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Research Article

Evaluation of Reamer Mediated Crestal Sinus Floor Elevation with Simultaneous Implant Placement in Periodontally Compromised Subjects with and Without Porous Titanium Granules: (Clinical and Radiographical Study)

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Abstract

Aim: To evaluate the efficacy of reamer mediated crestal sinus floor elevation with noninvasive sinus crestal approach technique in periodontally compromised patients with and without the use of porous titanium granules (PTG) as augmentation material.

Materials and Methods: Fourteen patients aged from 26 to 56 years. Patients were divided into two groups (seven patients each), Group I: the implant was placed in combination with sinus crestal approach technique with the use of collagen membrane and metallic porous titanium granules (Tigran granules). Group II: implant placed with the same technique as group I without any regenerative material. Patients were followed up clinically and radio graphically for six months.

Results: In group I and group II respectively the mean height of the residual sub antral bone was 7.40 ± 0.57mm and 7.71 ± 0.49mm, whereas mean elevation of the sinus floor were 3.03 ± 0.51 and 3.14 ± 0.56 mm. Marginal bone loss was 1.12 ± 0.5 mm and 0.55 ± 0.41mm. Newly formed bone was 2.89 ± 0.02 mm and 1.50±0.14 mm. Density of newly formed bone was 45.25 ± 0.72% and 24.50 ± 0.72%. None of the patients experienced any discomfort during the procedure.

Conclusions: The Sinus Crestal Approach kit provides an alternative, risk free method for sinus lift when compared to traditional methods. Porous Titanium Granules are a novel non-resourbable and genuinely osteoconductive bone graft substitute. Highly significant difference was founded in the amount of newly formed bone and its density in group I than group II ($P \leq 0.05$).

Keywords: *Titanium Granules; Implant; Exclusion Criteria; Surgical technique; Standardized Per apical radiographs*

Introduction

Dental implants placement is a challenging procedure in the presence of unfavorable local condition of the alveolar ridge [1]. In posterior maxilla, progressive ridge resorption and sinus pneumatization, together with increased occlusal forces and poor bone quality, usually induce anatomical limitation for implant placement [2]. Solutions suggested for managing the problem of a vertically-compromised bone volume in the maxillary posterior region include the use of short wide implants, vertical ridge augmentation and lifting the sinus membrane to increase the available length for implant placement [3].

Sinus lifting is intended to increase bone height in the posterior maxilla through formation of new bone in the caudal section of the maxillary sinus [4]. There were two major approaches for the sinus floor augmentation: (the lateral and crestal approaches) [5]. The crestal approach utilized the osteotome which had many disadvantages including limitation of the amount of augmentation of the sinus floor, it is difficult to control the osteotome tapping force while using these techniques in order to produce effective membrane lifting without membrane perforation [6].

Specially designed reamer enables easy, predictable internal sinus elevation and augmentation without the use of an osteotome and mallet. It can also safely elevate the sinus floor, regardless of its shape (e.g., irregularities in thickness or septum) [7]. Resorption of grafting material may lead to unpredictable long-term results when rehabilitating the resorbed posterior maxilla. Non restorable, osteo conductive bone substitutes may therefore be advantageous over autogenously bone grafts. Titanium granules were used as bone substitute in patients scheduled to receive augmentation of the sinus floor prior to or in conjunction with placement of dental implants [8].

Therefore the present study was designed to evaluate the efficacy of the sinus floor elevation with noninvasive sinus crestal approach technique in periodontally compromised patient, to test the predictability of Tigran as a new grafting material in sinus augmentation and implant survival, and to compare the result outcome of implant placement in augmented and non augmented sinus.

Materials and Methods

The present study was conducted on fourteen patients with chronic periodontitis. The patients were selected, examined, diagnosed and managed in Faculty of Dentistry, Tanta University.

Criteria of patients' selection and inclusion criteria

a. The patient in need for implant treatment in posterior maxilla.
b. The residual subantral alveolar bone height is not less than 6mm to provide primary stability of the implant fixture.
c. Good oral hygiene.

