ORIGINAL PAPER

MINIMAL INVASIVE CRESTAL SINUS TECHNIQUE USING AUTOLOGOUS FIBRIN GLUE VERSUS STICKY BONE WITH SIMULTANEOUS IMPLANT INSERTION: A PROSPECTIVE STUDY

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ABSTRACT

Introduction: Following tooth extraction, posterior maxilla frequently experiences bone resorption and maxillary sinus pneumatization, resulting in resorption of bone with insufficient dimension for adequate dental implants placement.

Objectives: This clinical investigation was performed to assess implant stability and radiographic outcomes using autologous fibrin glue (AFG) against sticky bone combined with crestal sinus lift procedure and simultaneous implant insertion.

Material and methods: The study involved 12 implants in ten patients with residual bone height from 5 to 9 mm, divided into two groups. In group A, AFG was applied for maxillary sinus augmentation, while in group B, sticky bone was used for maxillary sinus augmentation. All patients were followed-up clinically to evaluate implant stability at baseline (T^0), third month (T^3), and ninth month (T^9) as well as radiographically to evaluate residual bone height, implant protrusion, graft apical height, and graft sinus height at same time intervals. Data were analyzed using (IBM SPSS software, version 26.0). *P*-value ≤ 0.05 was considered statistically significant.

Results: A total of 10 patients (8 females, 2 males) participated in the study, with mean age ± SD of 29.83 ± 3.54 years in group A, and mean age ± SD of 32 ± 3.89 years in group B. At T^0, T^3, and T^9 follow-up, there was a statistical significance within each group (with $p < 0.001$ in all studied parameters). However, there were no significant differences between both groups, with $p = 0.843$, 0.296, and 0.451 regarding implant stability, $p = 0.221$, 0.244, and 0.276 in graft apical height, and $p = 0.435$, 0.494, and 0.673 regarding graft sinus height, respectively.

Conclusions: AFG can be applied as a non-inferior material during sinus lifting with advantages including fewer complications, easy preparation procedure, less time-consuming, and affordable cost.

Key words: AFG, crestal sinus technique, grafted sinus height, sticky bone.

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INTRODUCTION

Due to limited amount of accessible bone volume in posterior maxilla, sinus floor elevation has become a crucial pre-implant grafting treatment [1]. A lateral approach with Caldwell-Luc osteotomy or an axial approach using Summers' osteotomy, are the two methods used for sinus lifting. The remaining bone height of alveolar ridges plays a major role in the method selection. The Summers' osteotomy procedure, which results in reduced pain and no interval between grafting and implantation, is currently used to treat majority of simple cases [2].

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The use of AFG (autologous fibrin glue) appears interesting, since it contains a high amounts of platelets known to release growth factors that promote bone development. Additionally, its high fibrinogen concentrations can create a dense fibrin clot with enough adhesive power to keep bone fragments in the desired form [3]. Also, it is recognized as an attractive scaffold in tissue engineering, with cell migration and proliferation improvement. Additionally, it contains growth factors that can encourage and facilitate tissue repair [4].

In the study, sticky bone was used as an alternative to block bone and titanium mesh. It is a fibrin mesh-encased bony transplant material. Even when shaken with a cotton plier, it does not scatter because the particulate bone is strongly interconnected with each other by fibrin mesh. It can easily flex and compress, and it is well-suited for various shapes of bone deformities. Sticky bone also helps to keep the grafted bone stable [5].

Furthermore, the fibrin meshwork traps platelets and leukocytes, resulting in release of various growth factors that aid regeneration and repair. Fibrin mesh also reduces the likelihood of soft tissue incorporation into the adhesive bone [5].

OBJECTIVES

The purpose of this clinical study was to assess the healing benefits of using sticky bone against AFG in combination with the crestal sinus approach procedure and simultaneous implant insertion.

