

EVALUATION OF THE INFLUENCE OF BONE DENSITY ON SECONDARY IMPLANT STABILITY AFTER MAXILLARY SINUS AUGMENTATION WITH AND WITHOUT BONE GRAFTING: A RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT

The aim of this study was to examine the formation and density of new bone around dental implants inserted simultaneously after grafted versus non-grafted maxillary sinus floor augmentation and to correlate secondary implant stability to bone density. Twenty patients requiring the placement of implants in the posterior maxilla with deficient bone height were recruited for the study. Patients were randomly assigned to either group. The formation and density of new bone were evaluated using Cone-Beam Computed Tomography, performed postoperatively and after 6 months. Pearson coefficient was used to correlate bone density and secondary implant stability in both groups. All implants achieved adequate primary stability and were successfully loaded. Both groups showed comparable secondary stability with a mean of (77.9 ± 3.9) for the grafted and (74.8 ± 5.6) for the non-grafted group. Bone density values were (973.6 ± 142.5) and (443.7 ± 97.8), and bone height gain was (6.6 ± 0.5) and (6 ± 0.5) for the grafted and the non-grafted groups respectively, with the grafted group showing significantly higher values. Secondary stability showed a significant positive linear correlation with bone density in the grafted group ($r = 0.549$ at $p \leq 0.05$). In conclusion, Sinus floor elevation with and without grafting is considered an acceptable and successful procedure with simultaneous implants placement. Furthermore, higher density values in the grafted sinuses resulted in higher secondary stability.

KEYWORDS: maxillary sinus augmentation, non-grafted sinus lift, simultaneous implant placement, secondary implant stability, radiographic bone density

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INTRODUCTION

Maxillary sinus augmentation was first explained by Tatum, then it was clearly described by Boyne and James in their clinical study ^[1,2]. The introduction of grafting materials within the maxillary sinus revealed high success outcomes regardless of the material being used ^[3].

A variety of biomaterials can be used to achieve a proper sinus augmentation. These include autogenous bone grafts (donor location may be extra-oral, such as the calvarium and iliac bones, or intra-oral, such as the mandibular symphysis, ramus, and tuberosity), allogeneic bone grafts (transplanted bone from the same species, i.e. cadaveric origin), xenogeneic bone grafts (transplanted bone from a different species as bovine bone) and alloplastic or synthetic materials (hydroxyapatite, beta-tricalcium-phosphate (β -TCP), coral and algae-derived hydroxyapatite, collagen, and polymers) ^[3-5].

One of the synthetic biomaterials widely used for bone augmentation is Biphasic calcium phosphate which consists of a biphasic calcium phosphate (BCP) compound formed in the ratio of 20% Hydroxyapatite and 80% phase-pure β -TCP. HA has a supporting role in the new bone tissue to maintain structural stability. Tricalcium phosphate helps to spread the new osteoblastic cell adhesion surface by ion exchange with a rapid dissolution. The study by Okada et al., has declared that during the first year after direct sinus lifting, β -TCP was gradually displaced by newly formed bone ^[6].

Despite the success of the grafting technique for sinus augmentation, several drawbacks were encountered which included the need for a second surgical site in case of harvesting autogenous bone, the risk of infection of the used bone graft, extended time of the operation, increased rate of postoperative complications, and high cost of the used materials ^[7].

The maxillary sinus membrane's osteogenic potential was well demonstrated [8,9]. Based on the

principles of guided tissue regeneration, new bone was formed after sinus membrane elevation due to the establishment of a void with the presence of a blood clot, which induces bone deposition. ^[10,11] Also, a study has reported that after a cyst enucleation from the maxillary sinus, the Schneiderian membrane had the potential for bone formation and spontaneous deposition of new bone below the maxillary sinus floor ^[12]. Moreover, several studies have shown that dental implant implantation and rehabilitation may be done successfully without the use of any bone substitute following sinus lift procedures.

