

Efficacy of Sticky Bone (Combined Autologous Fibrin Glue with Bovine Bone) in Secondary Cleft Alveolar Bone Grafting

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ABSTRACT

Background: Bone grafting of the cleft maxilla before eruption of the permanent cuspid has become an accepted part of the management of patients with clefts involving the maxillary alveolus. The reasons for performing a bone graft are to stabilize the maxillary segments and provide bony support for the teeth adjacent to the cleft.

Objective: The aim of the present study is clinical and radiographic evaluation of the outcome and efficacy of sticky bone (mixture of autologous fibrin glue (AFG) and bovine bone graft) as a bone substitute for the treatment of alveolar cleft.

Patients and Methods: 41 patients with a total of 58 alveolar clefts, 17 bilateral and 24 unilateral clefts, treated by alveolar bone grafts using sticky bone. Their age ranged from 6 to 18 years with a mean of 11.6. The follow-up was up to one year.

Results: From a total number of 58 alveolar clefts. Adequate healing was resented in 47 of them [30 of them were class I (51.7%) and 17 were class II (17%)]. Inadequate bone healing occurred in 11 clefts [6 of them were class III (10.3%) and 5 were class IV (8.6%)].

Conclusions: Bone grafting of alveolar clefts is a mandatory step in the management of cleft lip and palate patients, sticky bone could be considered as promising and effective bony substitute and could be used efficiently for the treatment of cleft alveolus as an alternative to autogenous bone grafts to avoid harvesting bone of the patient and its complications and the earlier the grafting producers are done, the better quality of grafted bone.

Key Words: Alveolar cleft – Alveolar bone grafts – Bone substitute – Cleft lip and palate – Sticky bone.

Ethical Committee Approval: This study was approved by the Faculty of Dentistry Beni-Suef University Research Ethics Committee (Approval number: # REC-FDBSU/

02062022-01/EM). It was conducted in accordance with the principles of Helsinki and its modifications. All patients' parents or guardians provided written informed consent before the procedure.

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INTRODUCTION

Cleft lip and palate (CLP) are the most common congenital anomaly affecting the orofacial region. The alveolar cleft is a bony defect present in 75% of CLP patients. Surgical repair of the cleft alveolus is mandatory to improve the aesthetic and functional goals of the treatment of patients with CLP. It allows restoration of maxillary bone continuity which is the universal goal in alveolar cleft management, stabilizes the premaxilla in bilateral cases, improves the periodontal status, helps in the repair of any existing Oro-nasal fistulous tract, favors teeth eruption, and allows reconstitution of the floor of the nasal cavity [1].

Primary alveolar cleft grafting usually takes place at an early age in life. Secondary alveolar cleft grafting (SACG) for patients with a cleft involving maxillary alveolus was first advocated by Boyne and Sands in 1972 [2]. The grafting procedures could be done before the eruption of a permanent maxillary canine tooth, [3] or before the eruption of permanent maxillary incisors [4].

Although SACG is commonly accepted for these patients, controversy remains regarding the surgical technique and type of grafting material used. Autogenous bone grafting is considered the gold standard ideal grafting material as it provides compatible excellent bone quality through its osteoinductive, osteoconductive and osteogenic prop-

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erties. Surgical repair of cleft alveolus can be performed either using autogenous bone from different sites such as iliac bone, [5] mandible, tibia, [6] or calvarium [7].

Although this treatment approach has many advantages, it has some disadvantages like the need for a second surgical interference in another operation field, increased time of surgical operation, donor site morbidity, limited availability, and the possibility of graft resorption and subsequent complications [8].

The other approach usually used for alveolar cleft reconstruction is bone graft substitutes [9]. Bio-OSS (Geistlich Pharma AG, Wolhusen, Switzerland) is a mineral bovine hydroxyapatite, it has osteoconductive properties as it acts as a scaffold for the ingrowth of host vasculature and osteoprogenitor cells, which are essential for the formation of new bone, and can be used for bone grafting [10].

A mixture of autologous fibrin glue (AFG), with bovine graft, which is known as "sticky bone", depends on the fact that it contains a high concentration of platelets that release significant amounts of growth factors that promotes bone graft maturation, leading to graft integration and bone formation [11].

