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CLINICAL EVALUATION OF USING FIBLIN GLUE VERSUS TITANIUM PLATELET-RICH FIBRIN IN LATERAL SINUS LIFTING PROCEDURE (RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

BACKGROUND: Graftless sinus lift is one of the techniques that provides enough room for implant placement in the atrophic posterior maxilla. Blood clots can be thought of as bone-forming osteogenic graft material to which Osseo progenitors can circulate, differentiate, and regenerate bone.

AIM OF THE STUDY: This study was conducted with the aim of evaluating the clinical effectiveness of using Fibrin glue versus Titanium platelet-rich fibrin (T-PRF) as the sole filling material in lateral sinus augmentation and simultaneous implant placement.

MATERIALS AND METHODS: There were three groups each made up of ten participants: Study Groups 1 and 2 (S1 and S2), which received Fibrin glue and T-PRF as filling materials, respectively; and the negative Control Group (C). In the three groups, sinus floor augmentation via the lateral osteotomy approach and simultaneous implant placement were done. The patients were evaluated clinically in terms of pain, postoperative complications, and implant stability immediately postoperatively, after one week, and six months later.

RESULTS: Between the three groups under study, no significant difference regarding pain was revealed, either immediately following surgery or one week later. Regarding implant stability, there was a significant increase in the mean Implant Stability Quotient (ISQ) value between Fibrin-glue Group (S1) that was 73.30 ± 4.06, and T-PRF Group (S2) that was 70.10 ± 2.81 and the Control Group (C) that was 64.0 ± 6.13 ($p2<0.001$, $p3=0.015$, respectively). However, no significant difference was found between the two study groups (S1, and S2) ($p1 = 0.273$).

CONCLUSION: The use of Fibrin glue or T-PRF as a filling material significantly increased implant stability without causing any additional postoperative complications.

KEYWORDS: Graftless sinus elevation, Sinus floor augmentation, Tenting technique, Fibrin glue, T-PRF.

RUNNING TITLE: The effectiveness of using Fibrin glue versus T-PRF in lateral sinus lifting.

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INTRODUCTION

Currently and routinely used before or during implant surgery, sinus augmentation procedures provide the desired bone height for implant placement in the atrophied posterior region of the maxilla (1). After Tatum (2) first described it, Boyne and James included maxillary sinus augmentation in their clinical studies (3).

Although using different bone substitutes for sinus membrane elevation has been associated with reliable results and a high success rate, it also has a lot of drawbacks, for example, increased morbidity for autogenous bone harvesting sites, an increased rate of complications, infection of the bone graft, an increased surgical intervention time, and a higher cost (4).

Moon et al. (2011) (5) demonstrated the efficiency of the maxillary sinus floor augmentation with simultaneous implant placement and the use of peripheral blood as an intra-sinus filling, supporting the idea that a stabilized blood clot alone can initiate new bone formation regardless of the use of any bone grafts or substitutes.

A residual alveolar bone height of 3-5mm provides enough cortical and cancellous bone to permit the implant's primary stability. Moreover, the simultaneous implant placement during the sinus lifting procedure benefits from the surface treatment of the dental implant that enhances the

thrombogenic potential, the proliferation of osteoblasts, and the expression of platelet-driven growth factors (PDGF) (6).

Despite the fact that filling the sinus cavity with a stabilized blood clot continues to be very challenging to control, the choice of the most appropriate filler material for the sinus cavity after elevating the sinus membrane is currently a concern. This filling material has to stabilize the blood clot in the space and also acts as an anchoring element for the cells and growth factors (7).

When performing lateral sinus lift procedures or using the vertical osteotome augmentation technique, Platelet-rich fibrin (PRF) has long been recommended. Tunalı et al demonstrated the success of the utilization of PRF in sinus lifting, however: the reported concerns regarding the possible health hazard with glass-evacuated tubes with silica activator. With respect to its more solid fibrin texture and prolonged disintegration time, T-PRF, a novel platelet concentrate, is now believed to be more effective than PRF at activating platelets.(8)

Fibrin glue, commonly referred to as fibrin tissue adhesive, has been utilized as a vehicle for the delivery of growth factors, biomolecules, and cells (9). Fibrin, a naturally occurring polymer that takes part in the blood coagulation process, is formed by the action of thrombin on fibrinogen. Fibrin glue is viable, non-cytotoxic, and organically biodegraded by the action of fibrinolytic enzymes (10).

