



## **SINUS FLOOR AUGMENTATION WITH SIMULTANEOUS IMPLANT PLACEMENT USING BIO-OSS WITH AND WITHOUT PRF: CLINICAL STUDY**

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### **ABSTRACT**

**Objectives:** This study was to assess and compare the long term influence of Bio-Oss graft with and without PRF clots as a filling material during a lateral sinus lift with simultaneous implantation.

**Material and Methods:** 12 sinus elevations performed on 10 randomly selected patients and were divided into 2 groups. Group A received Bio-Oss mixed with PRF (Platelet Rich Fibrin) as graft and PRF membrane, and group B received Bio-Oss only as graft and Bio-Oss collagen membrane. The treatment outcome was evaluated at 6 and 12 months of healing clinically and radiographically. Bone height and bone density were measured preoperatively, at 6 and 12 months postoperatively and statistically analyzed.

**Results:** Statistical analysis showed that the bone height and bone density increased significantly ( $p \leq 0.05$ ) at 6, and 12 months postoperatively in both groups. By comparing the two groups, Group A showed statistically significant ( $P \leq 0.05$ ) increase in bone height and density than group B.

**Conclusion:** The use of PRF mixed with Bio-Oss was more superior to Bio-Oss only as graft after sinus lift and simultaneous implant placement regarding bone height and bone density.

**KEYWORDS:** Direct sinus lift, Implant in posterior maxilla, Bio-Oss, PRF.

### **INTRODUCTION**

Implant placement in partially edentulous patients especially in the posterior maxilla is most challenging and frequently complicated by unfavorable post extraction bone patterns, pneumatization of the maxillary sinus, poor quality

of the remaining alveolar bone and higher occlusal forces, making it insufficient for holding the implant. The need to increase the vertical dimension of posterior maxilla by surgical techniques has developed. <sup>(1)</sup> Sinus lift for implant placement is considered one of the most predictable procedures for augmenting bone in the posterior maxilla. <sup>(2)</sup>

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Sinus lift procedure has been developed in the mid-1970s after the experimental studies published by Boyne and James <sup>(3)</sup>, and Tatum <sup>(4)</sup> regarding grafts in the maxillary sinus to treat the loss of vertical bone height in the posterior maxilla. It is performed in two ways: A lateral window technique (direct) and an osteotome sinus floor elevation technique (indirect) associated with placing bone graft material to increase the height of the available bone. <sup>(5)</sup>

The lateral approach is historically the first main technique, where the maxillary sinus floor is grafted to provide a sufficient quantity of bone for the placement of endosteal dental implants. Considering the high osteogenic potential of the Schneiderian membrane and its periosteum-like behavior, it is considered that most materials, bone substitutes or autologous bone, are efficient in this situation. <sup>(6)</sup> Using this approach, implant placement can be performed in one or two surgical stages depending on the residual alveolar bone height. Misch <sup>(7)</sup> considered that 8 mm subantral bone height is the limit for the indirect sinus augmentation technique, 5 to 8 mm bone height is indicated for 1-stage direct augmentation with implants, and cases with less than 5 mm bone height are indicated for the 2-stage direct augmentation technique. <sup>(8)</sup> Moreover, Numerous studies have showed that when more than 5 mm of residual alveolar bone is present, simultaneous implant placement can achieve adequate primary stability. <sup>(9,10)</sup>

Sinus lift procedure with simultaneous implant placement (One-stage technique) shortens the treatment time and eliminates the need of the second operation for inserting the implant, thus reducing patient morbidity and cost. <sup>(11)</sup>

It is well-accepted that sinus lifting techniques require space makers for new bone generation. <sup>(12)</sup> Initially, the most popular bone grafting materials are autogenous bone grafts with the disadvantages of time consuming, high morbidity, the need to be

replaced, and insufficient quantity of bone. <sup>(13)</sup> Many bone substitutes had been tried in order to find a good alternative to autografts, but even the best among the bone substitutes is only osteoconductive (e.g. hydroxyapatite, allografts, xenografts, and alloplastic materials). These materials are suitable for sinus augmentation procedures since they are available in the needed quantity and maintain the original volume during the substitution process. <sup>(14, 15)</sup>