MATERIAL AND METHODS

Between August 2019 and May 2022, patients were selected for enrollment from the Oral and Maxillofacial Surgery Department's outpatient clinic at Mansoura University, based on the following inclusion criteria: patients with missing one of maxillary posterior teeth, patients willing to attain regular follow-up appointments, with the ability to collaborate and comply with predictable clinical outcomes; patients with remaining bone height ranging from 5 to 9 mm, with a patent maxillary sinus ostium and missing maxillary posterior tooth. On the other hand, patients with systemic diseases that preclude surgical intervention or bone healing, acute or chronic maxillary sinusitis, cysts, tumors, or root tips at the planned surgical site, heavy smokers (10 cigarettes daily) [6], elderly patients (over 60 years old), patients with poor oral hygiene or aggressive periodontal diseases, and individuals with low motivation or inability to maintain oral hygiene were all excluded from the study.

This prospective randomized controlled study was approved by both ethical committee with number of M02150620, and Clinicaltrials.gov, with ID No. of NCT05613335. The study included 12 implants in 10 patients of both gender, who were replacing a missed single or multiple teeth in posterior maxilla and suffered from pneumatization of maxillary sinus. The enrolled patients were categorized into two separate groups: group A underwent maxillary sinus augmentation using AFG and simultaneous implant installment, and group B underwent maxillary sinus augmentation using a sticky bone and simultaneous implant installment.

SAMPLE SIZE CALCULATION

Calculation of sample size was based on a difference of bone augmentation detected among autologous fibrin glue with collagen carrier during maxillary sinus lift procedure retrieved from a previous research [7]. The overall computed sample size was 10 cases using G*Power software version 3.1.9.4, to calculate sample size based on an effect size of 1.025, using 2-tailed test, and α error = 0.05 and power = 80.0%.

SAMPLE RANDOMIZATION

Simple random sampling technique was applied through sequentially sealed envelopes technique. Patients were asked to randomly select one of the envelopes.

PRE-OPERATIVE RECORDS

Study casts were utilized as records to assess each patient's occlusion, crown height, and mesio-distal width of any missing teeth. Pre-operative panoramic X-ray was used as a screening tool, followed by cone-beam computed tomography (CBCT) (Philips, Brilliance TMCT, v. 2.6.1.21045, multislice 64 workstation; Philips, extended Brilliance TM, Workspace, v. 3.0.1.5000; dose length product, 0.66 mSv per time) when a patient was considered a candidate for crestal sinus floor to evaluate remaining bone height and width. Pre-operative medication was provided with amoxycillin/clavulanate (Augmentin, 1 gm tablets, GlaxoSmithKline Pharmaceuticals, Egypt) 2 gm as a prophylactic antibiotic one hour prior to surgery, while levofloxacin (larivex, 500 mg tablet; Euro-Egy-Pharm, Egypt) 500 mg one tablet was prescribed for patients allergic to penicillin.

SURGICAL PROCEDURES

Patients was directed to rinse their mouth with a mouthwash containing 0.12% chlorhexidine (Listermix Plus mouthwash, SIGMA, Egypt), one minute prior to surgical operation. All surgical procedures were carried out using local anesthetic (Artinibsa 4%, 1 : 100 000, Inibsa, Spain) in the buccal and palatal regions. In order to expose the crestal bone, a full-thickness muco-periosteal flap was uncovered. After that, the implant site was prepared by using a pilot drill and a series of drills