The exclusion criteria

a. Presence of acute and chronic systemic disorders such as uncontrolled diabetes, hemorrhagic disorders and other conditions that can affect wound healing responses
b. Heavy smoker patients.
c. Traumatic occlusion, sever Para-functional habits (ex. bruxism, clenching …)

Study design

Patients conducted in this study were divided into two groups (seven patients each)

Group I: Test group (seven patients, one site for each patient) implant placement in combination with sinus crestal approach technique* with the use of collagen membrane** and metallic porous titanium granules (Tigran granules)***.

Group II: Control group (seven patients, one site for each patient) implant placement in combination with crestal sinus approach technique.

*Sinus Crestal Approach system, Neo biotech, Seoul Korea
**Bio collagen, Biotech
***Med eon science park, Malmo, Sweden

Implant Placement procedures

Preoperative Assessment

In this study all patients were evaluated in the following manner:

History:

Patient's charts were reviewed for information about

a. Personal data (name, age. Sex……..)
b. Past medical history
c. Past dental history

Preoperative preparation

a. All patients were subjected to proper oral hygiene instructions, scaling and root planning for all teeth and periodontal treatment if needed to provide an oral environment more favorable to wound healing.
b. Diagnostic study models of the prostheses were made and transferred to articulator for analysis and fabrication of a surgical template for guiding the position and axis of implant fixtures [9].
c. Radiographic evaluation Standardized Per apical radiographs were taken using (XCP) extension cone parallel technique Per apical radiographs were taken preoperatively to determine the residual sub antral alveolar bone height (RBH). Digitized panorama was taken to diagnose any abnormality in the sinus and to confirm the bone height [10].

Surgical technique

1. Local infiltration anesthesia was applied to all the patients participating in this study.
2. Crestal incision upon the osteotomy site.
3. Osteotomy site was prepared with drills mounted on a low speed hand piece and the drilling was done under normal saline cooling irrigation. Sequential drilling was 2 mm drill, then the 2.9 mm drill when placing a 3.5 mm implant in soft bone and 3.3 mm in case of hard bone. When placing a 4 mm diameter implant, the sequential drilling ended with the 3.3 mm drill in soft bone while 3.5 mm drill in hard bone. Osteotomy preparation was done by up to 1 mm below the sinus floor.

Sinus floor elevation was then accomplished using a suitable diameter reamer (2.4 mm S-reamer for regular diameter implant 1-3mm inside the sinus) firstly introduced 1mm shorter than RBH then to the RBH till the inferior cortical wall was reached and resistance lost.

The implant site was tested for perforation of the sinus membrane by observing the appearance of bubbles of blood coming out through the osteotomy when the patient tries to exhale gently through his nose while his nostrils are pinched. (According to the methods designed by Neobiotech booklet instructions).

In group II (Control group) the implant was placed and creating a space delineated by the elevated sinus membrane and maintained by the implant apex.

In group I (Test group) Collagen membrane and Trigram granules were inserted as showed in figure [1,2] and condensed by stopper mounted condenser .spiral bone inserter was used for pushing the bone into the sinus safely without any damage at the membrane after combination with 1mm long stopper. Bone spreader was used to spread the graft materials to lateral directions.

a. After sinus floor elevation, the implant was applied to the prepared osteotomy and turned in a clockwise direction until the implant body was seated within the bone and the platform is flush with the crestal bone.
b. The cover screw was then placed and tightened to seal the internal hex of the implant.

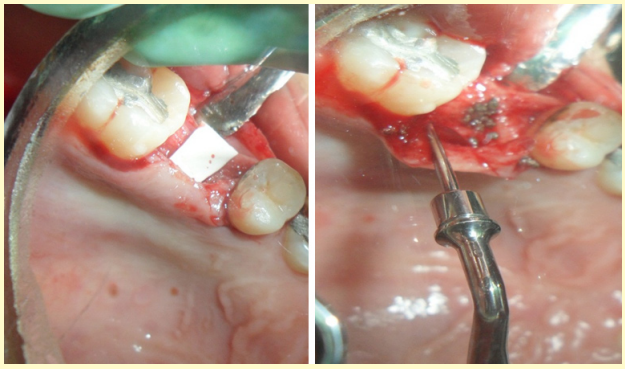

Figure 1&2: *Clinical pictures showing the collagen membrane and the Tigran granules in place after elevation of the sinus.*

Post-operative instructions and medication

a. Oral hygiene recommendations including the use of soft toothbrush.
b. Augmentin (1000 mg tablets) was prescribed twice daily for 5 days to avoid possibility of infection.
c. Brufen (400 mg tablets) was prescribed twice daily for 5 days to reduce inflammation, edema and pain.
d. Chlorohexidine gluconate 0.2% mouth wash, twice daily after the first 24 hours for 10-14 days.