Among the numerous xenografts proposed by many investigators, anorganic bovine bone (Bio-Oss) which is one of the most popular biomaterials used for sinus elevation surgery. <sup>(16-18)</sup> The biological interactions occurring at the bone-biomaterial interface are critical for long-term clinical success. <sup>(19)</sup> Bio-Oss is a xenograft consisting of deproteinized, sterilized bovine bone with 75–80% porosity and a crystal size of approximately 10  $\mu$ m in the form of cortical granules; it has a natural, non-antigenic porous matrix and is chemically and physically identical to the mineral phase of human bone; it has been reported to be highly osteoconductive and to show a very low resorption rate. <sup>(20,21)</sup> Different studies have been published about the long term performance of Bio-Oss. <sup>(22,23)</sup>

The use of blood preparations such as platelet concentrates or fibrin glues might seem an interesting option to improve the sinus-lift approach, but such preparations are often expensive and complicated to prepare. <sup>(24)</sup> Choukroun et al <sup>(25)</sup> was the first to describe platelet-rich fibrin (PRF) in France in 2001. It is a simple, natural, and inexpensive technique for the production of leukocyte- and PRF (L-PRF) concentrates. Moreover, PRF releases high amounts of growth factors (such as transforming growth factor- $\beta$ 1 [TGF $\beta$ -1], platelet-derived growth factor-AB [PDGF-AB], vascular endothelial growth factor [VEGF]), and matrix glycoproteins (such as thrombospondin-1) during at least 7 days in vitro. Thus, this biomaterial presents a specific biology. <sup>(26)</sup> Moreover, PRF stimulates many different

kinds of cells, particularly the proliferation and differentiation of osteoblasts. <sup>(27)</sup> The use of PRF during sinus-lift procedures has been advocated for many years during lateral sinus-lift or vertical osteotome augmentation. <sup>(28,29)</sup>

In recent years, dental cone-beam CT (CBCT) has been used in the dental field. Bone density of the oral cavity have been measured using CBCT. <sup>(30)</sup> The histological findings and CT results have validated CBCT readings. <sup>(31)</sup> Moreover, The resolution of CBCT is better than that of traditional CT, and the dosage required for CBCT is much less than that for traditional CT. <sup>(32,33)</sup> Accurate measurement of bone mineral density (BMD) and bone quantity in upper and lower jaw is most commonly assessed by CBCT without any invasive procedure and a considerable low radiation dose. <sup>(34)</sup> Accordingly, CBCT is an appropriate method for postsurgical follow-up assessments. <sup>(35)</sup>

The objective of this study was to assess and compare the long term influence of Bio-Oss graft with and without PRF clots as the filling material during a lateral sinus lift with simultaneous implantation.

## MATERIALS & METHODS

This study consisted of 12 sinus elevations performed on 10 randomly selected patients from those attending the Oral and Maxillofacial Surgery Department, MSA University. Sinus elevations were 8 unilateral and 2 bilateral. The patients included 7 females and 3 males with age range from 28 to 37 years. As the literature does not contraindicate this approach for sinus lift, no ethical problems were raised. The patients were informed about the aim and design of the study and written consent was obtained. For each patient, a pre-surgical radiologic examination was performed using Cone Beam

Computerized Tomography (CBCT). The clinical and radiographic examination showed atrophy of the maxilla in the premolar/molar area that required sinus lift before implantation. Sub-antral residual bone height was 5-8 mm and ridge width was at least 5mm as measured on CBCT scans. Pre-surgical standard blood analyses showed normal blood variables.

Patients to be included should have blood concentration of thrombocytes within the normal range with absence of maxillary sinusitis. Patients had to be compliant during their preliminary periodontal treatment, to accept the required follow-up, and to show, no clenching habits, or bruxism, and no smoking habit. Patients with immunologic diseases, uncontrolled diabetes mellitus, ongoing chemotherapy or radiotherapy, or other contraindicating systemic conditions were excluded.

In this clinical study, tapered Screw Plant implants \* have been used. The diameter of the fixtures varied between 4.7 mm and 5.7 mm depending on the width of the alveolar process. The length of the implants used was 13 mm.

