Outcome of Using Medical Grade Calcium Sulfate Hemihydrate (DentoGen) in Unilateral Alveolar Cleft Repair

Haidar Mohammed Al-Jwboory[1], Sabah Abdulaziz Issa[2]

[1]B.D.S. Specialist, [2]H.D.D., F.I.B.M.S. Specialist Department of Oral and Maxillofacial Surgery, Medical City Complex, Baghdad, Iraq

Abstract

Objectives: The aim of this prospective study was to evaluate the efficacy of fast setting (DentoGen) bone substitute for secondary alveolar cleft repair.

Materials and Methods: Ten patients with complete unilateral cleft lip and palate were included for alveolar cleft repair with fast setting (DentoGen) without autogenous bone graft in 2017 and 2018. Pre-operation and 6 months post-operation CBCT were used for measurement of bone density and bone volume in cleft site. The data was analyzed by using Pearson's correlation coefficient test and paired sample t-test via SPSS software version 24.

Results: The mean age of patients in this study was 10.4±2.657 years. The pre-operative mean alveolar cleft volume was 0.8996±0.117cm^3. Six months after grafting with fast setting (DentoGen) graft, satisfactory bone formation was observed in all patients except two patients. The mean bone density of cleft site was 303±42.843 HU which was significantly lower than the non-cleft side, and the mean percentage of new bone formation was 64.74±10.290% compared with original cleft volume.

Conclusion: Calcium sulfate hemihydrate (DentoGen) can represent a promising alternative to autogenous bone graft in repairing small unilateral alveolar cleft during mixed dentition.

Key words: *Alveolar cleft, autogenous bone graft, DentoGen.*

Introduction

Cleft of the lip, palate, and alveolus are the most common congenital deformity affecting the oro-facial region and the second most common congenital malformation of the whole body following clubfoot.[1] Repair of the alveolar cleft is adjunctive procedure to further improve the functional and esthetic rehabilitation of patient with unilateral or bilateral cleft lip and palate which is recommended during mixed dentition period. Alveolar bone grafting is an essence step in managing the patient with this defect.[2]

Secondary bone graft (SBG) is not the most perfect method, but long-term follow-up confirm that the graft is absorbed to a lesser extent, does not disturb facial growth, and support teeth and periodontal ligament.[3] The fresh autogenous bone graft from an anterior iliac crest is considered the gold standard technique for alveolar cleft repair.[4]

This bone grafting also has disadvantages, such as the need for surgery at another site, extension of surgery time, increased possibility of infection, long stay in hospital, sever post-operative pain, unsightly scar, gait disturbance and sensory disturbance at lateral thigh.[2,4]

To surpass the donor site morbidity of autograft, recently many researchers assaying to get new alternatives by utilizing the synthetic bone materials, bone morphogenetic proteins and allogeneic bone.[3] Several preliminary clinical studies have reported that medical-grade calcium sulfate hemihydrate (MGCSH) seems to be an acceptable graft material for alveolar defects because it completely resorped and allows new trabecular bone arrangement in a limited 3-months period.Calcium substitutes offer significant advantages and properties over other biomaterials as well as

autologous bone grafts particularly in the primary alveolar cleft repair. [5,6]

Calcium sulfate is a well-tolerated, biodegradable, osteoconductive bone substitute and is a reasonable alternative to autogenous bone graft.Where the blood clot and the graft are stabilized, and the epithelial and connective tissue cell migration is avoided, so that, the slow migrating osteogeneic cells can proliferate resulting in new bone formation. [7-9]

This prospective study aimed to evaluate the efficacy of fast setting (DentoGen) bone substitute for secondary alveolar cleft repair.

Materials and Methods

This clinical study was approved by the Iraqi Scientific Council for Medical Specialization, Baghdad, Iraq. A signed informed consent was taken from all patients parents.

Ten patients with complete unilateral cleft lip and palate were selected for alveolar cleft repair with fast setting (DentoGen) graft (Fig.1). All operations were doneat Ghazi Al-hariri Hospital for Surgical Specialties in Baghdad, Iraq between August 2017 and October 2018.

The male-female ratio was 3:2, and the mean age of patients was 10.4 years. Patient with non-syndromic unilateral alveolar cleft between the age 7 and 15 years were included in this study. Exclusion criteria include: any patient with systemic and hematologic disease, bilateral alveolar cleft, any patient with previous failed alveolar graft.

