**Introduction**

A technique for bone regeneration in maxillary posterior deficit (TGSL) was already codified by the Authors Pozzi and Moy (1), our study describes the ability to perform a technique TGSL without the use of bone grafting materials, using a highly minimally invasive protocol.

Due to the amount of pneumatization of the maxillary sinus, loss of teeth in the posterior quadrant is usually associated to the alveolar bone resorption (2) with a consequent reduction of the residual height of the alveolar ridge: this does not favor the insert of standard length implants (3, 4). Moreover, the low quality of bone in the posterior maxilla, has a negative influence on the survival rate of implants placed in this site (5). Nowadays, the treatment planning of implant-prosthetic rehabilitation in the atrophic rear maxilla offers vari-
ous possibilities linked to the choice of using short (6) rather than angled implants, or enhance the amount of residual bone with techniques to increase the sinus floor (7). In attempt to avoid a bone graft procedure, the choice to insert short implants often is the result of compromised biomechanical situations, in which implants are located in poor bone sites with low quality and high strength of occlusal loading (8-10); short implants have been associated with lower success rates compared with most of standard length implants (11).

Currently, in absence of an adequate bone height, the results obtained by the use of short implants may be comparable to those of longer ones placed in regenerated bone, (6) but further investigations are needed to confirm the long-term follow-up data at 5 months published to date. The severely atrophic maxilla is still a challenge, many clinical approaches have been recommended to increase the amount of available bone (12-14). Schneider’s membrane elevation can be achieved through a lateral (15) or transcrestal (8) surgical approach to increase the residual subantral bone (15-19). The bone grafts regeneration of maxillary atrophies and of the sinus floor is a proven long-term option of treatment (20-24); however, patients may refuse such procedure for the invasiveness of the technique, the increased time of healing and additional costs.

Lateral antrostomy can result in significant postsurgical morbidity and presents an increased risk of tearing of the membrane (21). Moreover, to achieve predictable results, the surgical experience along with a two-step procedure with delayed placement of implants is recommended (10, 25, 26). To overcome these limitations and potential complications of the sinus lift, the literature has suggested the use of inclined implants located in anatomical areas anteriorly or posteriorly to the sinus and, if it is present in the sinus septum, in the palate, and in pterygoid process to avoid implants endo-sinus (27-36). The inclined positioning of the implants in those areas allows the choice of greater lengths, thus improving the bone anchoring, by increasing the inclination angle and therefore the support for the prosthesis, thus avoiding the need for bone grafting. When inclined implants were splinted with axial implants placed in the anterior maxilla, they have shown success rates in line with the results of previous studies that have used similar techniques with individual inclined implants (29, 32, 36). The lifting of the sinus floor with a transcrestal approach is a “minimally invasive” technique because the surgical breach is run and greatly reduced by avoiding the lateral access, maintaining the vestibular wall of the sinus and significantly reducing post-operative morbidity. Pjetursson et al., in a study on the technique with osteotomes to increase trans-alveolar bone in the maxillary sinus, recorded a high rate of patient satisfaction at more than 9% (10). The transcrestal sinus lift was introduced for the first time by Summers (17). Subsequently, various modifications to the original technique have been performed in order to improve the reliability and safety, such as: the introduction of the osteotome for the sinus lift (17), the osteotome for positioning of bone (37) and the use of a balloon catheter for the membrane lifting (38-41). Fractures or perforation of the sinus floor are the main complications related to the transcrestal approach with technique of osteotomes (14, 16, 17) and drills with (18, 19) or without (15) depth stop; the limitations of this surgical approach are represented by: impossibility of a direct visualization of the sinus cavity and of the Schneider membrane, limited amount of bone increase and high risk of accidental perforation of the membrane, without the possibility of surgical repair than the lateral approach. In patients with severely maxillary bone resorption is recommended a conventional approach with surgical lateral window because of perceived limitations with the transcrestal approach (42). Nowadays the computer assisted implant-prosthesis, is gaining popularity among doctors and patients. The advent of 3D technology (CAD)/(CAM) optimizes the planning of implant treatment, allowing the doctor to place dental implants with high accuracy. The conversion of the data generated by the computer allows a minimally invasive procedure with a consequent low morbidity and reduction of the total time of treatment (43-46).
The purpose of this work is to verify the effectiveness of the minimally invasive technique TGSL even without the use of graft materials and with immediate implant placement. The bone increase was performed with a transcrestal guided approach of sinus lift (TGSL) (1), using a surgical technique or in combination with drills and osteotomes foam-compactors.