There is a lack of research regarding the clinical applications of Fibrin glue and TPRF in sinus lifting procedures, hence, this research has been conducted with the aim of evaluating the effectiveness of using Fibrin glue versus T-PRF as the sole filling material in lateral approach sinus augmentation and simultaneous implant placement in terms of pain, postoperative complications, and implant stability.

The null hypothesis asserts that no statistically significant difference would exist between using Fibrin glue versus T-PRF as the only filling material in lateral appraoch sinus lifting protocol with concurrent implant placement in comparison to a negative control group in terms of those clinical parameters.

MATERIALS AND METHODS

After obtaining the approval of the Ethics Committee, Faculty of Dentistry, Alexandria University (Approval No. 0371-01/2022), this research was conducted as a randomized controlled clinical trial that followed the CONSORT guidelines (11). **(Fig. 1)** The sample size was estimated based on assuming 5% alpha error and 80% study power. The minimum sample size was calculated to be 9 patients per group, increased to 10 patients to make up for lost to follow-up cases. Total sample = number per group x number of groups = 10 x 3 = 30 patients. Sample size was based on Rosner's method (12) calculated by G*Power 3.1.9.7 (13).

The study was carried out in the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University, and was conducted on thirty patients of both genders who suffered vertical bone loss in the posterior maxilla and/or sinus pneumatization and required lateral sinus lifting procedures and implant-supported restorations.

A computer-generated randomization website (randomizer.org) was used, and they were randomly allocated into three groups, each receiving 10 patients. Patients in Study Group 1 (S1) received Fibrin glue as a filling material, and patients in Study Group 2 (S2) received T-PRF as a filling material, although in the negative Control Group (C), they didn't receive any filling materials and relied solely on the blood clot for new bone regeneration.

Patients were chosen if they met the inclusion criteria, which included being between the ages of 20 and 60, needing implants to replace missing maxillary posterior teeth, having a residual bone height of 3-5 mm, and sticking to good oral hygiene.

Exclusion criteria included the presence of maxillary sinus pathologies, suffering from any disease that would preclude surgery, being a heavy smoker, exhibiting bad oral hygiene, and having received head and neck radiation therapy or chemotherapy in the past.

Preoperative assessment, surgical procedure, and postoperative care

Full personal information (name, age, occupation, etc.), the background of the medical condition or the medications used by the patient, the history of any periodontal disease or previous dental experiences, and the patient's chief complaint, concerns, needs, and expectations were all outlined.

A clinical evaluation of the soft tissue overlying the implant site and any horizontal or vertical defects was performed. The size of the implants and the remaining bone height between the alveolar bone crest and sinus floor were planned using Cone Beam Computed Tomography (CBCT). Before signing an informed consent form, all patients were made aware of the procedure's benefits and risks in order to ensure their satisfaction and safety.

The surgery was performed under local anaesthesia, Articane hydrochloride 4% (Inibsa Artinibsa 4% 1:100.000), which was injected as an infiltration anaesthetic solution at the site of the surgery five minutes before starting the procedure. A blade no. 15 was used to incise the gingiva, performing a trapezoidal flap with releasing vertical incisions mesially and distally. A periosteal elevator was used to elevate the mucoperiosteal flap, exposing the bony lateral wall of the maxillary sinus. Piezoelectric diamond-coated tips SL1 and SL2 (ACTEON®

Group, France) were used to cut the lateral window in an oval or rectangular fashion 5–6 mm cranial to the supposed implant site as planned from the preoperative CBCT **(Fig. 2)**.

The piezoelectric tip SL3 (ACTEON® Group, France), known as an elephant-foot-like tip, was used to dissect the bony window from the sinus membrane bluntly. After disclosing the sinus membrane, a special manual sinus elevation kit (EASY SINUS CURETTE®, Republic of Korea) was used to cautiously dissect the membrane from the sinus walls and floor until the desired height was obtained, and the Valsalva maneuver was then performed to make sure the membrane was intact **(Fig. 3A)**.