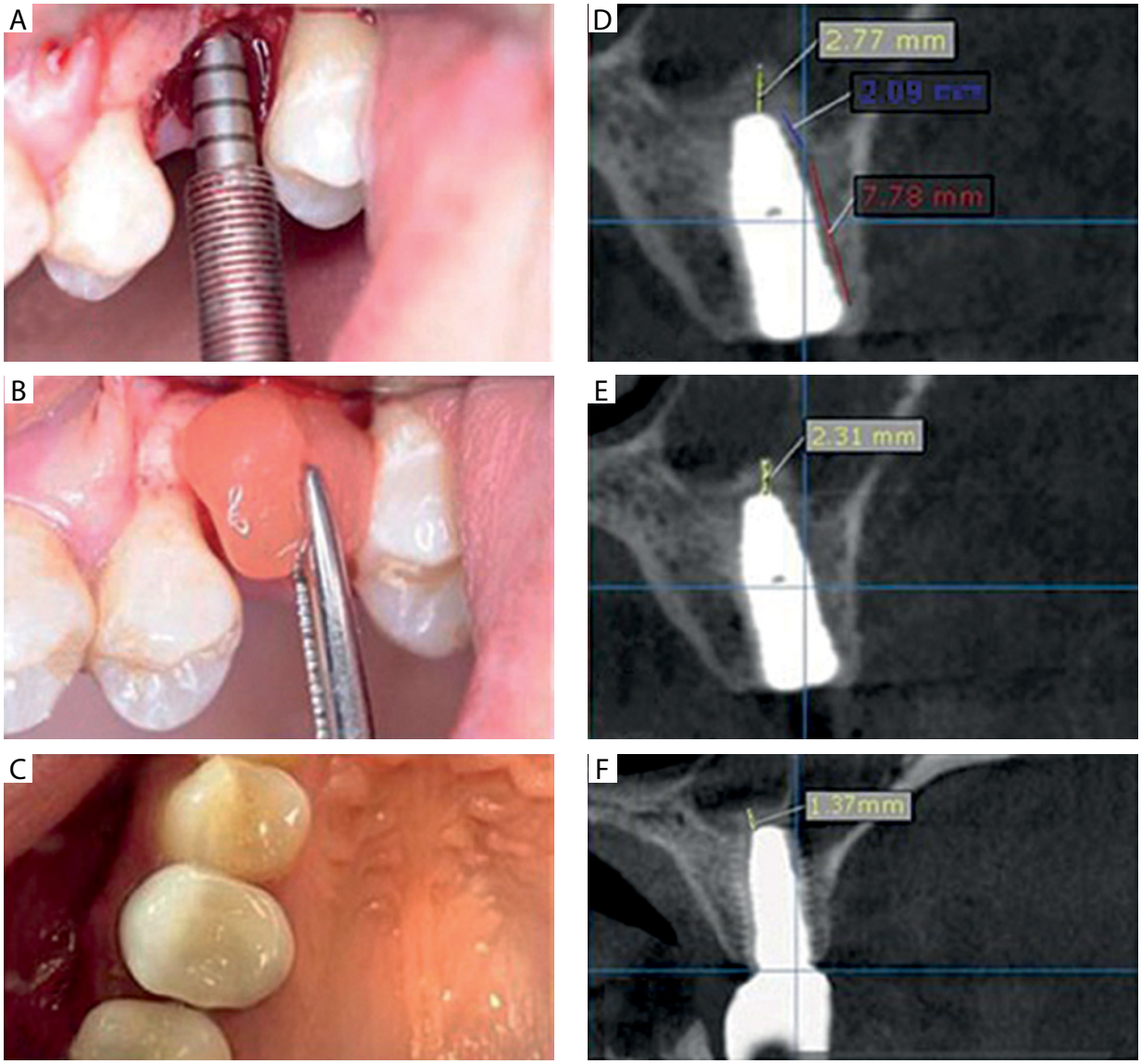

FIGURE 1. Osteotome application (**A**), AFG application (**B**), crown placement (**C**), post-operative CBCT (cross-section view) showing graft apical height, implant protrusion, and residual bone height at T^0 (**D**), GHa at T^3 (**E**), and GHa at T^9 (**F**)

from a surgical kit that were almost 1.0 mm shorter than the sinus floor. Osteotome (Thermos kit, MCT, Korea) was used to fracture the residual bone and elevate the sinus membrane (Figures 1A and 2A). To rule out sinus membrane perforation, the patient was instructed to perform a Valsalva technique [8].

AUTOLOGOUS FIBRIN GLUE [7] AND STICKY BONE PREPARATION [9]

Each patient had two white tubes with own blood to obtain AFG. After being centrifuged for 2-3 minutes at 2,700 rpm, the collected blood was divided into two separate layers. The upper layer with a straw-colored liquid called AFG was collected with a syringe kept standing, while the lower layer that contained red blood cells was discarded. Sticky bone preparation was done using trephine drill (3 mm size; Mr. Curette, Seoul, Korea) to collect a bone from osteotomy site before drilling in core form. The core was milled into particles using bone mill (stainless steel bone mill, T.C, India); AFG was mixed with particulate bone and left aside for around five to ten minutes. This indicated a homogenous mixture of bone particles that was trapped in-between fibrin meshwork. In the group A, AFG was applied to fill up the gap around the implant beneath the elevated sinus mucosal membrane (Figure 1B). In the group B, sticky bone was used to fill up the gap around the implant beneath the elevated sinus mucosal membrane. Finally, dental implants (SuperLine Implant, Dentium System, Korea) were placed at the same time (Figure 2B). At the end, the flap was repositioned