The review of the international literature allows to consider this work as the second prospective study with TGSL technique but unlike its predecessor does not resort to grafting materials as simply uses the same implant as a space maintainer (47, 48).

Materials and methods

The clinical study examines data collected from 39 patients with single or multiple edentulous sites located in the posterior maxilla; treatments were performed using an upward transcrestal sinus, with computer-guided implant surgery based on radiological and surgical templates (NobelClinician, Nobel Biocare AG, Zurich, Switzerland) and a protocol of foam-compactors osteotomes: the TGSL technique (1). Patients were selected and treated between October 2010 and February 2013. All patients were followed for a minimum period of three years in function (range 24-48 months, average 36.96 months). All the procedures were conducted in accordance with the rules for biomedical research involving human subjects. In the preliminary visit, the patients were informed about the procedures, the benefits, potential risks and complications, as well as on the assessments of the follow-up needed for clinical research. Patients were included into the study after obtaining a consent module written and signed. For screening and initial evaluation, preoperative radiographs including periapical and panoramic X-rays, Computed Tomography (CT), and cone beam CT were performed. A residual alveolar ridge of at least 3 mm in height and 5 mm in width distal to the canine, the need for an increase in bone of the maxillary sinus and the refusal to undergo a sinus lift with the conventional method, insertion torque of the implant between 45-55 Ncm and good periodontal health, means in absence of bleeding on probing and plaque index less than or equal to 25% were the main inclusion criteria of the study. Were considered exclusion criteria: stroke, recent heart attack, severe bleeding disorder, uncontrolled diabetes, cancer, psychiatric therapy, pregnancy, breastfeeding, untreated periodontitis, the presence of infection in the tissues adjacent to the implant sites provided, previous facial radiotherapy, edentulous, acute infection and inflammation (sinusitis) in the area intended increase bone and implant placement, severe bruxism, and poor oral hygiene. Radiographic dimes were produced in acrylic resin for models with diagnostic wax-up, which represent functional and aesthetic parameters of the ideal designed prosthesis. Eight radiopaque markers with 1.5 mm in diameter were placed in the flanges of the buccal and palatal template, away from metal restorations in order to avoid the effects of back scatter metal or struis-sero-view of the markers. To stabilize the mask against radiological teeth antagonists during the CT-scan was produced centric occlusion in vinyl-polysiloxane drive.

A CT-scan is obtained by each patient using the technique of double-scan: the first scan of the maxilla was taken in position by the planning dima, while the second one was performed by the only radiographic dima (48). The DICOM file (Digital Imaging and Communication in Medicine) of the two sets of scans were acquired and transferred in a 3D planning software (NobelClinician, Nobel Biocare AG) and the images were superimposed and assembled together (49). The virtual three-dimensional positions and angles of the plants were determined on the basis of the emergence profile prosthetic established on X-ray pattern (Figure 1).

The proportion of available bone (ABH) was calculated on the three-dimensional planning software (NobelClinician, Nobel Biocare AG) as the distance between the bone crest and the lower point of the sinus floor, measured on the long axis of the planned implant (Figure 2). The working length of each drill was equal to the ABH less than 1.0 mm, in order to avoid the pen-
etration in the antrum sinus. Once the treatment plan has been assessed and approved by the dentist, the data is sent digitally to a central workstation production (Nobel Biocare AB, Kloten, Switzerland) for the manufacture of stereolithography surgical mask, which records the positions of the provided implants. An index of a surgical occlusion is to help to adjust the vertical dimension of the occlusion between the surgical template/mask and the opposing dentition in order to allow the correct insertion and positioning of the surgical template during the surgery.