With several research suggesting that implants can be placed within the lifted sinus floor without the need for extra bone grafting, the attention moved to developing a technique that was both speedier and less intrusive. With high success rates, graftless sinus lifting can be used for both lateral and crestal sinus elevation. ^[7,8,11,12]

However, there is a lack of knowledge within the literature concerning the comparison between both grafted and graftless sinuses in terms of implant stability and bone density outcomes around the installed implants using either method. Therefore, the aim of this study was to detect whether there is a correlation between the implant stability quotient (ISQ) and bone density around dental implants inserted simultaneously in a grafted versus a graftless sinus lift procedure.

PATIENTS AND METHODS

Study design and setting: The current study is a randomized controlled clinical trial that was performed in the Faculty of Dentistry, Alexandria University following the CONSORT guidelines. Twenty patients requiring the placement of implants in the posterior maxilla with deficient bone height were recruited from the outpatient clinic of the Faculty of Dentistry, Alexandria University, and underwent direct maxillary sinus lifting with simultaneous implant placement. Ethical approval

has been obtained from the Research Ethics Committee (IRB 00010556-IORG 00088839) of the institution in accordance with the Declaration of Helsinki on medical protocol and ethics. The study was registered at clinicaltrials.gov with ID number NCT04625192.

Sample size estimation: A hypothesized total sample size of 20 maxillary sinuses to be operated has been estimated by the aid of the epitools.auvest.com.au website, taking into consideration 5% level of significance, and the power of the study was set to 0.8^[13].

Eligibility criteria: Patients with ages ranging between 35 and 50 years irrespective of the gender, with good oral hygiene, non-smokers and having pathology-free maxillary sinus, residual bone height 3-5 mm in the region of proposed implant placement, and at least 4 mm ridge width were included in the study. Patients with sinus pathology, medical conditions contraindicating surgery, acute oral infections, or a history of radiotherapy/chemotherapy were excluded.

Pre-surgical assessment and patient allocation: Full history taking, thorough clinical examination, ENT consultation, and initial screening with an orthopantomogram were done for each patient. Cone-beam computed tomography (CBCT) was then done for measurement of residual bone height, ridge width, and planning of implant placement. Eligible patients signed an informed consent explaining the procedure, possible complications, and their rights. Then they were divided equally into two groups and allocated randomly to either group using a computer-generated randomization table website; randomizer.org as follows:

Group 1 (Grafted sinus lifting): Consisted of 10 sinuses in which direct sinus lifting procedure was done followed by maxillary sinus augmentation using a mixture of autogenous bone and biphasic calcium phosphate (Ovis BCP, DENTIS Co., LTD) with simultaneous implant placement.

Group 2 (Graftless sinus lifting): Consisted of 10 sinuses in which direct sinus lifting procedure was done followed directly by simultaneous implant placement without application of any bone grafts.

Surgical procedure: Patients were instructed to rinse with an antiseptic mouth wash followed by local anesthesia application at the surgical site and elevation of a full-thickness mucoperiosteal flap. A bony window was created using the Piezotome device (ACTEON® Group, France) and the associated sinus lift tips (SL1 and SL2). Thereafter, elevation of the Schneiderian membrane has been accomplished using SL3 Piezotome tip and sinus elevation hand instruments (Dentium Advanced Sinus Kit #214, 501 Gyeonggi R&DB Center, Korea). Integrity of the membrane was checked using direct vision and the Valsalva maneuver. A collagen membrane (T-Gen, Alpha-Bio Tec Ltd., Korea) was then applied just beneath the Schneiderian membrane for protection against any minor perforations of the sinus membrane. In group 1, a mixture of autogenous bone graft (from trephine drilling of the implant osteotomy) and biphasic calcium phosphate [Ovis Bone BCP (Dentis Implant)] was applied, and implant was placed (figure 1). In group 2, the implant was placed without application of any bone grafts. Primary stability of the inserted implants (Superline Implant system, Dentium Co.,Ltd, Seoul, South Korea) was measured in both groups using Osstell ISQ device (Osstell ISQ, W&H, Sweden). The lower part of the previously applied collagen membrane was bent and adapted to cover the bony window opening and the flap was sutured (figure 2).

