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Original Research Article

Evaluation of Bone around Dental Implants with Sinus Lift Using Gelfoam Augmentation

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Abstract: ***Background:*** Many studies investigated the value of sinus lift with or without different bone substitute materials. However, sinus floor elevation with no graft material except a blood clot under the Schniderian membrane is becoming more popular. This study aims to evaluate both bone quantity and quality around dental implants inserted immediately after indirect graft-less sinus lift. ***Materials and Methods:*** Thirteen dental implants were used for the treatment of 8 patients with reduced posterior alveolar height using crystal approached sinus lift with the placement of Gel-Foam as an augmentation material before inserting the dental implant, from May to December 2017, then after 4 months from the surgery, a radiological evaluation was done by using Cone Beam Computed Tomography for assessment of the newly formed bone height and density. ***Results:*** preoperative and postoperative radiographic comparison using CBCT scan demonstrated the new bone formation within the compartment created by the sinus membrane elevation procedure with an average gain (2.75, ± 1.5) mm. The mean density of the newly formed bone was (298.1, ±130.1) Hounsfield unit. There is a postoperative increase in the native alveolar bone density around the dental implant from (398.9, ± 146.7) Hounsfield unit to (595.5, ±159.4) Hounsfield unit. ***Conclusion:*** There is A potential for a new bone formation of up to 7 mm bone in the maxillary sinus with Gel-foam supplement without the need for bone grafts. The newly formed bone quantity and the quality show promising results of the graft-less sinus lift with simultaneous dental implant insertion.

Keywords: Dental implant, indirect sinus-lift, bone quantity, bone quality, Gelfoam, CMC Technique.

INTRODUCTION

The masticatory force produced by the teeth stimulates the alveolar bone and reduces its resorption. Immediately after the avulsion of a tooth, significant bone modeling occurs with vertical bone loss averaging about 0.1mm/year with significant individual variations (Testoril, 2012). Progressive resorption of the alveolar process that occurs in cases of maxillary edentulism could reduce the thickness of the bone to be < 1mm. The pneumatization of the maxillary sinus plays a major role in this bone resorption. This has been attributed to increasing osteoclastic activity of the periosteum after tooth extraction and the increase of positive intra-antral pressure (Smiler *et al.*, 1992).

The management of alveolar bone shortage in an atraumatic way is important for the long-term success of implant placement. There are two main approaches to increase alveolar bone height below the maxillary sinus membrane; direct and indirect techniques (Alhamdani, 2018).

Indirect techniques, which have been developed by Summers in 1994 uses osteotomes for cases of low density 5-6 mm residual bone height. After incremental preparation of the bone, the elevation of the floor of the sinus is performed by several millimeters. In this technique, bone is compacted laterally and apically around the implant site with

a gradually increasing diameter of the osteotomes. This has been termed as Indirect Sinus Lift. This procedure might be performed with or without bone substitute materials.

It seems that indirect sinus lift with crestal approach sinus lifting technique is a more comfortable option from a patient's point of view (R. Nedir *et al*., 2013). The technique is less invasive than lateral window osteotomy sinus lift, thus the patient discomfort, implant healing time, and postoperative pain are most likely decreased.

The created space below the elevated sinus membrane is usually filled by bone substitutes to allow new bone formation using autogenous bone or allografts, which involve a remodeling period of 6 months or 9– 12 months (R. Nedir *et al*., 2013).

However, implants can be placed at the time of sinus lifting and left to osseointegrate without bone substitutes are cost-effectiveness and time-saving. Besides, there is less contamination associated with this procedure, as no external grafts or additional surgeries are involved.

Many studies investigated the value of sinus lift with or without different bone substitute materials (Al-Askar & Alsaffar, 2018; Elangovan, 2020; Kumar *et al*., 2018). Recently, many studies have been conducted on sinus floor elevation with no graft material except a blood clot under the Schniderian membrane (Bassi, Pioto, Faverani, Canestraro, & Fontao, 2015a; Wang, 2017). However, not many studies investigated the bone quantity and quality around the dental implant which has been simultaneously inserted after indirect sinus lift.

