Bone gain after maxillary sinus lift: 5-years follow-up evaluation of the graft stability

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ABSTRACT

Aim The aim of this study was to evaluate, through digital radiographic measurements, the long term changes in bone gain after maxillary sinus floor elevation surgery to obtain a stable and predictable volume augmentation for implant-prosthetic rehabilitation.

Materials and Methods A retrospective study was conducted on 72 patients affected by atrophy of posterior maxilla. All patients were treated with a lateral wall approach, using 100% deproteinized bovine bone mineral (DBBM) as graft material, with simultaneous implant placement. Panoramic radi-ographs were taken immediately after the sinus floor augmentation procedure (t0) and after 5-years follow-up (t1). For the analysis, the distance from the implant platform to the apex of the grafted material in the maxillary sinus at t0 and t1 was detected (d).

Results 166 implants were placed in patients ranging in age from 43 to 74 years. The results of this study showed a survival rate of 100% for all implants inserted. The mean change of "d" at t0 was 19.5 \pm 3.53 mm. The mean change of "d" at t1 was 18.25 \pm 4.25 mm. The mean of the difference between t1 and t0 re-sulted to be 1.37 \pm 0.138 mm. There was a statistically significant difference (p < .001) between measurements before and after sinus regenerative therapy (paired t- test).

Conclusions These results demonstrate that the graft material remained clinically and radiographically stable after 5-years follow-up, with an average vertical resorption of 1.37 \pm 0.138 mm.

KEYWORDS Sinus lift; graft stability; 5-years follow-up; bone gain

INTRODUCTION

The maxillary sinus is the largest of the paranasal cavities and occupies a large part of the posterior maxillary body. It has a pyramidal shape and the average dimensions of the maxillary sinus of the adult are 25-35 mm (width), 36-45 mm (height) and 38-45 mm (length), even if in the adult the size of the maxillary sinus increases further often a large part of the alveolar process is filled, sometimes leaving only a thin bone wall on the lateral and occlusal sides (1). This process, called pneumatization of the breast, varies greatly from person to person and even from part to part (2). The inner walls of the sinus are covered by Schneider's membrane, a membrane of variable thickness (3,4). The alveolar-antral artery runs in the bony thickness of the lateral sinus wall, at a variable height which may coincide with that chosen for the antrostomy in sinus lift procedures with lateral access. Its diameter is highly variable and in some cases the dimensions are such as to represent a risk factor to be analyzed in the pre-surgical phase, even if it is radiographically evident only in 50% of cases (5).

Within the maxillary sinuses there may be bony ridges called Underwood's septa, named after the author who first described them in 1910. The septa can be single or multiple and usually have a buccal-palatal course. They are present in about 30% of cases, with an average height of about 8 mm.

The elevation of the Schneiderian membrane in correspondence with these structures can create pitfalls, because it represents a risk factor for membrane perforation (6).

Bone resorption of the edentulous alveolar ridge is a challenge for the implant surgeon (7). At the level of the posterior maxilla, this reabsorption is in synergy with the pneumatization of the maxillary sinus which further contributes to the reduction of the amount of bone available for implant-prosthetic rehabilitation. To reduce the effects of sinus pneumatization and

thereby increase the amount of vertical bone cranial to the maxillary bone crest, elevation of the Schneiderian membrane from the sinus floor has been proposed.

Placement of implants in the posterior maxilla is often compromised or impossible due to alveolar process atrophy, caused by tooth loss, poor bone quality, and pneumatization of the maxillary sinus (8,9,10, 11,12). According to a recent radiographic study, maxillary sinus pneumatization averaged 1.56 ± 3.93 mm, and the greatest amount of pneumatization was associated with second molar extraction (13).

When the residual bone height is \leq 5 mm, a lateral window approach with a graft material is indicated. The lateral approach technique without graft material and simultaneous implant placement is suggested when a limited amount of bone regeneration is required (14,15) The sinus lift procedure with lateral approach was first introduced by Tatum in 1976, but the first publication of the technique was by Boyne in 1980 (15).. Multiple modifications to this technique have been published over the years.

In 2001, Vercellotti et al. introduced the Piezoelectric technique in the United States (introduced earlier in Europe) (16). Piezosurgery is based on ultrasonic principle with modulated frequency and controlled tip vibration range. Selective cutting is possible with different frequencies acting only on hard tissues. (17). It provides precise bone cut without much pressure, which helps to prevent excessive heat that would result in bone damage (18).