Post- operative assement

Patients of both groups were followed up both clinically and radio graphically for six months postoperatively as following:

Clinical evaluation

Patients were followed up immediate, 3, and 6 months to evaluate wound discomfort, wound healing, swelling, infection and absence of oriental fistula or symptoms of sinusitis.

1. A scale from Zero to 10 with Zero representing no pain and 10 representing the presence of unbearable pain according to the visual analogue scale [11].

No pain	0-1
Annoying	2-3
Uncomfortable	4-5
Dreadful	6-7
Horrible	8-9
Un bearable distress	10

Table 1: *Showing the scale of the pain.*

Of zero to 10 with zero representing very unsatisfied and 10 satisfied according to [12].

Very unsatisfied	Zero
Unsatisfied	1-5
Satisfied	6-9
Very satisfied	10

Table 2: *Showing the Patients satisfaction level scale.*

The implant survival was evaluated according to Buser., *et al*. [13] and Cochran., *et al*. [14]

Implants were classified in 1 of the following 3 categories according to outcome.
Surviving implant: Implant that remained in situ and in function, whether or not there were any complications, such as exudates, facial space abscess, and local implant fistula, pain or swelling at the implant site, purulence, per-implant radio lucency and /or crestal bone loss greater than 4mm.

Successful implant: Surviving implants that also fulfilled the following criteria:

a. Absence of mobility, assessed manually and by a manual torque test
b. Absence of per implant radio lucency
c. Absence of continuous pain or suppuration around the implant.
d. Absence of deep more than 5 mm pockets adjacent to the implant.
e. Bone loss less than 4 mm.

Failed implant: Implant that had been removed for any reason, e.g., pain, mobility or advanced bone loss. Early failures were those occurring up to 1 year after the surgery but before prosthetic restoration. Late failures were those occurring more than 1 year after implant placement or after restoration.

Radio graphical evaluation

Standardized Per apical radiographs (SPR)

a. Amount of sinus floor elevation. (Calculated as the difference between RBH and the inserted implant length)

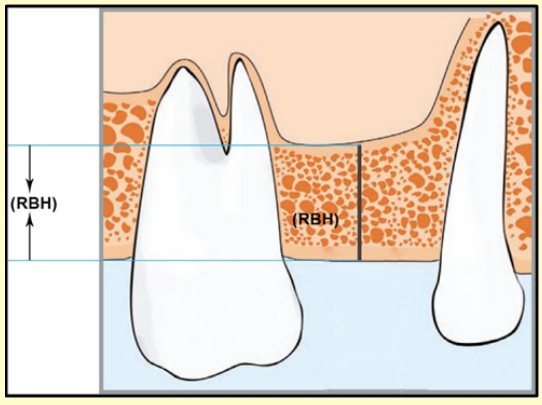

Figure 3: *Diagram showing Residual Bone Height (the distance from crest of the bone to the floor of the sinus).*

Marginal bone loss (MBL) around the implant. The mean of the Measurements of the marginal bone loss at the medial and distal aspects of all implants was calculated. The implant shoulder was the reference for readings.