Postoperative care and follow-up: Patients were given strict instructions to follow postoperatively including avoidance of suction, nose-blowing, and sneezing in addition to sticking to soft diet for 2 weeks and regular application of ice packs to the surgical site on the day of operation. The following medications were prescribed to patients of both groups: Broad-spectrum antibiotic Amoxicillin 875

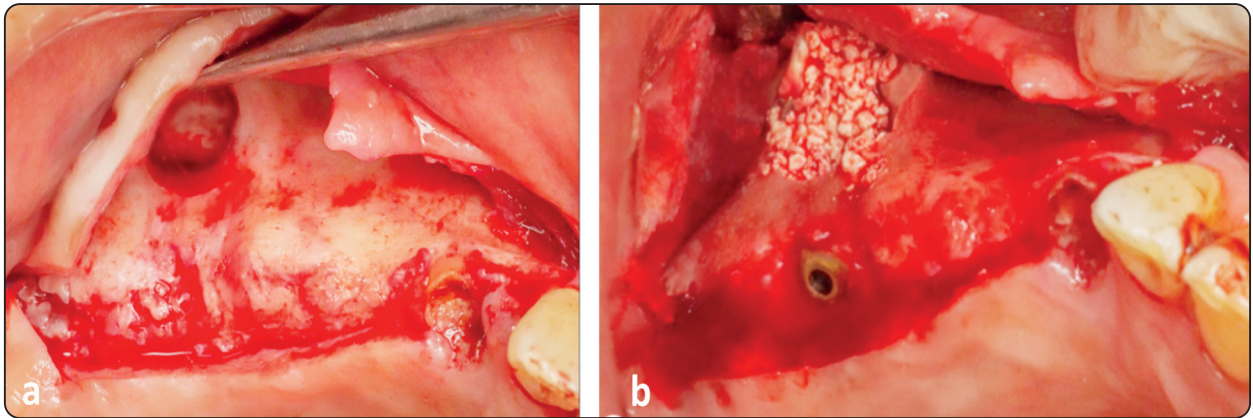


Fig. (1) Clinical picture for the grafted group (a) osteotomy window preparation (b) maxillary sinus grafted with a mixture of autogenous bone and biphasic calcium phosphate.

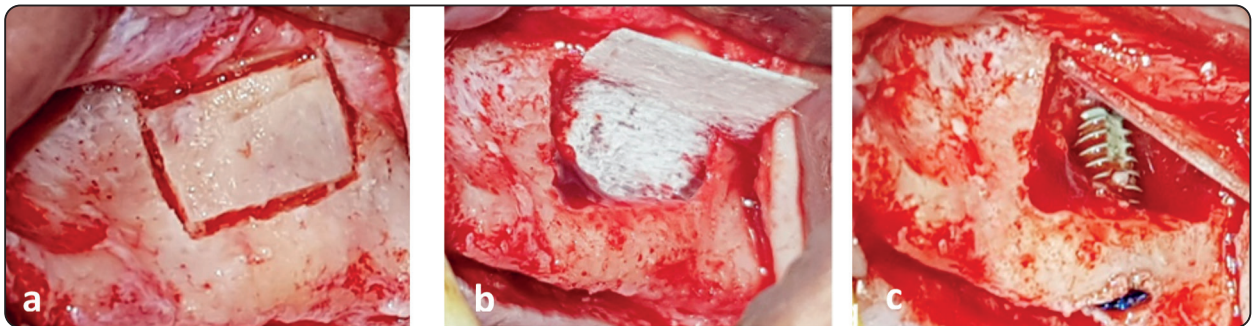


Fig. (2) Clinical picture for non-grafted group showing surgical procedures (a) bony window outline, (b) collagen membrane placement for tenting the schneiderian membrane, (c) dental implant insertion.

