Two-Center Prospective, Randomized, Clinical, and Radiographic Study Comparing Osteotome Sinus Floor Elevation with or without Bone Graft and Simultaneous Implant Placement

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ABSTRACT

Purpose: To evaluate stability and success rate of hydrophilic nanostructured implants placed via osteotome sinus floor elevation (OSFE) without grafting material or using β-tricalcium phosphate (β-TCP), deproteinized bovine bone (DBB), or their combination, and also to assess three-dimensional volumetric stability of endo-sinus bone gained in the aforementioned conditions.

Materials and Methods: OSFE with simultaneous implant placement (10-mm long SLActive-BL, Straumann, Basel, Switzerland) was performed. Grafting materials were randomly allocated to implant sites, whereas one site was left without graft. Implant stability was measured by resonance frequency analysis over 6 months. Implant success was evaluated after 2 years of loading. Volume of new endo-sinus bone was calculated from CBCT images using 3D Slicer® software.

Results: A total of 180 implants were inserted into posterior maxilla of 45 patients with 6.59 ± 0.45 mm of residual bone height, and all remained successful after 2 years. Implant stability steadily increased during healing, without significant difference between groups (p = .658). After 2 years, endo-sinus bone significantly shrank (p < .001) in all groups (DBB:66.34%; β-TCP:61.44%; new bone formed from coagulum: 53.02%; β-TCP + DBB:33.47%).

Conclusions: Endo-sinus bone gained after OSFE inevitably and significantly shrinks regardless of whether grafting material is applied or not. Grafting material offers no significant advantage to stability nor clinical success of hydrophilic and nanostructured implants placed simultaneously with OSFE.

KEY WORDS: bone graft, implant stability, implant success, no grafting, osteotome sinus floor elevation, posterior maxilla, volumetric changes

INTRODUCTION

Unfavorable conditions for implant placement, often present in posterior maxilla, comprising low bone density and reduced subantral height due to postextraction bone resorption or maxillary sinus pneumatization, could be successfully overcome by osteotome sinus floor elevation procedure (OSFE). The OSFE procedure, introduced by Summers,1 involves the up-fracturing of the sinus floor, subsequent elevation of the Schneiderian membrane using concave-tipped, tapered osteotomes via crestal approach, and simultaneous placement of the bone grafting material and the implant. Autogenous, allogenic, or xenogenic grafting

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material acts as shock absorber that prevents sinus membrane perforation during malting and maintains the space for new bone to anchor the implant. Reduction of the grafted volume, which inevitably occurs, is significant during the first 3 years, and afterwards, the graft is stabilized at or slightly below the level of implant apices.

As an alternative to sinus lift with different grafting materials, graft-free sinus lift was introduced in order to decrease invasiveness and increase cost-effectiveness of the treatment. Histological studies have documented formation of new bone from void beneath the elevated Schneiderian membrane initially occupied by the coagulum as well as implant osseointegration. However, the mechanism behind the early bone formation under the lifted membrane is incompletely explained, and the role of the Schneiderian membrane in this process is controversial. Initial studies reported mid-term success rates from 90.08% to 100% for implants placed via OSFE when no grafting material was used although lower success rate could be expected in sites with residual bone height less than 4 mm.

Implant surface topography and chemistry affect the osseointegration process. Successful application of sand-blasted and acid-etched implants as well as titanium plasma-sprayed implants simultaneously with OSFE procedure has been documented. Sand-blasted acid-etched active (SLActive) surface due to its nanoroughness and hydrophilicity can improve and accelerate osseointegration allowing implementation of early loading protocol for implants placed via OSFE without grafting material. Short-term results indicating efficiency of the OSFE with short, tapered, SLActive implants regardless of the use of grafting material in the extremely atrophic maxilla have been reported.

Published data might favor conclusion that the use of grafting materials with OSFE procedure has no significant advantage in terms of implant outcome, but it is usually based on the prospective cohort studies or retrospective studies without randomized allocation of the tested procedures or it comes from 2D radiographic analyses. The aims of this prospective, randomized, clinical study were to assess primary and secondary stability as well as 2-year success rate of hydrophilic and nanostructured implants placed via OSFE approach without grafting material or using β-tricalcium phosphate alone, deproteinized bovine bone alone, or their combination, and to evaluate and compare three-dimensional volumetric changes of endo-sinus bone gained in the aforementioned clinical conditions during 2-year follow-up using CBCT.

MATERIALS AND METHODS

Study Design

This two-center prospective, randomized, clinical, and radiographic study was performed according to Declaration of Helsinki and with approval of the Ethical Committees of School of Dentistry in Belgrade, Serbia, and Murcia, Spain.

