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Minimally Invasive Transcrestal Guided Sinus Lift (TGSL): A Clinical Prospective Proof-of-Concept Cohort Study up to 52 Months

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ABSTRACT

Purpose: This study describes a new procedure for sinus elevation using computer-guided planning and guided surgical approach through the use of computer-aided design (CAD)/computer-aided manufacturing (CAM)-generated surgical template in combination with expander-condensing osteotomes thus providing a minimally invasive surgical technique.

Materials and Methods: Sixty-six consecutive patients were treated with 136 implants placed by transcrestal-guided sinus floor elevation technique and the patients were followed for at least 3 years in function. The drilling protocol is customized based on the bone density of each implant site to achieve an insertion torque ranging between 45 and 55 Ncm. Titanium temporary abutments were connected to the implants with prosthetic screws tightened to 35 Ncm and an acrylic resin provisional restoration was adapted and delivered immediately. Six months after initial loading, a definitive CAD/CAM-generated restoration was delivered. Outcome measurements assessed were implant and prosthesis survival rate, biological or biomechanical complications, marginal bone level changes, total alveolar ridge bone height before and after procedure, periodontal parameters measured as well as patient's perception of pain levels during recovery period.

Results: Mean follow-up was 43.96 (range from 36 to 52) months. Cumulative implant survival rate was 98.53% at 3 years. No biological or mechanical complications were encountered and no prosthetic failures occurred during the entire follow-up period. Mean marginal bone loss (MBL) during the first year of function was 0.33 ± 0.36 mm, while at the 3-year follow-up, the mean MBL was 0.51 ± 0.29 mm. The mean residual bone height of the alveolar crest prior to grafting was of 6.7 ± 1.6 mm (range 5.1–9.2 mm), while, the mean bone height gained was 6.4 ± 1.6 mm (range 3.2–8.1 mm). All patients reported low levels of pain and found to have normal periodontal parameters.

Conclusion: This proof-of-concept study suggests that the use of guided surgery to perform transcrestal maxillary sinus floor elevation for alveolar ridge height augmentation is a successful minimally invasive technique for the short- to medium-term follow-up, thus avoiding the extended treatment time and morbidities associated with maxillary sinus floor augmentation.

KEY WORDS: computer-guided surgical technique, flapless implant placement, dental implants, expanding-condensing osteotomes, sinus floor elevation

INTRODUCTION

In the posterior maxillary quadrants, tooth loss is usually associated with alveolar bone resorption and an increased degree of sinus pneumatization,[1] resulting in reduced residual alveolar ridge height and preventing the placement of implants of standard length.[2,3] In addition, the poor bone quality of the posterior maxilla has a negative influence on the survival rate of implants placed in the maxillary posterior quadrants.[4] The treatment planning of the atrophic posterior maxilla for implant placement remains diverse, with the dilemma of whether to place short implants,[5] angulated implants, or to augment the floor of the maxillary sinus.[6] In attempting to avoid a bone graft procedure, the technique of placing short implants in the atrophic posterior maxilla often results in compromised biomechanical situations,

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with the implants placed in an area of poor quality bone and high loading forces.[7–9] Short implants have been associated with lower success rates when compared with longer implants.[10] Currently, in absence of adequate bone height, the outcomes of short implants may be comparable with those of longer implants placed in augmented bone,[5] but further long-term investigations are required to confirm the 5-month follow-up data published to date. The severely atrophied, posterior maxilla represents a clinical challenge, and different approaches have been recommended for augmentation to increase available bone have been reported.[11–13] The Schneiderian membrane elevation can be accomplished through a lateral (Caldwell-Luc) approach[14] or a transcrestal[7] approach to the antrum to augment the maxillary sinus cavity.[14–18] Bone grafting and sinus floor augmentation is a proven treatment option long-term[19,20]; however, patients may reject the bone grafting procedures because of the perceived invasive nature, the increased recovery time, and the additional expense of the augmentation procedure.[12,13,21] Lateral antrostomy may result in significant postsurgical morbidity and does present an increased risk of membrane tearing.[22] Furthermore, to achieve predictable results, surgical experience along with a two-stage procedure with delayed implant placement is recommended.[9,23,24] To overcome these limitations and potential complications with sinus floor augmentation, the literature has suggested the use of tilted implants in anatomic regions such as the anterior or posterior regions to such as the sinus septa if present, the palatal vault, and the pterygoid process to avoid the sinus cavity.[25–34] Placing tilted implants in such regions permits placement of longer implant, thus improving bone anchorage for the implant and increasing the anterior–posterior spread of implants to improve the support for the prosthesis by placing implants further distally in the maxilla while avoiding the need for bone grafting. When tilted implants were splinted with axial implants placed in the anterior maxilla, they exhibited implant success rates consistent with reports using similar technique using tilted implants alone in previous studies.[27–30,34]

