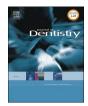
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Guided implant surgery and sinus lift in severely resorbed maxillae: A retrospective clinical study with up to 10 years of follow-up

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ARTICLE INFO

Keywords: Sinus lift Guided Surgery Critical defect Dental implants

ABSTRACT

Objectives: In the posterior maxilla, due to the presence of maxillary sinus, residual bone height lower than 3mm is a critical factor that can affect implant stability and survival. The use of guided surgery may facilitate the surgical procedures and the implant insertion in case of severely resorbed maxillae. Moreover, it may have beneficial effects on the long-term survival and success of implant-supported restorations. This study aimed to evaluate implant supported restorations on severely resorbed maxilla (<3 mm) after sinus lift with collagenated xenograft and guided surgery.

Methods: Forty-three patients with need for implant rehabilitation and residual bone height between 1 and 3 mm were recruited. Surgical and prosthetical aspects were planned following digital approach with the use of Realguide 5.0 (3diemme, Varese, Italy). Lateral window sinus lift was performed and implants were placed simultaneously to the augmentation procedure with a tooth-supported pilot drill surgical template. A pre-hydrated collagenated porcine bone matrix was adopted as regenerative material. Computer-aided-design/ computer-aided-manufacturing (CAD/CAM) restorations were delivered after six months of healing. Milled ti-tanium chamfer abutments with CAD/CAM crowns were used. Bone height at implant site level was measured using an image software analysis applied to the pre- and post-surgical radiographs and at the follow-up. Biological and technical complications were recorded during all the follow-up periods.

Results: Fifty-four sinus were treated. After a mean follow-up time of 5.11 years (SD: 2.47), no implants were lost nor showed signs of disease. The mean pristine bone height was 2.07 mm (SD: 075). At the final evaluation the augmented sinus height was 12.83 mm (SD: 1.23). Two cases experienced minor perforation of the membrane, while five patients developed minimal post-operative complications, completely resolved with pharmacologic therapy. No mid-term biological complications were experienced by the patients. No cases experienced periimplant mucositis and peri-implantitis during the whole follow-up period. Four patients (7.4%) faced an unscrewing of the prosthesis.

Conclusions: The present study showed the efficacy in the mid-term of the digital planning and the guided surgery in restoring severely resorbed posterior maxilla with dental implants.

Clinical Significance: This paper underlines the high potential of the digital approach in the mid-term to implant rehabilitation of severely resorbed maxilla simultaneously with sinus lift.

1. Introduction

Sinus floor augmentation became a widely accepted surgical

procedure to improve the amount of bone volume before implant placement.

According to the guided bone regeneration principles, in the sinus lift

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https://doi.org/10.1016/j.jdent.2022.104137

Received 16 August 2021; Received in revised form 18 March 2022; Accepted 19 April 2022 Available online 21 April 2022 0300-5712/© 2022 The Author(s). Published by Elsevier Ltd. This is an open access article under

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procedure, bone graft was demonstrated to act as space holder under the elevated sinus membrane [1]. This biological consideration highlights the importance of the osteoconductive property of the graft material adopted in the sinus lift. In fact, the osteogenic source for the bone healing derives from two different anatomic sites: the basal bone of the sinus cavity and the periosteum represented as basal cell layer of the Schneiderian membrane. Following this biologic principle, Mish developed a classification for the treatment of edentulous posterior maxilla based on the amount of bone available below the antrum and the ridge width [2]. This classification, based on the possibility to stabilize the implant at the first surgery, essentially suggests three treatment possibilities: from a clinical point of view, the threshold for a one stage surgery is 3mm of native bone crest height. The decision to use one- or two-stage techniques is based on the amount of residual bone available and the possibility of achieving primary stability for the inserted implants. Having a higher crest, a one stage technique using either a lateral or a transalveolar approach was suggested. On the other hand, below this limit, a two-stage technique with a lateral window approach, followed by implant placement after a healing period was recommended. Obviously, severely resorbed maxillae represent a critical condition for bone regeneration and therefore for implant success rate. In fact, published studies demonstrated a small amount of bone regeneration (lower than 10%) [3]. At the same time, this clinical scenario presented and high risk of implant failure also in case of autogenous bone as graft material (5-20%) [4].

