Transcrestal maxillary sinus floor elevation with injectable xenogeneic bone substitute in gel form: A clinical, radiological and histological analysis

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Abstract: Purpose: This retrospective study measured the increase in bone tissue using the transcrestal maxillary sinus floor elevation with injectable xenogeneic bone substitute in gel form with simultaneous implant placement. This procedure allows elevation of the sinus floor atraumatically, reducing the risk of perforation of the Schneiderian membrane. **Methods:** 52 subjects needing unilateral sinus floor elevation, with a residual crestal height from 2 mm to 5 mm, and a request for at least one implant-prosthetic rehabilitation in the posterior maxillary area were enrolled. Transcrestal maxillary sinus floor elevation was performed with injectable xenogeneic bone substitute in gel form. The sinus elevation was measured after the surgery and 6 months later with a CBCT. Average values were calculated for each measure. **Results:** 46 implants were simultaneously placed; six implants were placed after 4 months because of the lack of primary stability. All the placed implants, with a follow-up varying from 3 to 5 years after loading, osseointegrated successfully resulting in a survival rate of 100%. Average pre-operative bone height was 4.2 mm while after the surgery the average value reached was 10.1 mm with an average value of new bone gain of 6.43 mm. Histological analysis revealed the presence of 33.2% of vital bone. (*Am J Dent* 2024;37:25A-28A).

Clinical significance: Transcrestal sinus floor elevation with injectable xenogenic bone substitute in gel form is a minimally invasive technique that can reduce the incidence of Schneider membrane perforations, making a widely used method, such as sinus floor elevation, safer and less operator dependent.

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Introduction

Sinus floor (SF) elevation is a surgical procedure aimed at increasing the vertical bone dimension in the posterior maxilla for a proper placement of dental implants.[1]

Recent indications for the transcrestal sinus floor elevation (tSFE) include narrow sinus cavities with a residual bone height between 3 and 5 mm,[2] to obtain the primary stability of implants inserted immediately; the SF can be elevated up to 5 mm without perforating the membrane.[3]

The perforation of the Schneiderian membrane (SM) is the most common complication of sinus augmentation surgery, with a reported frequency of 0-21.4% in the indirect technique.[3]

Minimally Invasive Antral Membrane Balloon Elevation (MIAMBE) involves elevating the sinus membrane using a balloon made of latex material. In this procedure, the balloon is placed through a transcrestal osteotomy against the SF and is gently inflated with 2-4 mL of sterile saline or dedicated liquid. As the balloon expands, the SM is raised; then the created antral space is filled with a xenograft or allograft mixed with platelet-rich plasma.[4]

Therefore, the fluido-dynamic technique[5] is an evolution of the original MIAMBE sinus lift surgery; the main difference is the use of fluid biomaterials instead of balloon to detach the SM and fill the sinus cavity.

The advantages of this procedure include: the possibility of detaching and elevating the SM in an atraumatic way in order to prevent dangerous stretching of the membrane; the use of a fluid and smooth biomaterial without sharp edges in order to avoid perforation of the membrane.

This study evaluated, clinically, radiographically, and histomorphometrically, the increase in bone tissue using a system for a fluid-dynamic elevation of the transcrestal maxillary sinus with injectable xenogenic bone substitute in gel form.

Materials and Methods

Fifty-two subjects from the Department of Oral Surgery and Implantology of the Catholic University of Sacred Heart were selected for inclusion in this retrospective study.

Inclusion criteria: Absence of chronic systemic diseases; full mouth plaque score (FMPS) and full mouth bleeding score (FMBS) ≤ 15%; need of at least one implant-prosthetic rehabilitation in the posterior maxillary area; residual crestal height from 2 mm to 5 mm.

Exclusion criteria: Presence of chronic systemic disease; smoking of more than 10 cigarettes; uncontrolled diabetes; coagulation disorders; alcohol or drug abuse; poor oral hygiene; sinus pathologies.

The research was approved by the local IRB (0013947/22), and the medical devices evaluated had already been approved for the investigated clinical use. The study was conducted following the guidelines of the 2013 Declaration of Helsinki. All the patients signed written consent forms after receiving information about the objectives and aims of the research.

The crestal height was measured with a cone beam computed tomography (CBCT) before the surgery: in the middle cross-section image the bone height was measured 1 mm below the crestal ridge. The sinus elevation was measured after the sinus lift surgery with a CBCT 6 months later during the second stage of surgery. Average values were calculated for each measure.