According to study design, patients were treated by OSFE and simultaneous implant placement. Each patient received four implants (i.e., two implants per jaw side). Four test groups were formed regarding to the grafting material used: group 1, β-TCP; group 2, DBB; group 3, β-TCP + DBB; and group 4, no grafting material. Tested grafting materials were randomly allocated to the implant sites; thus, each patient received both materials and their combination, whereas one site was left without graft. The random assignments were done by an independent investigator, according to a computer-generated randomization list with sealed, numbered envelopes.

Patients

Eligible patients were at least 18 years old, requiring a total of four dental implants in the posterior maxilla bilaterally, with subantral bone height of 6 to 8 mm and jaw width ≥ 4 mm measured on CBCT at each implant site; teeth extractions at the implant sites were performed at least 4 months before surgery. Only patients without acute/chronic sinusitis, pathological lesions, scarring, odontogenic infections, or severe allergic rhinitis were included in the study. Eligible patients were included in the study after they had signed informed consent. Exclusion criteria were sinus membrane perforation as confirmed via Valsalva maneuver or insufficient primary implant stability measured by RFA (≤37 implant stability quotient [ISQ]).

Surgical Protocol

One hour preoperatively, patients had been given 4 mg of dexamethasone (Dexason®, Galenika, Belgrade, Serbia) intramuscularly and 2 g of amoxicillin (Sinacilin®, Galenika) or 0.6 g of clindamycin (Klindamycin-MIP®, MIP Pharma d.o.o. Belgrade, ...
Serbia) orally. Also, they used 0.12% chlorhexidine gluconate (Curasept ADS 212®, Curaden HealthCare s.r.l., Saronno, Italy) for mouth rinsing during 1 minute, half-hour preoperatively.

After local infiltration using 4% articaine Hydrochloride with epinephrine 1:100,000 (Septanest®, Septodont, Auckland, New Zealand), a midcrestal incisions with two vertical releasing incisions were performed bilaterally, and a full-thickness flaps were raised along the residual alveolar ridge. Each implant site (four sites per patient) was prepared using a series of drills with increasing diameter (Straumann®, Basel, Switzerland). Preparation using final drill of 3.5-mm–diameter was discontinued 1 mm caudally to the sinus floor. Thereafter, OSFE was performed. A 3.5-mm–diameter osteotome (Straumann) was used to up-fracture the sinus floor under gentle force, with care taken to avoid perforating the sinus mucosa (Figure 1). Preservation of the continuity of the sinus membrane was checked via Valsalva maneuver. Only sites with intact sinus membrane were included in the study. Out of four future implant sites per patient, three sites received previously randomly allocated grafting material: β-tricalcium phosphate alone (BoneCeramic®, Straumann), deproteinized bovine bone alone (Bio-Oss®, Geistlich Pharma® AG, Wolhusen, Switzerland), or their combination, whereas one site was left without graft in order to allow blood clot formation.

Implants with nanostructured, hydrophilic surface (SLActive Straumann Bone Level) were placed simultaneously with OSFE (Figure 2). Four implants per patient were intended to be placed. Implants were placed without pretapping at a speed of 15 rpm. Flaps were repositioned and sutured using the 4-0 silk sutures allowing transmucosal healing.

Postoperatively, patients took amoxicillin 0.5 g t.d.s. (Sinacilin) or clindamycin 0.6 g b.i.d. (Klindamicin-MIP) for the next 3 days and nonsteroidal anti-inflammatory drugs for pain relief, as needed. Patients received detailed instructions with regard to oral hygiene. Sutures were removed after 7 days.

After 6 months of healing, solid abutments were connected with a torque of 35 Ncm, and porcelain-fused to metal-fixed bridges or crowns were cemented.

In this study, the following clinical outcomes were assessed: primary and secondary implant stability and implant success rate, whereas radiographic outcome was endo-sinus volumetric change. Patients and outcome assessors were blinded to interventions.
Implant Stability Measurement

Implant stability was measured immediately after implant placement (primary implant stability) and afterwards (secondary implant stability) weekly for the next 6 weeks, than after 3 and 6 months using Resonance Frequency Analysis (RFA) as a method of measurement. The Osstell ISQ® device (Osstell, Göteborg, Sweden) and a commercially available transducer Smart Peg® type 54 (Osstell) adapted to Straumann Bone Level implants were used for RFA. The transducer was screwed into the implant body and stimulated magnetically by the hand-held probe (Figure 3). The probe was held pointing in the anteroposterior direction for one measurement, and in a perpendicular direction for the other measurement as suggested by the manufacturer (Osstell). The displayed ISQ value reflects the degree of stability. The scale ranges from 1 to 100; the higher the ISQ, the more stable the implant is. Each measurement was repeated until the same value was recorded twice, and this was taken as the authentic value.