Guided surgery was adopted to transfer the ideal position of the implant restoration from the radiographic analysis to the clinical reality [5]. Despite the possible error inside the procedure (deviation from the planned implant position and final clinical outcome), this approach might help in critical sinus lift to better analyze the potential difficulties in the surgery and choose the better site to stabilize the implant [5]. A better tridimensional positioning of the implants could lead to better restorations with adequate emergence profile. Better prosthesis could therefore allow for more careful maintenance by patients and decrease biologic complications. Younes et al. [6] in a recent randomized controlled trial comparing guided surgery and free-hand implant positioning, concluded that the additional cost for guided surgery is justified by a more precise final fixture position. A better implant angulation, with small apical global deviation prevented the use of a cement-retained implant restoration. The use of guided surgery in severely resorbed maxillae has been reported by some authors in the past. Planinic et al. [7] reported the same secondary stability when using flapless guided surgery and conventional surgery. An et al. [8] combined the use of guided surgery in flapless maxillary crestal sinus augmentation with immediate nonfunctional loading of dental implants, reporting a 100% survival rate and only minimal marginal bone loss after 37 months. Osman et al. [9] reported superior and more reproducible results with computer guided single stage sinus floor elevation implant placement. Finally, the digital approach to severely resorbed maxillary sinuses (2.6 to 4.9 mm) proved effective in achieving perfect maintenance of crestal bone levels around simultaneously placed implants, with no marginal bone loss after 1 year [10]. The pilot drill guided surgery technique was introduced some 15 years ago and is used to have a trace of the correct positioning of the implant, leaving the surgeon correction margin on the final position, thanks to the free-hand passage of the remaining drills. It is generally in contrast to the fully guided technique where the passage of all drills is planned before surgery and does not allow the surgeon to make corrections [11]. At present no studies evaluate the mid-term survival rate of dental implant placed with guided surgery simultaneously with lateral sinus lift augmentation.

The present study aims to clinically evaluate the mid-term survival of implant supported restorations after guided implant surgery in severely resorbed maxillae, simultaneously augmented using a pre-hydrated collagenated cortico-cancellous granules, properly mixed with collagen gel.

2. Materials and methods

2.1. Study design and patient selection

From Jan 2011, one dental surgeon (RP) consecutively recruited 43 patients scheduled for implant supported restoration in the severely resorbed posterior maxilla (<3 mm) with sinus augmentation procedure. All patients were in general good health, they were informed about the procedure and required to sign a consent form. They were followed till Feb 2021 for a mean period of 60 months after prosthetic rehabilitation. The only anatomical inclusion criterium was residual bone crest (distance between sinus floor and bone crest) ranged between 1 and 3 mm in height. Patients should also had more than 18 years, no relevant medical conditions, maximum 10 cigarettes/day and a full-mouth plaque score and bleeding score $\leq 25\%$. Patients were excluded in case of Schneiderian membrane acute infections or chronic sinusitis, allergies involving respiratory system, use of Bisphosphonates or with uncontrolled diabetes (HbA1c>6%, glycemic level>110 mg/dl).

The present study was performed following the principles outlined of the Declaration of Helsinki on experimentation involving human subjects. The clinical trial was conducted in accordance with the Good Clinical Practice Guidelines (GCPs) following the recommendations of the World Medical Association Declaration of Helsinki–ethical principles for medical research involving human subjects as revised in Fortaleza (2013). All patients were informed about the benefits and the possible risks of maxillary sinus lift procedure and its alternatives finally a signed written consent was obtained.

The study was done under the shield of the ethical committee (# 2021.43)

2.2. Preoperative and postoperative medication

Patients underwent a preoperative digital panoramic exam, subsequently used as baseline. CT scan was also required to investigate antral anatomy (Fig. 1a and b). Computer guided planning was used to prosthetically guide the implant positioning. However, particular attention was used to select the better bone site to reach a proper fixture inclination and to stabilize the implant.

The software used was 3Diagnosys (3diemme, Varese, Italy). After Jan 2019, the software was substituted by its updated version (Realguide 5.0, 3diemme, Varese, Italy). This software allowed a completely digital workflow, starting from the diagnosis and planning of the implant positioning to the design of a surgical guide and to the previsualization of the most suitable prosthetic solution. A surgical guide for the pilot drill was prepared accordingly.