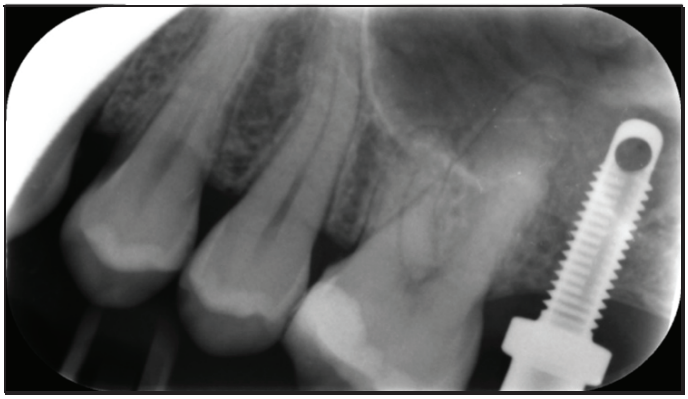

Fig. 1. Radiographic image of drivers screwed into the bone with two radial holes on the end section that needs to be carried into the sinus to allow injection of the biomaterial and lifting of the sinus floor.

Surgical procedures - The procedure was performed in the area between the first premolar and the second molar of the upper jaw. Subjects started oral amoxicillin 875 mg/clavulanic acid 125mg (Augmentin[a] 1000 mg) on the morning of the surgery and continued thereafter twice a day for a total of 5 days. The surgeons administered local anesthetic (articaine hydrochloride 4% with adrenaline 1:100,000 (Septanest[b]). A full-thickness flap was elevated to approach the bone crest.

Preparation of the osteotomy sites was performed sequentially, starting from the 2 mm pilot drill and the flathead drill 2.8 mm (for Ø 3 mm drivers), or with the 2.5 mm pilot drill and 3.3 mm flathead drill (for Ø 3.5 mm drivers). Flathead drills do not cut apically and are used to approach the floor of the sinus leaving approximately 1 mm cortical left, avoiding potential damage, and enlarging the initial osteotomy preparation. The choice of driver size was based on the diameter of the implants to be placed: the 3 mm driver was used for implants with a diameter of 3.75, while the 3.5 mm driver was selected for implants with a diameter of 4.2 or more. Drivers can be screwed into the bone with a contra-angle handpiece or even manually; they have an end section with two radial holes that must be carried into the maxillary sinus to allow the injection of the biomaterial and the lifting of the sinus floor, while the threaded part is screwed into the bone. Stops are screwed onto the driver (black - 3 mm, blue - 4 mm, red - 5 mm, green - 6 mm, yellow - 7 mm) to reduce the height of the threaded part (10 mm) and to lead inside the sinus cavity only with the perforated terminal part of the driver.

Once the driver of the selected size was positioned properly, the collagenic bone gel (OsteoBiol Gel 40[c]) was gradually injected through a specific infuser (Fig 1). The biomaterial used in this study was a gel of a 40% collagen matrix (type I and III) loaded for 60% of its volume with micronized heterologous bone (granulometry up to 300 µm), contained in a pre-filled syringe, which can be easily inserted into the appropriate dispenser available in the Sinus Flow Kit.[d]

The injection process was performed slowly (about 3 minutes), using a specially designed micrometric piston. After the first half of filling, the injector was rotated by 90° to obtain a radial filling of the sinus towards four space dimensions until it formed a dome shape, which will surround the implant. Once the progressive injection of the biomaterial in bone gel is completed, the driver is unscrewed manually turning counterclockwise or using the special spindle for contra-angle with rotation inversion.

After the driver was removed, the implant (Helix GM[e]) was placed with a contra-angle set at 15 rpm and 25 N/cm^2 without saline irrigation. The use of a calibrated manual wrench can help to secure the final implant position. A final torque of at least 25–30 N/cm^2 must be obtained. A periapical x-ray taken with the paralleling technique confirms that the implant is in the ideal position. Finally, the cover abutment was screwed, and the flap was sutured with interrupted 4-0 non-resorbable polytetrafluoroethylene[f] to achieve primary closure of the sites. The subjects were instructed to apply an ice bag intermittently for the first 4 hours and to rinse twice daily with 0.12% chlorhexidine (Curasept ADS[g] 0.12%) mouthwash. The operator checked the patients clinically 1 and 2 weeks after surgery. Sutures were removed after 14 days, and subjects could stop using chlorhexidine.

A new CBCT was performed 6 months after surgery and during that time, healing screws and sutures were inserted and the subject kept the area clean with chlorhexidine rinses. After 2 weeks, the sutures were removed and rinses suspended. All implants, both immediately inserted and delayed, were subsequently restored with screw-retained single metal-ceramic crowns and followed for 3-5 years after prosthetic loading.