Digitized panorama

Digitized panoramas were taken to determine

1. Gain and changes in the endosinus bone height (newly formed bone height in sinus).

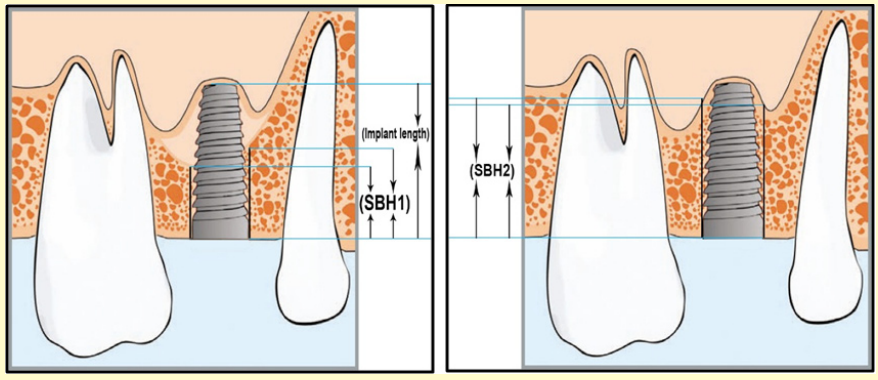

Figure 4&5: *DiagramShowing the Endosinus Bone Height measurement.*

Calculated as the difference between the secondary bone height after surgery (SBH1=the distance from implant shoulder to the apical most bone contact thread) and secondary bone height after 6 months (SBH2). Density of newly induced bone. Density of newly induced bone (The mean of the medial and distal lines paralleling to the implant in the area of newly formed bone)

Results

A total of fourteen implants were placed with sinus floor elevation; seven implants in conjunction with augmentation materials (collagen membrane and metallic porous titanium granules) and seven implants without augmentation materials. All patients were followed up clinically and radio graphically for 6 months. 13 the implants were successfully osseointegrated and only one failed.

Complete soft tissue healing was generally uneventful in all patients after implants placement. The patients reported minimal postoperative swelling or pain experiences with no occurrence of hematoma and minimal need for medications and analgesics. These results were revealed by clinical and radiographic evaluation.

Clinical Evaluation Results

Patients were followed up immediate, 3, and 6 months to evaluate wound discomfort, wound healing, swelling, infection and absence of oroantral fistula or symptoms of sinusitis.

Discomfort, Pain and Tenderness

All the patients in group I and group II were suffered from different degrees of pain ranged from no or mild pain to annoying pain immediately after surgery. During the 2nd and the 3rd evaluation periods, the pain disappeared except the 4th case in group I, the patient suffered from annoying pain in the 3rd evaluation period.

There was no statistically significant difference between the two groups through all study periods

Infection

Neither the patients in group 1 nor in group II experienced any signs nor symptoms of infection except after 6 months the case number (4) in Group I had been suffered from (localized mild pain and pus). Such case was treated with antibiotic and local antiseptic and anti inflammatory for one week until all signs ceased then the failed implant removed and wound closed as showed in fig (6,7&8).

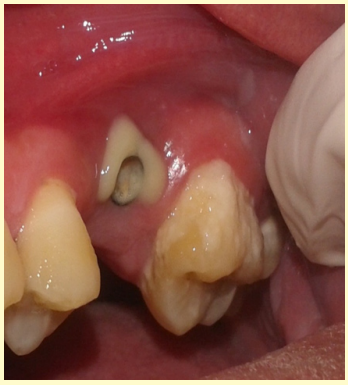

Figure 6: *Clinical picture showing pus around the implantcase number (4) in GroupI.*

Figure 7: *Clinical picture showing the removal of the failed implant.*

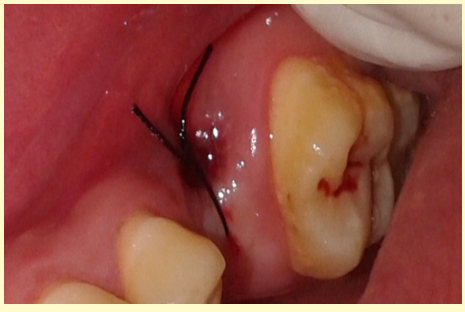

Figure 8: *Clinical picture showing the wound closure.*

The implant survival rate

In group I all the implants fulfilled the successful implant criteria except one case was early failed. The successful implants were 85.71% and the failed implants were14.28%.

In group II all the implants fulfilled the successful implant criteria 100% success

Radio graphical evaluation results

Standardized Per apical radiographs (SPR):

1. Amount of sinus floor elevation: The (M ± SD) values of amount of sinus floor elevation in Group I were (3.03 ± 0.51 mm) while in Group II were (3.14 ± 0.56mm). There was no statistically significant difference between the two groups.
2. Marginal bone loss (MBL)
3. The (M ± SD)values of the mean of MBL of the mesial and distal aspects in group I was (1.12 ± 0.50mm) while in group II was (0.55 ± 0.41mm).There was no statistically significant difference between the two groups.