One to seven days before surgical procedure, full mouth professional prophylaxis appointment was scheduled. Patients were covered with 1 g penicillin clavulanate 1 day prior to surgery and continued with 3 g per day for 6 days. Penicillin-allergic patients received 450 mg clindamycin. Just before surgery, patients underwent a 3 min mouthrinse with 0.2% chlorhexidine gluconate.

2.3. Surgical technique

The sinus area was prepared under local anesthesia. Palatal incision was designed to maintain template stability allowing open flap implant insertion. After flap elevation, the bony window was left attached to the Schneiderian membrane. The sinus mucosa was elevated using especially designed sinus elevators (Medesy, Maniago, PN, Italy) taking care to avoid any tear.

Osteotomies were performed using the narrower drill able to allow implant insertion in order to increase primary stability. Then the graft material (MP3, OsteoBiol by Tecnoss, Giaveno, Italy) was placed at the superior aspect of the sinus and against the medial aspect of the grafted compartment created in the sinus cavity. The graft material was meticulously condensed at each stage (Fig. 2). Then, one to three

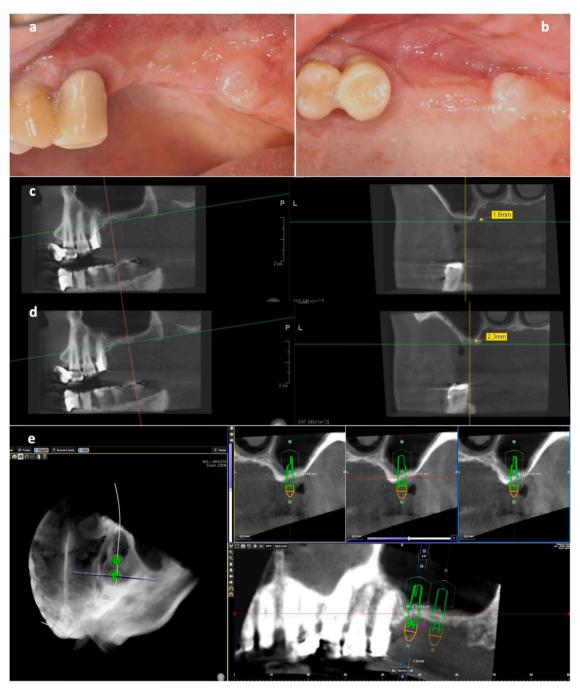


Fig. 1. preoperative clinical images (a, b) and CBCT analysis at the implant sites (c, d).

implants from different implant companies were placed with a torque value >10N using specific device (W&H, Innsbruck, Austria). A membrane (Evolution, OsteoBiol by Tecnoss, Giaveno, Italy) was used to cover the buccal window. The oral mucosa was then sutured with 5.0 resorbable, interrupted sutures.

2.4. Postoperative instructions

Patients were instructed to avoid blowing their noses for at least 7 days after surgery and to cough or sneeze with an open mouth to prevent increased pressure in the operated sinus. Patient underwent a new digital panoramic exam for postoperative evaluation. All the patients were asked to respect the following post-operative pharmaceutic regimen: beclometason diproprionate (Clenil A, Chiesi, Parma, Italy) by aerosol once a day for 6 days and Naphazoline (Rinazina Spray, GSK inc, London

UK) two puffs twice a day for 6 days. Six months postoperatively, uncovering procedure was performed. Minimal crestal incision just over the area corresponding to the implant was designed and cover screws were exposed and removed. Attached keratinized mucosa was left both on the palatal and buccal aspect around all implants. Using designed coping transfers, impression was taken and specific healing abutments were screwed at 10N. Clinical evaluation criteria at the time of implant exposure included stability in all directions, eventual crestal bone resorption, and any reported pain or discomfort. Two weeks later, titanium abutments were screwed at 32N and provisional restoration was seated. In case of a multiple implant rehabilitation, to allow a better occlusal forces distribution, splinted crowns were adopted. One week later, definitive crowns were cemented using a provisional cement (Temp Bond, Kerr, US) Fig. 3). Patients were recalled from Jan to Feb 2021 to check the implant survival rate, periodontal parameters and