AIMS OF THE STUDY

To evaluate the quantity and quality of the native and the new bone formed around dental implants with sinus lifting.

MATERIALS AND METHODS

Scientific Approval for the study was obtained by Arabic Board for Maxillofacial Surgery-Iraq. Eight adult patients participated in this study. They were recruited from a group of patients referred to the Department of Oral and Maxillofacial Surgery of Al-Shaheed Ghazi Al-Hariri Hospital (from May 2017 to August 2017) for dental implant treatment with maxillary sinus floor lift. These patients were treated with 13 dental implants.

Patients' Inclusion criteria

1. Patients required dental implant treatment in the posterior maxilla, in the premolar and molar regions.
2. Residual bone height was less than 8mm in the estimated implant positions.
3. The primary stability of the implant can be obtained.
4. The bone width of the alveolar ridge is at least 5mm in estimated implant positions.
5. Patients' exclusion criteria were as follows:
6. Maxillary sinus pathology that could affect dental implant and maxillary sinus membrane elevation.
7. There were no systemic or local pathological disease might affect the dental implant or the surgical procedure as judged from history taking, radiographic and clinical examinations.

All patients had no history of relevant systemic diseases, nonsmokers and none of them displayed signs and symptoms of sinus problems, as confirmed by clinical and radiographic assessments before surgery. Patients were subjected to thorough dental examination clinically, evaluating oral hygiene, and assess the status of all the teeth and gingiva. Besides, all patients had been examined by ENT specialists in the same hospital.

Patients who met the inclusion criteria were consented to the research protocol and were fully informed about the study and the frequency of the radiation exposure.

The preoperative radiographic analysis included panoramic views to confirm the need for sinus membrane elevation for placement of the dental implant.

Ater preliminary radiographic OPG examination (Fig. 1), Cone-beam computed tomographic scans by GRANEX 3D (Fig. 2.), were taken to evaluate the available maxillary alveolar bone heights and checking if any sinus pathology was present. Radiographs were examined for the presence of bony septa and their position and angulation in the maxillary sinus using RadiAnt DICOM Viewer software. The first CBCT before implantation was taken for assessing bone quality and the available bone volume, in particular, the distance to the floor of the maxillary sinus, these software programs allow the residual bone height to be measured directly in millimeters.

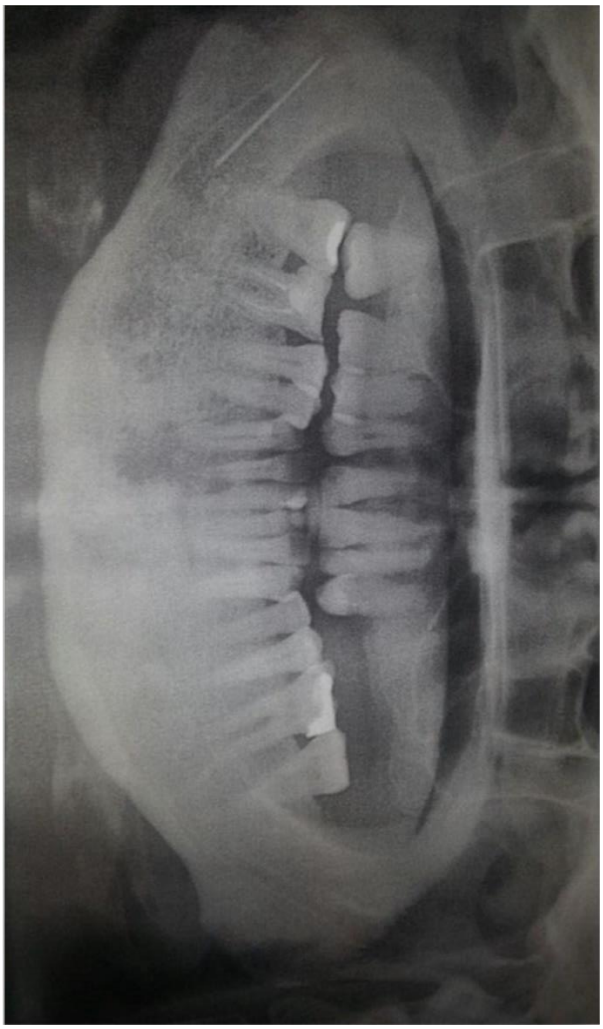

Fig-1: An OrthoPantomoGram (OPG) of patient with missing left posterior maxillary teeth and reduced alveolar bone height