The surgical procedures were performed under local anesthesia and under medication. Patients were randomly and equally divided into two groups, group A where direct one stage sinus lift receiving Bio-Oss\*\* mixed with PRF as graft and PRF membrane was performed, and group B where direct one stage sinus lift receiving Bio-Oss only as graft and Bio-Oss collagen membrane \*\*\* was performed.

Preoperative antibiotic therapy (amoxicillin and clavulanic acid 625 mg three times a day) was started a day before surgery for all patients included in this study.

\* Spectra-System®, ScrewPlant , Implant Direct™ L.L.G., Malibu hills, USA

\*\* Geistlich Bio-Oss , bone substitute, Geistlich Pharma North America Inc.

\*\*\* Geistlich Bio-Oss Collagen, Geistlich Pharma North America Inc.

### **Surgical technique**

Local anaesthesia (Lidocaine 2% containing 1:100,000 epinephrine) was administered. A horizontal incision was made along on the crestal bone in the edentulous area and continued as gingival incision from the canine eminence anteriorly to the zygomatic buttress posteriorly, and then vertical incisions were made to elevate the mucoperiosteal flap. After the elevation of the full thickness mucoperiosteal flap, the lateral sinus wall was exposed and its extension detected referring to CBCT scans. An osteotomy (window) was created with the help of small diamond bur with constant irrigation. The inferior osteotomy cut was made about 4–5 mm above the floor of the maxillary sinus, followed by anterior, posterior, and superior osteotomy cuts. All the cortical bone was removed up to the sinus membrane. The osteotomy size created was 1 × 1 cm approximately, sufficient to allow good access for easy dissection, sinus membrane elevation, and insertion of the graft. The sinus membrane was carefully dissected intact from the underlying bone starting from the inferior and lateral cuts using Sinus curettes. The implant was installed through the crestal bone by using the standardized preparation technique for Screw Plant Implant System. The implant was allowed to penetrate into the sinus cavity about two or three times the residual bone volume.

The primary stability was acceptable as judged by the surgeon during the implant installation. The sinus membrane was thus held up by the implant which acts as a tent pin for the membrane. The implant was surrounded by the bony walls of the adjacent teeth and at the top of it the sinus mucosa. A cover screw was adapted.

### **PRF preparation**

PRF clot was prepared as described by Choukroun et al <sup>(25)</sup> during surgery, 10 ml whole blood was drawn from the patient's anti-cubital fossa into glass-coated plastic tubes without anticoagulant and was immediately centrifuged at 3000 rpm for 10 minutes using table top centrifuge. The coagulation

cascade lead to the formation of a natural fibrin clot in the middle. The PRF clot was then cut from the top and bottom layers.

Bio-Oss was opened and poured in dish. In group A, The particulate graft mixed with PRF clot was placed in the sinus cavity around the exposed part of the implant and on top of it. In group B, the particulate graft only was used. The prepared graft was packed till the apical part of the fixture was completely covered with bone in all cases.

In group (A) A second PRF clot was prepared and transformed into a membrane by compression between two sterile gauzes. One or two PRF membranes were used to cover the lateral osteotomy window, avoid migration of the graft, and protect the filled sinus from mucosal invagination. Fig (1)

In group (B) an absorbable Bio-Oss collagen membrane was cut to extend beyond the outline of the lateral osteotomy window and placed over the graft. Fig (2) The flap was then repositioned with interrupted sutures. Sutures were removed after 2 weeks and abutment connection made after 6months followed by single crown therapy.

### **Post-operative instructions and medications**

Patients were instructed not to do anything that would abruptly raise or lower pressure in the sinus cavity for 10 days post-surgery, such as sneeze with mouth closed, blow the nose, fly on an airplane, suck through a straw, go swimming, do diving, blow up balloons, or play a wind instrument. Patients also were instructed not to eat on the side of operation and soft diet was recommended. Ice packs were provided after surgery.

After the surgery, patients continued on antibiotic therapy for a week and were advised to rinse their mouths daily with Chlorhexidine Gluconate Oral Rinse 0.12% during the healing period. All patients were prescribed non-steroidal analgesic (Ibuprofen 400 mg three times daily) for pain relief and swelling control to be self-administered. All patients were checked regularly to verify healing. Dental

panoramic radiograph was taken immediately after sinus surgery. A CBCT scan was taken 6 months and one year postoperatively.