Osteotomy for implant (V plus, Vitronex Co., Italy) placement was carried out using the system's conventional drills; the planned number of implants (according to the case) was placed simultaneously in the residual sub-antral bone; and the implant stability was evaluated by resonance frequency analysis (RFA) using an Osstell device (Osstell ISQ®, Sweden).

A resorbable collagen membrane (Colla-D, Medpark Co. Ltd., Korea) of sufficient size was used; the membrane had two incomplete cuts made in the middle on either side, allowing it to be bent into an L shape. One arm of the L-shaped membrane was inserted above the implant to support and patch the sinus membrane, and the other arm of the L was used to cover the lateral osteotomy to prevent soft tissue entrapment during healing **(Fig. 3B)**.

Regarding Study Group 1 (S1), Fibrin glue (Fibrogloo, Power of platelets. Ltd. (SG) Singapore) was supplied in the form of two containers **(Fig. 4A)**. The contents of the two containers (human fibrinogen and human thrombin) were mixed with distilled water and aspirated by two syringes **(Fig. 4B)**; after that, the solutions were injected around the implant under the maxillary sinus membrane **(Fig. 4C)**.

Blood was immediately drawn into sterile titanium tubes for Study Group 2 (S2) patients from the antecubital vein of one of their arms. The specimens were then centrifuged at room temperature for 12 minutes at 2800 rpm. A sterile tweezer was employed to pick up the T-PRF coagulate from the tubes after centrifugation. After being detached from the red blood cell base, the T-PRF clot was placed on sterile gauze and used to fill the empty space around the implants (8).

No material was used to fill the area around the implants in Control Group (C). Following the replacement of the flap, the incision was stitched with 4/0 polypropylene suture material (Ethicon J&J Medical Supply, New Jersey, United States).

Following surgery, patients were instructed to open their mouths when sneezing, eat soft foods for the first two days, and apply ice packs to their faces for five minutes every hour for 48 hours. Patients were also instructed to take the prescribed medications for 5-7 days following surgery, which included antibiotics (Augmentin 1g, Amoxicillin 875 mg + Clavulanic acid 125 mg, tablets: GlaxoSmithKline (GSK), UK), anti-inflammatory drugs (Cataflam: Diclofenac Potassium 50 mg: Novartis, Switzerland), and nasal decongestants (Otrivin nasal spray: GlaxoSmithKline (GSK), UK).

After six months, the cover screw was removed, the healing abutment was applied, and after two weeks of healing, the fabrication of the final porcelain fused to metal fixed prosthesis was done **(Fig. 5)**.

Clinical follow up

Postoperative pain:

This was assessed using a 10- point pain intensity scale (PIS) immediately after surgery and after one week postoperatively (0 = none, 1-3 = mild, 4-6 = moderate, 7-10 = severe) (14).

Presence or absence of intra or postoperative complications:

The presence of any complications from sinus lifting, such as Schneiderian membrane rupture, haemorrhage, postoperative sinus infections, and peri-implant inflammation, was checked in each case.

Implant stability:

This was measured via the implant stability quotient (ISQ) value using an implant stability measure-device (Osstell ISQ®, Sweden) immediately following implant placement and six months later as follows:

After removing the cover screw, a smart peg was placed, and the ISQ value was detected using the Osstell device (Osstell ISQ®, Sweden) from two different points: one buccal and the other palatal. The mean ISQ value for each implant was calculated both immediately postoperatively and six months later.

Statistical analysis of the data

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Qualitative data were described using number and percent. The Shapiro-Wilk test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation, median and interquartile range (IQR). Significance of the obtained results was judged at the 5% level.

RESULTS

Twenty-one participants were females, presenting 70% of cases, and nine were males, presenting 30% of cases. The age range was 38–55 years with a mean of 47.40 ± 5.60, 34–57 years with a mean of 44.90 ± 8.32, and 37–60 years with a mean of 47.70 ± 6.33 in Study Group 1 (S1), Study Group 2 (S2), and the control group (C), respectively.