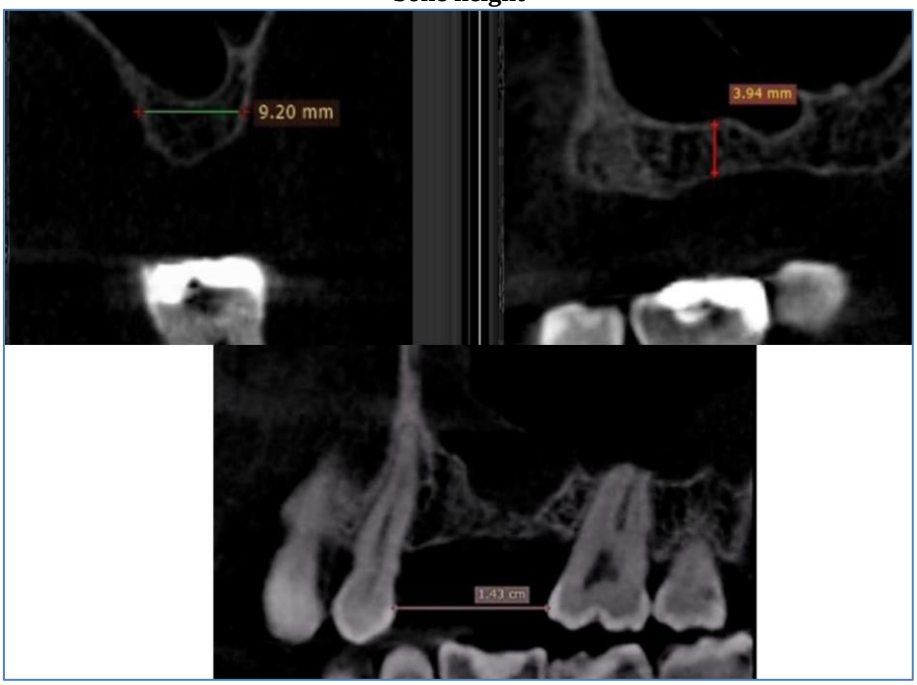

Fig-2: It shows the bucco-palatal, sagittal and mesio- distal measurements of the missing teeth area

1-The width measurements were made at the widest point of the alveolar ridge below the maxillary sinus. As shown in (Fig 2) measurements are performed for

a. alveolar bucco-palatal distance
b. alveolar height according to the site of the implant (from the crest of the alveolar bone till the cortical layer of the maxillary sinus)
c. the least mesiodistal distance between the adjacent teeth to the implant site (from proximal contact area).

Before surgery, all the patients were referred to the prosthodontics department in our hospital to prepare the surgical splint. Then make a drill hole in the splint at the occlusal surface of the implant site to make a guide for the site of the implant (Fig.3).