Evaluation of Endo-Sinus Bone Volumetric Changes

Volumetric changes of the endo-sinus bone were assessed from CBCT images. CBCT images were obtained preoperatively, in order to plan sinus lift procedure, and afterwards 6 months following sinus lift and simultaneous implant placement (baseline) as well as after 1 and 2 years of follow-up. All CBCT scans were performed under the same exposure parameters using Galileos® three-dimensional imaging unit (Sirona, USA). The images were exported in Digital Imaging and Communications in Medicine format. 3D Slicer® software package was used for visualization and image analysis. Endo-sinus bone was segmented manually on each coronal slice (Figure 4A), and the volume was calculated automatically by multiplying the sum of all plotted areas with the thickness of CBCT slices of 1 mm (Figure 4B). Volumes of endo-sinus bone were measured by two independent examiners, blinded to patient, graft type, and follow-up time.

Implant Success and Prosthetics Success Assessment

Implant success was assessed after 1 and 2 years of implant loading according to criteria proposed by Buser and colleagues (absence of clinically detectable implant mobility, pain, subjective sensation, peri-implant infection, and continuous radiolucency around the implant confirmed by CBCT images).

The criterion for success at the prosthetic level was an adequate function of the bridge/crown. Occurrence of technical complications was also noted.

Statistical Analysis

Statistical analysis was performed using the software package SPSS 22.0 for Windows (SPSS, Chicago, IL, USA). Mean and 95% confidence intervals of means were used for the description of ISQ values and volume of endo-sinus bone. Bone volume loss and implant and prosthesis success were expressed as the percentages. Interrater reliability for the two independent examiners who measured endo-sinus bone volume was estimated by intraclass correlation coefficient (ICC). Data were tested for normal distribution using the Kolmogorov–Smirnov test. As records from implants within one patient were not independent, data were analyzed using mixed model linear analysis with random effect for
patient and fixed effects for test group and time. All reported p-values were two sided. Differences were considered significant when p-value was <.05.

RESULTS

A total of 200 implant sites in the posterior maxilla of 50 patients were randomly assigned to four test groups; that was 50 implant sites per test group. Intraoperatively, sinus membrane perforation was diagnosed in five patients, and they were excluded from the study. Therefore, a total of 180 implants placed into premolar and molar maxillary regions of 45 patients (29 females and 16 males) with a mean age of 56.7 were included. The mean residual bone height was 6.59 ± 0.45 mm, and it was comparable in all test groups (p = .740).

Inserted implants supported 79 bridges and 22 single crowns. All included implants were analyzed for the clinical and radiographic outcomes up to the end of observation period. The mean follow-up period was 29.7 months.

Implant Stability

The mean and 95% confidence intervals for the ISQ values recorded in this study are presented in Figure 5. The difference in implant stability regarding the grafting material was not significant (p = .658). Dynamics of implant stability changes over time were comparable in all test groups (time × grafting material: p = .805). The effect of time was significant (p < .001). Implant stability steadily increased during the observation period.
Volumetric Changes of Endo-Sinus Bone

An ICC of 0.981 (95% CI: 0.830–0.998; \( p < .001 \)) indicated strong agreement between the two examiners who measured graft volumes.

In all test groups, a vast majority of baseline CBCT images recorded 6 months after OSFE demonstrated new endo-sinus bone that surrounded implants at least to the apical level. Recorded volumes were significantly different among tested graft types (\( p < .001 \); Figure 6). All graft types showed significant shrinkage over time (\( p < .001 \); Figure 6). Dynamics of volumetric changes over time were significantly different among tested graft types (graft type \( \times \) time: \( p < .001 \); Figure 6). For the DBB, \( \beta \)-TCP, and no graft groups, shrinkage was mostly recorded after the first year of monitoring and was the most pronounced for \( \beta \)-TCP. Combined graft, \( \beta \)-TCP + DBB, showed equable shrinkage over the 2-year of monitoring. After 2 years, shrinkage was the most pronounced for the DBB (66.34%) and least pronounced for \( \beta \)-TCP + DBB combined graft (33.47%), while bone loss was 61.44% for \( \beta \)-TCP and 53.02% for new bone formed from coagulum (controls without graft; Figure 7). At that time, cross-sectional CBCT images demonstrated full bone coverage over the apex for 20% (36) of implants, whereas 28.33% (51) implants had bone coverage at apical level. Remaining 51.66% (93) implants showed denuded palatal aspect of the apex or it was covered by thin bone layer, whereas thick bone dome was present above its facial and middle portions (Figure 8). Out of this 93 implants, 41 were controls without graft and 28 from DBB group.