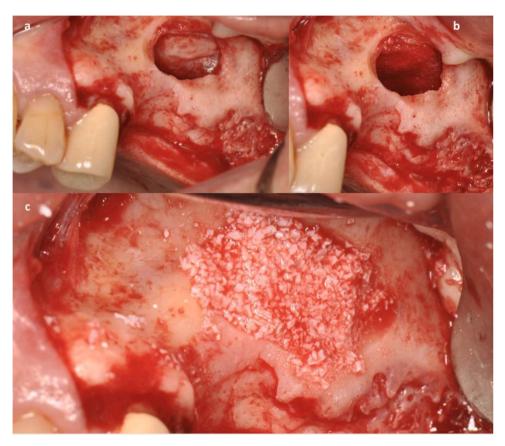


Fig. 2. bony window design with elevated sinus mucosa (a, b) and cavity filling with the study graft material (c).

regenerated sinus health. For this purpose, a digital orthopantomography was taken (Fig. 4).

2.5. Radiographic evaluation

The patients' grafted height was evaluated with a computerized measuring technique applied to digital panoramic radiographs. An image analysis software application (Autocad 2006, version Z 54.10, Autodesk) calculated the grafted bone height changes at level of implant site comparing pre-operative and follow-up panoramic films with the ability to compensate for eventual radiographic distortion ^{14, 15}. At each implant level images from the same patients were superimposed with the software by matching common landmarks and then the linear distance between the most coronal and the most apical point with mature bone was calculated. All measurements were conducted and collected by the same trained independent examiner, without input from the implant surgeon.

2.6. Outcomes

Biological and technical complications were recorded from the time of the surgery to the last visit follow up. Surgical immediate complications (minor and major membrane perforation, implant primary stability, wound dehiscence, osseointegration failure) and biological complications (swelling, epistaxis, sinusitis) were recorded during all the follow-up periods. Peri-implant mucositis and peri-implantitis were also recorded. According to the last EFP-AAP meeting [12,13], peri-implant mucositis was defined as an "inflammatory lesion of the soft tissues surrounding an endosseous implant in the absence of loss of supporting bone or continuing marginal bone loss", while peri-implantitis was defined as "pathological condition occurring in tissues around dental implants, characterized by inflammation in the peri- implant mucosa and progressive loss of supporting bone".

Mechanical complications (related to the implant prefabricated components such as dental implant fractures and retaining screw fracture or unscrewing) and technical complications (components provided by the dental lab, such as ceramic chipping or fracture), as described by Salvi and Brägger [14], were recorded.

2.7. Statistical analysis

Demographic data (sex, age) were collected from the patients. Descriptive statistics including mean values and standard deviation were used to describe changes of implant stability over the time. Bone height and width were collected prior and after surgery. Peri-implant health parameters such as PPD, BOP and PI were collected at the surgical site. The statistical analysis was performed with SAS 9.4 (SAS Institute Inc., Cary, NC, USA) for Windows.

3. Results

43 patients were and 54 sinuses were treated. One-hundred-thirteen implants were inserted in the augmented sinuses. All subjects joined the last study-follow up, so no drop-outs were registered. Age of the patients resulted 63.06 years (SD: 10.52). Eighteen female patients and 31 males were included in the study. Minimal perforations of sinus membrane occurred in 2 cases. They were repaired using a collagen membrane. No major mucosa perforations occurred.

Different implant brands were used: 19 patients (24 sinuses and 51 implants) were treated with In-Kone (Global D, Lyon, France), 14 patients (16 sinuses and 35 implants) with Anyridge (Megagen, Daegu, Korea), 4 patients (5 sinuses and 10 implants) with I.C.E. (Alphabio Tec, Tel-Aviv, Israel), 3 patients (4 sinuses and 7 implants) with Way extra (Geass, Udine, Italy), 3 patients (5 sinuses and 10 implants) with



Fig. 3. postoperative clinical images (a, b) and radiographic analyses after one year (c).

Premium Khono (Sweden & Martina, Padua, Italy)

However, the diameter used for all the implants ranged from 3.7 to 4 mm and the length was 9-to 11.5 mm. In all patients, at least two implants were placed.