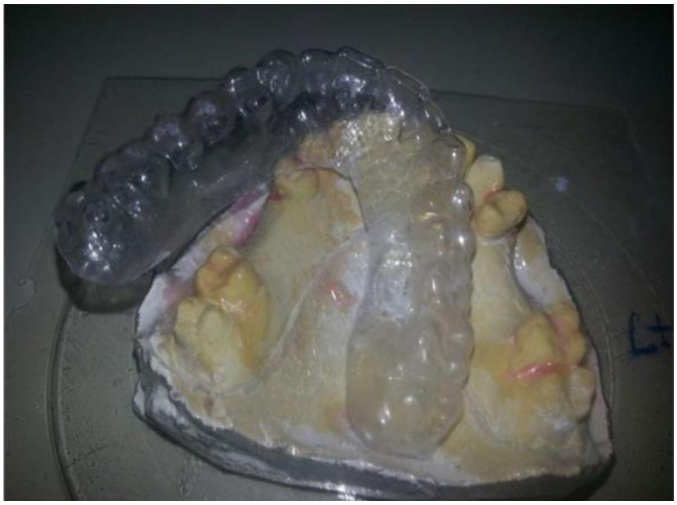

Fig-3: Preoperatively fabricated surgical template

All study participants received the same protocol of prophylactic oral antibiotics. Amoxicillin 500mg and Metronidazole 500mg both 3 times daily, beginning 1 day before the procedure and continuing for 7 days postoperatively. Diclofenac sodium (50mg) was prescribed for all the patients as analgesics. Before surgery, each patient rinsed their mouth with chlorhexidine digluconate 0.12% and cetylpyridinium chloride 0.05% solution for 2 min. Four patients were subjected to bilateral sinus surgery, and 4 patients underwent unilateral sinus surgery.

Surgery was performed under local infiltration anesthesia using 2% lidocaine with (1:100,000 epinephrine), infiltration was given along the surgical site. The surgical splint was used to mark the implant position. Measuring the gingival thickness was done by Periodontal Probe in the marked implant position to evaluate the depth of the gingiva.

The standard surgical protocol for sinus lift was performed as follows: after ensuring the anesthesia of the surgical site, an incision was placed palatal to the alveolar crest and carried a sufficient length to expose all implant sites. Two vertical releasing incisions were made at the anterior and the posterior end of the initial incision to allow adequate tension-free buccal reflection of the soft tissue flap. The buccal mucoperiosteal flap was elevated from the incision taking care not to perforate the flap at the alveolar crest.

For maxillary sinus lifting Crestal approach with Membrane Control (C.M.C) Technique by Wang (Wang, 2017) was employed. After reflecting on the flap, Magic Split was used to confirm bone quality clinically. This was followed by site preparation using Magic Marking Drill. Bone drilling then performed by Magic Drill shorter by 2 mm from the sinus floor (Fig. 4b). This was followed by sinus lifting by using Magic Sinus Lifter (MSL), which is gently tapped into the sinus with a hand lever (Fig. 4c). MSL has lateral blades for controlled lifting action and a 3mm space for offset-loading effect and control of bone block). Tapping force with the IBS Mallet must be gentle if the instrument does not advance Magic Short Drill was used to eliminate lateral cortical bony resistance.

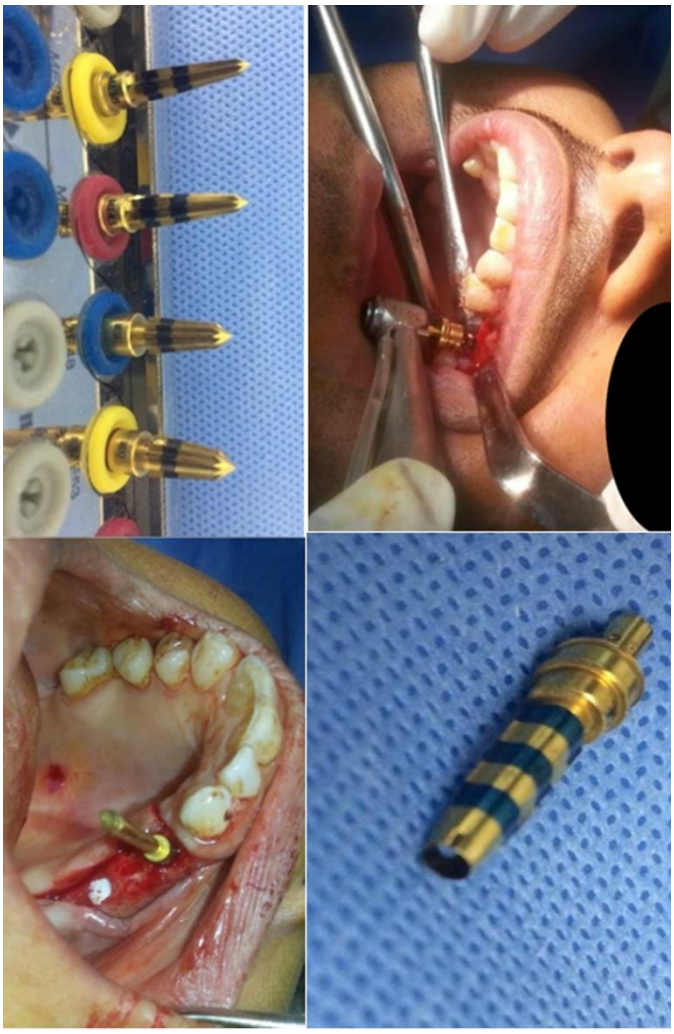

Fig-4: (a-upper LT) Magic Expanders. (b-upper RT) preparation of Implant site using Short Magic Drill. (c-lower RT) Magic Sinus Lifter. (d-lower LT) implant site augmentation with Gelfoam

