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The Efficacy of Osteon II Collagen (Synthetic Bone Graft with Bovine Type I Collagen) with Platelet Rich Fibrin on Bone Healing Process in Unilateral Alveolar Cleft

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ABSTRACT— Alloplastic material has been suggested to reconstruct the alveolar cleft to reduce surgery time, providing an abundant quantity of bone, and no need for the donor site. Platelet-rich fibrin has many growth factors effective in bone healing and tissue maturation. Evaluation of the effectiveness of the application of osteon II collagen with platelet-rich fibrin on the bone healing process in unilateral alveolar cleft patients. This study included 15 patients aged from 7to12 years, with a unilateral alveolar cleft. Osteon II collagen bone substitute with Platelet-rich fibrin membrane was used to reconstruct the alveolar defect. Postoperative density and buccopalatal thickness of Osteon II collagen bone substitute were assessed by cone-beam computerized tomography at immediate postoperatively,6, and 12months after surgery. The density and buccopalatal thickness of Osteon II collagen bone substitute increased after 6 months postoperatively, while it's highly significant increased after 12months, also valuable bone continuity was observed in all patients. We concluded the osteon II collagen bone substitutes with PRF have a regenerative effect, decrease bone substitutes resorption that leads to preserving the volume with increased bone substitutes density. Also, the PRF was used to accelerate the speed of bone formation and to reduce bone resorption.

KEYWORDS: Efficacy of Osteon II, Bone Healing Process, Platelet Rich Fibrin

1. INTRODUCTION

Cleft lip and palate are considered the common congenital craniofacial birth defects. The reconstruction of the alveolar cleft with bone grafting is recommended during the mixed dentition period [1]. Bone substitutes are biologically acceptable, allowing bone ingrowths and bone remodeling while maintaining volume [2]. Additionally, alloplastic materials have several advantages, such as the lack of required donor site, availability, and the nonexistence of disease transmission [3]. The platelet-rich fibrin is a second-generation platelet concentrate that has many advantages over PRP; it is simpler to prepare and does not require biochemical handling of the blood [4]. Also, PRF contains numerous growth factors, such as platelet-derived growth factor(PDGF), (TGF-β), and insulin-like growth factor(IGF). Cone-beam CT has been widely used to assess the alveolar bone defect before and after grafting. It provides volumetric analysis, gives more details about the dental and bony conditions around the cleft, determines the amount of bone needed for grafting, and assesses the quantities of bone formed after surgery. Recently, grafting volume calculation with cone-beam CT data was confirmed dependable [5], [6].

2. Patients and methods

This study was involved 15 patients;9 male and 6 female, their ages were ranged from 7to 12 years. The study was performed in the department of oral and maxillofacial surgery, Ghazi-Alhareery Hospital, from March 2019 to October 2020.any patients>6 years old age, non-syndromic congenital unilateral alveolar cleft without systemic or genetic disorders, and patients who will be available for follow-up were a candidate for this study. While the excluded patients were those who had syndromic congenital unilateral alveolar cleft with systemic and genetic disorders, any patients presented with abnormal hematological values, patients with a known allergy to collagen, and guardian refuses to sign the written informed consent. Written consents were obtained from the guardian for treatment and future publication of taken photos. The guardian was informed about the associated complications and the possible outcomes.