The mean follow-up time was 5.11year (SD: 2.47, range between 1 and 10 years). At the time of the last recall, no implants resulted lost or mobile or infected. Periodontal indices around implants in the regenerated sinus resulted in healthy conditions (PD<3mm, BoP<2, PI<2), although BoP and PI were present at 62.8% and 78.3% of the sites, respectively. No peri-implantitis were present at the end of the follow-up. The mean pristine bone height was 2.07 mm (SD: 075). The mean sinus medio-buccal width was 16.05 mm (SD: 2.79). After surgery, at the latest follow-up, the augmented sinus measured 12.83 mm (SD: 1.23).

As biological immediate post-operative complications, all patients (100%) experienced swelling. In 6 cases (11%) occasional episodes of epistaxis were mentioned at the suture removal appointment.

Sinusitis were also registered in 5 cases (9.2%) and were recovered prescribing different antibiotics (Avalox 400 mg once a day for 6 days) and mucosal vasoconstrictor (Rinazina spray, two puff every 12 h for 10 days). At the end of the treatment, no additional episodes were declared by involved patients.

Mechanical complications (unscrewing of the prosthesis) were faced in 4 cases (7.4%). In these cases, crowns were decemented and abutment were screwed. Once the crowns were re-cemented, occlusal contacts were checked and eventual disclusion pre-contacts were removed.

4. Discussion

The present study reported the clinical outcome of implants placed in sinus lift with critical pristine bone height using a digital approach. After an average follow-up period of 5.11 years, no implants were lost, nor showed signs of periodontal disease. In a recent systematic review with a follow up till 120 months Romero-Millàn et al. compared survival rates of dental implants placed in bone augmented by sinus lift and in native bone [15]. The authors reported similar clinical parameters for both groups but more clinical complications for sinus lift procedure. In our paper, only two out of fifty-four cases were associated with minimal perforations of the Schneiderian membrane and only five cases out of fifty-four were associated with minor post-operative complications. These complications did not lead to consequences for dental implants, which, at the time of the follow-up, were all healthy. These findings are in contrast to a recent systematic review with meta-analysis by Al-Moraissi et al. [16] who stated that intraoperative membrane perforation could increase the risk for implant failure, regardless the size of the perforations, which could be a confounding factor. Moreover, the amount of the residual alveolar ridge and healing time were not taken into consideration and this is clearly stated by the authors, who entrust 48% of implant failure cases to factors other than membrane perforation. On the contrary, other authors [17,18] reported no statistically significant implant failure rate differences in augmented sinus with or without membrane perforations.

All maxillary sinuses prior to the augmentation procedure showed an average residual height of 2.07 millimeters, so the authors opted for a lateral augmentation procedure. Several authors have estimated a minimum residual bone height to decide whether to proceed with a lateral or crestal elevation. Some authors suggested a cut-off of 5 mm [19,20]. Generally speaking, the amount of the residual bone should be taken into account to decide either to place immediately an implant or not, regardless the augmentation procedure. In the past, residual bone height has been investigated as a factor for the stability and osseointegration of dental implants. In an animal study Fenner et al. observed that implant stability was influenced by the amount of residual bone: the lower the amount of residual bone, the lower the implant stability. Furthermore, in the 2 mm residual bone group, the only two failures occurred. It is important to note, however, that the implants were placed simultaneously with the sinus lift procedure [21]. The effect of residual alveolar bone on implant survival in augmented maxillary sinuses was investigated by Rios et al in a literature review. From the reading of the eighteen selected articles, it emerged that implant survival in maxillary sinuses with an initial residual height ${<}5$ mm was 96% while in maxillary sinuses with an initial residual height> 4 mm was 99% [22]. Despite the small difference between the two percentages, it is yet interesting to note that in most of the examined studies implant insertion was performed simultaneously to the augmentation procedure and this factor is known to affect implant survival. Moreover, the digital planning and the guided surgery allowed the surgeon to better focalize on the bone quality and therefore on the last drill diameter, improving the primary stability of the implants.

The computer guided planning was already described for sinus lift to better design the bony window [23]. However, the present study presented different advantages compared to what described in the Literature.

