

Secondary closure of alveolar cleft with resorbable collagen membrane and a combination of intraoral autogenous bone graft and deproteinized anorganic bovine bone

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ABSTRACT

Objects: Secondary alveolar bone grafting is a method that enables an excellent oral rehabilitation of the patients having alveolar cleft. The aim of this work is to report the closure of the alveolar cleft with the use of harvested autogenous bone graft combined with deproteinized anorganic bovine bone (Bio-Oss) under local anesthesia. **Settings and Sample Population:** Nine patients with age range, 8–11 years were consulted for their unilateral alveolar cleft. **Materials and Methods:** A combination of symphyseal bone and deproteinized bovine bone mineral (DBBM) was placed into the alveolar cleft defect. Clinical and radiographical assessments were performed at 1, 3, and 6 months postoperatively. **Results:** The healing period was uneventful in all cases, and no complications, such as membrane exposure, infection, or harvest site morbidity, were observed. All treated defect sites exhibited excellent bone formation, with an average of 5.45 mm (range, 2–9 mm; standard deviation 1.93 mm) of augmentation achieved overall. **Conclusion:** The treatment of vertically deficient alveolar ridges with guided bone regeneration using a mixture of autogenous bone and DBBM and resorbable collagen membrane can be considered successful, using this technique in an out-patient office setting.

Keywords: Alveolar cleft, autogenous bone, DBBM, guided bone regeneration

INTRODUCTION

Clefts of the lip, palate, and alveolus are the most common congenital anomaly to affect the orofacial region. Repair of the cleft alveolus is an adjunctive procedure to further improve the functional and esthetic rehabilitation of a patient with unilateral or bilateral cleft lip and palate and is recommended during the mixed dentition period.^[1] Gingivoperiosteoplasty has been proposed as an alternative to the primary bone grafting until secondary autogenous bone grafting. Alveolar bone graft is an essential step in the overall management of a patient with cleft lip and palate.^[2]

Alveolar cleft bone grafting is performed for various purposes such as facilitation of oral hygiene by modification of the complex

morphology of the alveolar cleft, induction of canine eruption into the alveolar cleft, closure of vestibular fistulae, stabilization of the arch form during orthodontic treatment, creation of an alveolar

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bridge, and improvement in facial morphology by elevation of the alar base. Conventionally, this procedure is performed only after the patient has reached adolescence to prevent shrinkage of the maxillary dental arch, which will have been extended through orthodontic treatment.^[1,3]

Fresh autogenous bone is the ideal bone graft material because it supplies living immunocompatible bone cells essential to osteogenesis for optimum osteoconductive, osteoinductive and osteogenic properties. This bone grafting also has disadvantages, such as the need for surgery at another site, extension of surgery time, increased possibility of infection, and other complications.^[1,4]

The use of xenografts has the potential to reduce morbidity, as the harvesting of autogenous bone is unnecessary. The deproteinized bovine bone mineral (DBBM), Bio-Oss collagen® (Geistlich Pharmaceutical®, Wolheisen Switzerland), possesses osteoconductive and biocompatibility properties.^[5] It is characterized by a spongy structure and interconnected pore system that may facilitate cell adherence.^[6,7] Bio-Oss, which is commercially available in both spongiosa and cortical blocks, has been completely deorganified by means of a proprietary extraction process that renders it free from antigenicity. This permits its implantation as a matrix that appears to stimulate all normal physiological responses closely, mimicking the stages of bone repair.^[7]

In the last 10 years, the application of guided bone regeneration (GBR) principles for supracrestal bone jaw regeneration has provided the clinician the possibility to vertically augment the bone in sites where the alveolar crest has been resorbed. The rationale of this technique is to create a secluded space, with a barrier membrane, where the blood clot and the graft are stabilized, and the epithelial and connective tissue cell migration is avoided, and slow migrating osteogenic cells can proliferate, resulting in new bone formation.^[8,9]

The purpose of this study was to evaluate, from a clinical and radiographic perspective, the efficacy of a 1:1 mixture of deproteinized anorganic bovine bone (DBBM) (Bio-Oss) and autogenous bone graft associated with collagen resorbable membrane for Secondary closure of alveolar cleft.