It was administered a drug therapy to prophylaxis (thiamphenicol glycinate acetylcysteinate 810 mg/4 ml) and cortisone (betamethasone 1 mg) twice a day from the day before surgery and continued for 10 days after surgery. The day of surgery, a single dose of antibiotic (2 g of amoxicillin and clavulanic acid or clindamycin 600 mg in case of allergy to penicillin) one hour before the surgery and continued for 7 days (1 g of amoxicillin and clavulanic acid climdamicina or 300 mg twice a day) after surgery. Before the surgery, the patients performed ablutions with 0.2% chlorhexidine mouthwash for 1 minute. Local anesthesia was achieved with a solution of articaine 4% with epinephrine 1:100,000 (Ubistein, 3M / ESPE, Milan, Italy). It was used a technique without setting up a flap with the introduction of a rotary tissue punch through the stereolithography guided template (Nobel Biocare AB) was employed. In some cases it ran a mini-flap with partial thickness to
preserve and increase the amount of keratinized tissue, thereby improving the quality of the soft tissue around the implant. The drilling protocol recommended by the manufacturer draws a customized using drills designed for the specific implant, and using the protocol previously discussed, leaving the depth braking 1 mm shorter than the length aBH (Figure 2).

The receiving site was prepared according to the bone density, measured on the three-dimensional software planning (NobelClinician, Nobel Biocare AG) for the primary stability of the system to get a torque input between 45 and 55 Ncm. The initial counterbore drill recommended by the drilling protocol was not used in order to preserve the anatomy of the remaining crestal bone. Each drill was used by the surgical template/mask under copious irrigation and bringing the tip in and out of the guide to avoid heating until the desired depth. A depth stop has been applied to each tip to control the working length of each passage. They have been used of the foam-compactor osteotomes with a length of calibrated work up to 26 mm, compatible with the surgical dima NobelGuide, of increasing diameter from 3.1 mm to 3.2 mm drill diameter and 4.1 mm for the drill from 4.2 mm diameter, allowing a good margin of tolerance between the two different diameters. The depth stops for tips and the scarce cutting ability osteotomes has helped to avoid damaging the sinus membrane fact osteotomes once performed the first drilling are able to perform safely a slight bone fracture sinus floor and provide the best tactile feedback for this important step to minimize the risk of perforation of the membrane. The incidence of perforation of the membrane was evaluated by the Valsalva maneuver immediately after the fracture of the floor of the sinus, in the case where the Valsalva maneuver was positive for an injury to the Schneider membrane is proceeded to the positioning of 0.5 ml of fibrin glue (Tisseal, Baxter-Healthcare Corporation, Wien, Austria) in the apical portion of the implant site preparation, using a needle with a plastic flexible cap the programmed depth, and subsequently using the osteotome as a final plugger (Figures 3, 4).

The lifting of the sinus membrane was obtained thanks to the hydraulic pressure created by the system and the blood squeezed into the prepared site by osteotomes (50). Implant placement was performed by inserting the implant through the guide sleeve of the surgical template after deposit-

Figure 3
A depth stop was applied to each twist drill to control the working length.
ing another 0.5 ml of fibrin sealant (Tisseal, Baxter-Healthcare Corporation) to the new depth of the apical site prepared (1). All implant platforms (shoulder/neck) were placed at bone crest level. Two different types of implants (NobelSpeedy Groovy and NobelActiveInternal, Nobel Biocare AB) have been employed; all implants had the same porous anodized surface (TiUnite, Nobel Biocare AB). Healing screws were positioned to promote the maturation of the soft tissue and 5 months after healing, and a precision spoon opened impression was taken individualized with a polyether impression material (Impregum, 3M ESPE, Seefeld, Germany). Abutments CAD / CAM zirconium or titanium, have been linked to the implants with prosthetic screws tightened to 35 Ncm and the final restoration cemented after tightening the prosthetic abutment.

The patients were evaluated clinically with follow-up controls scheduled to 1, 2, 6, and 16 weeks, and then every 6 months after implant placement. The patients were recalled and programmed for oral hygiene every 3-4 months after surgery.

The primary objective was to intercept the failures that required the removal of the implant and measure changes in the peri-implant bone or any adverse event (biological or mechanical complications that had taken place during the period of follow-up) (51, 52). In addition, it assessed the perception of pain by the patient as well as the measures of periodontal parameters (bleeding on probing and plaque scores).

The success criteria used in this survey are the success criteria proposed by Van Steenberghe (52).