Maxillary sinus floor elevation using a transcrestal/transalveolar approach is thought of as "minimally invasive" because of the minimal surgical flap required, maintaining an intact lateral sinus wall and reduced postoperative morbidity. Pjetursson and colleagues, while investigating trans-alveolar osteotome technique for sinus floor augmentation, recorded high rate of patient satisfaction in more than 9% of the patient sample.[9] The transcrestal sinus floor elevation was introduced for the first time by Summers.[16] Subsequently, various modifications to the original technique have been reported in order to improve the reliability and the safety, such as the "Osteotome Sinus Floor Elevation,"[16] the "Bone Added Osteotome Sinus Floor Elevation,"[35] membrane elevation using inflation of a balloon catheter,[36,37] the use of hydraulic[38] or negative pressure,[39] and a technique advocated by Cosci and Luccioli ("Smart Life").[17] The main concerns related to the transcrestal approach are fracture or perforation of the sinus floor with the osteotome technique,[13,15,16] burs with[17,18] or without[14] stop drills, no direct visualization of the sinus cavity and Schneiderian membrane, the limited amount of bone augmentation achieved and the high risk of inadvertent perforation of Schneiderian membrane, without the possibility to repair the torn membrane compared with the lateral surgical approach. Thus a conventional lateral window approach is recommended for patients with severely resorbed maxillae due to the perceived limitations with the transcrestal approach.[40]

Today computer-guided, template-assisted implant placement is gaining popularity with clinicians and patients. The advent of three-dimensional computer-guided/computer-aided design (CAD)/computer-aided manufacturing (CAM) technology optimizes implant treatment planning by allowing the clinician to place dental implants with high accuracy. The conversion of the computer-generated data permits a minimally invasive procedure resulting in low morbidity and reduction of total treatment time.[41–44]

The aim of this paper is to investigate a novel technique for minimally invasive, transcrestal sinus grafting with immediate implant placement and immediate loading. The bone augmentation was performed with a transcrestal-guided sinus lift (TGSL) approach, using a template-assisted surgical approach in combination with drills and expander-condensing osteotomes. To the best of our knowledge, this is the first prospective study using this approach to elevate the sinus membrane and guided implant placement.

MATERIALS AND METHODS

This study written according to the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) guidelines.[45] The clinical study examines

data collected from 66 consecutive patients with single or multiple edentulous sites located in the posterior maxilla, treatments performed using a flapless, transcrestal maxillary sinus floor augmentation, a computer-guided, template-based implant surgery (NobelClinician, Nobel Biocare, AG, Zurich, Switzerland) and an expanding-condensing osteotome protocol, a new TGSL technique. The patients were recruited and treated in two specialized dental implant rehabilitation centers in Rome, Italy, and Los Angeles, CA, USA, between June 2008 and February 2009. All patients were followed up with a minimum period of 3 years in function (range 36 to 52, mean 43.96 months). All procedures were conducted in accordance with the Helsinki Declaration of 1964 for biomedical research involving human subjects, as amended in 2008. The Scientific Technical and Ethical Committee of Tor Vergata University of Rome approved the study protocol. In the preliminary visit, patients were informed about procedures, benefits, potential risks, and complications, as well as follow-up evaluations required for the clinical trial. Patients were enrolled after obtaining a signed consent form. Preoperative radiographs including periapical and panoramic X-rays, computed tomography (CT) scan, or cone beam CT were obtained for initial screening and evaluation. As this study was designed for a proof-of-concept report, a sample size was not calculated.

Partially edentulous patients, age 25 years or older and requiring restoration of the atrophic posterior maxilla, were recruited for the study. Main inclusion criteria were as follows: a residual alveolar crest of at least 5 mm in height and 5 mm in width distal to the canine, the need for bone grafting of the maxillary sinus and refusal to undergo a conventional lateral sinus augmentation procedure and periodontally healthy, defined as absence of full mouth bleeding on probing and full mouth plaque index lower than or equal to 25%, and an implant insertion torque ranging between 45–55 Ncm. Exclusion criteria were: positive medical findings (such as stroke, recent cardiac infarction, severe bleeding disorder, uncontrolled diabetes, or cancer), psychiatric therapy, pregnancy or nursing, untreated periodontitis, infections in adjacent tissues of the planned implant sites, previous radiotherapy of the oral and maxillofacial region, absence of teeth or a removable denture in the opposing jaw, acute infection/inflammation (sinusitis) in the area intended for bone augmentation and implant placement, severe bruxism, and poor oral hygiene.

Radiographic acrylic resin templates were fabricated from diagnostic waxed casts, representing functional and esthetic parameters of the desired prosthesis. Approximately 10 radiopaque markers (Hygienic Temporary Dental Stopping, Coltène/Whaledent Inc, Cuyahoga Falls, OH, USA) measuring 1.5 mm in diameter were placed in the vestibular flanges and palatal vault of the template, away from metal restorations so as to avoid the effects of metallic scatter obstructing the view of the markers. A centric occlusion index made of rigid vinylpolysiloxane (Exabite II NDS, GC America, Inc., Alsip, IL, USA) was fabricated to stabilize the radiographic template against the opposing dentition during CT scanning. Participants obtained a CT scan (LightSpeed VCT, GE Healthcare, Waukesha, WI, USA) using the double-scan technique[46]: the first scan was taken of the maxilla and with the planning template in place, while the second scan was of the radiographic template only. The Digital Imaging and COmmunication in Medicine data of the two sets of scans were transferred to a three-dimensional software planning program (NobelClinician, Nobel Biocare AG) and images were superimposed on each other.[47] The virtual tri-dimensional implant positions and angulations were determined based on the prosthetic emergence profile captured on the radiographic template (Figure 1). The available bone height (aBH) was calculated on the three-dimensional software planning program (NobelClinician, Nobel Biocare AG) as the distance between the bone crest and the most inferior 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 minus 1.0 mm,