Digitized panorama

Digitized panorama was taken preoperative, immediately after surgery and at 6 months postoperatively to determine:

1. Gain and changes in the endosinus bone height.
2. In group I the newly formed bone was ranged from 2.85mm to 2.92mm with a (M ± SD) of (2, 89 ± 0.02mm). In group II the newly formed bone was ranged from1.25mm to 1.75mm with a (M ± SD) of (1.50 ± 0.14mm).
3. There was statistically significant difference between the two groups.

	Group I	Group II	*T test value*	*P value*
Newly formed bone	2.89±0.02	1.50±0.14	9.50	0.0007*

Table 3: *Illustrating the changes in the endosinus bone height of both groups.*

**: Significant at P ≤ 0.05.*

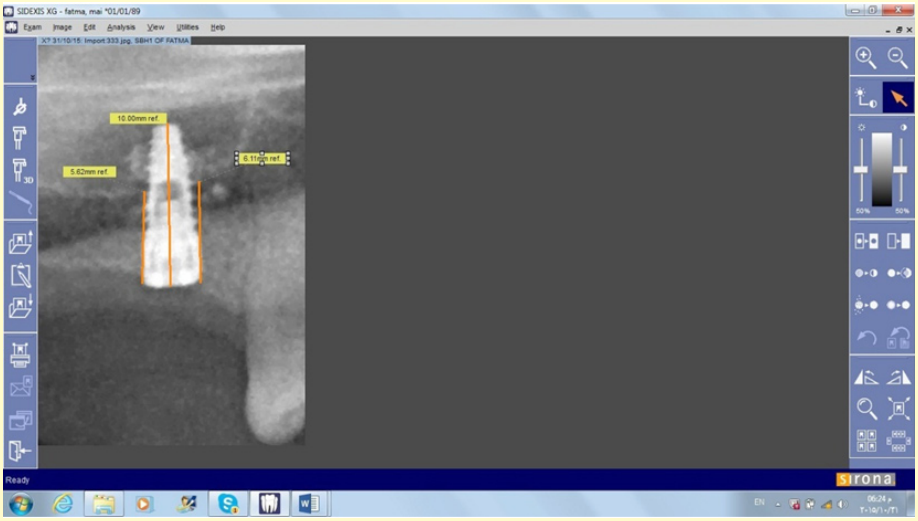

Figure 9: *Radiographic picture showing the calculation of SBH1.*

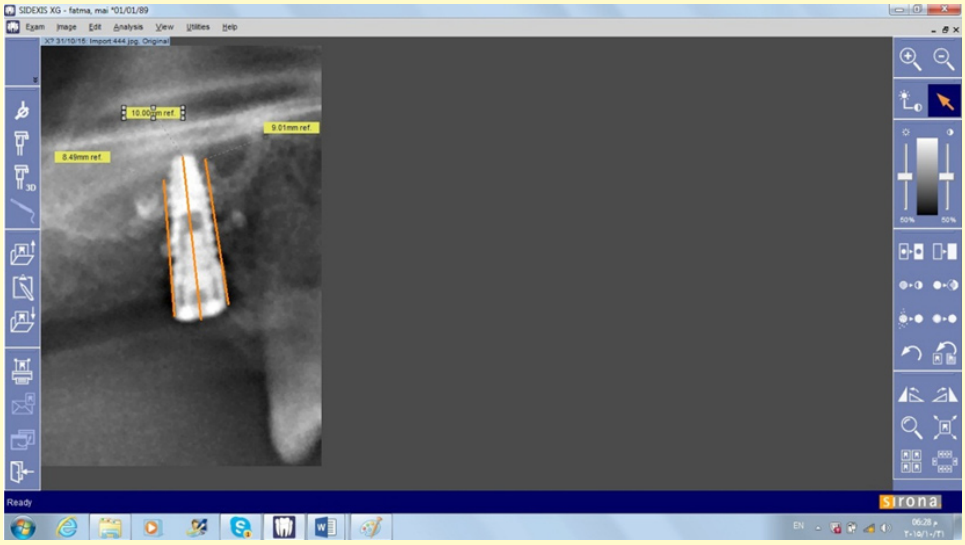

Figure 10: *Radiographic picture showing the calculation of SBH2.*

Density of newly induced bone: (The mean mesial and distal lines paralleling to the implant in the area of newly formed bone).