2.1 Surgical procedure

All the procedures will be performed under GA with nasal intubation. The sterile preparation and draping were carried out to all patients in the same conventional manner. Infiltration of the oral cavity with a local anesthetic solution with vasoconstrictor helps intraoperative hemostasis during and after reflection of the mucoperiosteal flap. Incision of the mucoperiosteal flaps starting by using blade No.15 in the buccal sulcus posteriorly along the gingival margins from the upper 1st molar on the cleft side to the upper 1st molar on the non-cleft side. then reflection the flap around the cleft and separation of oral mucosa from nasal mucosa, nasal closure achieved in all cases with interrupted sutures using a 3/0 vicryle synthetic absorbable suture material on a round needle FIG(1a). during the operation,20 ml of fresh venous blood took from each patient and transferred into PRF tubes. The tubes were placed quickly in the centrifuge, which was adjusted to 3,000 rpm for ten minutes. Now we have three distinct layers inside each tube FIG(1b).a fibrin clot is then obtained from the middle of the tube FIG(1c),then packed tightly using the PRF box to obtain resistant fibrin membranes FIG(1d).After that, the Osteon II collagen adapted to the alveolar defect directly, the reconstruction was concentrated on the alveolus and Piriform area FIG(1e).Then prepared PRF membrane was adapted beneath nasal mucosa and over Osteon II collagen bone substitute FIG(1f).Finally, buccal mucosa over the bone substitute closed in a tension-free manner by interrupted 3/0 silk sutures on a round or cutting needle FIG(1g).

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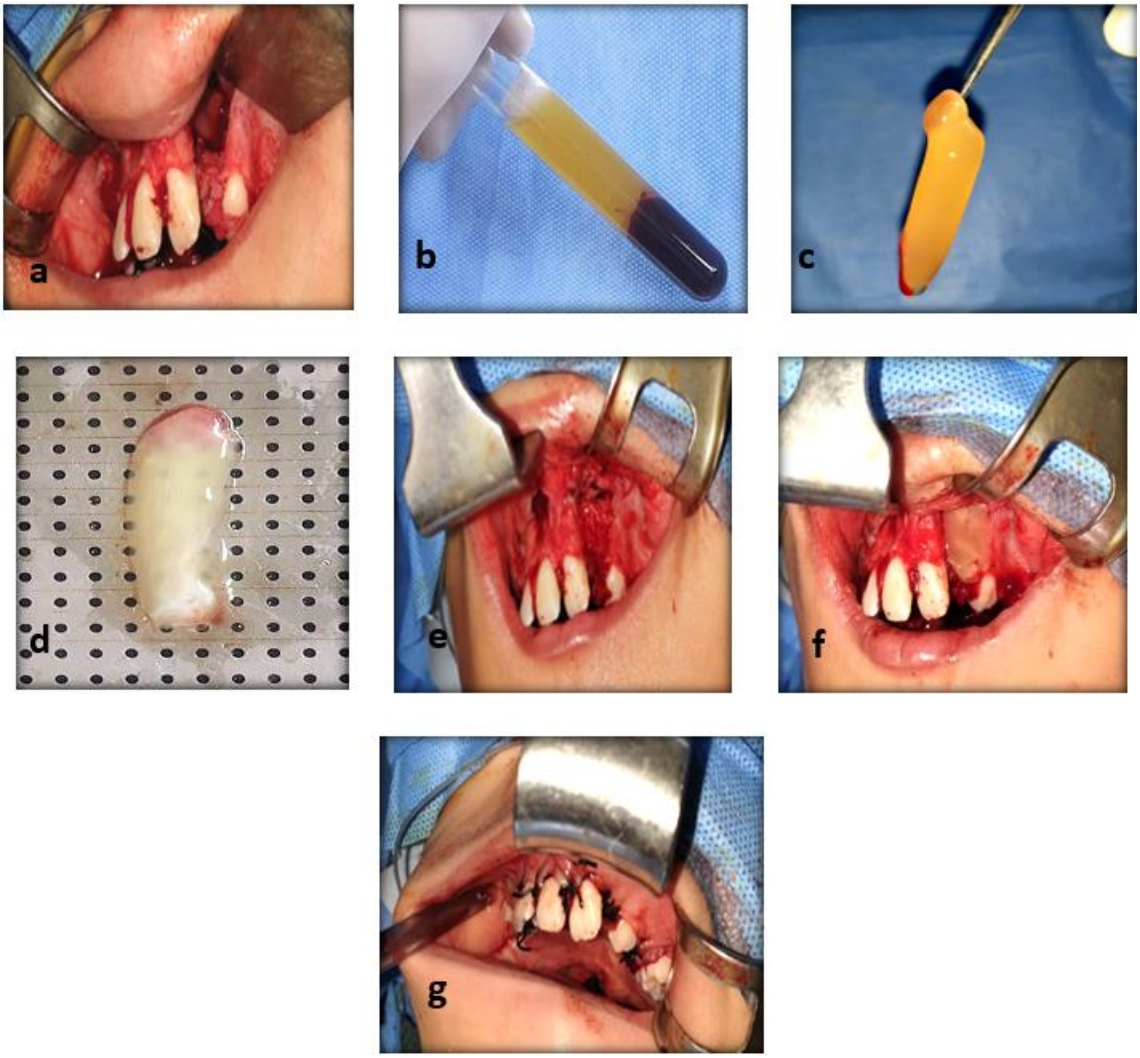