As the Magic Sinus Lifter advances into the maxillary sinus, proceed slowly with gentle tapping only. Strong strikes will make an irregular sinus floor bone-block which may lead to sinus perforation. The fractured bone block should be larger than the diameter of the Sinus Lifter, the outer bevel shape of the Sinus Lifter creates a bone block that is circumferentially larger than the apex of the instrument, ensuring that the instrument does not come into direct contact with the membrane of the sinus.

Gentle tapping allows atraumatic detachment of the sinus membrane. The 3mm space of the apex of the Sinus Lifter instrument enables direct control of the bone-block and consequently the membrane, which is connected to the bone-block.

After elevation of the sinus membrane 1 mm deeper than 1mm from the desired depth length of the fixture to be used to prevent the sharp tenting of the membrane over the fixture. Remove the Sinus Lifter, slightly moving it mesiodistally. Check the hole to see if there is any sign of profuse bleeding. Start augmentation of the space with Gel-Foam (absorbable gelatin compressed sponge). About 4-5 pieces were cut into small pieces and inserted into the space created below the membrane of the maxillary sinus (Fig. 4d).

The Crestal approach with Membrane Control (C.M.C) Technique for sinus lifting was done for the first 4 cases out of 13 cases as a pilot study. For more patient-convenient procedures a modification to the second sinus lifting technique invented by Wang (Bone Expansion Technique) was suggested. After reflecting on the flap, start splitting the bone with Magic Split (Ø 2,5 diameter) with a hand lever. Both lateral blades of the 'Magic Split 'should be aligned mesiodistally and entering the direction of 'Magic Split 'should be aligned with the longitudinal axis of the alveolar bone where the implant is planned to be placed.

This was followed by Magic Expanders (Fig. 3e), By manual and gentle force moving upward direction toward the sinus while expanding the bone split by a mesiodistal movement to form an initial hole with Magic Split up to 2mm away from the floor of the maxillary sinus as measured previously in CBCT, then start expanding the hole with manual force by using Magic Expanders (Ø3.8, Ø4.3, and Ø4.8 Diameter), this expanding should be increased gradually in size until reaching one size smaller than the fixture that will be used. Sinus lift using IBS Magic Expanders should not be performed for more than 3 mm to avoid sinus membrane perforation, elevating the membrane 1 mm with each size of Magic Expander.

Finally, fixture selection and placement, fixture selection was done according to the size of the alveolar ridge by measuring its length and width using CBCT.

While fixture placement was done after augmentation of the Sub-antral space of the sinus with Gel-foam, the fixture was installed in the conventional method by using a Micro-motor engine with an angled handpiece.

Inserting of the fixture continues until a slight resistance was felt, then changing from mechanical to manual installation by using Torque Ratchet. The Torque Ratchet was used to screw the implant tightly into the bone till all the sides of the implant came in alignment with the crest of the alveolar or slightly submerged below the crestal bone level. Then cover the fixture with the cover screw (Fig. 5). The flap was sutured using silk sutures (3/0) to achieve passive primary closure. An immediate Panoramic View took to ensure the implant is in its proper position and alignment.