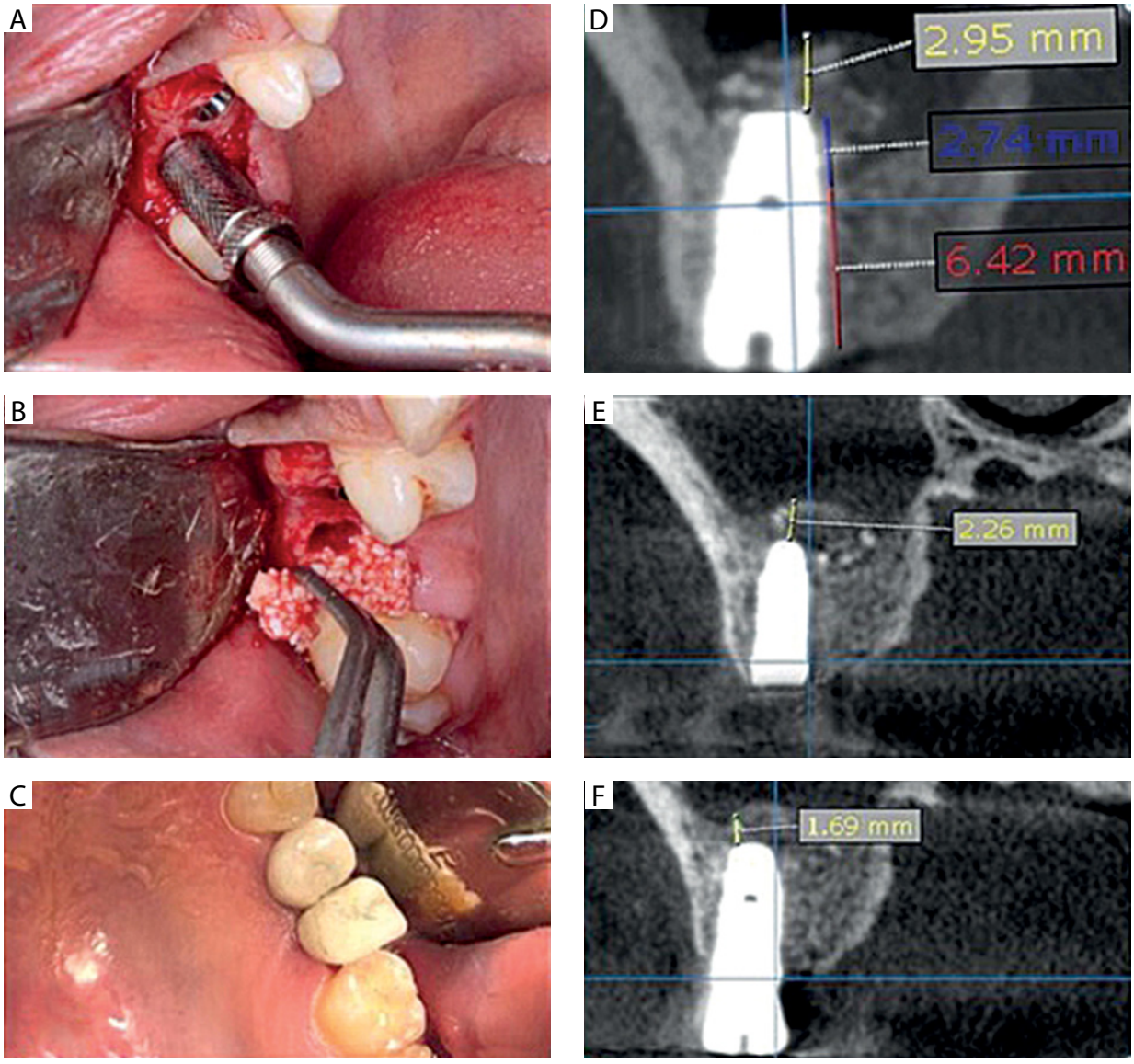

FIGURE 2. Osteotome application (**A**), sticky bone application (**B**), crown placement (**C**), post-operative CBCT (cross-sectional view) showing graft apical height, implant protrusion, and residual bone height at T^0 (**D**), GHa at T^3 (**E**), and GHa at T^9 (**F**)

and sealed with 4.0 polypropylene sutures (Ghatwary Medical GMS, Egypt) in an interrupted manner.