Figure.1 a.Mucoperiosteal flap reflection and Separation of nasal mucosa from oral mucosa, b,c. PRF layers were formed after centrifugation of a patient's blood, d.PRF membrane, e.Osteon II collagen adapted in the alveolar cleft, f.PRF membrane adapted beneath nasal mucosa and over bone substitute, g. Mucoperiosteal flap suturing.

2.2 Radiographical assessment

Preoperative and Postoperative radiographic assessment had been done by using CBCT 3D system (Kavo OP PRO, Germany), with tube voltage range of 90 kV, tube current range of 9.2 mA, exposure time 8.1s, and 0.5 mm slice thickness. All CBCT measurements were performed by the same radiologist.

The preoperative CBCT was used only as a guide to the site and the size of the alveolar cleft FIG(2a) and as a comparative value of the alveolus continuity 6 and 12 months after surgery. Using the axial view to measure the buccopalatal thickness of Osteon II collagen bone substitute in the immediate postoperative day,6 and 12 months after surgery, by drawing two parallel lines on the buccal and palatal bone plate, then measured the distance between them. The bone substitute density was measured in the densest area and collected in the same labeled layer on the immediate postoperative day,6 and 12 months after surgery by using CBCT density scale was measured by the HU unit that was used in CT(Table1).The immediate postoperative CBCT is considered a baseline value for the buccopalatal thickness and the density of bone substitutes FIG(2b,2c).At 6 months postoperative CBCT was used to evaluate the buccopalatal thickness and the density of bone substitute compared with the immediate postoperative baseline value FIG(2d,2e).

While12 months postoperative CBCT was used to evaluate the buccopalatal thickness and the density of bone substitute compared with immediate postoperative baseline value and 6 months postoperatively FIG(2f,2g). Finally, continuity of the alveolar bone was evaluated in the axial and 3D views 6 and 12 months postoperativelyFIG(2h).