MATERIALS AND METHODS

Three females and six males with mean age of 9 years, age range of 8–11 years were consulted to private practice in Cairo, Egypt, for their unilateral alveolar cleft. The study was conducted in accordance with the moral, ethical, regulatory, and scientific principles governing clinical research as set out in the Declaration of Helsinki (2004). All patients were fully informed about the treatment before the surgical procedure and provided written consent for the procedure. All procedures and materials were approved by the local Ethics Committee of Future University. Cases with complete clinical records, orthodontic study models, pre- and post-operative intraoral periapical radiographs (IOPAR) and maxillary occlusal radiographs to assess bone attachment, canine position, and alveolar crest height, were included in the sample from 2014 to December 2015.

Surgical procedure

The patient was prepped and draped for intraoral dentoalveolar surgery, and the oral cavity was cleaned with 0.1% chlorhexidine gluconate solution and the gingiva and upper buccal sulcus were infiltrated with 1% mepivacaine in 1:200,000 epinephrine. To provide sufficient mobility of the flap, which is going to cover the graft, it is necessary to cut through the periosteum at the base of the flap. Anteriorly, an incision was extended along the gingival border to the center of the cleft side central incisor. Vertical incision was made along the edges of the cleft. On the palatal side, mucoperiosteal flaps were raised along the edges of the cleft. A wide exposure of the cleft area was achieved with these incisions. During the exposure of the cleft, every effort was made to avoid traumatizing the thin bone lamella that covers the dental roots adjacent to the cleft. Nasal floor was reconstructed, if necessary and pushed upward. On palatal side, the mucoperiosteal flaps were sutured together with everting mattress sutures. This left a well-defined cavity, whose walls are periosteum and denuded bone. The cleft defect was exposed completely with the creation of a nasal layer that was closed primarily using 3-0 chromic gut. A resorbable collagen membrane (BioMend, Zimmer, San Diego, California) was next placed to re-enforce the recreated nasal lining.

The bone graft was harvested from the symphyseal region, using trephine bur number 5 in the form of small cylindrical blocks and then particulated in a bone mill (R. Quéting Bone-Mill, Roswitha Quéting Dental Products). A combination of this particulated autogenous bone and deproteinized anorganic bovine bone (Bio-Oss, Geistlich Pharma) (i.e., composite bone graft) in a 1:1 mixture by volume was then placed into the cleft defect. The composite bone graft was immobilized and covered with resorbable collagen membrane. Buccal flaps were elongated from both distal and mesial aspects of the alveolar defect and the oral mucosal layer was closed with 3-0 chromic gut in a tension-free manner [Figure 1]. Perioperative broad-spectrum antibiotics were used and continued for 1 week.

Clinical assessment

Clinical assessment was based on wound healing, pain, swelling, discharge, and dehiscence. Any complications in bone graft healing, such as membrane exposure, subsequent infection, and/or morbidity associated with the harvest site, were recorded. The patients had a follow-up of 1–6 months for clinical observation after the operation.

Radiographic assessment

The evaluation of the bone levels in the grafted areas was carried out using intraoral radiographs – a standardized upper anterior occlusal taken through the cleft line and a periapical part of the cleft region.

The assessment was performed according to the Oslo grading system,^[10] also known as Bergland's scale. The height of the interdental septum was observed and classified into 4 categories: Type I to Type IV [Figure 2]. In addition to evaluate the success rate of the radiographic bone graft using the Chelsea scale, the position of the bone tissue in relation to the teeth adjacent to the cleft was analyzed by separating the radiographic images^[11]