Sticky bone is a moldable mass that adapts to various bony defects. It offers several advantages; The volume of augmented bone remains constant during the healing time since macro and micro-movement of the graft are minimized, Platelets and leukocytes entrapped in the fibrin network release growth factors which help in the regeneration of soft tissue and bone. Also, fibrin interconnection decreases the in-growth of soft tissue into the graft [12].

The aim of this study was to evaluate (clinically and radiographically) the efficacy of a bovine bone graft mixed with autologous fibrin glue (AFG), as a graft material for the secondary closure of alveolar cleft.

PATIENTS AND METHODS

A- Study sample and design:

This prospective case serious multicentric study included (41), 27 females (65.85%) and 14 males (34.1%). All cases were treated at Oral and Maxillofacial Surgery Departments at Faculty of Dentistry Beni-Suef University and Faculty of Dentistry, Assiut University, between January 2020 and December 2022. A total of 58 alveolar clefts were

treated in this study, 17 patients were suffering from bilateral alveolar clefts, while 24 patients were having unilateral alveolar bone clefts. Age ranged from 6 to 18 years with a mean of 11.6 years. All clefts were grafted using a mixture of bovine bone grafts with autologous fibrin glue known as sticky bone.

Inclusion criteria: Patients who agreed to be included in this study, all patients with unilateral or bilateral cleft lip and palate with no other craniofacial abnormalities.

Exclusion criteria: Patients who refused to be included in the study, patients with very poor oral hygiene, systemic disease interfere with bone metabolism, and patients with a history of failed alveolar bone grafting.

Ethical approval: This study was approved by the Faculty of Dentistry Beni-Suef University Research Ethics Committee (Approval number: # REC-FDBSU/02062022-01/EM). It was conducted in accordance with the principles of Helsinki and its modifications. All patients' parents or guardians provided written informed consent before the procedure.

B- Preoperative patient preparation:

Preoperative patient preparation included full medical history, Intra-oral and extra-oral clinical examination, and digital radiographs including Cone beam computed tomography (CBCT) (Fig. 1). Routine lab. investigations (complete blood count CBC, coagulation profile, blood chemistry) in addition to electrocardiogram ECG and chest examination were done prior to surgery to all patients included in this study.

Orthodontic preparation: The orthodontic maxillary expansion was done for those patients presented with collapsed maxillae (Fig. 2). This was done by the use of a transverse maxillary expander to improve the transverse dimension of the maxillary arch and prepare the cleft area for bone grafting (Fig. 3). Alveolar bone grafting was done after complete maxillary expansion (the maxillary intercanine distance is larger than the mandibular intercanine distance).

C- Surgical technique:

All patients were operated on under general anesthesia with oral endotracheal intubation. Patients were prepared for intraoral surgery by draping followed by local infiltration of 2% lidocaine in 1:100000 adrenaline, to facilitate dissection and to aid in hemostasis. The incision was extended anteriorly along the gingival crevice to the center

of the cleft side, then a vertical one is made along the cleft edges, then raising of the mucoperiosteum on both sides of the palatal cleft. This incision allows wide exposure of the cleft. The nasal floor was created via suturing of the palatal mucoperio-

steal flaps. Minimal bony decortication of both sides with preservation of the thin bony layer that covers the teeth roots. At this stage, we have a well-defined cleft defect with a nasal layer ready to receive the sticky bone graft (Figs. 4,5).