### Radiographic evaluation

All the patients underwent cone beam computed tomography (CBCT) scan prior to the surgical procedure, for evaluation of bone height and density. Follow up CBCT were made 6 months after insertion, and 6 months later after loading (1 year after insertion). CBCT were evaluated for bone height [above the implant apex] and bone density at the study intervals. Evaluation was obtained by Scanora 3D, with OnDemand3DApp 1.0.10.4304 viewer. Measurements were calculated by an

oral radiologist who was blinded to the surgical procedure and the evaluation were made twice with 10 days period interval. Fig. (3)

### Statistical Analysis

The collected data were statistically analyzed. The significance of the difference between the pre-operative and postoperative data regarding bone height and bone density at the same group was assessed with the Student T test (paired and unpaired). The two groups were compared to each other using also the Student T test (paired and unpaired). The statistical analysis was carried out using SPSS software (statistical package for social science on windows 2013). A probability value  $\leq 0.05$ .

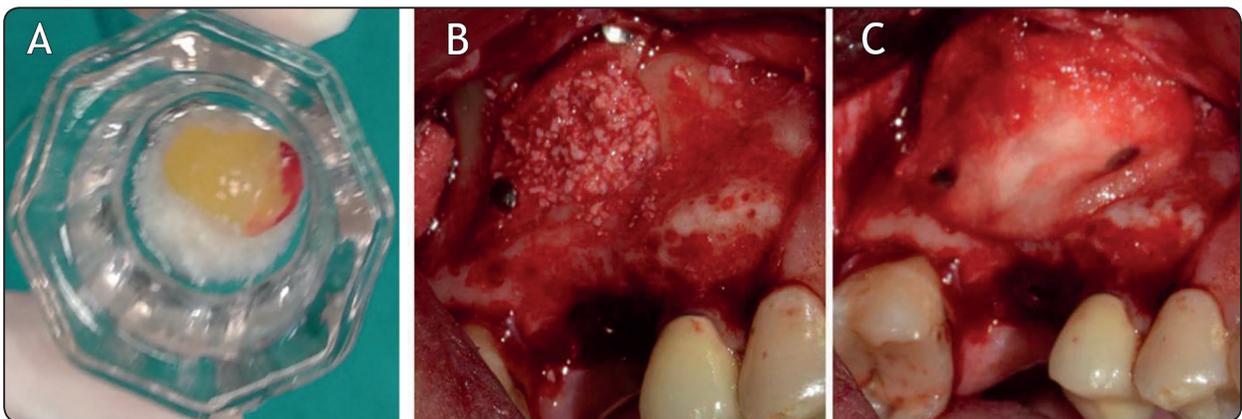


Fig (1) A) Bio-Oss Graft mixed with PRF clot, B) The subsinus cavity is filled with PRF clot mixed with Bio-Oss graft after sinus lift, C) PRF membrane covering the osteotomy window and implant was inserted.

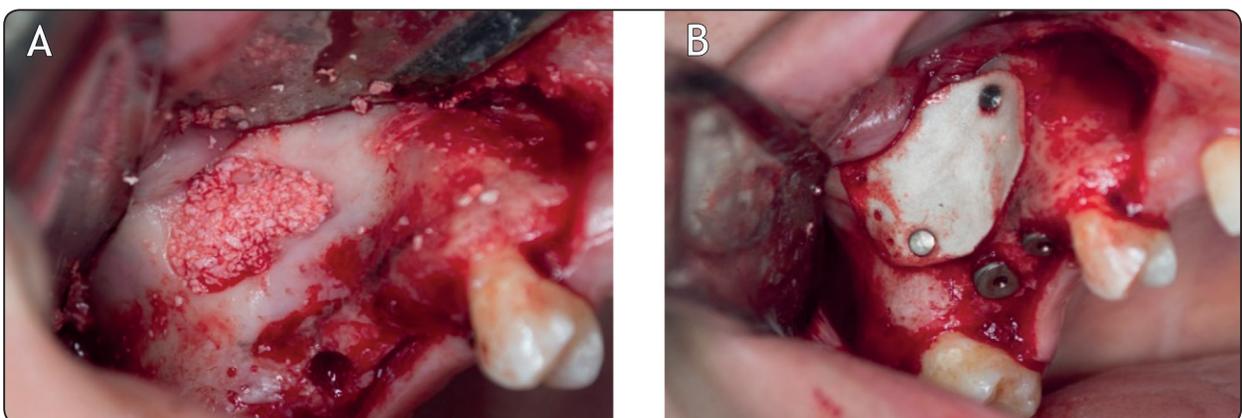


Fig (2) A) Bio-Oss graft on the subsinus cavity after sinus lift, B) Bio-Oss collagen membrane covering the osteotomy window and implants were inserted.