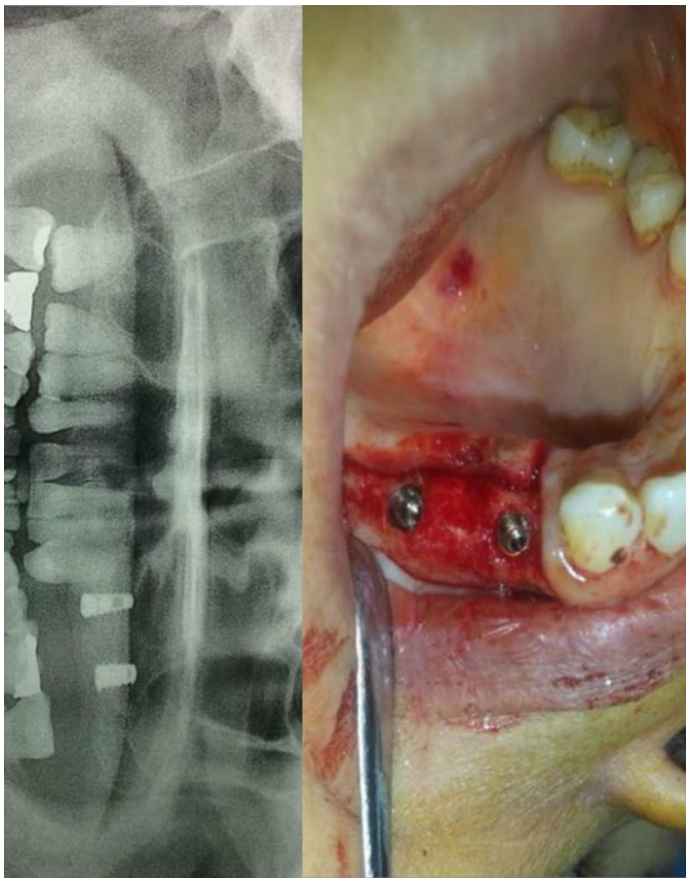

Fig-5: (a) surgical site after implants' insertion (b) Panoramic view shows the implant

Immediately after surgery patients were instructed not to blow their noses for 2 weeks after the surgery, also not to cough or sneeze with an open mouth, and to keep on chlorhexidine mouth wash for 1 week. The sutures were removed 7 days after the surgery.

Four months postoperatively, the CBCT examination was performed to measure the height of the newly formed bone in 4 points: mesially, distally (using sagittal view), buccally, and palatally (using coronal view).

Using the same coronal and sagittal view bone quality assessment was done by measuring the bone density of this new bone around the installed dental implant. The density values in Housefield Unit (Hu) of each surface of the bone around each implant in three regions of interest and at four points: (A) Apical region, below the elevated sinus

membrane, (B) Middle region, midway of the new bone length, and (C) Cervical region, 1 mm above the native alveolar bone.

The statistical analysis was performed using the Statistical Package for Social Sciences, version 22.0 (SPSS, IBM). The Wilcoxon Signed Rank Test was used to measure the statistical difference between bone heights and quality pre and 4 months postoperatively.

RESULTS

Table 1 shows the biographic information of the study sample. Of the patients included in this study, 5 patients were males and 3 were females. The patients were treated with 13 MAGIC FC® Dental Implants (IBS Co., Daejeon, Korea). Female patients received a total of 6 implants while male patients received a total of 7 implants. Five patients were treated with two implants. The minimum size of the implant was 4 Ø, whereas the maximum size was 5 mm. Two implant lengths were used in the included study (7 and 9 mm).

Table-1: Patients' biographics for the eight included cases

Case No	Age	Gender	Implant site	length/mm	diameter/Ø
1	29	M	3&14	7& 9	5& 4.5
2	38	M	5& 13	9& 9	4.5& 4.5
3	69	F	3& 4	7& 9	5 4
4	34	M	3	7	5
5	60	F	3& 14	7& 7	4.5& 4.5
6	52	F	5& 12	9& 9	4.5& 4
7	55	M	3	7	4.5
8	35	M	14	7	4.5

Table 2 shows the mean values of all the sides around the dental implant pre-surgery, post-surgery by 4 months, and the amount of the newly gained bone respectively. Also, the maximum amount of the gained bone height was 5.85 mm, while the minimum amount was 1.09 mm.