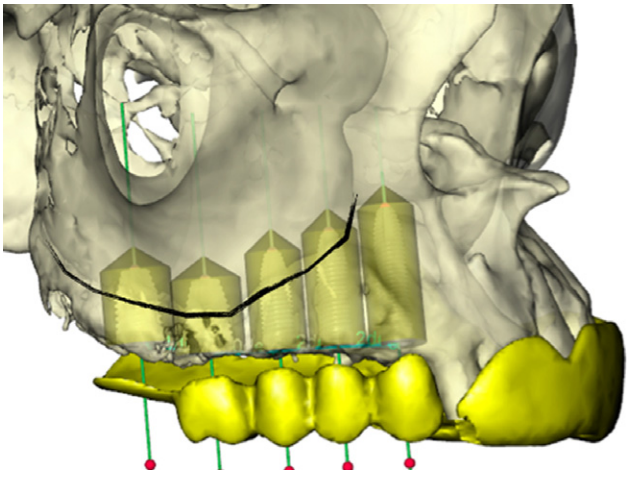

Figure 1 Preoperative three-dimensional planning and virtual implant placement according to prosthetic-driven philosophy.

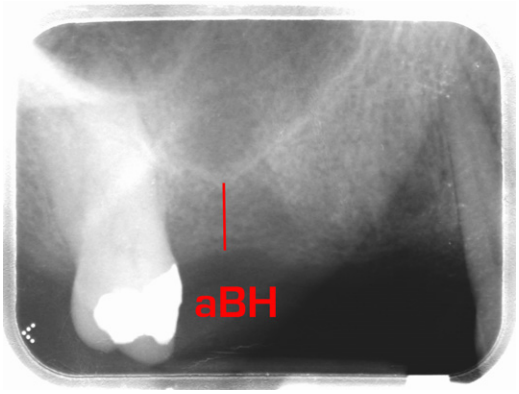

Figure 2 Periapical preoperative radiograph with aBH measurement (aBH = available bone height).

in order to avoid penetration into the sinus antrum. The definitive implant length was determined intraoperatively by means of a periapical radiograph taken with the parallel technique and a customized radiograph holder, after the transcrestal grafting procedure. Once the treatment plan is verified and approved by the clinician, the data is sent digitally to a central production workstation (Nobel Biocare AB, Kloten, Switzerland) for the fabrication of the stereolithographic-generated surgical template, which registers the planned implant locations. A surgical occlusion index (Exabite II NDS, GC America, Inc.) is fabricated to register the vertical dimension of occlusion between the surgical template and the opposing dentition to enable accurate seating and positioning of the surgical template during surgery.

Intranasal spray therapy (thiamphenicol glycinate acetylcysteinate 810 mg/4 mL) and cortisone (betamethasone 1 mg) were administered twice a day starting 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 if allergic to penicillin) was administered prophylactically 1 hour prior to surgery and continued for 7 days (1 g amoxicillin and clavulanic acid or 300 mg clindamycin twice a day) after surgery. Prior to the start of surgery, patients rinsed with chlorhexidine 0.2% mouthwash for 1 minute. Local anesthesia was provided using 4% articaine solution with epinephrine 1:100,000 (Ubistein, 3 M/Espe, Milan, Italy). A flapless technique was used introducing a guided rotary tissue punch through the stereolithographic template (Nobel Biocare AB). A partial thickness mini-flap was reflected to preserve and increase the amount of keratinized tissue, thus improving the soft tissue surrounding the implant. The drilling protocol recommended by the manufacturer was customized by using the twist drill tooling designed for the specific implant being placed and using the protocol previously discussed leaving the depth of the twist drills 1 mm shorter than intended length. The recipient site was prepared according to the bone density, measured on the three-dimensional software planning program (NobelClinician, Nobel Biocare AG) in order to obtain primary stability of the implant to permit an insertion torque ranging between 45 and 55 Ncm. The guided counterbore start drill recommended by the company was not used in order to preserve the contours and anatomy of the crestal bone. Each drill was used through the surgical template under copious irrigation and bringing the tip of the drill in and out of the guide to avoid overheating until the desired depth was achieved. A depth stop was applied to each twist drill to control the working length of each drill. Expanding-condensing osteotomes with a calibrated working length up to 26 mm, compatible with the NobelGuide tooling (Sinus lift Osteotomes for surgical guides, Salvin Dental Specialities, Inc., Charlotte, NC, USA) were used through the sleeves of the surgical template instead of using a tap that is provided in the guided drilling set, in order to maintain the working length. The osteotomes' width was 3.1 mm for the 3.2-diameter guided drill and 4.1 mm for the 4.2-diameter guided drill, allowing for different tolerances between the two different diameters. The depth stop for the twist drills and noncutting nature of the osteotomes helped to avoid damaging the sinus membrane. Careful, gentle tapping on the expanding-condensing osteotomes was performed to infracture the bony sinus floor and provide the best tactile feedback for this important step and thus minimizing any risk of membrane perforation. The incidence of membrane perforation was evaluated by the Valsalva maneuver immediately after the sinus floor infracture and immediately after the completion of delivery of the graft biomaterial. If an injury to the Schneiderian membrane occurred, 0.5 mL of fibrin sealant (Tisseal, Baxter-Healthcare Corporation, Wien, Austria) was deposited into the apical portion of the prepared osteotomy site, using a flexible plastic needle with a stopper at the planned depth. An average of 500 mg of grafting material (Bio-Oss collagen, Geistlich Pharma, AG, Wolhusen, Switzerland) was mixed with antibiotic solution (Rifocin 250 mg/10 mL, Sanofi-aventis SPA, Milan, Italy), the granules were formed in the shape of the root and placed into the implant site