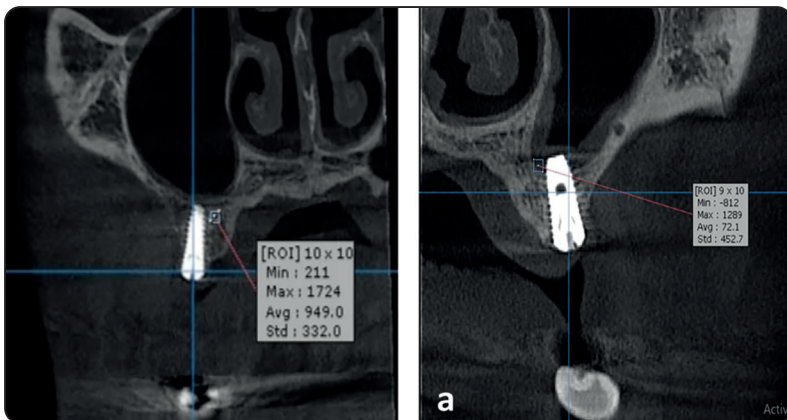


Fig. (3) bone density measurement on CBCT image for (a) grafted group, and (b) non-grafted group

mg + Clavulanic acid 125 mg (Augmentin 1g tablets: GlaxoSmithKline (GSK), UK) every 12 hours for 5 days in combination with Metronidazole 500mg (Flagyl: metronidazole 500mg: GlaxoSmithKline, UK) every eight hours for 5 days to avoid post-operative infection. Non-steroidal anti-inflammatory analgesic Diclofenac potassium (Cataflam: Diclofenac Potassium 50mg: Novartis-Switzerland) 50mg was prescribed every eight hours for 5 days to reduce the post-operative pain, edema, and inflammation. Nasal decongestant drops Ephedrine hydrochloride + Naphazoline nitrate 0.5% (Deltarhino nasal spray: Ephedrine hydrochloride 0.5 % w / v + Naphazoline nitrate 0.125 % w/v: Global Napi Pharmaceutical, GNP) every 6 hours for 5 days. Chymotrypsin + Trypsin 300 E.A.U (Alphintern: Chymotrypsin 300 E.A.U. (14 micro Katal) + Trypsin 300 E.A.U.: Amoun Pharmaceutical Co. S.A.E) every 8 hours for 5 days. Chlorhexidine (Hexitol: Chlorhexidine 125 mg / 100 ml, concentration 0.125 %: Arabic drug company, ADCO) antiseptic mouth wash starting from the next day 3 times daily for 2 weeks.

Patients were followed up for 6 months postoperatively. The following parameters have been assessed: Clinically, pain and edema were evaluated on the second and seventh postoperative days. Also, incidence of complications was assessed in addition to measuring implant stability at the time of implant placement (primary stability) and at 6 months after surgery at the time of loading (secondary stability). Radiographically, the average bone density around the installed dental implants was measured by inserting a rectangle using the specified tool of the OnDemand 3D™ software on the buccal and palatal aspects at the apical third of the implants. The average of the two readings was taken as the mean bone density surrounding the implant measured immediately postoperative and at 6 months after surgery.

Prosthetic phase: after 6 months, implants were exposed, abutments applied then impressions taken 2 weeks after, followed by try-in and delivery of the final restoration.

Statistical analysis:

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). For continuous data, they were tested for normality by the Shapiro-Wilk test. Distributed data were expressed as range (minimum and maximum), mean, standard deviation, and median. Student t-test was used to compare two groups for normally distributed quantitative variables, while Paired t-test was used to compare between two periods. And Pearson coefficient for correlating between two normally distributed quantitative variables was used. Significance of the obtained results was judged at the 5% level.

RESULTS

A total of 20 patients (12 men and 8 women), ranging in age from 35 to 50 years (average 43.5 years) met the criteria for inclusion in the present study. All patients were examined clinically and radiologically preoperatively, at 1 week, and 6 months postoperatively. The results of bone augmentation after sinus lifting using a mixture of autogenous bone and biphasic calcium phosphate with simultaneous implant placement versus sinus lifting without application of bone graft, yielded successful bone formation and osseointegration of all installed implants.