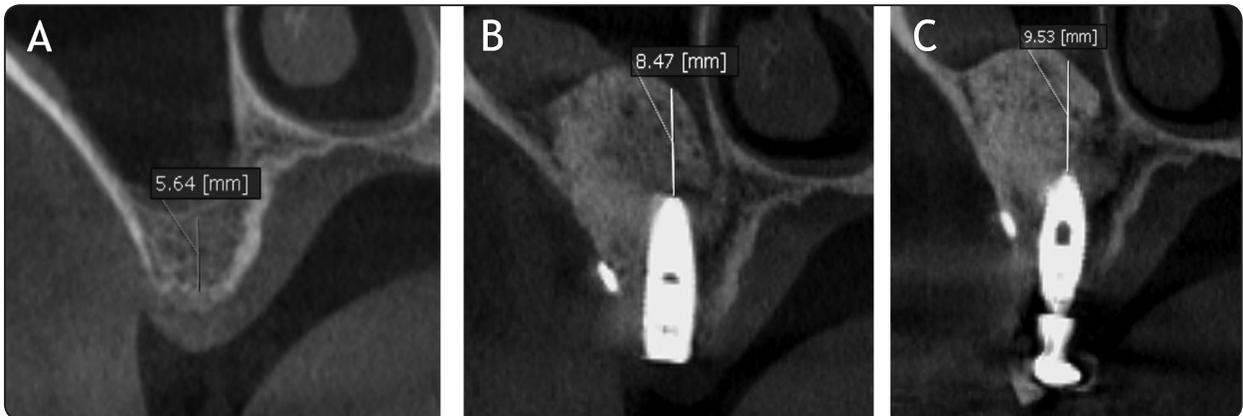


Fig (3): A) CBCT showing preoperative measurement of residual bone height, B) CBCT showing the bone height above the implant at 6 months postoperative, C) CBCT showing the bone height above the implant at 12 months postoperative.

**RESULTS**

The present study was undertaken to compare the use of PRF and Bio-Oss mixture to the Bio-Oss only as subsinus graft after sinus lift and simultaneous implant placement. A total of 10 patients with 12 implants have been followed clinically and radiographically for 12 months. No clear sinus membrane perforation was observed. Clinically, there were no reports of side effects or complications. The marginal gingiva is healthy in all the patients Six months after surgery. All patients had crown rehabilitation at 6 months postoperatively. No implant was lost, leading to a 100% success rate after 12 months. All implants were clinically stable during abutment tightening.

The mean residual bone height below the sinus floor was at start  $5.37 \pm 0.81$  mm in group A, and  $5.31 \pm 0.56$  mm in group B. The bone height at 6 months postoperatively was in mean  $7.42 \pm 1.83$  mm in group A, and  $6.95 \pm 2.17$  mm in group B. At 12 months postoperatively the bone height increased to a mean  $8.41 \pm 1.51$  mm in group A, and  $8.20 \pm 1.11$  mm in group B. The increase in bone height after 12 months was statistically significant ( $p \leq 0.05$ ) in both groups.

At 6 and 12 months postoperatively, group A had statistically significant ( $p \leq 0.05$ ) higher bone height than in group B. Fig (4)

Regarding the bone density, it was  $905.17 \pm 137.71$  HU, and  $872.17 \pm 98.11$  HU in group A and B at 6 months postoperatively and increased to  $1085.33 \pm 198.96$  HU and  $914.17 \pm 93.04$  HU in both groups respectively at 12 months postoperatively.