Another way to perform sinus floor elevation is the osteotome technique first described by Summers in 1994 (19).

In situations in which there is vertical dimension of residual bone < 5mm or when there is an inclination of the sinus floor, it is indicated to perform a procedure with lateral access (14). In cases of multiple implants it could be difficult and take longer time to use a crestal access than a lateral access. Another discriminant is the width of the maxillary sinus in terms of distance between the buccal and palatal walls. It has been reported that sinus floor elevation with a crestal approach is more effective in cases of "narrow" sinus (width <12mm) (20). The crestal approach involves performing an osteotomy through the residual bone crest to the Schneiderian membrane, without damaging or causing a perforation. Membrane lift is achieved by gently pushing well hydrated graft material. It can be performed in a single surgical phase if the height of the residual bone allows for sufficient primary stability to be obtained or in a double surgical phase by deferring implant insertion 6 months after the graft.

The sinus floor elevation is a safe and well documented surgical technique but it's not always possible to perform due to some intraoral, local and medical contraindications such as uncontrolled diabetes, psychiatric conditions, not compliant patient, chemotherapy or radiotherapy in the head and neck zone in the 6 months before the procedure, immunocompromised patients, medical conditions related to the bone metabolism, alcohol and drugs abuse.

Testori et al. (21) examined the impact of smoking habit on the success of implant therapy with sinus floor elevation procedure and concluded that smoking more than 15 cigarettes/day was significantly associated with low implant survival.

There are some alterations of the correct mucociliary clearance of the maxillary sinus or an alteration of the nasal-maxillary complex could be a contraindication to the sinus floor elevation. These types of pathologies, often asymptomatic, are rhinosinusitis of viral, bacterial or fungal origin, odontogenic sinusitis, sinusitis caused by the presence of foreign bodies. Absolute local contraindications are acute sinusitis, allergic rhinitis and chronic recurrent sinusitis, scarring and hypofunctional mucous membranes, aggressive benign tumors (eg, inverted papilloma, myxoma, ethmoidal-maxillary fibromatosis), malignant tumors (eg. epithelium, neuroectodermal, bone, soft tissue, odontogenous, lymphomatosis, metastatic-originated).

The aim of the present study was to evaluate radiographically long-term changes in sinus graft height after lateral maxillary sinus augmentation using deproteinized bovine bone mineral (DBBM) graft and understand the volume of bone and graft material to be positioned apically to the implant to obtain, through a stable and functional sinus floor, an implant-prosthetic rehabilitation.

MATERIALS AND METHODS

This study was conducted as a retrospective study, in compliance with ethical standards of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Federico II University of Naples (05/03/2018; No 347/18). The study was conducted on 72 patients affected by atrophy of posterior maxillae, lacking sufficient bone for implant placement without sinus floor augmentation, treated from February 2017 to September 2018 and the controls were performed 5 years after surgery.

The informed consent for the retrospective study data evaluation and publishing has been obtained from all included subjects. Before the intervention, all patients signed a written consent form.

All patients received detailed explanations of the difficulties and complications of the surgical procedure. Informed consent was obtained from all subjects involved in the study.

Exclusion criteria were:

- presence of periodontal diseases;
- the presence of maxillary sinus infection;
- Inflammatory lesions at surgical site;
- Systemic diseases that could compromise

osseointegration such as uncontrolled diabetes

- Use of antiresorptive or antiangiogenic drugs
- Radiation therapy in the craniofacial region within the previous 12 months;

•Smoking more than 15 cigarettes/day.

Smoking is an important confounding factor so smokers were excluded (22,23).

All patients underwent lateral maxillary sinus lift procedures with implant placement (one stage). The lateral wall approach was used for all surgical procedures. Panoramic radiographs were taken at the end of the surgical procedures and then at 5 years of follow-up. Implant survival rate was evaluated.

Sinus floor augmentation procedure and implant placement

Surgeries were performed by a single surgeon in a private dental practice in Sala Consilina (SA), Italy.

All patients received professional oral hygiene prior to the surgical procedure and received a prophylactic antibiotic therapy.