Clinical results

Intraoperatively all the cases went without any complications except for three cases, one in the grafted group and two in the non-grafted group that were complicated with small membrane perforation during the process of membrane elevation. The applied collagen membrane covered the perforation, and the procedures were completed with no postoperative complications.

All patients showed uneventful healing with no signs of postoperative infection, dehiscence, or

oroantral communications. No patients were lost during follow-up, and data of all patients were included for analysis. No implants were lost during the follow-up period, and at the prosthetic stage, all implants in both groups were clinically stable and were successfully loaded.

Implant stability

A total of 39 implants were placed; 20 implants were inserted in the grafted sinus group and 19 implants in the graftless sinus group, all of which achieved adequate primary stability even in a thin residual bone height. The grafted group showed significantly higher ISQ value as shown in Table (1) ; a mean of (67.4 ± 2.6 and 63.5 ± 5.2) was reported for the grafted and the non-grafted groups respectively. Implant stability after 6 months showed significant increase for both groups. Comparable results were obtained after 6 months (77.9 ± 3.9 and 74.8 ± 5.6) with no statistically significant difference indicating that both procedures provided similar implant stability.

Bone density

The mean value of bone density increased significantly for both groups after 6 months. The mean bone density of the grafted group was (973.6 ± 142.5) compared to the non-grafted group (443.7 ± 97.8). The difference between groups was statistically significant ($p \leq 0.05$).

Bone height gain

The mean value of bone height gain was significantly higher in the grafted group than in the non-grafted group. The mean bone height gain of the grafted group was (6.6 ± 0.5 mm), compared to (6 ± 0.5 mm) in the non-grafted group.

Correlation between Secondary Stability and Bone Density

Secondary stability showed a significant positive linear correlation with bone density in the grafted

group ($r = 0.549$ at $p \leq 0.05$). However, no significant correlation was found in the non-grafted group ($r = 0.062$), (Table 2)

DISCUSSION

Rehabilitation of the posterior region of the maxilla following tooth loss is often compromised due to limited bone volume. The lateral window technique to approach the maxillary sinus for bone augmentation in the posterior maxilla is a well-established and documented surgical procedure allowing for simultaneous or staged dental implant placement^[14,15]. Graftless sinus membrane elevation avoids donor site morbidity after harvesting autogenous bone, and prevents the use of any kind of bone replacement material^[16].

Despite the fact that published data include several reports regarding new bone gain, the density of the newly formed bone after sinus membrane elevation without bone grafting was not clearly reported. Thus, the current study was conducted to evaluate the quality and quantity of the new bone after maxillary sinus augmentation with and without bone grafting, using the bone density values determined by CBCT; and to determine the possible impact of bone density on secondary implant stability.

The results of the current study showed that the space created underneath the Schneiderian membrane by elevation without additional graft material led to new bone formation in the maxillary sinus, similar to results reported in previous studies^[16-18]. Tenting of the sinus membrane with simultaneous implant placement without grafting material can only be successful if the remaining alveolar height guarantees primary implant stability^[18-20]. This is because immediate implant installation is necessary to preserve and support the elevated Schneiderian membrane, allowing coagulum to form around the exposed implant surface in the sinus cavity.

Table (1): Comparison between the two studied groups according to implant stability, bone density, and bone height