The residual bone height ranged from 3-5 mm, ridge width ranged from 5.8 to 8.4 mm which was enough for implant placement. The implant sizes

were 3.7*10, 4.2*10, and 5.0*10, which were selected according to the ridge width detected by CBCT preoperatively. The total number of implant supported final restorations received by the patients were 30 porcelain fused to metal (PFM) crowns.

Postoperative Pain:

In Fibrin-glue Group (S1), the median (IQR) pain score immediately postoperatively was 6.50 (6.0–7.0), and there was a statistically significant decrease in the pain score one week postoperatively to be 0.50 (0.0–1.0) (P = 0.004). In T-PRF Group (S2), the median (IQR) pain score was significantly decreased from 7.0 (6.0–7.0) immediately postoperatively to 1.0 (0.0–1.0) after one week (P = 0.004). Furthermore, in the control group (C), the median (IQR) pain score was 6.0 (6.0–7.0) immediately after surgery, which was also significantly decreased one week postoperatively to 1.0 (0.0–1.0) (P = 0.004).

However, a comparison of the groups revealed that neither immediately following surgery nor one week later, a significant difference in the median (IQR) pain scores was outlined between the three groups under study. (P = 0.377 and 0.834, respectively) **(Table 1)**.

Postoperative complications:

There were no complications experienced, neither during the surgery nor throughout the six-month follow-up period.

Implant stability:

In Fibrin-glue Group (S1), the mean ISQ value was 63.70 ± 3.47 immediately postoperatively and was significantly increased to 73.30 ± 4.06 after six months (P<0.001). In T-PRF Group (S2), the mean ISQ value was 61.30 ± 3.02 immediately after surgery, and there was a significant increase in this value to be 70.10 ± 2.81 six months following the surgery (P<0.001). Also, the Control Group (C) showed a statistically significant increase in the mean ISQ value from 58.0 ± 5.94 to 64.0 ± 6.13 immediately after surgery and after a six-month follow up period, respectively (P<0.001) **(Table 2)**.

When the three groups were compared with regard to implant stability after a six-month follow-up period, it was discovered that there was a statistically significant difference in the mean ISQ value between the three groups. Between the Fibrin-glue Group (S1) and Control Group (C) (p2<0.001), as well as between T-PRF Group (S2) and the Control Group (C) (p3 = 0.015), there was a significant increase in the mean ISQ value. However, there was no statistically significant difference in the mean ISQ value between Fibrin-glue Group (S1) and T-PRF Group (S2) (p1 = 0.273) **(Table 3) (Fig. 6)**.

Table (1): Comparison between the three studied groups according to pain

Pain	Group I (S1) (n = 10)	Group II (S2) (n = 10)	Group III (C) (n = 10)	H	P
Immediate postoperative					
Min. – Max.	5.0 – 7.0	5.0 – 7.0	4.0 – 7.0		
Mean ± SD.	6.40 ± 0.70	6.50 ± 0.71	6.0 ± 0.94	1.950	0.377
Median (IQR)	6.50 (6.0 – 7.0)	7.0 (6.0 – 7.0)	6.0 (6.0 – 7.0)		
After 1 week					
Min. – Max.	0.0 – 2.0	0.0 – 2.0	0.0 – 2.0		
Mean ± SD.	0.60 ± 0.70	0.70 ± 0.67	0.80 ± 0.79	0.362	0.834
Median (IQR)	0.50 (0.0 – 1.0)	1.0 (0.0 – 1.0)	1.0 (0.0 – 1.0)		

H: H for **Kruskal Wallis test**

p: p value for comparing between the three studied groups

IQR: **Inter quartile range** SD: **Standard deviation**

Table (2): Comparison between the different periods according to Implant Stability ISQ on each group.