Local anesthesia was administered using mepivacaine with epinephrine at ratios 1:100000 or 1:50000. A middle-crest horizontal incision was made in the edentulous area, with two vertical buccal incisions. The elevation of a full-thickness flap allows the access to the anterior bony wall of the sinus. A window was prepared in the wall of the maxillary sinus using piezosurgery inserts (OT5 - Mectron, Carasco, Italy), removing all the cortical bone to gain access to the Schneiderian membrane. The membrane was gently elevated, implants were placed and the space between the internal sinus floor and the Schneiderian membrane was filled by DBBM bone graft mixing 0.25-1 mm and 1-2 mm granules (Bio-Oss, Geistlich Pharma AG, Wolhusen, Switzerland), hydrated with saline solution. The surgical site was then covered by a collagen membrane (Bio-Gide, Geistlich Pharma AG, Wolhusen, Switzerland), fixed to the cortical bone by titanium pins. The full-thickness flap was repositioned and sutured with Vicryl 5-0, allowing a first intention healing (24).

Upon discharge, patients received post-surgical instructions:

- Antibiotic therapy (25)
- Avoid rinsing
- Refrain from blowing nose
- •Sneeze with open mouth
- •Sleep with the head raised

After 10 days, patients returned to the attention of the surgeon to check the healing and eventually remove sutures.

Patients were visited twice a month until the second surgical phase, that occurred at least after 9 months from the sinus lift procedure.

During the second surgical phase, a crestal incision was made in the edentulous area to expose dental implants and replace the cover screws with healing screws. After 15 days from the second surgical phase an abutment was connected to the implant and screw-retained metal-ceramic restorations were fabricated.

Radiographic analysis

Panoramic radiographs were taken immediately after sinus floor augmentation procedure (baseline) and after 5 years of follow-up.

Measurements on panoramic radiographs have been carried out using a digital caliper as suggested by Hatano et al (26). The implant length, alveolar crest, the original base line of the sinus and the base line of the sinus were traced on tracing paper.

The change in height of grafted sinus floor was evaluated for each implant using the following variables:

- Implant length: the distance from the apex to the head of the fixture.
- Bone level: the distance from implant platform to the apex of the grafted material in the maxillary sinus.

To evaluate changes in mass of the grafted material the BL/IL ratio has been calculated.

Statistical analysis

Frequencies and percentages for categorical data were calculated. A paired-samples t-Student test was performed to assess whether there was statistical significance in measurements before and after regenerative therapy in the maxillary sinus. An independent-samples t-student test was used to assess any association between the delta of measurements at t0 and t1 and sex. An Anova test was performed to assess whether there were differences between delta and patients divided by age groups at 10-year intervals. The Shapiro-Wilk test was applied to assess the normality of the delta distribution in relation to the two implant position groups (premolar and molar area). Since the sample failed to be normally distributed a non-parametric Wilcoxon-Mann-Whitney test was used to estimate whether there were statistically significant differences between the two groups and delta.

RESULTS

A total of 90 Rx OPTs were selected in 90 patients with posterior maxillary atrophy and rehabilitated in the time from February 2017 to September 2018 following sinus regenerative therapy with 211 implants. Only 72 of 90 had repeated Rx OPT examination at 5-year followup for control or occasionally (for investigation of other pathological conditions). A one-stage procedure of implant placement concurrent with regenerative therapy was possible in all patients. Table 1 contains all information about the distribution of the sample, the average age of the patients treated, the total number of

Patient's characteristics and number of implants inserted	Numbers
Male	35
Females	37
Mean age at implant insertion	63.1
Total number of implants inserted	166

TABLE 1

implants used.

Instead, Tables 2 and 3 present the sample distribution of implant lengths used and posterior maxillary areas rehabilitated.

There was a statistically significant difference (p < .001) between measurements before and after sinus regenerative therapy (paired t-test), as well as there was a statistically significant difference between measurements before and after sinus lift within the two groups, men (p < .001) and women (p < .001).

An Anova test was then performed to assess a possible association between patients, divided into 3 age groups (G1 </= 55y; G2 </= 65; G3 </= 75), and the difference between measurements at t0 and t1 of sinus regenerative therapy (p = 0.378). The last analysis aimed to evaluate a possible association between the delta of measurements between t0 and t1 and the two areas of implant rehabilitation (premolar and molar area through a non-parametric Wilcoxon-Mann-Whitney test (p = 0.224).