		Group 1 (n = 20)	Group 2 (n = 19)	P
Implant stability	Immediate postoperative			
	Mean ± SD.	67.4 ± 2.6	63.5 ± 5.2	0.007*
	Median (Min. – Max.)	66.5 (64 – 72)	65 (49 – 71)	
	After 6 months			
	Mean ± SD.	77.9 ± 3.9	74.8 ± 5.6	0.051
	Median (Min. – Max.)	77 (72 – 85)	77 (59 – 81)	
	(p ₁)	(p<0.001*)	(p<0.001*)	
Increase				
Mean ± SD.	10.6 ± 2.2	11.3 ± 3.1	0.379	
Median (Min. – Max.)	11 (6 – 14)	12 (6 – 18)		
Bone density	Immediate postoperative			
	Mean ± SD.	437.1 ± 84.7	25.2 ± 76.9	<0.001*
	Median (Min. – Max.)	419.4(311.3 – 584.8)	67.9 (-91.9 – 102.2)	
	After 6 months			
	Mean ± SD.	973.6 ± 142.5	443.7 ± 97.8	<0.001*
	Median (Min. – Max.)	996.6(640.5– 1146)	421.8(278.1–602.1)	
	(p ₁)	(p<0.001*)	(p<0.001*)	
Increase				
Mean ± SD.	536.5 ± 120.7	418.5 ± 67.3	0.001*	
Median (Min. – Max.)	534(274.7 – 742.1)	405.5(319.6 – 523.3)		
Bone height	Preoperative			
	Mean ± SD.	4.4 ± 0.5	4.4 ± 0.4	0.797
	Median (Min. – Max.)	4.5 (3.5 – 5)	4.4 (3.8 – 5.2)	
	Postoperative			
	Mean ± SD.	11 ± 0.6	10.4 ± 0.6	0.002*
	Median (Min. – Max.)	11 (10.2 – 12)	10.5 (8.7 – 11.2)	
	(p ₁)	(p<0.001*)	(p<0.001*)	
Increase				
Mean ± SD.	6.6 ± 0.5	6 ± 0.5	<0.001*	
Median (Min. – Max.)	6.7 (6 – 7.8)	6.1 (4.7 – 6.5)		

SD: Standard deviation

p: p-value for comparing the studied groups

p1: p-value for comparing two periods in each group

*: Statistically significant at p ≤ 0.05

Group 1: Grafted Sinus: autogenous bone + biphasic calcium phosphate

Group 2: Non-Graft Sinus

Table (2): Correlation between bone density and implant stability

		Group 1		Group 2	
		r	p	r	p
Implant stability after 6 months	vs. Bone density after 6 months	0.549	0.012*	0.274	0.256

r: Pearson coefficient

*: Statistically significant at p ≤ 0.05

Group 1: Grafted Sinus: autogenous bone + biphasic calcium phosphate

Group 2: Non-Graft Sinus

In the current study, residual bone height ranged from (3.5 -5.2) for both groups. The resultant average primary stability showed an ISQ value above 60 for both groups, with one case in the non-grafted group showing a value of 49. Values above 60 are sufficient and are considered favorable for a high implant survival rate ^[21]. Other authors have suggested values from 49-60 as a threshold for acceptable primary stability ^[22,23].

The grafted group showed significantly higher implant stability. However, this difference had disappeared after six months, which could be explained by the occurrence of osseointegration. Studies have demonstrated that when the implant is stable in the bony bed during placement and during healing, new bone will predictably fill the bone-to-implant interface and most of the implant surface will become in direct contact with living bone ^[24].

On the basis of implant stability measurements, the cascade of bone formation around implants starts with an early phase of bone resorption process ^[25], followed by a phase of bone apposition along the implant surface ^[26]. This results in dental implants demonstrating increasing ISQ values and increasing bone-to-implant contact values over time. Our own findings coincide with the previous observations, where the average implant stability at 6 months showed a significant increase when compared to baseline values. An average increase of 10.6 and 11.3 was obtained for the grafted and the non-grafted groups respectively indicating successful osseointegration. The grafted group showed significantly higher secondary stability similar to the results reported by Fouad W et al. ^[27]. Other studies showed no significant differences between grafted and non-grafted groups regarding secondary stability ^[28,29]. Rodrigo et al. ^[21] reported that the evaluation of ISQ values had a statistically significant correlation with the success of implant placement. They reported 19% failure of implants with an ISQ < 60, while implants with an ISQ > 60 were all successfully loaded.