Figure 1: Pre-operative image of left alveolar cleft

Surgical Procedure

All patients were operated under general anesthesia with nasal intubation. Local anesthesia lidocaine 2% and epinephrine 1:100000 was infiltrated in the buccal mucosa around cleft site.

The alveolar cleft site was exposed by a marginal incision with a releasing incision in the buccal sulcus, then nasal mucosa was sutured (Fig. 2)

Figure 2. Suturing of nasal mucosa

Synthetic bio-absorbable calcium sulfate hemihydrate, DentoGen (Orthogen, LLC, Springfield, NJ) was then applied to all of the patient without autogenous bone graft.

DentoGen kit contained powder and liquid (regular set and fast set), the powder was mixed with fast set liquid, when the mixture comes to a putty-like consistency, then apply and compressing it in the cleft site with a sterile gauze pad held with tweezers saturated in fast set liquid (Fig. 3), then the buccal lateral sliding flaps closed after the graft has been dried.

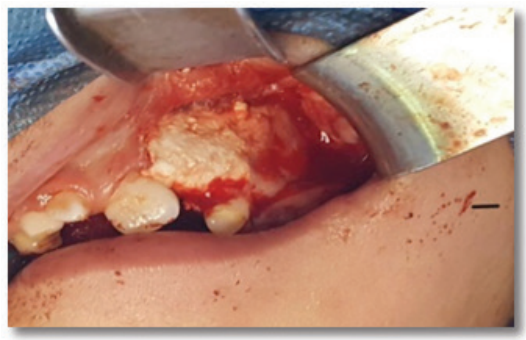

Figure 3. Placement of DentoGen bone graft to the alveolar cleft

Radiographic Assessment

A cone beam computerized tomography (CBCT) was carried out for all patients pre-operatively and 6 months post-operatively using a Planmeca ProMax 3D Classic Cone Beam 3D system device (Planmeca, Helsinki, Finland).

For consistency, CBCT scans analyses of all participants were performed by the same radiologist. The volume of alveolar defect was measured pre-operatively on axial plane by using special imaging software program. The volume of the pre-existing bone defect was compared in percentages with the total graft volume six months post-operatively. Finally, the bone density was measured and collected in same labeled layer on coronal view six months after surgery using CBCT density scale that measured by HU unit that used in CT.

Statistical Analysis

The data was analyzed by using Pearson's correlation coefficient test and paired sample t- test via SPSS software version 24.

Results

Ten patients were included in this study. The mean age at grafting time was 10.4±2.657 years. All patients healed uneventfully except three patients presented with wound dehiscence in the alveolar cleft site at the first week post-operatively. The dehiscence healed secondarily without infection. The mean pre-operation volume of alveolar cleft was 0.8996±0.117cm^3.

Six months after surgery, the volume of new formed bone and percentage of bone generation were 0.547±0.102cm^3 and 64.74±10.290% respectively (Table 1).

The results of CBCT bone density values are listed in table 2, the mean bone density of the cleft site was site was 303±42.843 HU and that of the non-cleft 416±69.637 HU, the difference was statistically highly significant (P = 0.002). The mean durations of operation time for patients in this study was 93.5±13.954 min.

Table 1: Descriptive statistics of cleft, bone graft volumes and percentage of bone formation

Variables	Cleft volume (cm3)	Graft volume (cm3)	Bone formation (%)
Mean	0.8996	0.547	64.74
S.D.	0.117	0.102	10.290
Min	0.673	0.421	44.8
Max	1.015	0.694	74.8

Table 2: Comparison of bone density between normal site and cleft site

Sides	Normal side (HU)	Cleft side (HU)
Mean	416	303
S.D.	69.637	42.843
t-test	4.393	
P-value	0.002	
Sig.	(HS)	

Discussion

Secondary alveolar bone graft (SABG) has become common practice because of its ability to establish the overwhelming majority of the aims of alveolar cleft repair such as: closure of oronasal communications, osseous support for the alar base, creation of intact dental arch and to allow eruption of teeth especially permanent canine tooth in the cleft site.[10]

Although there is a worldwide consensus that autogenous bone of the anterior iliac crest is the gold standard bone graft for the alveolar cleft repair, there is no enough studies and literatures on using alloplastic material as an alternative to iliac graft.[3] In this study, an assessment of the effectiveness of fast setting (DentoGen) graft for repairing alveolar defects by radiographic evaluation of the quality and quantity of bone formation in cleft sites was done.