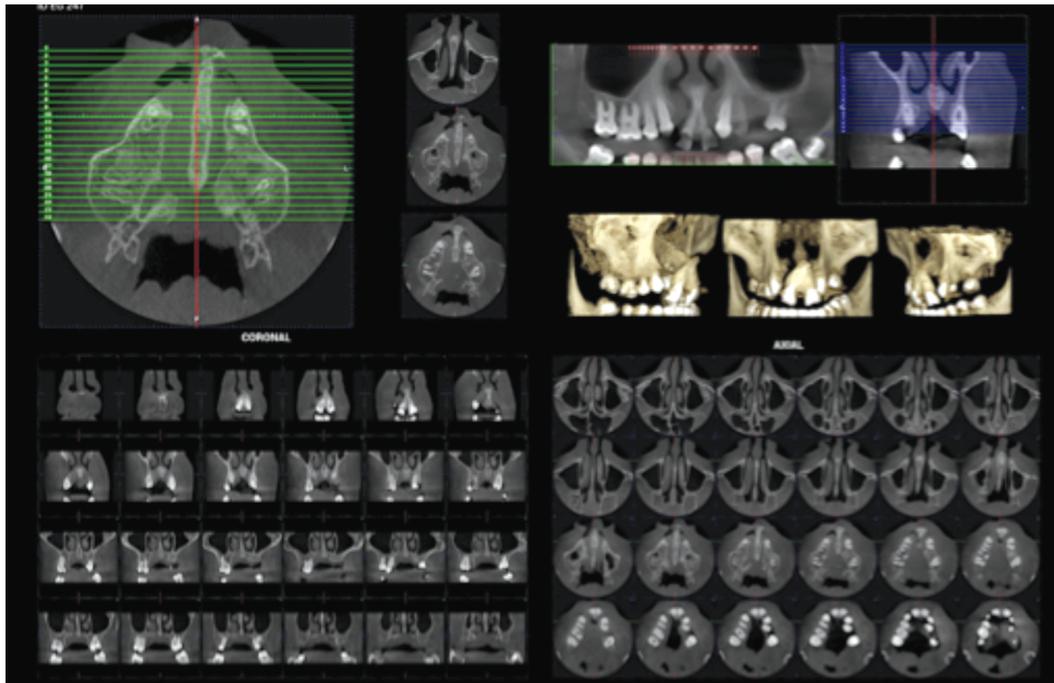


Fig. (1): Preoperative CBCT for a bilateral cleft alveolus.



Fig. (2): Initial setting, before starting orthodontic expansion for a patient with the collapsed maxilla.

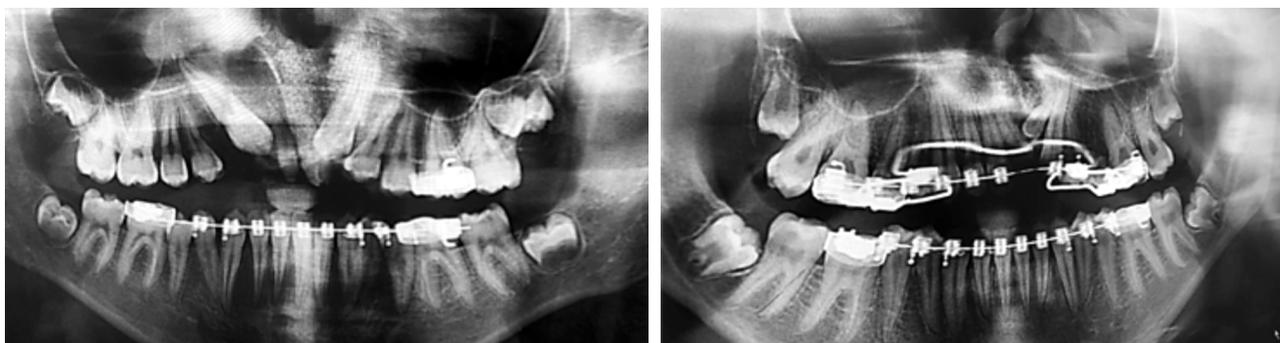


Fig. (3): Orthodontic maxillary expansion.