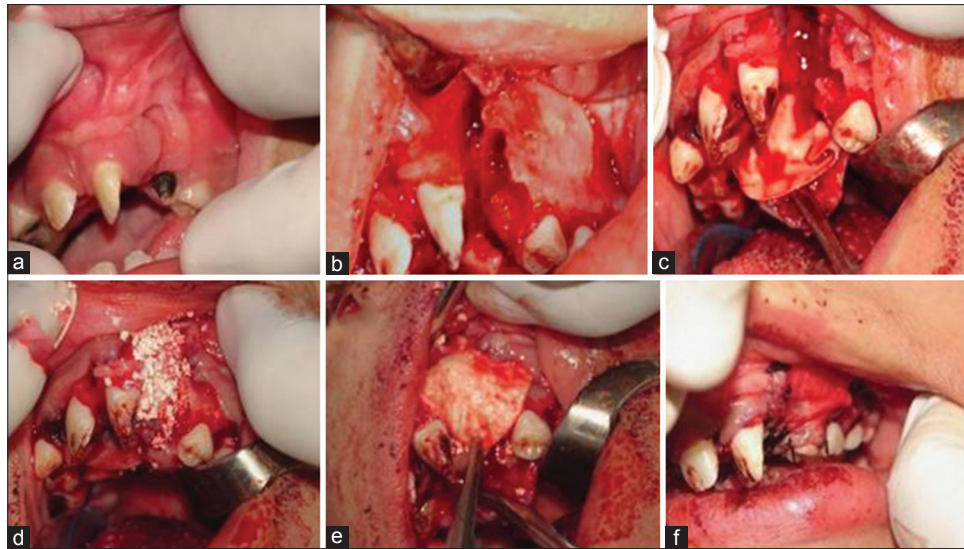


Figure 1: Subsequent stages of the alveolar osteoplasty in a 9-year-old patient with cleft of the left side: (a) Preoperative, (b) gap in the alveolar process, with the incision line of the mucoperiosteal flaps surrounding the alveolar process gap (c and d) placement of the composite graft into the cleft gap. (e) Placement of resorbable collagen membrane over the graft. (f) Oral mucosal layer was closed in a tension-free manner

which rates bone graft take by six categories (A to F) depending on the volume and the position of the bony bridge spanning the cleft-related to the cleft teeth [Figure 3]. The categories A, B, and C are considered to be acceptable and D, E, F as less than satisfactory.

1. Measurement of cleft width: Cleft width at the narrowest point, determined by inspection, was measured on a presurgical maxillary occlusal radiograph which was confirmed using study models
2. Assessment of canine position: Six points on the presurgical IOPAR were used to measure the amount of permanent cuspid crown emerged into the cleft beyond the adjacent alveolar bone and the total crown length of this tooth.

Statistical analysis

Numerical data were presented as mean and standard deviation (SD) values. Qualitative data were presented as frequencies and percentages. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows (United States).

RESULTS

In this study, secondary alveolar bone grafting was performed in all the cases.

Clinical evaluation

The healing period was uneventful in all cases, and no complications, such as membrane exposure, infection, or harvest site morbidity, were observed [Figure 4]. The postoperative swelling was remarkable in most cases, with maximum swelling at 48 h postoperatively. Swelling subsided gradually but was still visible at 1 week and disappeared completely after 10 days in all cases. Postoperative discomfort was primarily associated with tension from the

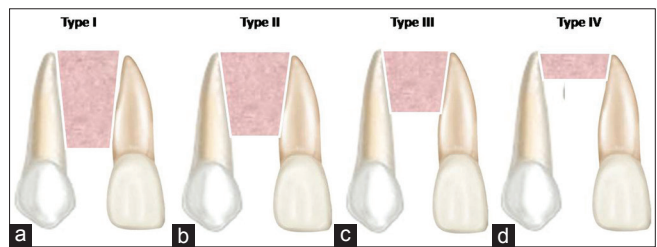


Figure 2: Sketches of Bergland classification.^[10] (a) Type I: 0%–25% of bone resorption. (b) Type II: 25%–50% of bone resorption. (c) Type III: 50%–75% of bone resorption. (d) Type IV: 75%–100% of bone resorption with no continuous bony bridge through the cleft

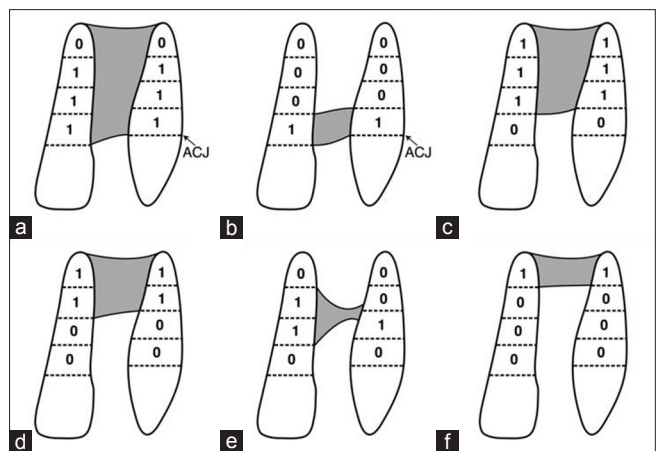


Figure 3: Sketches of six categories of the Chelsea scale.^[11] (a) At least 75% of both roots must be covered with bone; (b) bone must be present at the amelocemental junction and at least 25% of both roots, (c) bone must be present across at 75% of the cleft roots from an apical direction; (d) bone must be present across at 50% of both roots from an apical direction; (e) any bony bridge but without bone apically and coronally; (f) bone of 25% or less across both roots from an apical direction. Minimal scores shown in bold face

swelling, but pain was minimal. No major complications, such as hemorrhage and postoperative infection, occurred in any patients in this study. There were no device-related adverse effects related to the use of the membrane in these augmentation procedures.