In the qualitative analysis, bone density can be measured objectively in HUs unit by CT and CBCT.[11] The bone density in cleft side was statistically highly significant lower than the mean bone density in non-cleft side and this comes in agreement with the results of study done by Benlidayi et al[12], when they found that the mean bone density in cleft site grafted with autogenous bone graft from anterior iliac crest was significantly lower than the non-cleft side. The reason for this result may be related to the technique of mixing and application of (Dentogen), stratification and dry compaction may play very important role in improving mechanical strength and reduced resorption rate of the graft material.[13]

In the quantitative analysis, the complete bone bridging was noted in all patients in this study and these findings were comparable to the results of many studies that used either autogenous or allogeneic bone graft for alveolar cleft repair (Figure 4).[14,15]

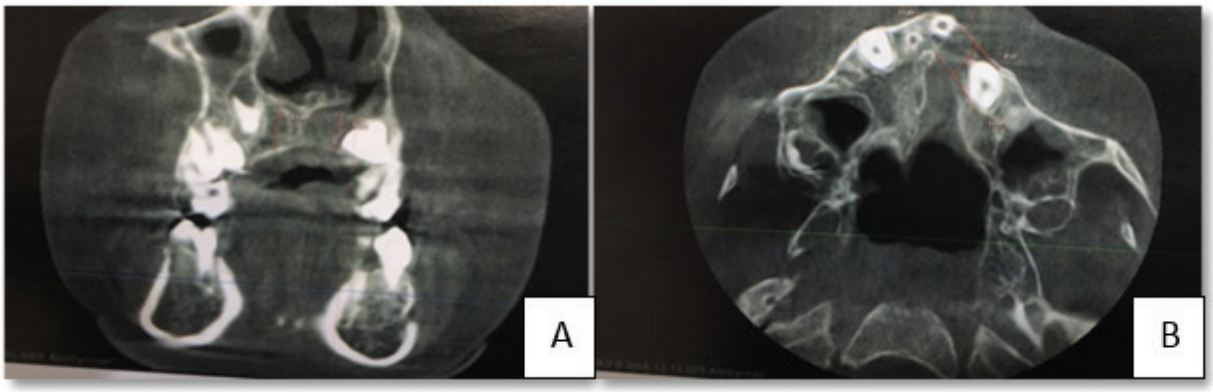

Figure 4: A. Coronal view and B. Axial view of CBCT 6 months postoperatively

The mean percentage of bone formation in cleft site to the cleft volume at 6 months post-operatively was 64.74±10.29%. In this study sample, there were 8 patients below 11 years of age and 2 patients above 11 years of age. The percentage of bone formation in those eight patients was ranged from 66.6% to 74.8% while in the other two patients; the percentage was 44.8% and (46.6%) respectively. The reasons for this result may related to many factors such as: rapid bone resorption due to absence of functional stress on the bone, poor oral hygiene and width of the cleft.[16] The other factor could be the changes in the healing potential with increasing age.[17] These results come in agreement with the findings of study done by Dantana et al. [18], when they found that mean percentage of bone resorption after 3 months of alveolar cleft repair with the cancellous bone and marrow from the anterior iliac crest was 36.46%.

Tai et al. [19] evaluated secondary alveolar bone grafting among 14 unilateral and bilateral cleft patients by using CT scan and found that the percentage of bone loss 1 year post-operatively was 43.1% which is in accordance with the findings of the present study when only patients with unilateral cleft are considered.

The mean duration of this surgical procedure was 93.5±13.954 min. Macisaac et al. [20] mentioned that the

mean duration of alveolar cleft surgical repair with iliac bone graft was 147 min.

Wound dehiscence was occurred in three patients (30%) at second to third week post-operatively and this finding agreed with the results of Benlidayi et al. [12] study. The major causes for this results may be attributed to the patients themselves and surgical technique not to the graft material, such as poor oral hygiene, the tension of wound closure and extraction of teeth within the cleft site intra-operatively. [16]

Conclusions

Despite the limitation of the study, which was conducted on small number of patients and short period of follow up, calcium sulfate hemihydrate (DentGen) provided less invasive, more economical and seem to be very promising grafting option.

It represented a reasonable alternative to autogenous bone graft in repairing small unilateral alveolar cleft during mixed dentition after the eruption of permanent central incisors and before the eruption of canine in a short surgery duration.