DISCUSSION

The aim of the present study was to evaluate radiographically long-term changes in sinus graft height after lateral maxillary sinus augmentation using only DBBM bone graft material and understand the volume of bone and graft material to be positioned apically to the implant to obtain a stable and functional sinus floor for implant-prosthetic rehabilitation.

Several classifications of lateral-posterior maxilla defects have been proposed. In 2008 Chiapasco et al. classified these defects according to the width and the height of the residual alveolar ridge and according to the interarch vertical and horizontal relationship, aiming to define a surgical protocol for each class of defect (27). Vercellotti et al. proposed in 2009 a classification on the jaw bones that is more useful for clinical purposes, based on the amount of cortical and spongiosa present in the area of interest to be rehabilitated. Great importance has the evaluation of bone density in which implant placement is performed, especially since the posterior maxilla is a critical area for this therapy.

All the patients enrolled in the study received lateral sinus floor augmentation procedure, having a severe sinus pneumatization and minimal residual alveolar

Implant length	Frequency	Percentage	Cumulative %
8.5	3	1.8%	1.8%
9.0	4	2.4%	4.2%
9.5	38	22.9%	27.1%
10.0	4	2.4%	29.5%
11.0	60	36.1%	65.6%
11.5	5	3.0%	68.6%
12.5	22	13.3%	81.9%
13.0	30	18.1%	100.0%

TABLE 2

Implant position	Frequency	Percentage	Cumulative %
14	5	3.0%	3.0%
15	24	14.5%	17.5%
16	45	27.1%	44.6%
17	5	3.0%	47.6%
24	7	4.2%	51.8%
25	18	10.9%	62.7%
26	48	28.9%	91.6%
27	14	8.4%	100.0%

TABLE 3

ridge height.

Traditionally, implants were placed after an initial healing period from the sinus floor augmentation procedure. In 1989, a one-stage procedure has been introduced, consisting in implant placement contextually with sinus floor elevation. This option is possible if the residual bone allows primary stability. In fact, poor bone quality and quantity can cause implant displacement into the sinus cavity (28). A two-stage approach in implant placement is also associated with increased new bone formation due to:

- Possible detachment of the blood clot from the implant surface
- Implant placement during the second phase generates an expansion in the surrounding bone that activates strain signals, important for new bone formation
- The second surgical trauma is a stimulus for angiogenesis and osteoprogenitor cell migration

Our study shows that the graft material is stable 5 years after surgery.

The study is based on panoramic radiographs that were performed immediately after sinus floor augmentation procedure (baseline) and after 5 years of follow-up (26). Obviously, this has its limits, in fact the position of the floor of the maxillary sinus can be difficult to evaluate on two-dimensional radiographs, due to poor visualization. To better evaluate the graft in 3 dimensions, tomography is recommended for identification the outline of the floor of the grafted sinus and a measure the height and volume of the bone available for implant placement.

However, only panoramic radiographs were evaluated in our study, as this is a retrospective study and we did not want to expose the patients to excessive x-rays emitted by CT dental scans.

In the literature, the data on the use of graft material in maxillary sinus lift are controversial.

A recent systematic review underlined that bone growth can be induced in the maxillary sinus floor by membrane elevation even without augmentation (29–31).

This is explained by a physiological process in which bone formation in an artificially created space under the sinus membrane occurs like callus formation in secondary bone healing or osteogenesis for distraction (32).

This is the most likely theory, as most of the literature dealing with this topic reports reliable bone formation in animal and human studies (33).

This would imply that elevation of the sinus membrane is a prerequisite for the formation of a stable blood clot, which ossifies secondarily. The membrane itself is reduced to the function of a barrier whose own questionable osteogenic potential may not be necessary at all.

Several theories have been postulated to explain bone formation that is created without the use of a bone graft particulate. Srouji et al. demonstrated that cells from the sinus membrane can proliferate in culture expressing osteoprogenitor cell markers and that it is possible to induce osteogenic differentiation as well as new bone formation in the graft area (3).

This shows that there are cells within the Schneiderian membrane that can differentiate into the bone cell line. Membrane elevation is a crucial factor in this process, as the pluripotent mesenchymal cells migration occurs from the exposed sinus wall (34).