Comparing the two groups, group A showed statistically significant ( $p \leq 0.05$ ) higher bone density than group B at 6 and 12 months postoperatively. Fig (5)

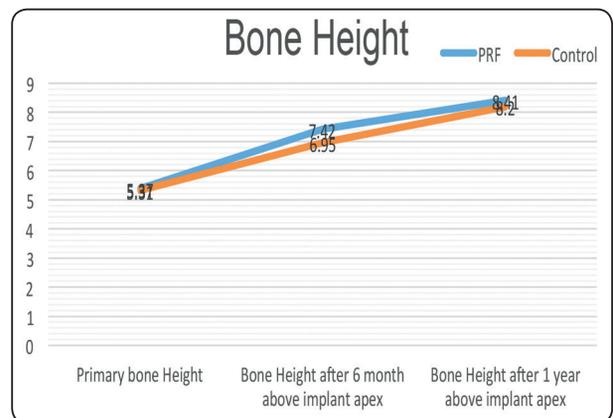


Fig (4) Line Chart showing the bone height of the study groups at 0, 6, 12 months intervals.

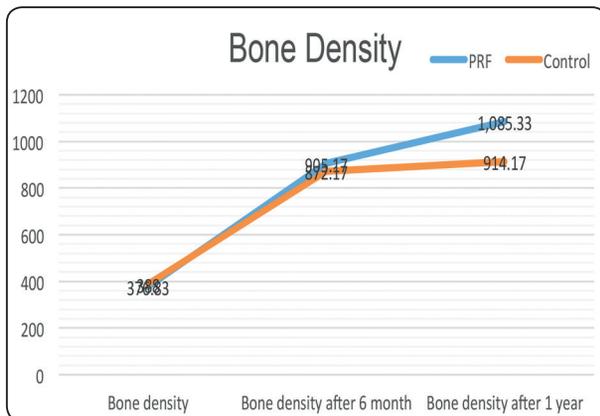


Fig (5) Line Chart showing the bone density of the study groups at 0, 6, 12 months intervals.

## DISCUSSION

Various materials have been used for sinus floor augmentation. However which graft materials are clinically more suitable for this procedure remains unclear when bone regeneration is the goal of the prosthetic rehabilitation. Bio-Oss has become one of the most widely used materials as it has demonstrated favorable results for sinus floor augmentation.

In the current study, augmenting the sinus using Bio-Oss with and without PRF clot has resulted in significant increase in bone height and density after one year follow up. This finding is in agreement with those of Valentini et al<sup>(36)</sup> and Hallman et al<sup>(37)</sup> On the other hand, some studies reported no change or slow and decreasing resorption in the graft overtime.<sup>(38-40)</sup> This could be explained by the maturation model. If the used biomaterial promotes early bone formation in the apical part of the graft, the graft is less likely to collapse by the effect of pneumatization or air pressure. Also, this possibility is decreased by the presence of mineralized tissue in the apical part of the graft, beneath the sinus membrane, and by a lower amount of non-mineralized tissue in the graft.

Adding PRF to Bio-Oss resulted in increased bone formation and density above and around

the implant. This could be attributed to the osteoinductive effect of PRF and growth factors. This finding is consistent with those of other studies.<sup>(41-43)</sup>

In the current study, Implant loading at 6 months postoperatively didn't cause graft resorption. This could be attributed to that Implant loading may exert a stabilizing effect on the maintenance of bone graft height. This finding is consistent with the findings of Listrom & Symington.<sup>(44)</sup>

Our study revealed success rate of 100% using lateral window osteotomy technique with the subsinus residual bone height of 5-8mm. This agrees with the systematic review of Chao et al<sup>(45)</sup> who evaluated the effect of initial bone height on implant survival rate and reported that the lateral approach has a very predictable outcome for bone height 4 mm or greater, near to 100% implant survival rate.

According to a systematic review of sinus elevations, membrane coverage on the lateral osteotomy window of the sinus had a significantly better survival rate than without membrane coverage.<sup>(46)</sup> This could explain the 100 % success rate in the current study using PRF membrane in group A and Collagen membrane in group B. This finding is also in agreement with those of Tawil & Mawla<sup>(47)</sup>, and Choi et al.<sup>(48)</sup> Therefore, membrane coverage for the lateral osteotomy window is now widely accepted for clinical application.

Based on our findings, we are able to show that PRF mixed with Bio-Oss has an enhancing effect on new bone formation regarding bone height and density after sinus lift with simultaneous implant placement at one year follow up.

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