Radiographic evaluation

On the Oslo scale, there were 5 (55%) patients rated Type I (septal height approximately normal); 3 (34%) Type II; 1 (11%) Type III [Table 1] The results of bone grafting according to the Chelsea scale are presented in Table 2. The ultimate outcome – category A was obtained in six patients (66.6%), whereas the less favorable but still satisfactory outcome – category C was observed in two patients. The unsatisfactory outcome – category E was registered in 1 patient only. According to Oslo classification and Chelsea score, good results of bone graft were obtained in 83% of patients.

The cleft width ranged from 0.2 to 0.7 cm (average: 0.4 cm). Except for one cleft site, in which the canine was almost into occlusion at the time of grafting, the majority of teeth migrating into the bone bridge during the 6 months were canines, and the lateral incisors had migrated into the area in a few cases [Figure 5]. In general, all treated defect sites exhibited excellent bone formation, with an average of 5.45 mm (range, 2–9 mm; SD 1.93 mm) of augmentation achieved overall. None of the cases demonstrated bone resorption throughout the follow-up period. All alveolar cleft repairs showed good maturation of the bone graft on the follow-up, with evidence of normal bone architecture. In fact, it was sometimes difficult to distinguish the bone graft from the normal alveolus.

DISCUSSION

The principles of surgical repair for unilateral clefts include proper closure of nasal floor mucosa to seal the communication between the nose and the oral cavity; filling the defect with grafted bone, and approximation of the oral mucosa on the labial and palatal aspects to achieve a watertight closure over the grafted bone.^[12] The goals of surgery are to provide a stable foundation for which the partially formed canine and lateral incisor can erupt, provide a stable bridge between the major and minor segments, repair any existing oral-nasal fistulous tract, and improve the projection of the nasal base.

Currently, the standard treatment for alveolar cleft at most institutions is grafting with autogenous bone from the iliac crest; on the other hand, bone grafts harvested from different sites have been recommended to reduce morbidity.^[13,14] Due to the reduced need for bone volume in the current study, the

grafts analyzed were obtained from the intraoral region, so there was no need to represent any control group of extraoral grafts. This approach represents a safe and successful procedure and is also better accepted by patients.^[15] Moreover, the donor area was not found to influence the effectiveness of the bone grafts, which is in agreement with a previous study.^[16] In this study, the patients were not interested in a hospital-based operation and a prolonged period of recovery potentially affecting their ambulatory status. Mandibular symphyseal bone was used as it has some advantages, such as obtaining from the same operative site, less donor site morbidity, ease of harvesting, an invisible scar in the labial sulcus and can be used in smaller or narrow defects as preferred in the presented cases.^[15] The symphysis has been reported to provide sufficient bone to augment a deficient ridge by 4–6 mm in the horizontal dimension, and up to 4 mm in the vertical dimension, covering a length of up to a 3-tooth defect.^[16,17]

GBR is a technique that works on the principle of separating particulate graft material from surrounding soft tissue to allow

Table 1: Gender and types of healing according to the Bergland scale

Category of bone healing	Males N=5	Females N=4	Overall N=9
Type I	3	2	5
Type II	1	2	3
Type III	1	0	1
Type IV	0	0	0

Table 2: The results of bone healing among 9 patients according to the Chelsea scale

Category of bone healing	Males N (%)	Females N (%)	Overall N (%)
A	4	2	6 (66.6)
B	0	0	0
C	1	1	2
D	1	0	1
E	0	0	0
F	0	0	0
Overall N(%)	6 (66.6)	3 (33.4)	9 (100)