Table-2: The bone formation around each implant

Case No.	Mean Value		
	Pre- Surgery	Post-Surgery	Bone Formation
1.	3.95	9.8	**5.85**
2.	4.82	8.98	**4.15**
3.	7.31	8.79	**1.47**
4.	2.16	5.34	**3.17**
5.	7.87	9.58	**1.7**
6.	4.76	7.51	**2.75**
7.	1.95	6.92	**4.96**
8.	7.13	9.08	**1.95**
9.	2.21	5.85	**3.79**
10.	7.08	8.73	**1.65**
11.	5.87	7.09	**1.22**
12.	4.62	6.67	**2.05**
13.	5.72	6.88	**1.09**

Table 3 shows the total mean values of bone density in (Hu) in each case 4 months postoperatively, with the average mean of all the 13 cases is 298.13 Hu (SD = ±130.1), (Max =494, Min= 116).

Table-3: Native and newly formed density

Case No.	Bone Density	
	Native Bone	New Bone
1.	431	354
2.	557	473
3.	547	403
4.	518	361
5.	643	494
6.	307	191
7.	322	244
8.	416.7	349
9.	505.5	386.5
10.	261.5	238
11.	257	138.7
12.	206.3	127.5
13.	213.5	116

Table 4 clarifies the bone density difference between native bone and the newly formed bone, which has been measured 4 months postoperatively. The mean value of the 13 cases of native bone density (398.9 Hu) with (SD = ±146.7), while the bone density of the newly formed bone in all the 13 cases was (298.1 Hu) with (SD = ±130.1). the difference in the mean bone density between the native and newly formed bone in all implant sides was found statistically insignificant (P= 0.592).

Apart from one case with sinus membrane perforation (about 2mm), no serious complications were reported in this study sample. There were two cases presented with a dull pain at the implant area for about 1 week; one case complained of metallic taste and one case complained of mild swelling for 2 days.

Table-4: The difference between native bone density before and after surgery

Case No.	Total Mean Density (Hu) of The Native Bone	
	Pre-Surgery	Post-Surgery
1.	431	670
2.	557	683
3.	547	802
4.	518	551
5.	643	780
6.	307	462
7.	322	361
8.	416.7	552
9.	505.5	643.5
10.	261.5	471.5
11.	257	399.2
12.	206.3	345
13.	213.5	367

DISCUSSION

The space created underneath the Schneiderian membrane by elevation without bone substitute was loosely packed Gel-foam. The aim was to enhance rapid blood clot formation around the placed implants in the maxillary sinus. Gel-foam is an absorbable hemostatic agent with a not fully understood mode of action is. It appears, however, that its action is more mechanical than chemical. This material when placed in soft tissues usually absorbed completely within four to six weeks, without inducing excessive scar tissue (GTG, 1974; JH, HC, EJ, & Jr., 1972; Lindstrom, 1956).

The explanation behind bone formation after sinus lifting without bone substitute addition has been attributed to the fact that the Schneiderian membrane is carefully elevated. The bone in the sinus floor is exposed and mesenchymal cells can migrate to the blood clot and differentiate to osteoblasts, which are bone formation. (Nynke Lie *et al*., 2015) suggested that the bone-forming process is resembling a callus-based bone formation in a space surrounded by bony walls, the hematoma forming in this artificially created space seems to have sufficient potential and stability to transform into new bone.

It is worth mentioning the closed compartment with the blood clot underneath the maxillary sinus membrane with the presence of the implant, which prevents membrane collapse (Sohn, Moon, Moon, Cho, & Kang, 2010). Sohn *et al.* reported new bone formation underneath the Schniderian Membrane without bone substitutes after 6 months. However, they had 2 failed implants due to the lack of primary stability. This has not been encountered in this study. In this study, no primary stability problem was encountered, even with bone height less than 2 mm. This might be attributed to the Fin Thread design of the implant itself, which stabilizes the implant during bone formation.