The mean density in area of newly formed bone after surgery was measured as (D1). The mean density in area of newly formed bone was measured after six months as (D2).

In group I the (M ± SD) of the values of (D1) was (41 ± 0.58) and (D2) was (45.25 ± 0.72).
In group II the (M ± SD) of the values of (D1) was (37 ± 0.57) and D2 was (24.50 ± 0.72).
There was statistical significant difference between the two groups.

Density	Group I	Group II	T test value	P Value
D1	41±0.58	37±0.57	4.89	0.008*
D2	45.25 ±0.72	24.50±0.72	20.33	0.0001*

Table 4: *Illustrating Comparison of the Density of newly induced bone of both groups.*
**: Significant at P ≤ 0.05.*

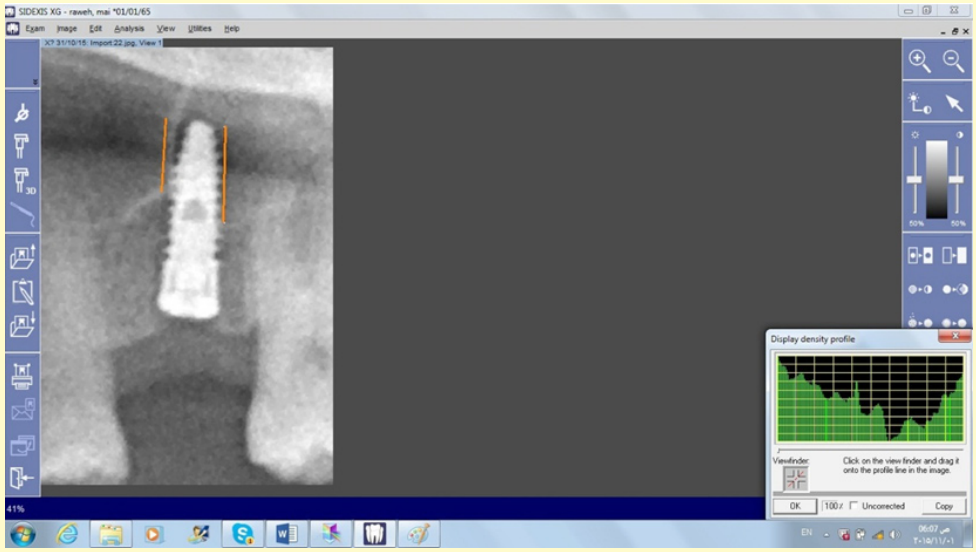

Figure 11: *Radiographic picture showing the calculation of density of newly formed bone in group II (D1).*

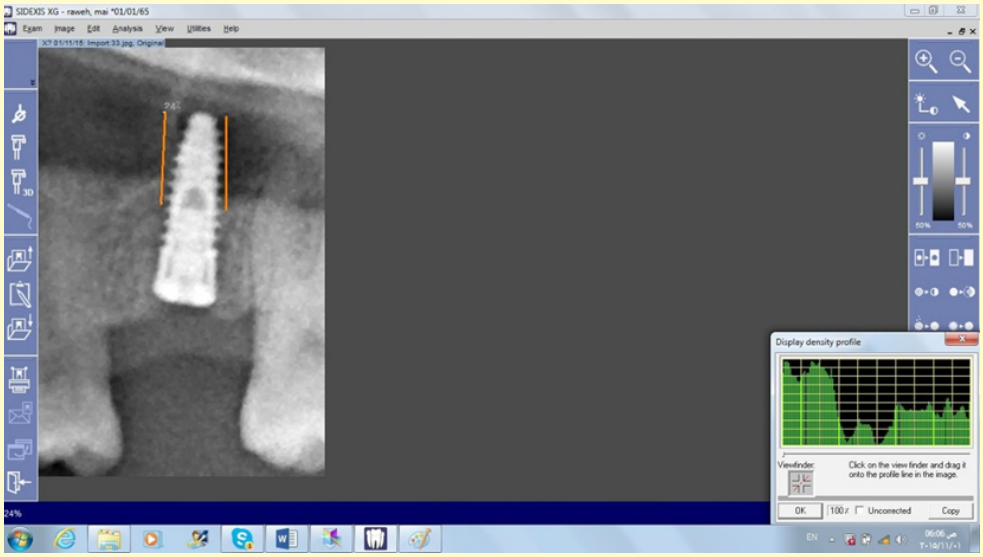

Figure 12: *Radiographic picture showing the calculation of density of newly formed bone in group II (D2).*