The success of a plant is when: the implant does not cause allergic reactions locally or systemically infectious or toxic; it provides anchoring functional denture; shows no signs of fracture or bending; shows no mobility when tested for percussion; shows no sign of a radiolucent intraoral radiography using a parallel technique strictly perpendicular to the interface bone-implant. A survivor facility is a facility that remains in the jaw and is stable, even if all the individual success criteria were not met, while a failed system is a system that has been removed.
The marginal bone level changes were revalued annually using the intraoral radiographs taken with a parallel technique. The distance from the edge most coronal implant collar to the point of contact most coronal bone-implant was measured and compared with bone crest level. The values of the radiographic measurements mesial and distal were taken for each facility at the time of implant placement and then annually for a minimum of three years. The Marginal Bone Loss (MBL) for each interval was calculated by subtracting the Bone Crest Level (BCL) recorded at each follow-up visit by measuring BCL starting. X-rays have been used only orthogonal to record ABH. The increase of available bone [(Increased Height Of The Bone (IBH)] was calculated as the distance between the bone crest and the sign radiopaque more superior to the system, measured along the long axis of the implant (Figure 5).

In order to avoid distortions, bone increase was calculated as the difference between IBH and ABH.

Perception of pain the patient was assessed by a questionnaire. Each patient was asked to score the intensity of the perception of pain in the first week after implant located, and the number of analgesic tablets taken after surgery. Pain was assessed using a scale numbered 0-10, 0 being no pain and 10 as maximum perceived pain. The questionnaires were collected and analyzed one week after implant located.

The last visit of follow-up were recorded the plaque index (PI, defined as the presence of plaque/no) bleeding on probing (BOP) using a periodontal probe Hu-Friedy (Chicago, IL, USA) (Figures 6, 7).

The measurement of the complex PI abutment/restoration was obtained with a periodontal probe around the implant, probing parallel to the abutment surfaces. The BoP was obtained, 20 seconds after a careful insertion of a periodontal probe 1 mm in the mucosa parallel to the wall of the groove abutment, (0 = no bleeding; 1 = visible bleeding) in 6 sites for implantation. The periodontal parameters of recording were measured immediately before maintenance therapy by dental hygienist.
Results

A total of 39 patients (22 men and 17 women) partially edentulous in the maxillary posterior sectors, with height of the alveolar bone crest residual between 3 and 9 mm, were consecutively inserted in this study and treated with guided technical of transcrestal sinus lift by using software to generate surgical masks, guided implant surgery and foam-compactors osteotomes (50). All patients were followed for a minimum of 3 years, allowing the collection of data in the short term. The mean age of patients was 54.5 years (range 33-76). 31 of 39 patients were non-smokers, while 8 patients were smoking less than 10 cigarettes/day.

No patients has been lacking for the whole period of follow-up and there has been no change from the original protocol. The first patient was treated in October 2010 and the last in February 2013. Overall, 66 implants (22 NobelSpeedy Groovy, and 44 NobelActive, Nobel Biocare AB) with surface (TiUnite, Nobel Biocare AB) were placed in 44 maxillary posterior quadrants, with a torque between 45 and 55 Ncm (Table 1).

All the implants were between 10 and 13 mm long with regular platform and large diameters of 4.0, 4.3, mm, respectively (Table 2).

All patients achieved the follow-up of 3 years (average 42.96, 36-48 months). An implant (Nobel Speedygroove 4.0 mm in diameter and 13 mm in length) has failed before the step of final prosthesis, determining a cumulative success rate system to 3 years of follow-up of 98.83%. The system failed was immediately replaced and loaded after 3 months of healing.

<table>
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<th>Table 1 - Implants and site anatomic features.</th>
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<td>Available bone height (aBH)</td>
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<td>aBH &gt; 3 &lt; 5,5</td>
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<td>Total number of inserted implants (n=66)</td>
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<tr>
<td>Total number of treated posterior sextants (n= 44)</td>
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<td>Total number of posterior sextants treated with one implant (n= 35)</td>
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<td>Total number of posterior sextants treated with two implants (n = 9)</td>
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<th>Table 2 - Implant distribution.</th>
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<td>Type of Implant</td>
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<td>Total number of inserted implants (n=66)</td>
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<tr>
<td>4/4.3 mm width and 10 mm long n = 15 (22,3%)</td>
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<tr>
<td>4/4.3 mm width and 11.5 mm long n = 29 (44,5%)</td>
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<tr>
<td>4/4.3 mm width and 13 mm long n = 22 (33,2%)</td>
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<th>Table 3 - Mean marginal bone loss at different time periods.</th>
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<td>Different time Periods</td>
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<td>Marginal bone loss (n = 66)</td>
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All implants were included in the analysis. It was classified a total of 66 implants with single crowns. No prosthetic complication has occurred during the study period, which represents a success rate of prosthetic of 100%. No biological or mechanical complication was identified during the whole period of follow-up (such as mobility, pain or discomfort, no screw loose or pillars fracture of the structures in titanium or zirconium).