POST-OPERATIVE CARE

All patients received instructions on how to keep good dental hygiene and to avoid eating solid-tack food. Post-operative antibiotic (augmentin 1 gm tablets, GlaxoSmithKline Pharmaceuticals, Egypt) was prescribed taken twice daily for 1 week as well as topical nasal decongestant drops (Otrivin 1%, Novartis, Germany) twice daily for one week, and ibuprofen 400 mg twice daily as a pain killer. Patients were re-called to the clinic after one week for suture removal. Implants were exposed three months later, and healing abutments were then positioned after an analog impression, centric record, and shade taken. The healed abutments were obtained two weeks later. Patients returned for functional testing, follow-up, and temporary cementing of the fixed ceramic prosthesis (Medicem, GIC, Promedica, Germany) (Figures 1C and 2C).

CLINICAL EVALUATION

Clinical assessments (implant stability) were done during T^0 (baseline), T^3 (third month), and T^9 (ninth month) follow-up visits, assessed with ISQ scale graded from 0 to 100.

TABLE 1. Epidemiological data (age, sex) distribution in both groups, and level of significance

Factor	Group A	Group B	*p*-value
Age, years (M ± SD)*	29.83 ± 3.545	32.0 ± 3.899	0.33
Sex**, *n* (%)			
Male	1 (16.7)	1 (16.7)	1.00
Female	4 (83.3)	4 (83.3)	

**Test of significance is independent-samples t-test. **Test of significance is χ^2 test. P-value ≤ 0.05 was considered statistically significant.*

TABLE 2. Implant length and width in both groups, and level of significance

Implant characteristic	Group A	Group B	*p*-value
Length (mm)			1.000
10.0	2 (33.3%)	2 (33.3%)	
11.0	2 (33.3%)	2 (33.3%)	
11.5	2 (33.3%)	2 (33.3%)	
Width (mm)			1.000
4.0	3 (50.0%)	3 (50.0%)	
4.5	3 (50.0%)	3 (50.0%)	

Data is n (%). The test of significance is Fisher's exact test. P-value ≤ 0.05 was considered statistically significant.

RADIOGRAPHIC EVALUATION

Radiographic evaluation was performed with CBCT scan at the same time intervals. Images were interpreted by a clinician to assess residual bone height (distance between the alveolar crest and the maxillary sinus floor at the intended implant placement site), implant protrusion (distance between the sinus floor and the implant's apex), graft apical height (distance from the implant apex to the highest level of the grafting material), and graft sinus height (equal to the sum of the implant protrusion and graft apical height [10]).

STATISTICAL ANALYSIS

Data were entered and analyzed using IBM SPSS software (IBM Corp., released 2019, version 26.0. Armonk, NY, USA). Comparison of the mean among two groups of numerical (parametric) data (inter-group) was done using independent samples *t*-test. Comparison of the mean at different time intervals within each group was performed with one-way repeated measurement ANOVA test. *P*-value ≤ 0.05. was considered statistically significant.

RESULTS

In the epidemiological data distribution, no significant difference was found among both the studied groups (p = 0.33 and p = 1.00 for age and sex, respectively) and implant specification (length, width), with p = 1.000 (Tables 1 and 2).

CLINICAL EVALUATION

Implant stability (IS) is demonstrated in Table 3, showing that in the group A, the mean ISQ value at T^0 was 63.67. Additionally, it was 60.33 and 67.17 at T^3 and T^9, respectively. On the other hand, in the group B, the mean ISQ at T^0 was 63.83. Additionally, it was 60.38 and 67.83 at T^3 and T^9, respectively, with no statistical difference regarding ISQ values at different time intervals of follow-up. While in each group, a high statistically significant differences were recorded when comparing ISQ values recorded at T^0 against those recorded at T^3 and T^9 (p = 0.003, 0.002, 0.006, and 0.001, respectively).