Discussion

In the present study a novel a traumatic technique using a traumatic drills and reamers that can rotate in proximity to sinus membrane and not perforate. This technique has been utilized to make the use of osteotomes redundant. A traumatic drill is advanced to the floor of the sinus and then reamer is employed to drill any bone left at the floor of the sinus and elevate the membrane. Following slight elevation of the membrane with the reamer, a carrier is used to deliver bone graft through the osteotomy and further advance the membrane. This technique was in agreement with Mazor., *et al*. [15].

In our limited knowledge of information, in the present study PTG was used for the first time as augmentation material for reamer mediated crestal sinus floor elevation. It was used on the basis Lambert., *et al*. [16] who reported that PTG, bovine hydroxyl apatite granules and hydrated bovine hydroxyl apatite granules were relevant candidates for sinus floor augmentation prior to implants as they showed acceptable 3-D stability and osteogenesis and Vandeweghe., *et al*. [17] who noticed the bone filled the space between the single porous titanium granule and did not elicit any foreign body reaction as the Bio-Oss and concluded that PTG can be considered as an alternative treatment option for sinus grafting procedures.

Patient satisfaction level of the reamer procedure was very high .All the patient was satisfied by the procedure. This was in agreement with Ahn., *et al*. [7] who found only 2.4% of the 380 patients experienced either no discomfort or were subjected to minimal inconvenience ranging from light to moderate malign from the prolonged mouth opening after reamer mediated trans alveolar sinus floor elevation.

One case in Group I (test group) suffered from annoying pain immediately after surgery. A localized extra oral swelling and moderate wound healing after seven days. The patient treated by local antiseptic, anti-edematous and anti-inflammatory. After six months the patient suffered from annoying pain, signs and symptoms of infection without oriental fistula.

Perhaps bone quality is the major cause of the failure of this case, since not only adequate bone quantity but also density is necessary for secure anchoring of endosteal implants. Studies have reported increased failure rates with implants placed in type IV bone [18]. The negative effect of poor bone quality on the primary stabilization of the implant can be compensated by increasing the number and diameter of fixtures [19].

Also Infection played an important role in failure of implant in this study. No single micro-organism has been closely associated with infection of the implant/site of implant placement. The microbial flora was the same that was traditionally associated with periodontitis [20]. Staphylococci presented within the oral cavity Staphylococcus aurous was demonstrated to have the ability to adhere to titanium surfaces. This was significant in the colonization of dental implants and subsequent infection [21].

The overall success rate of implants in group I (test group) was 85.71% success. Only one implant 14.28% had a postoperative sinus infection which was treated with antibiotics; however this implant was found mobile and removed at abutment connection time. This was in accordance with Bystedt., *et al*. [8] who achieved 87% success rate of 23 implants installed after lateral sinus floor augmentations using PTG prior to or in conjunction with placement of dental implants. Three implants (13%) were found mobile and were removed. Perhaps the higher failure rate in group I in our study was due to the little sample size so the one case failure affects the result of group I than group II and in future ingoing research we will take this in our consideration.

Although the implants in group II were installed without augmentation material, success rate was high 100% this was in agreement with Ahn., *et al*. in [7] who reported a 95.4% success rate after reamer mediated sinus floor elevation with simultaneous implant placement without grafting material. The increased success rate in group II in our study may be due to the quality of the bone. Most of the patients in this group belong to type III bone. Santos., *et al*. [22] stated that a gross estimation of the bone quality can be obtained from radioghps, however it is certainly determined only during surgical procedure.