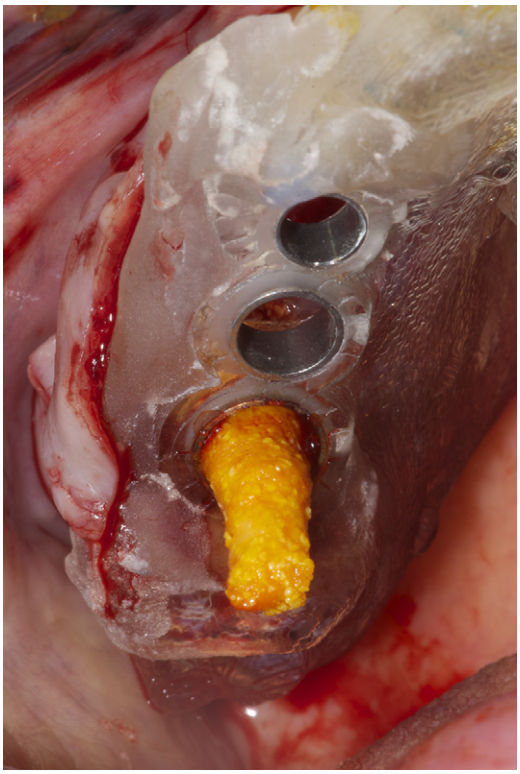

Figure 3 The grafting material reshaped as a root form and handled into each implant site throughout the sleeve of the surgical template.

using the final osteotome to act as a plugger (Figures 3 and 4). Elevation of the sinus membrane was achieved secondary to the hydraulic pressure created by the grafting material and blood as it was compressed into the prepared site by the osteotomes. The implant placement was performed by inserting the implant through the guide sleeve of the surgical template after depositing another 0.5 mL of fibrin sealant (Tisseal, Baxter-Healthcare Corporation) at the new apical depth of the prepared site after delivery of the graft material. All the implant platforms (shoulder/neck) were positioned at crestal bone level. Three different types of implant were used (NobelSpeedy Replace, NobelSpeedy Groovy and NobelActive, Nobel Biocare AB); however, all implants had the same porous anodized surface (TiUnite®, Nobel Biocare AB).

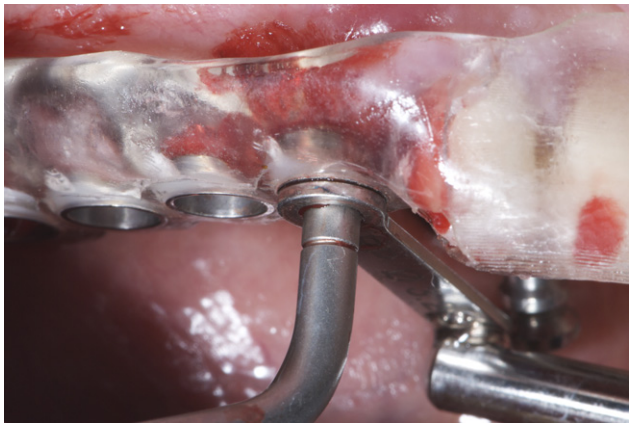

Figure 4 Osteotome carefully tapping performed throughout the sleeve of the surgical template.

A prefabricated, acrylic-resin temporary restoration relined with an auto-polymerizing polyurethane resin (Voco GmbH, Cuxhaven, Germany) was cemented with zinc phosphate cement (Harvard Dental International GmbH, Hoppergarten, Germany) mixed with 30% petroleum jelly (Vaseline, Unilever, Englewood, NJ, USA) onto standard titanium temporary abutments which were tightened into the implants at 35 Ncm setting. All centric contacts were assessed and occlusion adjusted until light occlusal contact was obtained, while lateral interfering contacts were completely removed. Five months after initial loading, an open tray impression was taken using a polyether impression material (Impregum, 3M ESPE, Seefeld, Germany) with a custom open tray technique (Diatray Top, Dental Kontor GmbH, Stockelsdorf, Germany). CAD/CAM-customized abutments, composed of zirconia or titanium, were connected to implants with the prosthetic screws torqued tightened to 35 Ncm and the definitive prosthesis connected after the abutment tightening. Patients were evaluated clinically at each planned follow-up visit (1, 2, 6, and 16 weeks, and then every 6 months after implant placement). The patients were enrolled and scheduled for oral hygiene maintenance visits every 3–4 months after surgery.