N=sample size, %=Percentage

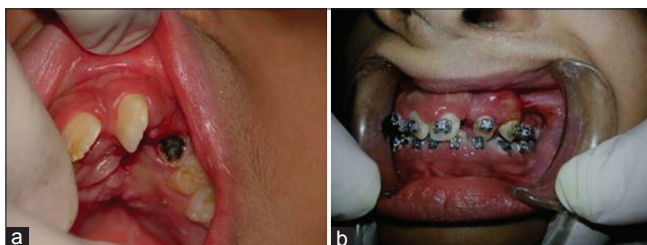


Figure 4: (a) Preoperative intraoral view. (b) Six months after secondary closure of alveolar cleft with eruption of tooth in the grafted cleft

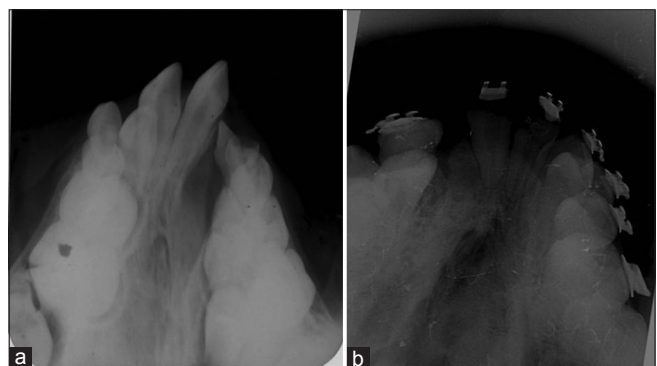


Figure 5: (a) Occlusal radiograph before secondary bone grafting. (b) Occlusal radiograph after bone grafting. The comparison of occlusal radiographs, before and after bone grafting, reveals the structural difference on the alveolar ridge, assigned to the bone grafting

for bone regeneration, which occurs at a slower rate compared to soft tissues.^[18] Resorbable (usually collagen based) or nonresorbable (usually expanded-polytetrafluoroethylene based) membranes are frequently used to stabilize the graft material, limit graft resorption and act as an occlusive barrier toward the surrounding soft tissue regeneration and infiltration.^[19] Bone resorption has been reported with the use of autografts without membranes. Therefore, membranes are utilized in nonspace making bone defects that require space maintenance and prevention of soft tissue ingrowth where bone regeneration is required.^[20]

In some clinical studies, xenograft and collagen barrier membranes in combination with mandibular bone block graft were performed by different authors.^[21,22] The authors deduced that adding graft material and a collagen membrane around and over a mandibular bone block graft could reduce graft resorption during healing. Several authors recommend the use of bovine apatite in GBR techniques with both resorbable and non-resorbable membranes.^[23,24] The rationale of mixing autogenous bone with DBBM is to combine the scaffold properties of the xenograft to the osteogenic and osteoinductive properties of the autograft. Moreover, the use of this combination allows for a reduction of the amount of autogenous bone harvested, subsequently decreasing the invasiveness of the technique and postoperative discomfort of the patient.^[25]

Previous evidence indicates that primary bone grafts, when performed in the deciduous dentition, interfere with the growth of the anterior and inferior maxilla, thereby increasing the risk of crossbites and undermining the angles formed by the teeth and premaxilla.^[26,27] Late or tertiary bone grafts performed in adults still have potential surgical success, although less than that observed in adolescents in the mixed dentition.^[28]

This study confirms the benefits of bone graft that can permit eruption of teeth, support normal tooth bearing function, and undergo remodeling to allow orthodontic movement. Early secondary bone grafting, between the ages of 2 and 6 is done primarily to provide alveolar bone support for the eruption of the lateral incisor. The lateral incisor is often malformed, congenitally missing, or erupts ectopically. Radiographic evaluation of the lateral incisor and canine associated with the cleft defect will help to determine timing of the graft. 95% of the anteroposterior and transverse growth is completed by the age of 8 and therefore the most common time for alveolar cleft grafting is between the ages of 9 and 11 (before the eruption of the canine when the root is 1/2–2/3 formed). Anteroposterior and transverse growth is completed by this age and only vertical growth remains. Grafting between the ages of 9 and 11 does not have much effect on midface growth and will provide bony support for the erupting canine.^[29]

From an orthodontic point of view, the most important benefit of secondary bone grafting is that the newly grafted bone acts as the alveolar bone, allowing for spontaneous migration of the adjacent canine toward the alveolar ridge.^[29,30] When the canine does not erupt spontaneously, it is necessary to perform orthodontic traction. When the canine eventually erupts, it creates a periodontium of support and protection that usually maintains an interdental bone septum of good height. Thus, periodontal

conditions are better when bone graft is performed before the eruption of the permanent canine.