Implant Stability ISQ	Immediate postoperative	After 6 months	t	p
Group I (S1) (n = 10)				
Min. – Max.	59.0 – 68.0	68.0 – 79.0	25.863*	<0.001*
Mean ± SD.	63.70 ± 3.47	73.30 ± 4.06		
Group II (S2) (n = 10)				
Min. – Max.	58.0 – 67.0	65.0 – 74.0	14.851*	<0.001*
Mean ± SD.	61.30 ± 3.02	70.10 ± 2.81		
Group III (C) (n = 10)				
Min. – Max.	48.0 – 64.0	54.0 – 73.0	9.487*	<0.001*
Mean ± SD.	58.0 ± 5.94	64.0 ± 6.13		

t: Paired t-test

p: p value for comparing between **Immediate postoperative** and **After 6 months**

*: Statistically significant at $p \leq 0.05$

SD: **Standard deviation**

Table (3): Comparison between the three studied groups according to implant stability ISQ after six months

Implant Stability ISQ After 6 months	Group I (S1) (n = 10)	Group II (S2) (n = 10)	Group III (C) (n = 10)	F	P
Min. – Max.	68.0 – 79.0	65.0 – 74.0	54.0 – 73.0	10.821*	<0.001
Mean ± SD.	73.30 ± 4.06	70.10 ± 2.81	64.0 ± 6.13		
Sig.bet.Grps	p_1=0.273, p_2<0.001*, p_3=0.015*				

F: F for One-way ANOVA test, Pairwise comparison bet. each 2 groups was done using Post Hoc Test (Tukey)

p: p value for comparing between the three studied groups

p_1: p value for comparing between group I and II

p_2: p value for comparing between group I and III

p_3: p value for comparing between group II and III

*: Statistically significant at $p \leq 0.05$

SD: Standard deviation

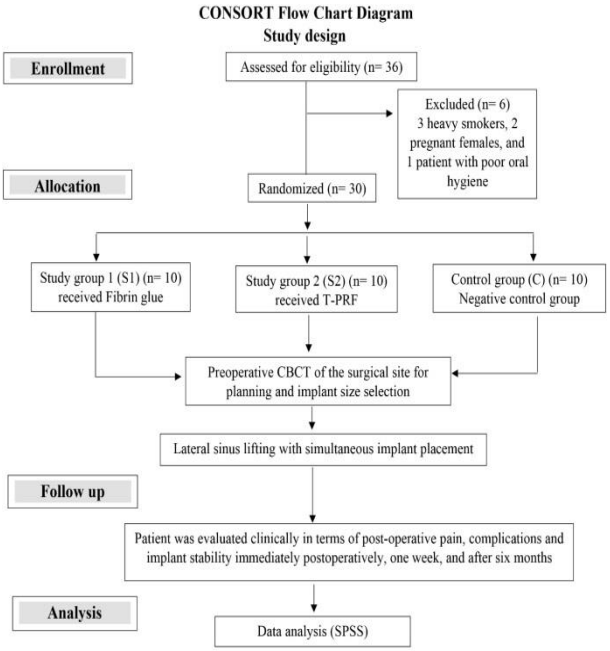

Figure (1): Consort flow chart diagram illustrating the study design.

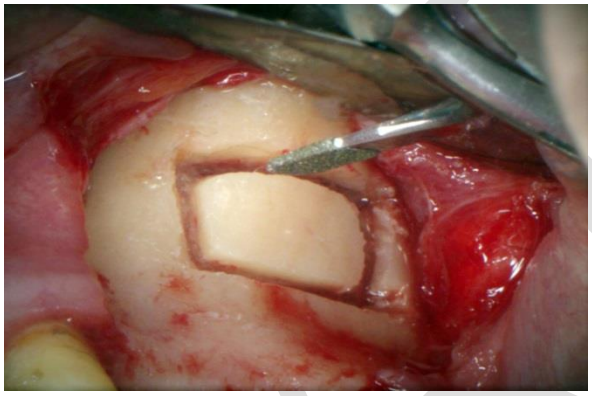

Figure (2): Lateral window osteotomy using piezo surgical tip SL1 (ACTEON® Group, France).