Histomorphometric analysis - After 6 months, during the second stage of surgery, a 10 mm bone sample was taken with a 3 mm diameter trephine drill[h] at the implant sites not to affect the subject morbidity, and submitted for histological analysis. The biopsy samples, which were analyzed and compared, had to contain a graft portion of at least 4 mm in length.

Blinded histomorphometric analysis was performed on the bone samples by independent examiners. Bone samples were fixed in 10% phosphate-buffered formalin, followed by decalcification in a hydrochloric acid/formic acid solution (4/5%). After decalcification, samples were dehydrated in a series of alcohol baths and then embedded in paraffin. Full-length 5 µm-thick histological sections were then prepared and stained with hematoxylin/eosin. Sections were digitally scanned at various magnifications, and images of each area were analyzed using image analysis software ImageJ[i] and LOCI-Laboratory for Optical and Computational Instrumentation.[j] The percentages of residual xenogenic material, newly formed bone, and other tissue components (bone marrow and/or connective tissue) in each sample were delimitated and calculated.

Results

The results of the present study are shown in the Table.

Fifty-two subjects (37 females and 15 males; age range between 35 and 73 years, average 50.76 years) were included in this study and underwent transcrestal sinus floor elevation.

All implant sites healed uneventfully. Simultaneous sinus floor elevation and implant placement were performed in 46 cases (88.5%), while in six cases (11.5%) implant insertion was not possible and took place 4 months later due to the impossibility of achieving primary stability at the time of sinus lift. The complication of perforation of the Schneider membrane occurred in only two cases (3.8%). A single implant was placed in each subject for a total of 52 implants; the average diameter of the implants was 4.4 mm for molars and 3.7 mm for premolars. Twenty-seven implants (52.8%) were

Table. Data records and observed value.

Number of cases = 52	Average values	
Age		50.8
Gender	Males	28.8
	Females	71.2
Smoking		4.3
Residual bone height		4.2 mm
Sites	1st premolar	31.5%
	2nd premolar	52.8%
	1st molar	10%
	2nd molar	5.7%
Sinus elevation	Molar	6.1 mm
	Premolar	3.5 mm
Implant insertion	Immediate	46
	Delayed (4 months)	6
Membrane perforation		2
Histomorphometric results	Bone	33.2%
	Marrow	61%
	Graft	5.8%

placed at the site of the upper second premolars, 16 implants (31.48%) were placed at the site of the upper first premolars, three implants (5.7%) were placed at the site of the upper second molars and six implants (10%) were placed at the site of the upper first molars. The average residual bone height of the patients was 4.2 mm. Sinus elevation measured with a CBCT at 6 months after surgery showed an average bone gain of 6.1 mm for molars and 7.2 mm for premolars ensuring an average final bone height of 10.1 mm, with an average bone gain of 6.43 mm.

Histomorphometric analysis of the bone sampling showed the presence of bone marrow in 61% of the sample, 33.2% vital bone and 5.8% xenogenic material (Fig. 2).

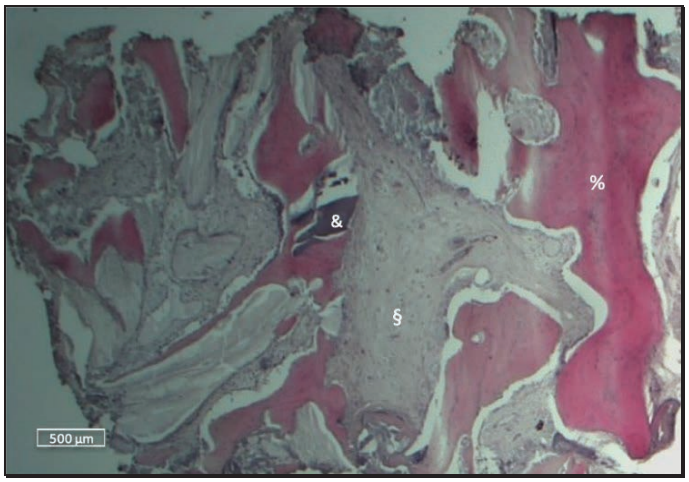

Fig. 2. Histomorphometric microphotogram of the bone sampling. The regenerated tissues 6 months after the procedure stained with hematossilin & eosin. Legend: & xenogenic material; % vital bone; § marrow/soft tissue (scale bar = 500 µm).

Discussion

This study aims to clinically, histologically and radiographically evaluate the bone gain obtained by tSFE using an injectable xenogeneic bone substitute in gel form.