The primary outcome measurement was implant/prosthetic failure requiring the removal of the implant and/or prosthesis.[48] Secondary outcome measurement was peri-implant bone level changes or any adverse event (biological or mechanical complication that occurred up to the end of the follow-up). In addition, the patient's perception of pain was evaluated as well as measurements of periodontal parameters (bleeding on probing and plaque scores).

The success criteria used in this investigation are modifications of the success criteria suggested by Van Steenberghe.[48] A successful implant is an implant which:

1. does not cause allergic, toxic, or gross infectious reactions either locally or systematically;

2. offers anchorage to a functional prosthesis;
3. does not show signs of fracture or bending;
4. does not show any mobility when individually tested by tapping or rocking with a hand instrument (not applicable for multiple unit restorations, i.e., in this protocol); and
5. does not show any signs of radiolucency on an intraoral radiograph using a paralleling technique strictly perpendicular to the implant-bone interface. A surviving implant is an implant that remains in the jaw and is stable, even though all the individual success criteria were not fulfilled, while a failed implant is an implant that has been removed.

Marginal bone level changes were evaluated annually using intraoral radiographs taken with the parallel technique by means of a custom radiograph holder. The distance from the most coronal margin of the implant collar to the most coronal bone-to-implant contact was measured and compared to bone crest level. Measurements were made to the nearest 0.01 mm using the Kodak Digital Imaging Software 6.11.7.0 (Kodak, Eastman Kodak, Rochester, NY, USA). The software was calibrated for every single image using the known length of the implant placed. The radiographic values of mesial and distal measurements were taken for each implant at the time of implant placement and then annually for a minimum of 3 years. Marginal bone loss (MBL) for each interval was calculated by subtracting the bone crest level (BCL) recorded at each follow-up visit from the baseline BCL measurement. Only orthogonal radiographs were used to record aBH, and were accepted or rejected for evaluation based on the clarity of the image. The increased available bone (increased bone height [iBH]) was calculated as the distance between the bone crest and the most superior radiopaque sign of the graft material, measured along the implant long axis (Figure 5). The bone augmentation achieved was calculated as the difference between the iBH and aBH. In order to avoid bias one blinded clinician, who was otherwise not involved in the study, performed all radiographic measurements.

Patient's perception of pain was evaluated by a questionnaire. Each patient was asked to score the intensity of pain perception in the first week after implant as well as the number of analgesic tablets taken after the surgical intervention. Pain was evaluated using a 0–10 numbered scale, 0 corresponding to no pain at all, and 10 as the maximum pain imaginable. The questionnaires were collected and analyzed by an independent assessor not involved with the surgical procedure 1 week after implant placement.

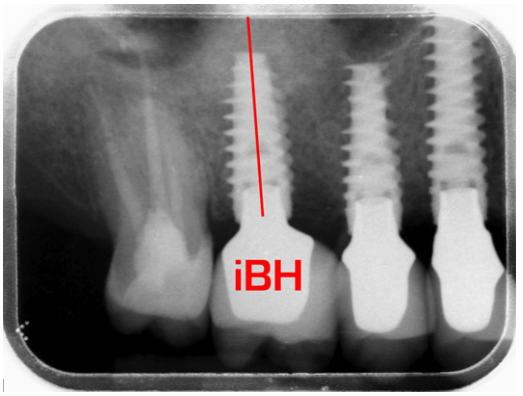

Figure 5 Postoperative periodical radiograph with iBH measurement (iBH = increased bone height).

At the last follow-up visit, plaque index (PI, defined as the presence of plaque yes/no) scores and bleeding on probing (BoP) were recorded using a Hu-Friedy periodontal probe (Chicago, IL, USA) (Figures 6–8). The PI measurement of the abutment/restoration complex was scored with a periodontal probe around the implant, probing parallel to the abutment surfaces. BoP, defined as bleeding elicited 20 seconds after careful insertion of a periodontal probe 1 mm into the mucosal sulcus parallel to the abutment wall, was scored (0 = no bleeding; 1 = bleeding visible) at six sites per implant. The hygienist recording periodontal parameters measured immediately before maintenance therapy was also blinded to the study.