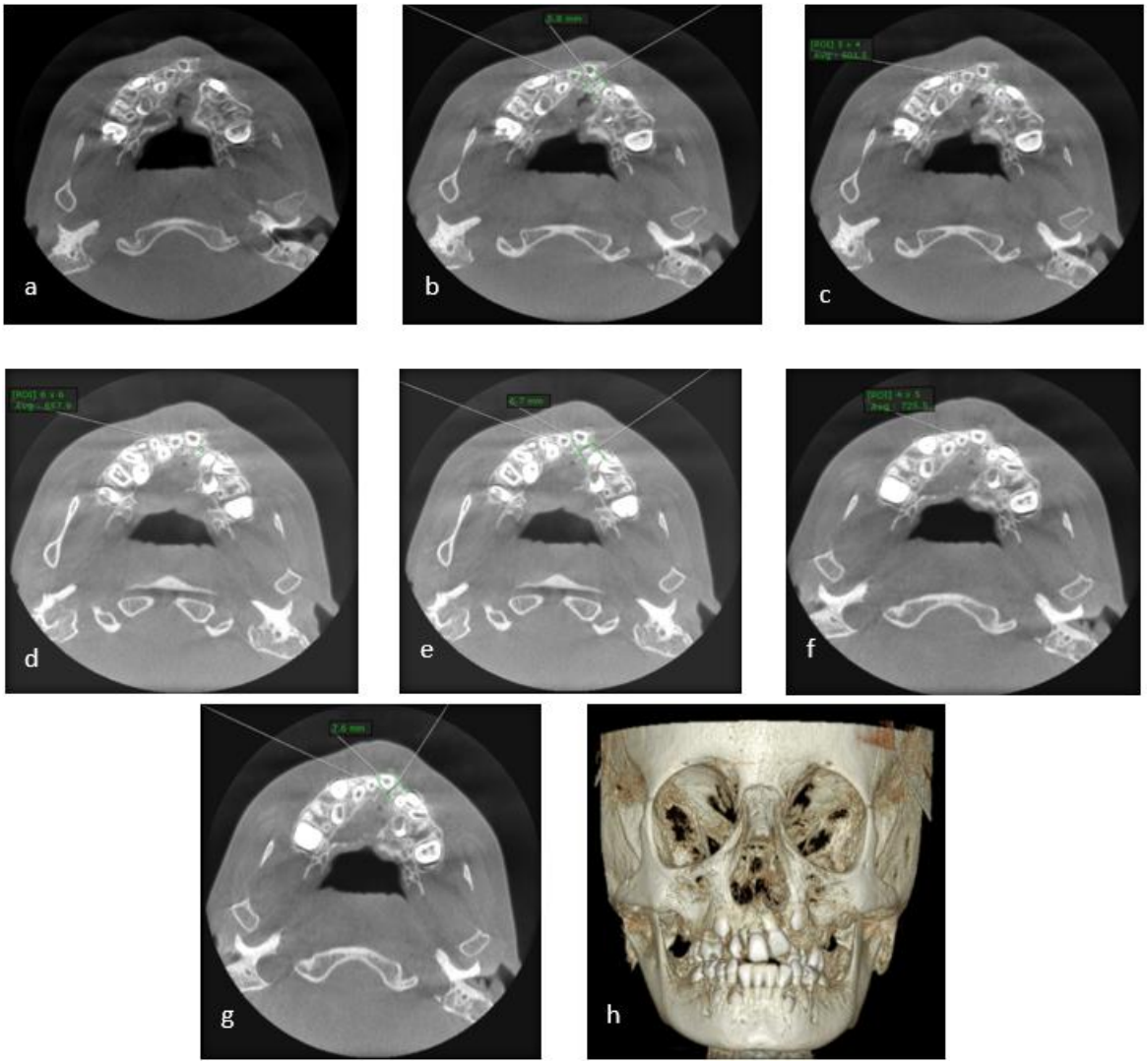

Figure. 2 a.Preoperative axial view showing the site and size of alveolar cleft,b. The bucccopalatal thickness of the grafted bone substitute immediate postoperative day,c. The bone density of grafted bone substitutes on the immediate postoperative day,d. The bone density of grafted bone substitute 6 months postoperatively,e. The buccopalatal thickness of grafted bone substitute 6 months postoperatively,f. The bone density of grafted bone substitute 12months postoperatively also shows bone continuity,g. The buccopalatal thickness of grafted bone substitute 12months postoperatively, h.3D view showing bone continuity after 12 months postoperatively.

Table 1: Classification based on CT determination of bone density [7].

Density	Hounsfield Units
D1	1250
D2	850-1250
D3	350-850
D4	150-350
D5	<150

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3. Results

The comparison in the mean value of buccopalatal thickness was significantly increased 6 months postoperatively compared to that immediately after the operation (7.57 versus6.98mm) as shown in(table2), while highly significant and significantly increased after 12 months when compared with the immediate after the operation and 6 months postoperatively respectively (7.81 versus 6.98 versus 7.57mm) as shown in (table 3).

The comparison in the mean value of bone substitute density was significantly increased 6 months postoperatively compared to that immediately after the operation (755.82 HU versus720.57 HU) as shown in (table 4), while highly significant and significantly increased after 12 months when compared with the immediate after the operation and 6 months postoperatively respectively (765.30 HUversus720.57 HU versus 755.82 HU) as shown in(table 5).

Also, satisfactory bone continuity was observed in all patients after 6 months postoperatively, It became more obvious after 12 months postoperatively.