Reda., *et al*. in [23] installed twenty implants after osteotome sinus floor elevation with and without bone augmentation material (OsteoBiol, Tecnoss, Italy) and found the mean amount of sinus floor elevation was 3.79 ± 0.74mm and 3.61 ± 0.85mm respectively by digitized intraoral radiograph. He reported no statistically significant difference between the two groups. These results were in accordance with our results, in which the mean amount of sinus floor elevation was 3.03 ± 0.51mm in group I and 3.14 ± 0.56mm in group II. Also no statistically significant difference existed between the two groups evaluated by digitized intraoral radiograph.

However these results were contradicting the findings of Pjetursson., *et al*. in [24]; who stated that only a moderate gain of new bone could be detected mesial and distal to the implants when the trans alveolar sinus floor elevation was performed without utilizing grafting material. On the other hand, when grafting material was used, a substantial gain of new bone was usually seen in the radiograph. However in our study no statistically significant difference existed between the two groups and this may be due to the difficulty in placing the graft material completely subinterval due to the difficulty in prediction the way of going of the granules.

The mean marginal bone loss was determined by digitized intraoral radiograph after six months and there was no statistically significant difference between the two groups. These findings were in agreement with Si et al. [25] who found no statistically significant difference in the amount of marginal bone loss after six months when comparing OSFE with and without graft. However the value of marginal bone loss after six months was similar to Rungcharassaeng., *et al*. [26] who found the marginal bone loss after 12 months follow up was 1.16 ± 0.89 mm. Also this was in agreement with Anastasios [27] who found 1.1 ± 0.8 mm marginal bone loss after 12 months. The higher mean marginal bone loss may be due to the patient periodontal condition. Courtney., *et al*. [28] concluded that patients with a history of periodontal disease demonstrate a significantly higher frequency of peri implantitis and peri implant bone loss. Supportive periodontal therapy seems to be a key factor in enhancing the long term implant survival.

In the present study the mean endosinus bone height in group I (tested group) was 2.89 ± 0.02 mm while in group II (control group) was1.50 ± 0.14 mm. There was highly statistically significant difference between the two groups. This finding is in agreement with Si., *et al*. [25], who stated that there was significant difference in the endosinus bone height between the two groups of OSFE with and without graft 6 months after surgery. The augmentation material ensures the space between the schneiderian membrane and the floor of the sinus cavity for adequate bone regeneration, while in the other group the sinus membrane is elevated and maintained by a blood clot and the implant apex served as a tent pole.

As regarding the density of newly formed bone, in the present study there was a highly significant difference in the density of area of localized sinus elevation immediately postoperative between the two groups. These findings were in agreement with Reda., *et al*. In [23] who illustrated that the highly significant difference in the density immediately postoperative was attributed to the radiopacity of graft material in the area created by sinus floor elevation in group I (OSFE with graft). On the contrary, this area was only filled by blood in the second group (OSFE without graft) accounting for the relatively lower density scores immediately postoperative. After six months group I (tested group) still showed a statistically significant higher mean change in the bone density than group II (control group) which had marked decrease density values. The increased density values after six months in group I insures the properties of the titanium granules and confirm using it as alternative augmentation material in sinus floor elevation surgeries. This was in agreement with Bystedt., *et al*. in [8].

Conclusion

Based on the limitation of the results of the present study, it was concluded that:-

1. The SCA kit provides an alternative, risk free method for sinus lift when compared to traditional method of lateral wall or crestal augmentation utilizing the osteotome technique.
2. PTG's are a novel non-resource able and genuinely osteo conductive bone graft substitute.
3. Highly significant differences in the amount of newly formed bone and its density when augmentation materials (collagen membrane &PTG) were used in conjunction with reamer-mediated sinus floor elevation procedure than without using augmentation material.

Recommendations

Therefore, the following recommendations can be presented for further researches about our topics:

1. Further comparative studies on reamer mediated sinus floor elevation with different types of augmentation material

2. Forthcoming studies involve long-standing follow-up intervals to extend beyond loading to evaluate the change in the amount of the elevation.
3. Evaluating the prolonged outcome of the health of the grafted sinus using computed tomography scans.
4. Recommendation to manufactures to change the technical design of the condenser supplied with the SCA kit to dyeline the pathway of the granules to the desired place.

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