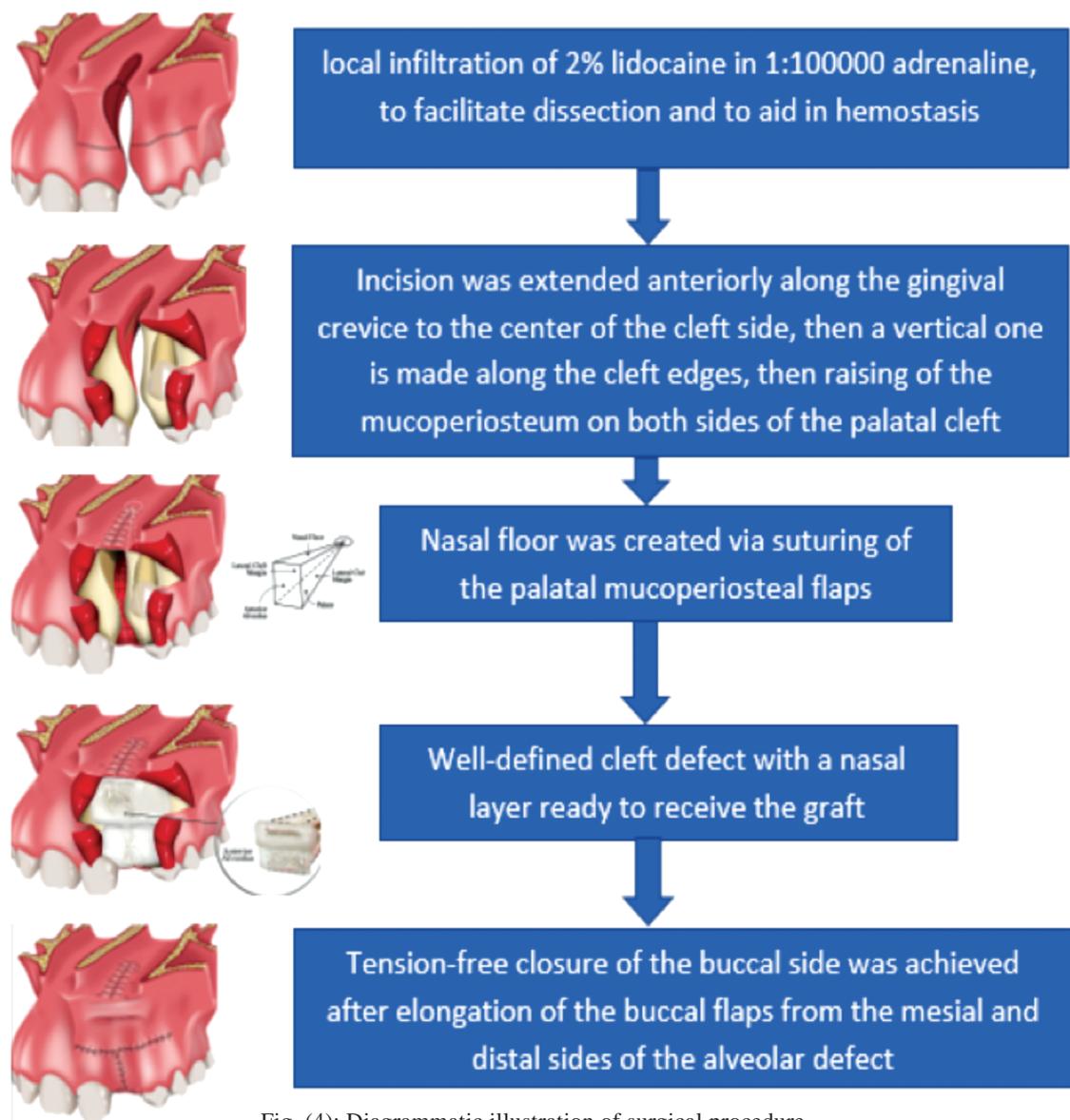


Fig. (4): Diagrammatic illustration of surgical procedure.



Fig. (5): (A) Preoperative view of a unilateral alveolar cleft after the orthodontic expansion and alignment of maxillary segments and teeth, (B) The flaps were raised over the greater and lesser segments of the maxilla in the subperiosteal plane, (C) A well-defined cleft defect with an intact nasal layer.

Graft preparation:

After preparation of the surgical bed, 20-40 cc of the patient venous blood was obtained by venipuncture of the median cubital vein, in the antecubital fossa. The drawn sample is distributed into 2-7 glass-coated tubes without anticoagulants.

Then blood was centrifuged for 2 minutes at 2400-2700 rpm. The centrifuged blood was presented as two separate layers, the lower layer of red blood cells was discarded, while the upper one was presented as straw-colored liquid and known as autologous fibrin glue (AFG) used in our study. AFG

was mixed well with particulate bovine bone powder (Bio-Oss), then left for 5-10 minutes for polymerization, giving a pliable mass rich in mesenchymal cells, leucocytes, and platelets, which is known as "sticky bone" [13]. (Fig. 6).

Tension-free closure of the buccal side was achieved after elongation of the buccal flaps from the mesial and distal sides of the alveolar defect. Postoperative broad-spectrum antibiotics and analgesics were prescribed for 1 week postoperatively. Also, Postoperative instructions were explained and oral hygiene measures were demonstrated. Procedures for patients with bilateral cleft alveolus were done in two stages, one side was first operated followed by the other side 3 months after to avoid risk of damaging the tenuous blood supply to the

premaxilla so bilateral cleft alveolus cases were done in two stages to avoid jeopardizing blood supply of premaxilla.