The results of this study showed only a weak correlation between preoperative canine position and age at bone grafting. This indicates that to obtain the favorable bone form at the alveolar cleft, the timing of surgery should be planned not according to the age of the patient but according to other factors such as the position of the neighboring canine. On the one hand, if bone grafting is performed too early, maturation and migration of the germ of the canine would need a long period, leading to disuse atrophy of the bone bridge. As a consequence, bone grafting would become valueless. On the other hand, if the bone grafting is delayed, the canine might erupt abnormally, and subsequent orthodontic treatment would become quite difficult. Moreover, because more favorable bone formation can be achieved when the position of the canine is close to the alveolar plane, one can assume that the physiological stress caused by canine eruption is closely related to bone formation. These findings indicate that the optimal timing for surgery is when the canine cusp is close to the alveolar plane. X-ray findings revealed that where the lateral incisor is next to the alveolar cleft, the lateral incisor would erupt from the bone bridge earlier than the canine would. It has already been proposed that the presence of a lateral incisor can indicate the timing of bone grafting.^[28,30] The results of this study confirmed that if the germ of the tooth is present, a part of the lateral incisor could migrate into grafted bone and help to form a good bone bridge 6 months postoperatively. The migrated lateral incisor will erupt and will contribute to symmetrical, healthy dentition, and occlusion. Other conditions need to be taken into consideration in further study.^[30,31]

The evaluation of bone bridge formation after bone grafting in alveolar clefts is usually done by dental, occlusal, or panoramic radiographs. Three-dimensional analysis, however, has also been performed using computed tomography scans,^[28] but Rosenstein *et al.* found no significant differences in the results with the two methods and therefore concluded that routine dental radiographs can be used to estimate bone support for the roots of cleft-adjacent teeth.^[32] Hynes and Earley^[33] also concluded that IOPAR is a cost-effective and simple method of assessment of success and results in low X-ray exposure. Successful results were obtained with this technique and alveolar clefts were reconstructed and oronasal fistulas were closed at one stage.

Radiographic follow-up demonstrated adaptation of the symphyseal bone to the host area, making it impossible to distinguish the mesial and distal limits of the cleft. In addition, it was radiographically apparent that canines migrate toward the occlusal plane through the grafted bone and create good periodontal conditions. The findings of the present study agree with other studies in which teeth erupted through the grafted bone. Composite bone graft is quickly incorporated and vascularized and most importantly, does not interfere in the presence of the tooth contributes to the preservation of the grafted bone and the differentiation of the periodontal support.^[28,34]

The success rates of secondary bone grafts in the present study were 83% (Bergland scale) and (Chelsea scale), which is consistent with earlier investigations reporting rates of 70.3%–86%.^[10,11]

Moreover, these rates were shown to increase, reaching values up to 98%, for grafts performed before eruption of the permanent canines adjacent to the cleft.

The pre- and post-augmentation clinical measurements demonstrated significant bone regeneration. These results are comparable to those reported in other studies; Matsui *et al.*,^[35] evaluated the combined of autografts and titanium meshes in a series of 15 patients with cleft lip-palate, and reported a mean increased bone width of 4.6 mm. Proussaefs and Lozada^[6] reported a mean horizontal augmentation 3.82 ± 1.47 mm, using titanium meshes and a 50:50 combination of autogenous bone and bovine bone mineral in 17 consecutive patients, these was in agreement with our results, as the cleft width ranged from 0.2 to 0.7 cm (average: 0.4 cm). All treated defect sites exhibited excellent bone formation, with an average of 5.45 mm (range, 2–9 mm; SD 1.93 mm) of augmentation achieved overall. It can be suggested that a combination of autogenous bone graft and deproteinized bovine bone graft may be a good treatment choice depending on the early radiographical view of the defect and uneventful healing.

CONCLUSION

The treatment of unilateral alveolar cleft with GBR using a mixture of autogenous bone and DBBM and resorbable collagen membrane can be considered successful. This opens up the possibility of avoiding harvesting iliac crest bone graft and its associated morbidities and expense with using this composite bone graft and a GBR technique in an out-patient office setting.

Long-term follow-up regarding the maxillary development and changes of dentition/occlusion, as well as further improvement of the method of assessment of the bone bridge, are necessary.

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Conflicts of interest

There are no conflicts of interest.

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