The MBL average during the first year of operation was of 0.33 ± 0.36 mm.

Between 1 and 2 years of follow-up, the MBL average was 0.1 ± 0.19 mm, and between 2 and 3 years of follow-up, the mean MBL was 0.08 ± 0.1 mm, indicating an average level marginal bone stable after the second year of operation. The MBL cumulative average between implant placement, at 3-year follow-up, was 0.51 ± 0.29 mm (Table 3).

All procedures have been as successful as expected. ABH average of the alveolar crest was 6.7 ± 1.6 mm (range 5.1 to 9.2 mm), while the average of gained height bone was 6.4 ± 1.6 mm (range 3.2-8.1 mm).

All patients reported lower pain levels. The mean pain score in the first week after implantation was 3.17 ± 1.82 (median, 3.00; 95% CI: 2.51 to 3.49), while the average number of analgesic pills taken was 3.6 ± 1.31 (median 3.00; 95% CI: 2.65-3.35).

All patients showed clinical measurements of success of periodontal parameters (PI and BoP <25%). In particular, 1-year follow-up, the score PI showed plaque buildup of 9.01% of the 66 implants analyzed. BoP showed a peri-implantation bleeding in 5.09% of the 224 sites analyzed. A 3-year follow-up, the PI was 10.04%, while the BoP was 4.98.

Discussion

This prospective study was performed to evaluate the clinical and radiographic outcome of 66 implants placed consecutively, in the posterior maxilla using TGSL, guided implant surgery, and osteotomes. This clinical research provides evidence that the use of osteotomes combined with implant placement guided of individual implants can make us reach high success rates implant when the implants are placed in the alveolar crest with limited bone height (ABH > 3 <5.5 mm).

The main limitation of this study was the lack of a control group, as well as the lack of randomization which is obtained by controlled clinical trials. The clinical and radiographic results of this survey are similar to those reported by Wells et al. in a recent, multicentric, medium-term (48.2 months) of follow-up prospective study of 136 implants placed in elevation sinus floor transcrestal with TGSL technique (1). In their study, the Authors reported a rate of implant survival of 98.53%, with an average height of residual bone 3.46 ± 0.91 mm and a radiographic bone gain of 6.4 ± 1.6 mm.

The significant difference of our study compared to other similar was the surgical technique which included the use of a planning CT three-dimensional, with minimally invasive surgery guided through the use of a surgical mask generated by a software CAD/CAM, and the non use of bone grafting materials in thicknesses of residual bone crest less than 5 mm. The predictability of the technique TGSL with immediate implant placement is strictly dependent on the ABH to obtain adequate primary stability. The success and the survival rate of dental implants decrease with reduced height of residual bone (8, 53, 54).

In a retrospective multicentric study (53) was evaluated the result of the Summers technique for placement of implants below the floor of the maxillary sinus: the success rate was 96% when the residual bone height was equal or exceeding to 5 mm, but dropped significantly to 85% when the height of the crestal bone was less than 4 mm. Pjetursson et al. have reported a survival rate of 91.3% when the residual bone height was between 4 and 5 mm (10). The procedure investigated in this study was also performed in the implant sites with a ABH less than 3 mm, even if the initial implant stability was not optimum in all cases, so the minimum recommended ABH was 3 mm for this study.

Most publications on vertical bone gain in sinus...
transcrestal elevation reported an average of less than 5 mm (19). The amount of bone gain reported with TGSL technique used in this study was 6.4 ± 1.6 millimeters and this gain was maintained for all 3 years of radiographic examinations.

The main contribution to the success of the technique TGSL is the use of a surgical template that guides the placement of the implant so that the membrane is raised and kept on by the implant, that’s used as a space maintainer to stabilize the clot and to start the physiological intrasinusal bone regeneration (62).