RADIOGRAPHIC EVALUATION

In residual bone height (RBH), no significant difference among both the groups was found, as represented in Table 3 (p = 0.818). The mean RBH was 6.57 mm in the group A, while the mean RBH was 6.46 mm in the group B (Figures 1D and 2D).

Regarding implant protrusion (IP), the mean IP value recorded immediately after implant insertion was 3.12 mm in the group A, while in the group B, it was 2.90 mm, with no statistically significant difference among both the groups (p = 0.579), as shown in Table 3, and Figures 1D and 2D.

As for graft apical height (GHa), in the group A, the mean GHa at T^0 baseline was 2.13 mm (Figure 1D). Additionally, it was 1.73 mm and 1.23 mm for T^3 and T^9, respectively (Figures 1E and 2F). While, in the group B, the mean GHa at T^0 was 2.72 mm (Figure 2D). Moreover, it was 2.25 mm and 2.25 mm for T^3 and T^9, respectively (Figures 2E and 2F), with no significant differences. However, in each group, a statistically significant differences were recorded when comparing GHa values at T^0 against those recoded at T^3 and T^9 (p = 0.001, 0.001, 0.001, and 0.001) in both the groups, respectively, as demonstrated in Table 3.

Regarding graft sinus height (GSH), in the group A, the mean GSH at T^0 was 5.25 mm. Also, it was 4.86 mm and 4.36 mm at $T^3$and T^9, respectively. On the other hand, in the group B, the mean GSH at T^0 was 5.62 mm. Additionally, it was 5.46 mm and 4.54 mm at T^3 and T^9, respectively, with no significant differences found (p = 0.43, 0.49, and 0.67). In each group, high statistically significant differences were observed when comparing GSH values at T^0 with those recorded at T^3 and T^9 (p = 0.002, 0.001, 0.001, and 0.001) in both the groups, respectively (Table 3).

TABLE 3. Implant stability, residual bone height, implant protrusion, graft apical height, and graft sinus height in both groups, and level of significance

Factor	Group A		Group B		*p*-value
	Mean	SD	Mean	SD	
Implant stability					
Baseline	63.67	1.211	63.83	1.602	0.843
3 months FU	60.33	0.516	60.38	0.983	0.296
9 months FU	67.17	1.941	67.83	0.753	0.451
p-value	< 0.001		< 0.001		
Residual bone height	6.570	0.807	6.467	0.705	0.818
Implant protrusion	3.12	0.700	2.90	0.620	0.579
Graft apical height					
Baseline	2.13	0.942	2.72	0.580	0.221
3 months FU	1.73	0.866	2.25	0.570	0.244
9 months FU	1.23	0.741	1.65	0.490	0.276
p-value	< 0.001		< 0.001		
Graft sinus height					
Baseline	5.25	0.930	5.62	0.592	0.435
3 months FU	4.86	0.823	5.46	0.589	0.494
9 months FU	4.36	0.801	4.54	0.574	0.673
p-value	< 0.001		< 0.001		

Independent sample t-test was used as test of significance when comparing inter-group variables at different time points. Test of significance was applied when comparing intra-group variables at different time points using repeated one-way ANOVA.
P-value ≤ 0.05 was considered statistically significant.
FU – follow-up

DISCUSSION

Following tooth extraction, the posterior maxilla frequently experiences bone resorption and maxillary sinus pneumatization, resulting in resorption of the bone and insufficient dimension of the adequate size/length for placement of implants [11]. The maxillary sinus floor elevation has been reported in literature using two main approaches. It is available to employ either a lateral opening approach or a trans-crestal approach with or without bone graft. The trans-crestal approach is advantageous, and the access is made through the implant osteotomy site, resulting in minimum flap elevation and minimal surgical damage [12].

The hypothesis of the present study was based on whether the use of AFG in conjunction with crestal sinus lift technique could yield same or better results in terms of clinical and radiographic outcomes, when compared with sticky bone technique.