D- Postoperative follow-up and graft assessment:

Follow-up of the patients was done in outpatient clinics to evaluate healing progress and to detect any complications.

Clinical evaluation of wound healing regarding wound dehiscence, Oro-nasal fistulae, signs and symptoms of infection, and the eruption of teeth through the grafted cleft was done after surgery (Fig. 7). Radiographic evaluation of the early results was done using CBCT as well to evaluate the continuity of the maxillary arch and graft integration (Fig. 8).

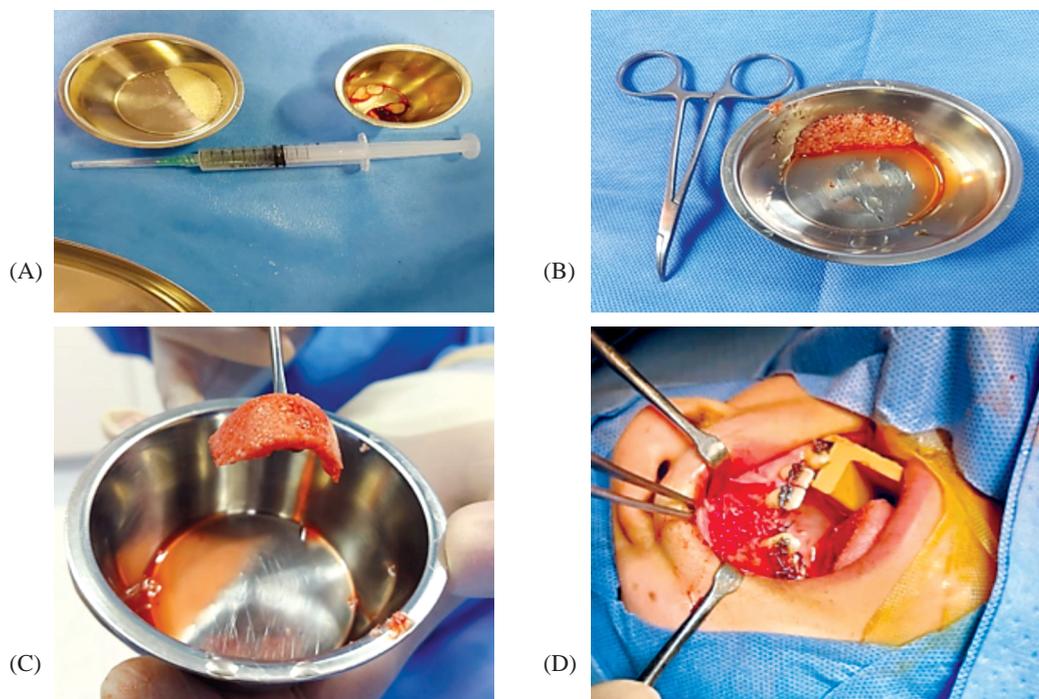


Fig. (6): (A) AFG retrieved after centrifugation, (B) Mixing AFG with particulate bovine bone powder and left for 5 to 10 minutes for polymerization, (C) Sticky bone (pliable mass rich in mesenchymal cells, leucocytes, and platelets), (D) The moldable sticky bone adapted well in the defect.