Ethical Clearance: The Research Ethical Committee at scientific research by ethical approval of both MOH and MOHSER in Iraq

Conflict of Interest: None

Funding: Self-funding

References

1. Peter E, Larsen D. Reconstruction of the Alveolar Cleft. Principles of Oral and Maxillofacial Surgery. Peterson's 2nd ed. M. miloro. Vol. 859–870. 2004
2. Boyne PJ, Sands NR. Secondary bone grafting of residual alveolar and palatal clefts. J Oral Surg 1972; 30: 87-92.
3. Khan MSR, Shaung M, Liu XL, Xu S, Liang HF. Current concept in alveolar cleft management. Bangabandhu Sheikh Mujib Med Univ J 2017; 10: 195-203.
4. Walia A. Secondary alveolar bone grafting in cleft of the lip and palate patients. Contemp Clin Dent 2011; 2: 146-54.
5. Guarnieri R, et al. Medical-grade calcium sulfate hemihydrate (surgiplaster) in healing of a human extraction socket –histologic observation at 3 months. Int J Oral Maxillofac Implants 2005; 20: 636-41.
6. Lazarou SA, Contodimos GB, Gkegkes ID. Correction of alveolar cleft with calcium-based bone substitutes. J Craniofac Surg 2011; 22: 854-857.
7. Strocchi R, et al. Bone regeneration with calcium sulfate: evidence for increased angiogenesis in rabbits. J Oral Implantol 2002; 28: 273-8.
8. Proussaefs P, Lozada J. Use of titanium mesh for staged localized alveolar ridge augmentation: clinical and histologic-histomorphometric evaluation. J Oral Implantol 2006; 32: 237-47.
9. Bernabe PF, Melo LG, Cintra LT, Gomes-Filho JE, Dezan E JR, Nagata MJ. Bone healing in critical size defects treated with either bone materials: A histological and histometric study in rat tibiae. Clin Oral Implant Res 2012; 23: 384-8.
10. Epker BN, Stella JP, Fish LC. Dentofacial Deformities and Surgical Correction.Vol.3. St. Louis: Mosby; 1998. pp.1487-1570.
11. Lee S, Gantes B, Riggs M, et al. Bone density assessments of dental implant sites: 3. Bone quality evaluation during osteotomy and implant placement. Int J Oral Maxillofac Implants 2007; 22: 208.
12. Benlidayi ME, Tatli U, Kurkcu M, Uzel A, Oztunc H. Comparison of bovine-derived hydroxyapatite and autogenous bone for secondary alveolar bone grafting in patients with alveolar clefts. J Oral Maxillofac Surg. 2012; 70: e95-e102.
13. Pecora G, De Leonardis D, Ibrahim N, Bovi M, Cornelini R. The use of calcium sulphate in the surgical treatment of a 'through and through' periradicular lesion. Int Endod J 2001; 34: 189-97.
14. Maxon BB, Baxter SD, Vig KW, Fonseca RJ. Allogeneic bone for secondary alveolar cleft osteoplasty, J Oral Maxillofacial Surg 1990; 48: 933.
15. Tomar K, Sahoo NK. Evaluation of graft uptake from the iliac crest in secondary alveolar bone grafting: Bergland's criteria revisited. J Oral Biol Craniofac Res 2018; 8: 171-176.
16. Akadiri OA, Akinbami BO, Kejeh BM. Tertiary bone grafting with or without premaxilla osteotomy in adult alveolar cleft-Techniques and early outcome. Open J Stomatol 2012; 2: 122-129.

17. Sindent-Pedersen S, Enemark H. Comparative study of secondary and late secondary bone-grafting in patients with residual cleft defects. Short-term evaluation. Int J Oral Surg 1985; 14: 389-98.
18. Dantana S, Chattopadhyay PK, Kadu A. Bony bridge resorption after secondary alveolar grafting and correlation with success of orthodontic treatment: A prospective volumetric cone beam computed tomography (CBCT) study. Med J Armed Forces India 2019; 75: 375-82.
19. Tai CC, Sutherland IS, McFadden L. Prospective analysis of secondary alveolar bone grafting using computed tomography. J. Oral Maxillofac Surg 2000; 58: 1241–1249.
20. Macisaac ZM, Rottgers SA, David III AG, Ford M, Loose JE, Kumar AR. Alveolar reconstruction in cleft patients: decreased morbidity and improved outcomes with supplemented demineralized bone matrix and cancellous allograft. Plast Reconstr Surg 2012; 130: 625.