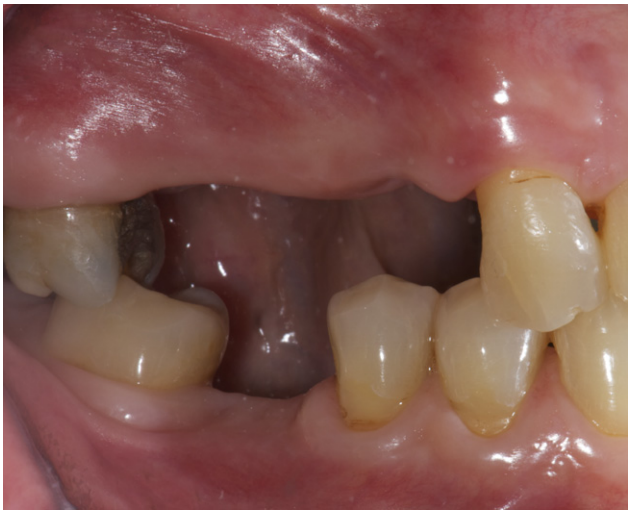

Figure 6 Preoperative intraoral view.

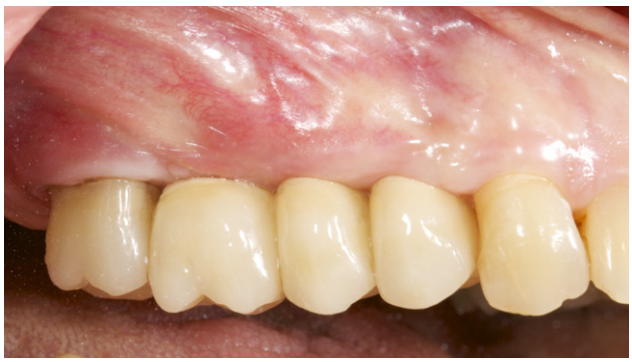

Figure 7 Postoperative intraoral view.

RESULTS

A total of 66 partially edentulous patients (28 men and 38 women) in the posterior maxilla (40 monolateral and 26 bilateral), with residual alveolar ridge bone height ranging between 5 and 9 mm, were consecutively enrolled in this study and treated with guided transcrestal sinus floor elevation technique, using computer-generated surgical templates, guided implant surgery and expanding-condensing osteotomes protocol. All patients were followed for a minimum of 3 years, allowing for short-term data to be collected and validating the proof of concept. The mean age for patients was 51.3 years (range 39–79). A total of 50 out of 66 patients were nonsmokers, while 16 patients smoked less than 10 cigarettes/day. All patients were treated in two centers located in Rome, Italy, and Los Angeles, CA, USA. No patient dropout occurred for the entire follow-up period and no deviation from the original protocol occurred. The first patient was treated in October 2007 and the last in February 2009. Overall, 136 implants (60 NobelSpeedy Replace, 39 NobelSpeedy Groovy, and 37 NobelActive, Nobel Biocare AB) with moderately rough, highly crystalline and phosphate-enriched titanium oxide surface (TiUnite, Nobel Biocare AB) were placed in 92 maxillary posterior quadrants, with an insertion torque ranging between 45 and 55 Ncm and immediately loaded (Table 1). All implants were 10 to 15 mm long with regular and wide platform with diameters of 4.0, 4.3, and 5.0 mm, respectively (Table 2). All patients reached the 3-year follow-up (mean 43.96 range 36–52 months).

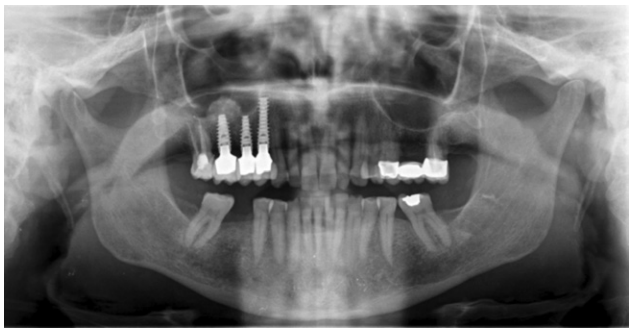

Figure 8 Three-year postoperative ortopantomograph.

Two implants (1 NobelSpeedy Replace 4.3 mm width, 13 mm in length, and 1 NobelActive 4.3 mm width, 15 mm in length) failed in two different patients before the final impression phase, resulting in an implant cumulative success rate at the 3-year follow-up of 98.53%. Failed implants were immediately replaced and loaded after 3 months of healing. After replacement, healing was uneventful and to date no other implant failure has occurred. All implants were included in the analysis. A total of 136 implant-supported single crowns were delivered. The opposing jaw presented either natural dentition or restored with fixed implant-supported prosthesis. No prosthesis failure occurred during the study period, accounting for a cumulative prosthesis success rate of 100%. No biological or mechanical complications (such as mobility, pain or discomfort, abutment screw loosening and/or fracture, titanium or zirconia abutment fracture, or zirconia framework fracture) were identified during the entire follow-up period.

The mean MBL during the first year of function was 0.33 ± 0.36 mm. Between the 1- and 2-year follow-up, the mean MBL was 0.1 ± 0.19 mm, and between the 2- and 3-year follow-up, the mean MBL was 0.08 ± 0.1 mm, indicating a stable mean marginal bone level after the second year of function. The cumulative mean MBL between implant placements at the 3-year follow-up was 0.51 ± 0.29 mm (Table 3).