The use of guided surgery allowed to increase the implant stability at the time of surgery. In fact, during the digital planning, within the prosthetic limits, the best site for implant insertion was selected [5]. Also, the bucco/palatal and the mesio/distal angulation of the implant was selected to favor the tridimensional bone regeneration pattern. At the same time, surgical guide allowed to minimize the micromovements on the implant during the removal of surgical insert tools. The results of

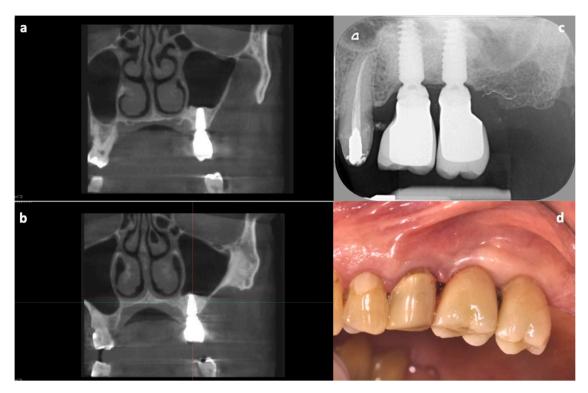


Fig. 4. Postoperative radiological [CBCT exam using implants as reference (a, b), and endoral x-ray (c)] and clinical images at 7-year follow-up (d).

this study are in accordance with the recent work by An et al. [8] who inserted implants simultaneously with sinus augmentation and reported 100% of survival rate. While the residual bone height was similar (<3mm), An et al. used a crestal approach. The authors of the present study believe that a lateral approach could help surgeons to better place the graft and to a more careful control of possible membrane perforations.

The experienced complications were few and comparable to data available from recently published literature [24]. The only mechanical complication occurred was the unscrewing of the prosthesis, which occurred only in four cases and was easily solved. No peri-implant mucositis and no peri-implantitis were reported at the end of the follow-up. In the authors opinion, the use of a digital approach allowed for an optimal position of the fixtures and, subsequently, an optimal design of the final prosthesis. This could have had an influence on the incidence of peri-implant diseases in the mid-term. Moreover, the initial digital planning optimized the design of the prosthesis and the low complications rate could have benefit from this.

The pilot drill technique used in this article is generally opposed to the fully guided technique, where the passage of all drills and the insertion of the implant are already foreseen in the surgical planning. In this study, the use of the pilot drill alone was necessary due to the reduced amount of initial bone. In this way the surgeon was able to check the quality of the preparation at any time so as not to compromise the achievement of the primary stability of the implants. Furthermore, any possible errors in the initial surgical planning can be corrected after the passage of the pilot drill, allowing a personalization of the surgical protocol according to the clinical situation. Although the fully guided approach guarantees superior predictability in the final implant position with respect to planning, the scientific literature agrees that the accuracy of pilot-drill surgery is comparable to fully-guided surgery [25,26]

Some limitations of the present study include the small sample size and the retrospective design of the study, which do not allow for comparison with other sinus lift methods, with different implant insertion times and with different guided approaches. The mean follow-up of the study is in line with previous studies.

5. Conclusions

The present retrospective study demonstrated the efficacy of the digital approach in the rehabilitation of severely resorbed maxillae. The digital planning allowed clinicians for implant insertion simultaneously with the bone augmentation procedure, even with less than 3 millimeters of native bone height. The optimization of the final position of the implants allowed the execution of prostheses with the correct shape and design and this may explain the low rate of mechanical complications (four cases of prosthesis unscrewing) and the absence of biological complications in the medium term. More than 10 mm of bone augmentation was obtained at the end of the treatment.

CRediT authorship contribution statement

Pistilli Roberto: Visualization, Conceptualization, Writing – review & editing. Canullo Luigi: Visualization, Conceptualization, Data curation, Formal analysis, Writing – review & editing. Pesce Paolo: Visualization, Conceptualization, Writing – review & editing. Pistilli Valeria: Visualization, Conceptualization, Writing – review & editing. Caponio Carlo: Visualization, Conceptualization, Writing – review & editing. Sbricoli Luca: Visualization, Conceptualization, Writing – review & view & editing.

Declarations of Competing Interest

None

Acknowledgments

The study is completely self-supported.

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