Table 2: Comparison in the mean of buccopalatal thickness immediately and 6 months postoperatively.

Time	Buccopalatal thickness(mm) Mean±SD	P-value
Immediately after operation	6.98 ± 0.966mm	
6 months postoperatively	7.57 ± 0.979mm	**0.026**

Table 3: Comparison in the mean value of buccopalatal thickness after 12 months compared with immediately after the operation and 6 months postoperatively.

Time	Buccopalatal thickness(mm) Mean±SD	P-Value	Time	Buccopalatal thickness(mm) Mean±SD	P-Value
12 Months postoperatively	7.81 ± 0.875mm	**0.004**	12 Months postoperatively	7.81 ± 0.875mm	**0.022**
Immediately after operation	6.98 ± 0.966mm		6 months postoperatively	7.57 ± 0.979mm	

Table 4: Comparison in the mean of bone substitute density immediately and 6 months postoperatively.

Time	Bone Density Mean±SD	P-Value
Immediately after operation	720.57 ± 165.12	**0.015**
6 months postoperatively	755.82 ± 149.80	

Table 5: Comparison in the mean value of bone substitute density after 12 months compared with immediately after the operation and 6 months postoperatively.

Time	Bone Density Mean±SD	P-Value	Time	Bone Density Mean±SD	P-Value
12 months postoperatively	765.30 ± 150.14	**0.002**	12 months postoperatively	765.30 ± 150.14	**0.020**
Immediately after operation	720.57 ± 165.12		6 months postoperatively	755.82 ± 149.80	

4. Discussion

The autogenous bone graft is considered the gold standard procedure in the treatment of alveolar clefts

because of its efficiency. Our study aimed to evaluate the efficacy of the alloplastic material (osteon II collagen) with PRF on the bone healing process, with eliminating donor site necessity. Osteon II (Dentium. Co. Ltd, Suwon, South Korea), is a particle-type graft material, composed of Hydroxyapatite and beta-tricalcium phosphate with a weight ratio of 30/70 % which are so close to intrinsic mineral components of the human bone [8], with favorable biocompatibility and osteoconductivity properties. In our study, we found a gradual increase in bone substitute density after 6 and 12 months postoperatively. The same finding occurred with [9] who study the effect of Osteon II collagen in maxillary sinus graft healing, they concluded that after 6 months, the density of bone trabecula and cancellous bone was good, and minimal resorption in grafted material indicates the ability of the graft to induce more bone remodeling and increasing in density. Also the spontaneous increase of buccopalatal thickness of bone substitute after 6,12 months postoperatively. So, we agree with [10] who pointed to the benefit of combining the slow-resorbing HA will conserve the volume, while fast resorption of β-TCP will promote bone regeneration. Also, [11] concluded the addition of collagen type I to Osteon II material to increase its osteoconductivity by slowly absorbing it after helping the initial shaping. Also, agreement with [12] who found combinations of (30% HA and 70% β-TCP) are effective in alveolar ridge augmentation. In our study, we used PRF to increase the rate of bone formation and decrease bone resorption. PRF contains a high concentration of platelets and is an autologous source of growth factors (PDGF, tumor growth factor, and VEGF), cytokines, and leukocytes that affect the healing and maturation of the bone and soft tissue. We agreement the result of [13] who used PRF to advance bone formation and decrease bone resorption in alveolar cleft reconstruction. Also, agreement with [14] demonstrated that the use of PRF can increase the density of the newly formed bone because of the presence of concentrated growth factors in the PRF.

5. Conclusion

In our study we found, there are Increased in buccopalatal thickness and bone substitutes density after 6 and 12 months postoperatively, good alveolar bone continuity, PRF membrane has a good effect on mucosal healing with the absence of infection and graft exposure, and Osteon II collagen appears to be easily handled and manipulation with biocompatible and osteoconductive properties.

So we concluded the use of the osteon II collagen bone substitutes with PRF has a highly regenerative effect, decreasing bone substitutes resorption that leads to preserving the volume with increased bone substitutes density.

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