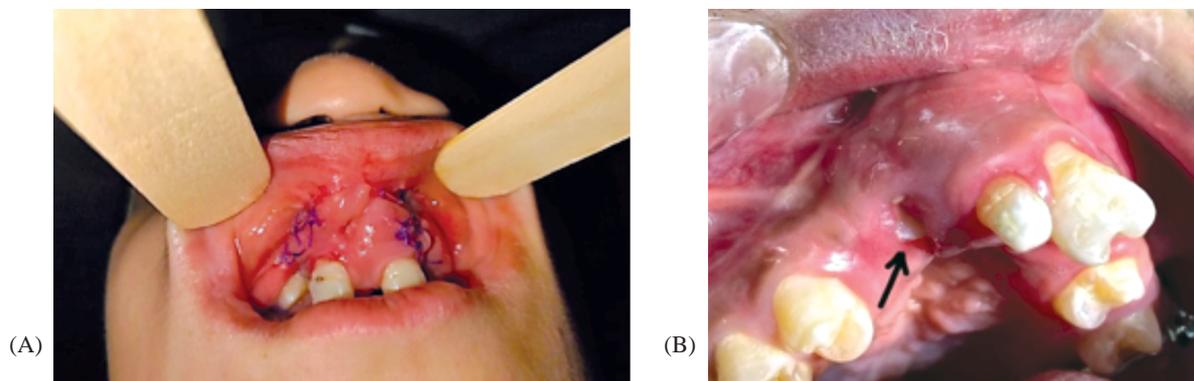


Fig. (7): (A) Postoperative view of bilateral grafted alveolar clefts showing good wound healing, (B) Cusp tip of the canine demonstrating eruption of the tooth through the grafted cleft.

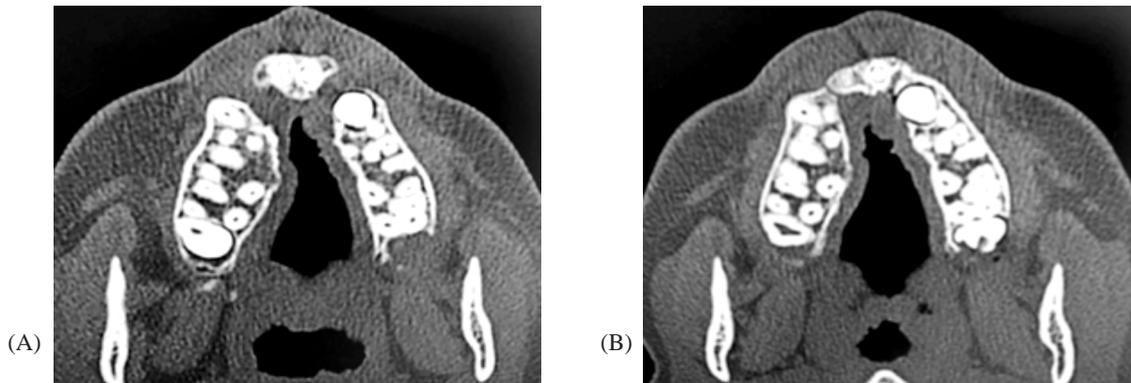


Fig. (8): (A) Preoperative CBCT of bilateral alveolar clefts, (B) Postoperative CBCT showing continuity of the maxillary arch after grafting procedure.

Graft assessment:

Bergland Scoring grading or coding system [14] (Table 1) was used to assess the success of bone grafting after one year through CBCT, the height of the interdental septum between the incisor and canine or premolar adjacent to cleft, the distance from cervical areas and root apex of these teeth, were evaluated and classified into one of four categories. Type I and type II, are considered satisfactory, while type III and type IV are considered unsatisfactory. The same CBCT device was used for all patients.

The system classifies the grafted site into the following:

Table (1): Grading or coding system "Bergland scale"

Type I	0-25% resorption of the grafted bone	Satisfactory
Type II	25-50% resorption of the grafted bone	Satisfactory
Type III	50-75% resorption of the grafted bone	Unsatisfactory
Type IV	75-100% loss of the grafted bone	Unsatisfactory

RESULTS

A total of 41 cleft patients were included in this study. 27 females and 14 males. 17 cases were bilateral while 24 cases were unilateral with a total number of 58 alveolar grafts. Their age ranged from 6 to 18 years with a mean of 11.6 years (Table 2).

26 patients presented with collapsed maxillae, and needed preoperative orthodontic transverse maxillary expansion, till the maxillary inter-canine distance is larger than the mandibular inter-canine distance.

All patients were operated on under general anesthesia and discharged after 1-2 days following

surgery. After discharge, antibiotics and analgesics were continued for 7 days.

Two patients showed infection, and dehiscence at the surgical site and were managed conservatively. No patients had a postoperative hemorrhage. The most common migrating teeth into the grafted bone were the canines, followed by lateral incisors. After one year of follow-up, according to Bergland (Oslo) scale, there were 30 clefts with type I (51.7%), 17 clefts with type II (29.3%), 6 clefts with type III (10.3%), and lastly 5 clefts with type IV (8.6%). So, 81% of the grafted clefts showed a satisfactory graft success rate (Type I & II on the Bergland scale), while only 11 grafted clefts showed unsuccessful results (Type III & IV on the Bergland scale) (Figs. 9,10). Statistical analysis demonstrated the presence of significant relationship between the age & failure rate. The younger the patients, the more successful is the procedure (Table 3).