All grafting procedures were successfully carried out as planned. The mean aBH of the alveolar crest was 6.7 ± 1.6 mm (range 5.1–9.2 mm), while the mean bone height gained was 6.4 ± 1.6 mm (range 3.2–8.1 mm).

All patients reported low levels of pain. The mean pain score in the first week after implant placement was 3.17 ± 1.82 (median 3.00; 95% CI: 2.51–3.49), while the mean number of analgesic tablets taken was 3.06 ± 1.31 (median 3.00; 95% CI: 2.65–3.35).

All patients showed successful clinical measurements of periodontal parameters (PI and BoP $< 25\%$). Specifically, at the 1-year follow-up, the PI score showed plaque accumulation of 9.01% of the 136 analyzed

TABLE 1 Implants and Site Anatomic Features Distribution

Available bone height (aBH)	aBH ≥ 5 ≤ 7	aBH ≥ 8 ≤ 10
Total number of inserted implants ($n = 136$)	94	42
Total number of treated posterior sextants ($n = 92$)	63	29
Total number of posterior sextants treated with one implant ($n = 60$)	41	19
Total number of posterior sextants treated with two implants ($n = 20$)	13	7
Total number of posterior sextants treated with three implants ($n = 12$)	9	3

aBH = available bone height.

implants. BoP showed peri-implant bleeding in 5.09% of the 924 analyzed sites. At the 3-year follow-up, the PI was 10.04% while the BoP was 4.98%.

DISCUSSION

The present prospective, cohort study was designed to evaluate clinical and radiographic outcomes of 136 consecutively placed, immediately loaded implants in the posterior maxilla using flapless transcrestal maxillary sinus floor elevation/grafting, computer-guided implant surgery, and expanding-condensing osteotomes protocol. This clinical research provides proof-of-principle evidence that the use of expanding-condensing osteotomes in combination with computer-guided implant placement and immediate loading of single implants can result in high implant success rates when implants are placed into alveolar ridges with limited amount of bone height (aBH ≥5 ≤ 9 mm). The main limitation of this study was the lack of a control group due to the original design of this study as a proof-of-concept study as well as lack of randomization found with controlled clinical trials, thus providing sufficient sample size calculations.

The clinical and radiographic results of this investigation are similar to those reported by Bernardello and colleagues in a recent, multicenter, medium-term (48.2 months) follow-up retrospective study regarding crestal sinus lift with sequential drills and simultaneous placement of 134 submerged implants.[22] In their report, the authors reported an implant survival rate of 96.3% with an average residual bone height of 3.46 ± 0.91 mm and a radiographic bone gain of 6.48 ± 2.38 mm.

The significant difference with this investigated procedure compared to other similar studies was the surgical technique which incorporated the use of a three-dimensional CT planning, minimally invasive

TABLE 2 Implant Distribution

	NobelSpeedy replace	NobelSpeedy groovy	Nobel active
Total number of inserted implants ($n = 136$)	60 (44%)	39 (29%)	37 (27%)
4/4.3 mm width and 10 mm long, $n = 8$ (5.9%)	4	3	1
4/4.3 mm width and 11.5 mm long, $n = 16$ (11.8%)	7	4	5
4/4.3 mm width and 13 mm long, $n = 29$ (21.3%)	13	8	8
4/4.3 mm width and 15 mm long, $n = 21$ (15.4%)	6	8	7
5 mm width and 10 mm long, $n = 8$ (5.9%)	4	2	2
5 mm width and 11.5 mm long, $n = 16$ (11.8%)	7	5	4
5 mm width and 13 mm long, $n = 21$ (15.4%)	8	7	6
5 mm width and 15 mm long, $n = 17$ (12.5%)	11	2	4

TABLE 3 Mean Marginal Bone Loss at Different Time Periods

	Baseline – 1 year Mean (SD)	1 year–2 years Mean (SD)	2 years–3 years Mean (SD)	Baseline–3 years Mean (SD)
Marginal bone loss ($n = 136$)	0.33 (0.36)	0.1 (0.19)	0.08 (0.01)	0.51 (0.29)

guided surgery through the use of a CAD/CAM generated surgical template, and immediate loading of implants. The predictability of the TGSL technique with the immediate implant placement and loading is strictly dependent on the aBH in order to obtain adequate primary stability. The success and survival rates of dental implants decrease with reduced residual bone height.[7,49,50] In a multicenter retrospective study, Rosen and colleagues[49] evaluated the outcome of the Summers' technique for the placement of implants below the maxillary sinus floor: the success rate was 96% when the residual bone height was 5 mm or more, but dropped significantly to 85% when crestal bone height was 4 mm or less. Pjetursson and colleagues reported a survival rate of 91.3% when the residual bone height ranged between 4 and 5 mm.[9] The procedure investigated in this proof-of-concept study has been performed also in implant sites with an aBH less than 5 mm, however, initial implant stability was not achievable in all cases, thus the minimum recommended aBH was 5 mm for this study.