The maintenance of the sinus membrane integrity and its elevation so that there is sufficient space for bone formation and blood clot formation are preconditions for bone formation. The volume maintenance is achieved by the primary stability of the implant on which the membrane is placed.

Recent systematic reviews evaluated studies of nongraft sinus lift. However, no review included prospective male only RCTs comparing de novo bone formation in sinus membrane augmentation without sinus floor graft augmentation with bone substitutes using the lateral window approach (35–39).

In our study, all patients were treated with DBBM covered with a collagen membrane (Bio-Gide), fixed to the cortical bone by titanium pins.

From the data in the literature, there do not appear to be statistically significant differences in the stability of the

implants after sinus floor augmentation with or without covering the lateral window with a barrier membrane.

However, covering the graft with a barrier membrane, as in our case, seems to increase the percentage of newly formed bone while minimizing the proliferation of non-mineralized tissue. Therefore, although there are no statistically significant differences between the two methods, the coverage of the barrier membrane seems to be advantageous for the stability of the graft material (14).

All cases considered were treated with DBBM bone grafts mixing 0.25-1 mm and 1-2 mm granules (Bio-Oss). According to a recent systematic literature review there is no difference between the use of Bio-Oss and Bio-Oss mixed with autologous bone based on existing animal studies (40).

The materials used for this technique are different. Another review of the literature underlined that after 6 months, from the insertion of biomaterial, the xenograft showed the least volume reduction $(7.30 \pm 15.49\%)$, compared to the autogenous graft (41.71 \pm 12 .63%) (41).

The stability of the implants and graft material is of paramount importance for survival and implant success. However, the removal of plaque on implantsupported prostheses should not be overlooked, which is an important long-term prognostic factor for the maintenance and stability of dental implants and for the prevention of biological complications. A consensus report by Jepsen et al. discussed the development of mucositis and peri-implantitis and evaluated their management with preventive measures. Jepsen et al. particularly emphasized the importance of implant placement and the accuracy of prosthetic restorations, as these two factors must allow for adequate personal oral hygiene procedures (42)

There are several techniques described in the literature for lifting the maxillary sinus and there are various differences in the choices on the type of implants, in the treatment of the patient, in the amount of bone present, in the type of graft material inserted.

The insertion of the implants in conjunction with the sinus lift and the insertion of the biomaterial is a technique widely described in the literature. Blomquist et al. underlined how costs and times are reduced with this technique in minimizing both the costs and times of the intervention (43).

This finds a scientific rationale as many studies have demonstrated that there are no clinical or histological differences between immediate implant placement with maxillary sinus lift or deferred sinus lift (44,45). However, there are prognostic factors to be able to determine whether to insert the implants concurrently with the elevation or deferred, as for the residual bone height.

In fact, if the height of the bone crest is less than 5 mm, there are problems in fixing them at the same time as

Different methods for the home control of plaque on implant-supported prostheses have been described in the literature; these include the use of manual or electric toothbrushes and proximal cleaning dental devices

Keep in mind the use of home adjuvant products, such as ozonated gels, against various species of candida and the use of probiotics and postbiotics (47,48).

CONCLUSIONS

These results show that the graft material remained clinically and radiographically stable after 5 years of follow-up, with an average vertical resorption of 1.37 \pm 0.138 mm. In all treated cases, the implant apex was covered with graft material.

Although this retrospective study showed clear and consistent results, more randomized clinical trials are needed to draw clear conclusions.

Author Contributions

Conceptualization, M.C. and F.G.; methodology, F.D.A.; software, A.A and B.S.; validation, F.D.A., A.A. and F.G.; investigation, M.C. and A.A.; resources, B.S.; data curation, B.S. and A.A.; writing—original draft preparation, M.C., A.A. and B.S.; writing—review and editing, A.A. and B.S..; visualization, M.C. and F.G; supervision, M.C. and F.G. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement

Ethical review and approval were waived for this observational study because our retrospective analysis was conducted through RX OPT examinations.

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Data Availability Statement

All data generated or analyzed during this study are included in this article

Conflicts of Interest

The authors declare no conflict of interest.

Institutional Review Board Statement

This study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of Federico II University of Naples (05/03/2018; No 347/18).

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