Furthermore, the procedure TGSL assisted by the surgical mask CAD/CAM has enabled the physician to carry out the elevation of the Schneider membrane without sinus penetration which increases the potential for tearing of the membrane itself. In an in vivo study of the implementation of a similar procedure with guided surgery, Pommer and Watzek (55) reported a bone gain in average of 10.6 ± 1.6 mm with the technique of gel pressure.

Vasak et al. (45) evaluated the accuracy of the planning wizard with the same software used in previous research, and have found that the mean deviations measured were 0.43 millimeters (bucco-lingual), 0.46 mm (mesio-distal), and 0.53 mm (depth) at the level of the implant shoulder, while slightly higher than the average values of 0.7 mm (buccolingual), 0.63 mm (mesio-distal), and 0.52 mm (depth) in the apex of the implant.

However, all investigative procedures reported have been executed in partially edentulous patients with surgical guides entirely docked to the teeth. This is known because accuracy is significantly higher when the model has a dental support rather than a mucosal one (45, 56-59). In addition, it affects the learning curve demonstrating that the surgeon has more or less familiar with the surgical procedures.

It has been shown that the lifting of Schneider’s membrane is possible through the introduction of liquids into which the volume remains constant. Pascal’s Law states that the pressure exerted on a portion of a liquid is unaltered transmitted through the entire volume of the liquid itself.

The graft material, in our case the blood (liquid), actually lifts the sinus membrane transmitting the pressure generated by a careful and precise movement of the osteotome.

However, it should be noted that the force exerted by the graft material in the compaction can not be easily controlled, and this can sometimes be harmful to the integrity of the sinus membrane (60). In order to minimize the risk of tearing the membrane with this technique, a fibrin sealant glue was positioned deep apically to the prepared site to minimize the risk of injury.

Membrane perforation can occur as soon as the forces exceed the elastic properties of the sinus membrane. The cushioning effect of the highly viscous fibrin absorbs the hydraulic pressure, minimizing the risk of perforation of the membrane.

Tilted (44) and short implants (6) have been proposed as alternative methods of sinus grafting. The use of short implants with roughened surfaces showed acceptable clinical results in the treatment of posterior maxilla, after a healing period of 6 months, with a success rate of 90% after 5 years (61). The use of short implants in the premolars and molars maxillary areas, poor of bone quality and exposed to high support forces, generally it causes a biomechanical situation compromised with insufficient crown-implant ratio. More follow-up studies are necessary to assess the short implants prognosis in the posterior maxilla.

Tilting individual implants to the palate, or placing them in the septa, inclined mesial or distal may involve compromises emergency prosthetic profiles with unfavorable moments load and long-term prognosis of the final restoration unpredictable because of difficult hygiene maintenance.

The TGSL technique represents a transcrestal minimally invasive procedure that avoids the setting up of flaps extended and the removal of the side wall of the maxillary sinus.

The main advantages of the TGSL technique include less bone resorption as there is a full thickness skeletonization, keeping the blood supply to the alveolar process (62), minimal postoperative discomfort, and greater patient acceptance for this surgical procedure. The minimal invasiveness of TGSL is reflected
with the minimum use of analgesics during the first few days after surgery, and low postoperative morbidity. The treatment time has reduced because of the combined approach of the grafting procedure with immediate implant placement (the same period of healing for both procedures).

The reduction in the total time of treatment minimizes the number of surgical procedures, medications for pain required, recovery time and lower total cost of treatment for the patient.

The main indication of the TGSL procedure is implant minimally invasive treatment of the single missing tooth in the rear area of the maxilla with insufficient height of alveolar bone, where the conventional lateral approach would have a high cost for these patients, both in terms of post-operative morbidity, discomfort, and treatment costs.

Conclusions

The results at three years, in the medium term of the present study, suggest that the use of guided surgery, CAD/CAM, in the elevation of the sinus floor by transcrestal, with protocols of immediate implant placement without the use of graft materials, it’s a predictable procedure. Within the limits of this study, the results can expand the indications of the traditional transcrestal approach. In addition it’s necessary to confirm these preliminary multicentre, randomized, and prospective clinical trials results to compare the TGSL with the known, conventional approach, for the lateral sinus elevation, obviously without grafting materials.

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original research article


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