The achieved outcome in this study concerning bone height gain and achieved new bone quality is comparable with other studies (S, G, VC, LA, & L., 2008; TW, HS, KW, YL, & SY., 2007). Although the mean gain of alveolar height concurs with available evidence in the literature (Perez-Martinez, Martorell-Calatayud, Penarrocha-Oltra, Garcia-Mira, & Penarrocha-Diago, 2015), there are cases where the bone gain height was more than 7 mm. This bone height gain is unusual. This difference in the bone gain between the studies could be explained as either the implant's sizes which were used in that study are all (13 mm, 4.3Ø), which is longer than the size of dental implants that were used in this study (7-9 mm, 4-5 Ø). The second reason might be the technique in measuring the length of the new bone gain is different. They considered that the newly formed bone is from the alveolar ridge to the floor of the sinus membrane above the apex of the implant along all the sides. However, Bassi, Pioto, Faverani, Canestraro, and Fontao (2015b) found that the mean of bone gain was about (7.2) mm after 3 months of follow-up.

The ability to raise the sinus membrane more than 7 mm using CMC might indicate the effectiveness of this technique in cases where a high sinus membrane is required to encompass the implant. A case report by one of the authors reported about 8 mm elevation of sinus membrane using CMC Technique (Alhamdani, 2018).

The result of this study showed that the mean bone density value of the newly formed bone in most of the cases lies within the soft bone and very soft bone category (Wang, 2017) (D3 and D4) according to Misch's Classification for bone density (Misch, Strong, & Bidez, 2008). The mean value of the native alveolar bone for all the cases before the surgery was within the soft bone (D3). This might explain the insignificant statistical differences between the two bone qualities.

N. Lie *et al*. (2015) reasoned the level of bone density in the newly formed bone by the nature of the original bone itself, which is soft and not as dense as D1 or D2. Bensaha and El Mjabber (2016) found that the density of the newly formed bone ranged from (200 – 500) Hu, which is comparable to the results of this study (191 – 494) Hu. They, however, stated that their results might be related to the incomplete calcification of the newly formed bone at the time of examination. The mean bone density in this study result is close to the findings of Altintas, Senel, Kayipmaz, Taskesen, and Pampu (2013) regarding the non-grafted group in their study (about 254.91 Hu).

The mean value of bone density in the non-grafted group in Altintas et al. study was higher than the mean value of bone density in the grafted group (after 6 months). They explained that by the resorption process of the allograft material with the subsequent remodeling of the bone graft material. Thus, the formation of new bone in the grafted site might require a longer duration (9 to 12 months). (Thor, Sennerby, Hirsch, & Rasmusson, 2007; TW *et al*., 2007). In contrast, in the non-grafted group, new bone formation starts at the time of implant placement, with faster recruitment of the osteoprogenitor cells at the surgical site and subsequent rapid healing. This would be evident when both groups are examined at 6 months postoperatively (Altintas *et al*., 2013).

In this study, the density of the alveolar bone in the implanted site has increased after the implant installation. This finding supports other studies' findings (Elkhidir, Wei, Suyang, Xie, & Yang, 2017; TJ & KB., 2002). An obvious

increase in bone density can be attributed to the compression of bone at the site of implant placement, which is beneficial for the initial implant stability especially in areas of poor bone quality in the posterior maxilla (Elkhidir *et al*., 2017). Turkyilmaz and McGlumphy in their study on 300 implants after 3 years found that the mean bone density of all 300 implant sites was (620 Hu, SD= ±251), whereas the mean bone density at the time of implant placement for 280 implants was (645 Hu, SD= ±240). This indicated statistically significant differences for each parameter ($p<0.001$) (Turkyilmaz & McGlumphy, 2008).

After one week of the study, all the symptoms were subsided. While for the metallic taste which occurred only with one patient, it was managed by the cessation of Metronidazole, because it was one of its side effects. Finally, regarding the mild swelling post-operatively as one of the patients complained, it was managed by reassurance the patients it is one of the expected complications after any surgical procedure, it has subsided within 3 days after surgery.

It is agreed that the indirect approach might not give the surgeon full control of the surgical field with limited access, which might increase the chance of unnoticeable sinus membrane perforation (R Nedir *et al*., 2013). However, the encountered case of perforation might be the result of not following the standard surgical protocol in this particular study.

CONCLUSIONS

There is A potential for a new bone formation of up to 7 mm bone in the maxillary sinus with Gel-foam supplement without the need for bone grafts. The newly formed bone quantity and the quality show promising results of the graft-less sinus lift with simultaneous dental implant insertion.

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