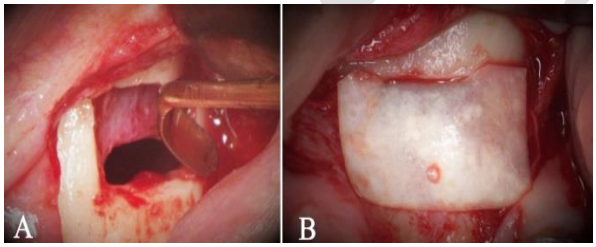

Figure (3): (A) A special manual sinus elevation kit (EASY SINUS CURETTE®, Republic of Korea.) was used to cautiously dissect the membrane from the sinus walls. **(B)** Resorbable collagen membrane covering the bony window.

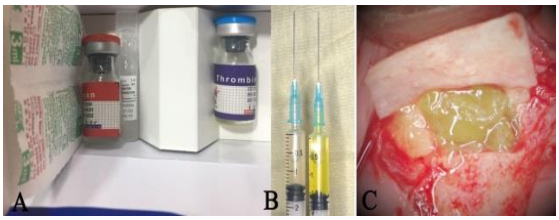

Figure (4): Fibrin glue (A) supplied in the form of two containers (human fibrinogen and human thrombin), (B) the contents of the containers were mixed with disstelled water to be injected in the empty space around the dental implant, (C) a clinical photo of the surgical site after application of the Fibrin glue.

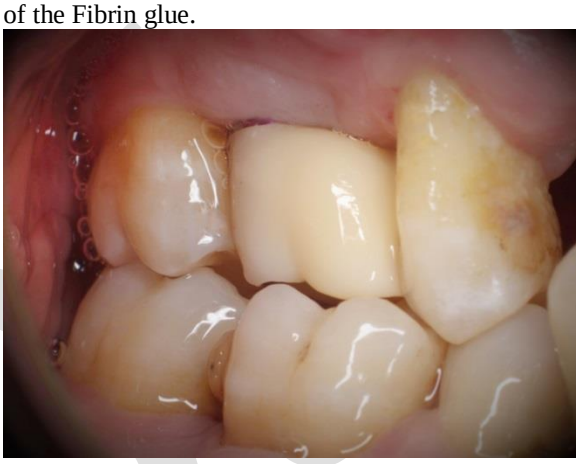

Figure (5): Porcelain fused to metal final prosthesis.

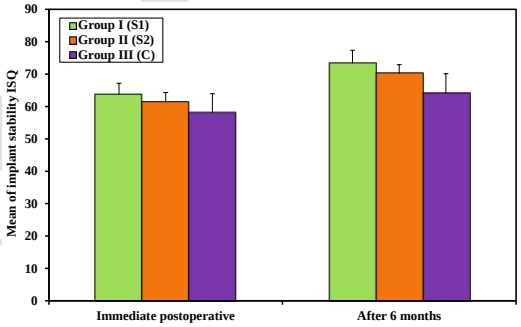

Figure (6): Comparison between the three studied groups according to implant stability ISQ.

DISCUSSION

A plethora of sub-antral filling materials can be utilized for blood clot stabilization after sinus lifting, it may include various grafting, bone substitutes, and blood-driven materials. Hence, this study was conducted to evaluate the effectiveness of using Fibrin glue versus T-PRF as the sole filling material in lateral approach sinus augmentation and simultaneous implant placement.

Regarding the use of platelet concentrates alone or in combination with bone replacement grafts, there have been conflicting reports in the literature. While some researchers came to the conclusion that the combined use of platelet concentrates with bone grafts was more clinically effective, others showed that it offered no additional benefits (15).

Tajima et al. (2013) (16) evaluated the use of regular PRF as a sole grafting material in sinus floor elevation with simultaneous implant placement revealed a significant improvement in ISQ values denoting sufficient implant stability.

To the best of our knowledge, this is the first clinical study to evaluate the biological effects of the use of Fibrin glue as a sole sub-antral filling material in sinus lifting. Fibrin glue is a natural blood derived polymer that has some advantages over other biomaterials when used as a delivery system, in addition to serving as a hemostatic and healing agent. The fibrin glue also enables uniform cell distribution throughout the scaffold, and this scaffold can be implanted using a less invasive method as it is an injectable material, allowing the surgical site to be completely filled (17).