The majority of publications on transcrestal sinus lift elevation reported a mean vertical bone gain lower than 5 mm.[18] The amount of bone gain reported with the TGSL technique used in this study was 6.4 ± 1.6 mm and this gain was maintained throughout the 3-year radiographic examination. The main contributor to the success of the TGSL technique is the use of a surgical template guide that guides the placement of the bone graft as well as the implant ensuring that the graft will be placed apical to the exact location that the implant is being placed which optimizes the total amount of grafted ridge height gained. Furthermore, the TGSL procedure assisted by the CAD/CAM surgical template allowed the clinician to perform the elevation of the Schneiderian membrane without penetration into the sinus antrum which increases the potential for tearing the membrane itself. In an ex vivo study performing a similar computer-guided template-assisted procedure, Pommer and Watzek[51] reported a mean sinus floor elevation of 10.6 ± 1.6 mm with the gel-pressure technique. Vasak and colleagues,[43] evaluating the accuracy of guided planning with the same software used in the previous investigation, reported that the mean deviations measured was 0.43 mm (bucco-lingual), 0.46 mm (mesio-distal), and 0.53 mm (depth) at the level of the implant shoulder, and slightly higher with average values of 0.7 mm (bucco-lingual), 0.63 mm (mesio-distal), and 0.52 mm (depth) at the level of the implant apex. However, all the investigated procedures that have been reported were performed in partially edentulous patients with purely tooth-supported templates. This is noted since accuracy is significantly higher when the template is tooth-born compared to ones supported by a mucosal bearing area.[43,52–55] Moreover, a learning curve was found as the surgeon became more familiar with the surgical procedures.

It has been shown that elevation of the Schneiderian membrane is possible through the assistance of liquid dynamics where the volume of liquid remains constant. Pascal's law states that the pressure exerted on a portion of a liquid is transmitted unaltered through the entire volume of liquid. The donor graft material (fluid) effectively raised the sinus membrane by transmitting the pressure generated by careful tapping of the osteotome. However, it should be noted that the force exerted by graft material compaction cannot be easily controlled which may result in detrimental effects to the integrity of the sinus membrane sometimes.[56] In order to minimize the risk of tearing the membrane with this technique, a fibrin sealant was deposited at the apical depth of the prepared site to minimize the risk of injury. Membrane perforation can occur as soon as elevation forces exceed the elastic properties of the sinus membrane. The cushioning effect of the highly viscous fibrin sealant adsorbs the hydraulic pressure, minimizing the risk of membrane perforation.

Tilted[42] and short implants[5] have been proposed as alternatives to the sinus grafting procedures.

The use of short implants with roughened surfaces showed acceptable clinical outcomes in the treatment of the posterior maxilla, after an unloaded healing period of 6 months, with reported success rate of 90% after 5 years.[57] Other reports on immediately loaded 6.5 mm-long single implants, placed without elevating a flap and placement of an implant with a minimum insertion torque >40 Ncm, have remained successful up to 4 years after loading, comparable to a study performed on early loaded implants.[58] The use of short implants in the premolar or molar areas of the maxilla usually results in a compromised biomechanical situation with inadequate crown-to-implant ratio, in an area of poor quality bone and exposed to high loading forces. Longer follow-up studies are needed to evaluate the prognosis of short implants in the posterior maxilla.

Tilting single implants towards the palatal vault, septa, or angulating in a mesial/distal direction may result in compromised prosthetic emergence profiles with unfavorable loading pattern and unpredictable long-term prognosis of the definitive restoration due to difficult hygiene maintenance.

The TGSL technique represents a minimally invasive, transcrestal procedure that avoids a large flap elevation or the removal of the lateral wall of the maxillary sinus. The main advantages to the TGSL technique include less bone resorption as there is no flap elevation, thus maintaining blood supply to the alveolar ridge, maintenance of vascularization to the graft material,[40] minimal bleeding, minimal postoperative discomfort, and better patient acceptance for this surgical procedure. The minimum invasiveness of the TGSL is reflected by the minimal use of analgesics during the first few days following surgery and low postoperative morbidity. The cumulative treatment time is reduced due to the combined approach of the grafting procedure with immediate implant placement (the same healing period for both procedures) and immediate loading of the implant. Reducing the total treatment time minimizes the number of surgical procedures, the pain medications required postsurgically and recovery time, resulting in reducing the total cost of treatment for the patient. The main indication of the TGSL procedure is the minimally invasive implant treatment single missing tooth in the posterior area of the maxilla with inadequate alveolar bone height, where the conventional lateral approach to augment the sinus with its postoperative morbidity, discomfort, and increased treatment costs would be required for these patients.

CONCLUSIONS

The 3-year, medium-term results of the present study suggest that the use of computer-guided, CAD/CAM generated, template-assisted transcrestal sinus floor elevation, with immediate implant placement and loading protocols, is a predictable procedure. Within the limits of this proof-of-concept study, the results may broaden the indications of the traditional transcrestal approach. Further multicenter, randomized, prospective clinical studies comparing the TGSL with the conventional, well-proven, lateral approach for sinus grafting, are needed to confirm these preliminary results.

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