In the present study radiographic assessment of intra-sinus new bone formation and bone density after 6 months revealed the formation of new bone around all installed implants. In all cases, the new bone formation was notable, with good continuity with the native sinus floor. The radiographic assessment showed a significant increase in bone density during the observation period. However, bone density was significantly higher when a mixture of autogenous bone graft and biphasic calcium phosphate was used when compared to the graftless sinuses. The significant differences can be explained by the fact that it takes time for new bone to arise from the blood clot in the graftless when compared to the grafted sinuses, which already possess bone-like properties and show opacity on a radiograph immediately and thereafter.

The bone density values ranged from (640.5–1146) in the grafted group with a mean of (973.6 ± 142.5), compared to (278.1–602.1) in the non-grafted group with a mean of (443.7 ± 97.8). These values were higher than those reported by Khaled H et al. ^[28] who reported bone density values ranging from (507-584) in the grafted group with a mean of (548 ± 25), compared to (384- 460) in the graftless group with a mean of (420 ± 23). The higher density values of the grafted sinuses reported by our own study in comparison to this study could be a reflection of the higher radiodensity of the Hydroxyapatite. The presence of remaining graft particles in the obtained biopsies from grafted sinuses after more than 6 months was reported in a previous study ^[29]. Thus, the merits of high density values should not be overestimated.

On the other hand, Altintas et al ^[30] reported a higher density of bone in the nongrafted than that in the grafted group, 6 months after surgery. The degree of changes in bone quality is largely dependent on the duration of the healing process in addition to the resorption rate of the bone substitute and its ability to promote new bone formation ^[31]. The presence

of residual graft material might interfere with the normal healing process ^[32].

In the current study the Pearson correlation test revealed a significant positive correlation between bone density and secondary implant stability in the grafted group ($r = 0.549$). However, in the non-grafted sites, the different density values did not correlate significantly with implant stability.

Similarly, Vasilena Ivanova et al ^[33] reported a positive correlation between secondary stability and bone density ($r = 0.498$). They underwent a socket preservation procedure with allograft or platelet-rich fibrin (PRF) and after 4 months, a total of 90 implants were placed. The values of the correlation coefficients revealed an average significant association of secondary stability with bone density and the percentage of newly formed bone. Indicating that increased secondary stability could be a reflection of the amount of newly formed bone in the implant bed. Furthermore, Turkyilmaz et al. ^[34] suggested a strong relation between bone density, Computed Tomography parameters and stability parameters. However, these results were contradicted by Huwiler et al. who found no relationship between bone trabecular connectivity and bone volume density with ISQ values after 8 and 12 weeks post-implantation ^[35].

Regarding vertical alveolar bone gain, the average values after six months were 6.6 ± 0.5 mm in the grafted group, and 6 ± 0.5 in the non-grafted group, with the grafted site achieving a significantly higher bone gain. Several studies ^[27,28] showed more bone gain on the grafted site than on the graftless site. However, Felice et al ^[36] reported slightly higher bone gain in the nongrafted site tented with a rigid resorbable membrane than in the grafted site, with no significant difference between groups. Non grafted sinuses have shown an average bone gain of 5.0 mm ^[28], 7.9 mm ^[37], and 14 mm ^[36] in different reported studies. This heterogenicity in the results could be explained by the fact that the gain in intra-

sinus vertical alveolar bone height could show a significant increase for implants protruding longer into the sinus cavity compared to implants with only a minor part of the implant tip protruding.

Superiority of grafted sinuses in terms of bone density and height didn't seem to affect the overall survival rate of implants placed without grafting the elevated sinus membrane. Studies have reported 100% ^[38] and 99% ^[39] for implants installed without the use of graft materials. Furthermore, a recent meta-analysis showed a high overall implant survival rate in graftless sinus lift groups of 97.92% ^[40].

In conclusion, the present study proved that sinus floor elevation with and without grafting is considered an acceptable and successful approach for sinus floor augmentation with simultaneous implants placement. Furthermore, higher density values in the grafted sinuses resulted in higher implant secondary stability. However, the clinical outcome of both groups was comparable.

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