Complications:

No patients had a postoperative hemorrhage. Two patients had mild infection and dehiscence at the surgical site due to poor postoperative oral hygiene and were conservatively managed by antibiotics and saline irrigation.

Table (2): Distribution of the studied cases according to demographic data (n=41).

	No. (%)
<i>Sex:</i>	
Male	14 (34.1%)
Female	27 (65.9%)
<i>Age (years):</i>	
Mean \pm SD.	11.6 \pm 3.3
Median (Min. - Max.)	11 (6-18)
<i>Side:</i>	
Unilateral	24 (58.5%)
Bilateral	17 (41.5%)

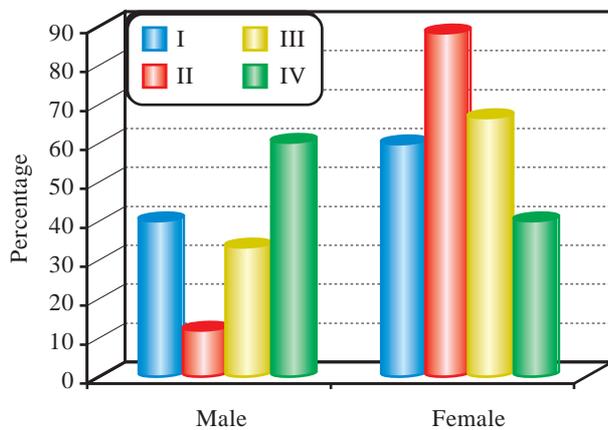


Fig. (9): Relationship between sex & failure rate.

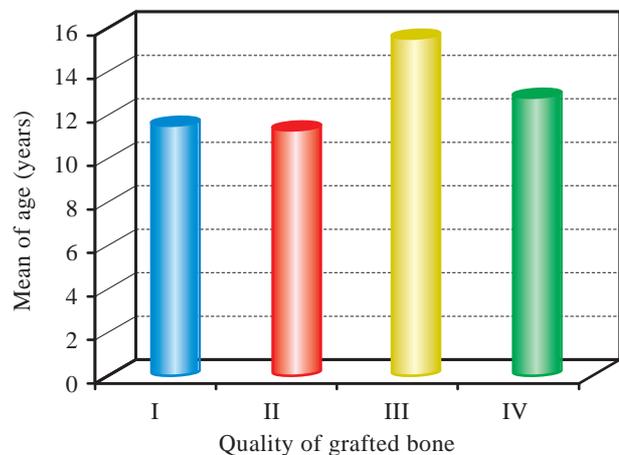


Fig. (10): Relationship between age (years) & failure rate.

Table (3): Relationship between age & failure rate.

	Quality of grafted bone				Test of sig.	p
	I (n=30)	II (n=17)	III (n=6)	IV (n=5)		
Sex:						
Male	12 (40%)	2 (11.8%)	2 (33.3%)	3 (60%)	$\chi^2=6.021$	MC $p=0.095$
Female	18 (60%)	15 (88.2%)	4 (66.7%)	2 (40%)		
Age (years):						
Mean \pm SD.	11.5 \pm 3.4	11.3 \pm 2.8	15.5 \pm 2.4	12.8 \pm 1.6	F=3.400*	0.024*
Median (Min. - Max.)	11 (6-18)	11 (6-17)	16.5 (12-18)	13 (10-14)		

F: F for ANOVA test. χ^2 : Chi-square test. p: p-value for comparing between the studied groups. SD: Standard deviation. MC: Monte Carlo. *: Statistically significant at $p \leq 0.05$.

DISCUSSION

Bony bridge evaluation after bone grafting of the alveolar cleft can be done by simple dental, panoramic, and occlusal radiographs. Also, three-dimensional analyses can be used using computed tomography scans [15]. Some authors as Rosenstein et al., mentioned that there is no difference between simple dental radiographs and three-dimensional analysis using computed tomography scans [16]. In this study, we used Cone beam CT as a radiographic means of assessment as it can provide three-dimensional evaluation, we can use a panoramic view through it, in addition, it can be considered nowadays as a simple, available, cost-effective radiographic modality with low radiation exposure.