In the study, the mean IS at T^0 was 63.67 and 63.87 in the groups A and B, respectively. This was satisfactory according to previous reports of Shiigai *et al.* [13] and Anitha *et al.* [14], who stated that the primary implant stability with ISQ above 62 was considered suitable; however, Lai *et al.* observed a mean ISQ of 68.0 with RBH of 4-8 mm [15].

There was significant difference of IS detected within each group when compared with each time point. Meanwhile, variations in ISQ values were indicative of the biologic changes developing at the bone implant interface. These findings were in agreement with Kim *et al.* [16], who performed a study based on evaluation of the implant stability among various implant systems.

After 3 months of implant insertion, both the groups' ISQ values showed a modest decline, and stability values presented a rise at 9 months after implant insertion. This shift in stability was consistent with the stability of implants placed during standard surgery without sinus lifting. Differences in ISQ readings are reflective of the biologic alterations at the bone implant interface. This result agrees with that published in the published literature [17].

In the current study, CBCT images taken at T^9 time point showed re-pneumatized maxillary sinus and notable decrease in visibility of the previous sinus floor. This is in line with a study by Simonpieri *et al.* [18], who noted that the new sinus floor's final level consistently continued with the implant's apical end.

The mean RBH was 6.57 mm and 6.46 mm in the group A and B, respectively, with no statistically significant difference. It was satisfactory for trans-alveolar sinus lifting reported by Attar *et al.* [19], who showed

mean RBH of 7.9 ± 1.27, and Fugazzotto *et al.* [20], who reported that trans-alveolar sinus lift is typically considered when the initial RBH is greater than 5 mm.

According to the mean IP in this study, in the group A, it was 3.12, and in the group B, it was 2.9, with no significant difference in-between the groups. That finding is similar to results of Gargallo-Albiol *et al.* [21] study, who reported mean sinus elevation of 3.4 ± 1.0 mm measured radio-graphically as the distance between the implant apex and initial sinus floor.

At any given time point, there was no statistically significant difference in GHa between the two groups (p-value = 0.22, 0.24, and 0.27). This may be explained that AFG may have served as a "placeholder" to some extent, providing the necessary scaffold for bone generation [22]. Sticky bone would be effective in maintaining Schneiderian membrane at a higher position due to its physical advantages [7].

According to numerous studies, this decrease in graft volume is caused by typical physiologic graft contraction and re-modeling [23, 24], which is consistent with Kuo's [25] observation that the volume of the graft diminished by 15% throughout the course of healing process within the first six months. Another explanation is that the tension of the sinus membrane would increase with elevation, and this tension may eventually change into a force that compresses the grafting materials and cause shrinking [25].

Regarding GSH, the mean values were 5.25, 4.86, and 4.36 mm, and 5.62, 5.46, and 4.54 mm in the group A and B, respectively, at the same follow-up time intervals, with no statistically significant difference. The results are in contrast with these obtained by Bernardello *et al.* [23], who reported mean GSH values of 6.48 ± 2.38 mm.

The findings of the current study are in line with Toffler *et al.* [26] and Diss *et al.* [27], who found a mean GSH value of 3.4 mm. The discrepancy in implant length extending into the sinus may be the cause of this outcome as graft sinus height is equal to the sum of implant protrusion and graft apical height. Deeper implant protrusions into the sinus serve as longer tent pegs, forming a wider space for the formation of a new bone [7].

In the current study, using AFG was not disappointing, as there was insignificant difference between both the groups regarding the investigated parameters. This outcome was in line with earlier research that demonstrated a beneficial effect of fibrin glue alone or in combination with hydroxyapatite-tricalcium phosphate on the repair of calvarial bone defect [28].

LIMITATIONS

The limited sample size, short follow-up time, and inclusion of only two male patients are considered limitations of this study.

CONCLUSIONS

From a clinical point of view, AFG and sticky bone are considered safe materials when applied locally. Although there is a doubt which one is better; from a clinical point of view, AFG was easier in preparation, was less time-consuming, and at affordable cost.

CONFLICT OF INTERESTS

The authors declare no potential conflicts of interest concerning the research, authorship, and/or publication of this article.

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