Although implants with rounded apices protruding 2-3 mm into the maxillary sinus following elevation of the sinus membrane without grafting material may have resulted in spontaneous bone formation extending all around the implants in animals,[6] the predictability of such bone regeneration without the application of grafting material may be questioned. Pjetursson et al[7] compared the bone remodeling of implants inserted following transalveolar elevation without the addition of any material or with the addition of deproteinized bovine bone. The average alveolar bone gain in terms of height was found to be 4.1 mm in cases with biomaterial, a value clearly higher than just 1.7 mm in case of elevation without graft.[7]

Over time, clinicians have increasingly preferred to perform the transcrestal approach of sinus lift with grafting materials, having the possibility to choose between allograft, autogenous bone or heterologous materials, and platelet derivatives themselves or combined with grafting materials.[8]

In the present study, the average bone gain (BG) recorded after 6 months of healing was 6.4, greater than the average BG recorded in previous meta-analyses analyzing studies on transcrestal sinus floor elevation with and without grafting materials.[9]

The considerable bone gain shown in this study could be linked to the injection of the xenogeneic bone substitute in gel form, which acts as a filler and displacement agent, facilitating the formation of primary blood clots and the subsequent invasion of repairing and regenerative cells. Moreover, the collagen gel component contained in the xenogenic bone substitute is rapidly resorbed and therefore does not leave any particles of the biomaterial in the maxillary sinus.[10]

CBCT after 6 months showed uniform distribution of the bone substitute material around the dental implants, the identical consistent dome shape of the bone substitute, and no leakage of bone particles from sinus membrane space into the sinus cavity space. This regular arrangement of the biomaterial had already been reported in other studies on transcrestal sinus lifts, using the sinus balloon technique.[11]

The SF recorded elevation was between 4 and 8 mm, with an average value of 7.1 mm in premolar area, and 6.2 mm in molar area. These results are in line with those reported by Zhou et al.[12]

The most common complication during sinus floor elevation is Schneiderian membrane perforation.[3] In this study, accidental perforation occurred in two cases confirmed clinically in all cases by Valsalva maneuver; however, this did not influence the integration of the peri-implant bone, and no sinus-related pathologies were induced. An almost absence of Schneiderian membrane perforation could be attributed to the non-traumatic surface of the driver and the gel's gentle slow injection. The progressive erosion of the cortical bone of the maxillary sinus is facilitated by atraumatic burs that allow more respect for both the adjacent residual bone and the SM. Two of the most important aspects of this procedure are the easy stabilization of the dispenser and the micrometric insertion of fluid biomaterials, which ensure a safer surgery.

Also, the absence of pain, edema, bruising or bleeding could be correlated to the mini-invasive nature of the surgery. These findings were coinciding with those of Hu et al[13] in 2009, who observed in their study minimal postoperative swelling and pain, resulting in greater patient comfort and reduction of analgesic use.

No implant loss was recorded during the entire follow-up period in the present study; these survival rates (100%) are also in agreement with previous studies reporting on implants inserted using the transalveolar sinus floor elevation approach.[12]

In this study no significant difference in implant survival of the simultaneous and delayed inserted implants was noted. The possibility to perform a transcrestal sinus lift through small size access (up to 3 mm) and the simultaneous implant placement is the main advantage of this technique. In addition, if an implant failure occurs, the risk of oro-antral communication is reduced because of the small size of the alveolar access.[14] Finally, the reduced percussive trauma and the consequent risk of paroxysmal positional vertigo,[15] the low invasiveness and the consequent benefit for the soft tissues are additional advantages of this approach.

Although promising results were obtained, the current study presents some limitations, including a short follow-up, a small sample, and the absence of the control group. Further randomized controlled trials with a larger sample and longer follow-ups are needed to corroborate the efficacy and safety of the transcrestal maxillary sinus floor elevation with injectable xenogenic bone substitute in gel form.

Maxillary sinus floor elevation utilizing a transalveolar approach and injection of bone substitute in gel form is feasible for the implant rehabilitation of maxillary molar and premolar areas, and its clinical effect is satisfactory. The technique shows comparable bone gain to that obtainable with more invasive techniques, such as the lateral approach, and a 100% survival rate.

a. GlaxoSmithKline S.p.A., Verona, Italy.
b. Septodont, Saint-Maur-des-Fosses, France.
c. Tecnoss, Giaveno, Italy.
d. ROEN, Pianezza, Turin, Italy.
e. Neodent Straumann, Basel, Switzerland.
f. Omnia Srl, Fidenza, Italy.
g. Curaden Healthcare, Saronno, Italy.
h. Hager & Meisinger, Neuss, Germany.
i. National Institutes of Health, Bethesda, MD, USA.
j. University of Wisconsin, Wisconsin, Madison, USA.

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