The proper time of cleft alveolus grafting is important and depends on dental development and maxillary growth at the cleft site [17]. Most surgeons do alveolar cleft grafting at the mixed dentition stage, in between the time of eruption of permanent incisors and eruption of permanent upper canines. 9-11 years old is the ideal age, when one-third to two-thirds of the roots of permanent upper canines have formed and not erupted yet (their crowns are still covered by bone) [18]. Unfortunately, some of

our patients came late neglected after this ideal age. They were operated on for closure of the oronasal fistula and unification of the maxillary arch. In this study, statistical analysis revealed that the younger the patient's age, the better the outcomes of the procedures. This was also observed by Dissaux and his coauthors [19].

Autogenous bone graft (extraoral or intraoral), is considered the first choice as a grafting material as it is completely biocompatible and stimulates new bone formation and the iliac crest is considered to be the preferable site for autogenous bone graft, as it provides a considerable volume of cancellous or cortico-cancellous autogenous bone with a high success rate but still has some limitations; such increased time of surgical operation, need for a second surgical intervention in another surgical field, prolonged hospitalization time, and possible gait disturbances [20].

Mandibular symphysis was used for grafting of alveolar cleft as it has some advantages like ease of harvesting, an invisible scar in the labial sulcus, and working in the same operative field [21] but still has some disadvantages like increased operative time and the possibility of teeth injury. Iliac bone is the most commonly used bone in bone

grafting because it is easy to harvest and can provide a large amount of cancellous bone, with a success rate of about 85.5% [22].

Cranial bone graft has a low resorption rate and minimum postoperative pain with the advantage of a hidden scar. Hudak et al., mentioned that the survival rate of cranial bone grafts is approximately 85% [7]. However, it has a long operative time and can be associated with considerable complications such as seroma, hematoma, Dural tears, or cerebrospinal fluid leakage [23].

Bone substitutes, such as bovine grafts could be used to overcome the disadvantages and limitations of using autogenous bone grafts in addition to providing a bony scaffold for new bone formation. Moreover, these bone substitutes have a low resorption rate compared to autogenous bone grafts which help to maintain the graft volume for a longer time [24].

Autologous fibrin glue (AFG) is an autologous preparation of the patient's own blood. It contains a high concentration of platelets; it does not carry any transmissible disease and does not lead to any hypersensitivity responses [25].

A high concentration of platelets in the autologous fibrin glue (AFG), leads to a huge diversity of growth factors, such as platelet-derived growth factor (PDGF), fibroblast growth factor (FGF), insulin-like growth factor (IGF), transforming growth factor (TGF), vascular endothelial growth factor (VEGF), and epidermal growth factor [26]. So, a combination of autologous fibrin glue with bovine bone graft leads to synergistic effects on vascular in-growth and bone remodeling.

Bone morphogenic proteins (BMPs) are a group of proteins involved in osteogenesis, BMP-2, and BMP-7 are most used for intraoral applications with favorable outcomes [27]. These proteins were added to the bovine graft for the reconstruction of alveolar clefts with encouraging results [28]. Unfortunately, these proteins are expensive and unfeasible to everyone.

In this study, radiological evaluation of the bony bridge through CBCT was done twice by two different researchers independently for graft assessment and patient subgrouping according to the Bergland classification system.

The present study showed favorable, successful, and encouraging results in 47/58 (81%) of the grafts confirmed by radiologic post-operative examination, Bergland type I and II. Our results were

consistent with earlier investigations reporting success rates of 70.3 to 86% [29]. Also, the clinical evaluation revealed high success rate after grafting based on proper healing, tooth movement, and eruption near or within the grafted area. On the other hand, 11/58 of the grafts (19%) were unsuccessful, Bergland type III and IV, and second surgical interference was required for reinforcement of the alveolar cleft. Only 5 grafts (Type IV) of these had complete bone resorption with no bony bridges.

The results of this study are similar to those obtained by Mikoya et al., 2010 who used mandibular cortical bone for alveolar grafting with an 85% success rate [30].

Conclusions:

Bone grafting of alveolar clefts is a mandatory step in the management of cleft lip and palate patients. Sticky bone could be considered as promising and effective bony substitute and could be used efficiently for the treatment of cleft alveolus as an alternative to autogenous bone grafts to avoid harvesting bone of the patient and its complications. However, further studies with a larger number of patients are required to compare the use of sticky bone versus the use of autogenous bone grafts.

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