According to research using CT and histomorphometric analysis, fibrin glue, either by itself or in combination with hydroxyapatite-tricalcium phosphate, has been effective in repairing calvarial bone defects in rabbits 4 and 8 weeks after surgery.(18) In a different study, Santos et al. (2015) (19) evaluated the potential of fibrin glue for bone repair in promoting new bone formation in a rat calvarial defect model after 8 weeks and demonstrated the advantages of using it in promoting new bone formation in treated defects compared to untreated defects.

In the present study all patients suffered mild to moderate pain after surgery that decreased one week later. None of the postoperative complications associated with sinus lifting, including bleeding, sinus membrane perforation, and epistaxis, were noted. Shokry et al. (2018) (20), obtained similar results regarding the pain and reported complication rates.

The utilization of minimally invasive piezo-surgery and meticulous surgical protocol may be a culpable factor for the outstanding clinical performance reported in this study in all groups. According to Shokry et al. (2018) (20), piezo-surgery, despite appearing to be a time-consuming procedure, is effective in performing harmless sinus membrane elevation because there is a decreased risk of membrane rupture, improved post-surgical patient satisfaction, and improved individual life quality.

Additionally, this was consistent with Delilbasi et al. (2013) (21), who made the claim that piezo-surgery brings out less postoperative pain and swelling in comparison to the conventional technique.

When it comes to implant stability, a post-surgical and six-months postoperative Implant Stability Quotient (ISQ) analysis was performed for the analysis of the overall implant stability across the healing un-loaded period in a non-invasive manner. Quesada et al. (2009) (22) performed a review article which indicated that Resonance Frequency Analysis (RFA) can be used to assess implant stability in a non-invasive manner.

The mean ISQ value in the Fibrin-glue group (S1) reported a significant amplification after six months in comparison to the immediate post-operative value ($P = 0.001$). This was also reported in the T-PRF group (S2) and the control group (c), where a significant amplification was calculated ($P < 0.001$, $P = 0.001$ respectively).

With regard to implant stability after a six-month follow-up period, a significant increase in the mean ISQ value was revealed between the fibrin-glue group (S1) and the control group (C) ($p < 0.001$). The outcome of the Fibrin-glue group (S1) was comparable to those reported in the literature with the utilization of various grafting, bone substitutes, and blood-driven materials (16, 23,24).

Also six-months postoperatively the T-PRF group (S2) demonstrated a significantly increased ISQ values in comparison to the control group (C) ($p = 0.015$). Olgun E et al (2018) (25) reported no significant difference regarding implant stability ISQ values comparing T-PRF with allograft as a sole filling material in sinus lifting procedures. Their reported results demonstrated a comparable outcome as in the T-PRF group (S2) in this study.

While comparing the two study groups (S1, S2), the mean ISQ value between the Fibrin-glue group (S1) and the T-PRF group (S2) did not reveal any significant difference after the six-month follow-up period ($p = 0.273$).

The exemplary ISQ improvement values reported in this study indicates the proper surgical technique utilized in all groups that allowed a sufficient primary stability and the biological activity of the blood-driven materials utilized in both study groups in achieving a satisfactory superior secondary stability in comparison to the control group.

While conducting this research, some limitations have been encountered, including the collection of a sample that fulfils the inclusion and exclusion criteria, the thorough clinical evaluation of all participants along the follow-up period, and finally the lack of radiological evaluation of the bone height gain and bone density, as well as the absence of a histological evaluation revealing the amount of viable bone regenerated around the implants.

With respect to the limitation of the study, the utilization of T-PRF and Fibrin glue as a sole sub-antral filling material in single-stage sinus lifting with simultaneous implant placement resulted in a satisfactory clinical and implant stability outcome that are superior to the conventionally utilized technique.

CONCLUSION

Graft-free sinus lifting procedures using the piezo-assisted lateral window approach with simultaneous implant placement could be considered a reliable technique. Fibrin Glue and T-PRF showed promising results; hence, it was discovered that they significantly enhanced the stability of the dental implants that were simultaneously placed during the single-stage sinus lifting procedures

without causing further postoperative complications.

CONFLICT OF INTEREST

The authors informed that they have no conflict of interest.

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