect caused by the failure of the palatal shelves to fuse resulting in a soft tissue fistula and a bony gap.^[7,10] AC treatment presents a significant challenge for surgeons due to the abundance of options. The surgeon's decision may be influenced by various factors such as the patient's dental or chronological age, the size and type of cleft, the child's social and academic development, occlusion, the necessity of perioperative procedures like jaw expansion or teeth alignment, the dynamics of the cleft team and even success metrics specific to each procedure.^[11]

Bone grafting is not controversial, despite some authors support for non-grafting methods that use alveolar moulding followed by gingivoperiosteoplasty or prosthodontic approaches.^[12] Age-based classifications for cleft bone grafting include primary which is done concurrently with lip repair, early secondary which is done between the ages of 2 and 5 years and secondary which is done following the eruption of the maxillary central incisor but prior to the eruption of permanent canines. Secondary bone grafting is considered an ideal choice. Wolfe and colleagues have justified its use due to: (1) stabilization of the maxilla, (2) permitting tooth eruption, (3) eliminating the oronasal fistula, (4) improving esthetics and (5) improving speech. Also, autogenous donor sites during this age window will attain a suitable size.^[13] In 2023, Alfeerawi et al published a CBCT volumetric study comparing the outcomes of early vs late secondary alveolar bone grafting in unilateral non-syndromic cases. They reported significant great bony bridge thickness, longer post graft incisor root length and greater periodontal bone coverage on the root of the cleft-adjacent incisor in patients aged 8-11 years.^[14] Patients between the ages of 7 and 9.5 were treated in our study. A bony space for canine eruption and orthodontic movements were created within this window. Additionally, restoring the shape of the labial arch, giving the ala strong support, facilitate closure of the naso-palatal fistulae and avoiding arch collapse were achieved.

In AC grafting, autogenous bone is the gold standard because it is osteogenic, non-immunogenic, histocompatible and does not pose a risk of disease transmission. The calvarium, ribs, ilium, tibia and mandible are among the autogenous bone donor sites used in secondary AC grafting. Also, bio-ceramics, stem cells and recombinant human bone morphogenetic protein-2 were used. [3,15] The most often used graft for AC defects is particulate cancellous bone harvested from the anterior iliac crest. It also can be obtained as a cortico-cancellous block.^[2,4] It can be harvested with minimally invasive technique and provides a large volume of cancellous bone rich in pluripotent and osteoprogenitor cells. Furthermore, it offers osteogenic, osteoconductive and osteoinductive properties, accelerates revascularization plus other returns being autogenous. Prolonged hospital stays, pain, infection, nerve damage, bleeding, pelvic fracture and delayed ambulation are among the reported morbidities. Resorption, volume loss and no immediate structural stability represent other disadvantages of the iliac crest particulate graft utilization.^[16,17]

Uribe et al published a systemic review article that showed 59.12% \pm 18.59% average bone filling in clefts treated with iliac crest over a minimum of 6 months follow-up.^[18] Feichtinger et al reported a resorption potential of up to 64% by the end of the first year.5 Furthermore, a 60–80% success rates were reported in the literature suggesting that graft volumetric changes and success may be influenced by a variety of factors including surgical technique, graft type, preoperative cleft volume, timing of repair in addition to the donor site.^[19]

Current study describes a 3D computer guided iliac bone graft in secondary alveolar cleft reconstruction. Graft harvesting makes use of a concept of surgical and non-surgical procedures called dual surgical guidance. It is capable of precisely restoring the bony defect to the rebuilt blueprint. Based on the present study, the iliac superior cortex is wider than the alveolar bone at the nasal floor by 28.6 % (3.5 mm) allowing for better cleft defect reconstruction, greater palatal extension of the graft and volumetric change compensation in the future. In our study, it was possible to distinguish between the densities of the native alveolar bone and the graft by the end of the follow-up period, which enabled to record a 14.4% decrease in volume ratio.

In 2019, De Mulder et al published a systematic review on radiological evaluation of secondary alveolar bone graft and they reported resorptive changes of 29-63% at 6 months.^[20] Volumetric changes in our study were less than those reported in the literature. This may be attributed to the bicortical block nature of the graft which provided osteoconductivity and instant mechanical support by the cortical part plus osteogenicity by the spongy bone since most surgeons use particulate cancellous graft. Additionally, the surgical protocol, which ensured a graft volume and dimensions that mimic the reconstructed defect. In our cases, we could achieve adequate primary stability of the graft and this was attributed to the surgical guide designed to follow the side walls sparing minor in and out wall irregularities. Subsequently, it could provide primary stability by frictional contact along the defect bony wall minor irregularities.

The mean operating time for the presented surgical protocol was 74.6 minutes, which is shorter than what other users of the free hand for iliac bone harvest method reported. This can be explained by the fact that a surgical guide customized for the patient can save time by supplying a bone graft of precisely the same volume as the surgical defect, eliminating the need to revisit the donor site in the event that the graft is insufficient.^[21.22]

Although our surgical protocol involved lateral and medial cortices stripping to position the first surgical guide, recorded minor complication in terms of pain, gait disturbance and LFCN injury is comparable to other studies. Pain peaked at 2 days then significantly decreased at 1 wk which is consistent with the findings reported by Clarke et al. (2015) and Y. Lai et al. (2023) ^[23.24] Anterolateral femoral sensory disturbance was reported in one case accounting for 9% of the studied cases. The frequency of LFCN numbness after iliac harvest in children is described to be 1.3%–8% ^[24.25.26] Indirect trauma, such as from retractors, large medial hematomas, or scar tissue near the nerve, is the common causes of such complication. Gait disturbance was reported in 2 cases and it resolved by the end of the first postoperative week.

The limitations of this study included the small sample size and the fact that it was not a comparative study, which might be attributed to the incidence of unilateral AC and the inclusion criteria set in the research. The study also has a relatively short follow-up period.

Conclusions:

Within the study selection criteria, dual computer guided bone grafting procedures has a role in treating AC defects and providing near normal bony reconstruction, teeth and soft tissue support plus less graft resorption throughout a follow-up period of 6 months. A prospective, comparative study with a larger sample size would give definitive results, and further follow-up may be required to check for graft stability in growing children.

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