Implant and Prosthetic Success Rate

Two-year implant success rate was 100%, regardless of the grafting material used. Minor technical complications requiring chairside approach were recorded. The most frequent complication was ceramic chipping.
(3.9%) followed by decementation and loosening of the crown (1.66%). No abutment loosening or fractures were noted. This resulted in the 2-year prosthetic success rate of 100%, regardless of the grafting material used.

**DISCUSSION**

Primary stability is a factor that significantly influences survival of dental implants. In our study, RFA on implants placed through OSFE approach without grafting and those with different grafting materials showed comparable primary stability indicating that granulated grafting materials provided no support for the implant immediately after placement. Further, implants placed with simultaneous OSFE without grafting achieved primary stability sufficient for immediate loading. This result is in line with data from literature. Stability of implants placed with simultaneous OSFE without grafting steadily increased during our 6-month observation period. The lack of “dip” in the stability curve might be the advantage of hydrophilicity and nanostructure of SLActive implant surface that provides an accelerated and improved osseointegration. Dynamics of implant stability changes over time were similar in all test groups, indicating that implants placed through OSFE approach without grafting could be as successfully osseointegrated as those associated with different grafting materials.

Volumetric stability of the grafting material is of utmost importance for the long-term success of implants placed simultaneously with OSFE procedure. Not only the sufficient volume of bone but also its appropriate three-dimensional arrangement around the implant are necessary for optimal biomechanical conditions at bone-implant interface during functional loading. Endo-sinus bone following OSFE has been evaluated in numerous studies using two-dimensional panoramic radiographs or retroalveolar...
radiographs, whereas CBCT has been used in limited number of studies where linear measurements were performed resulting in lack of data regarding bone volume. In this study, volumetric changes of the grafting material were evaluated using CBCT. Interestingly, analyzing the cross-sectional CBCT images, we observed in all test groups that the graft resorption over time frequently resulted in denuded palatal aspect of the implant apex or it was covered by thin bone layer, whereas thick bone dome was present above its facial and middle portions. On two-dimensional panoramic radiographs or retroalveolar radiographs, this reduction of graft volume might be underestimated, and therefore, the use of three-dimensional imaging (CT/CBCT) seems to be mandatory for evaluation of changes of grafting material after sinus floor augmentation. CT has been proven to be reliable tool for calculating the volume of maxillary sinus inlay grafts. CBCT offers advantages in terms of low radiation dose and high resolution. Possible shortcomings of our study might be related to metal artifact or might arise from transient postoperative swelling of the Schneiderian membrane on baseline CBCT images. Further, manual segmentation of CBCT images could be a source of certain imprecision, but we found strong interexaminer agreement.

Results of our study indicate that grafting material is not prerequisite for osteogenesis following OSFE procedure. Elevation of the Schneiderian membrane and tenting effect of the simultaneously inserted dental implants seem to be sufficient for endo-sinus bone gain. This is in line with histological findings from sites treated with membrane elevation without grafting that demonstrated bone tissue formation from the coagulum under the lifted Schneiderian membrane. Previous radiographic examinations identified OSFE procedure without grafting material as predictable treatment approach for posterior maxilla with limited residual bone height. Bone gained under elevated sinus membrane was stable or even increased over the 2 years. However, we recorded significant shrinkage of new endo-sinus bone, but it had no influence on implant stability or function.

In sites where large bone gain is required, use of grafting materials together with OSFE procedure has been recommended in order to stabilize blood clot and increase the tent effect on the elevated Schneiderian membrane. Autogenous bone graft promotes osteogenesis but suffers from uncontrolled resorption, limited availability, and morbidity of the donor site. Nishida and colleagues reported significant reduction of apical height and width of autogenous bone 6 months after implant placement following OSFE, although at least 1 mm of grafting material surrounded dental implants. In the study of Jung and colleagues, simultaneous placement of SLA implants using OSFE approach together with β-TCP and demineralized freeze-dried bone resulted in marked reduction in graft height during the first 2 years. Despite of native bone height less than 4 mm, all implants were maintained successfully after 5 years. Longitudinal evaluation of mixture of DBB and autogenous bone for OSFE with simultaneous implant placement revealed significant decrease in graft height during the first 2 to 3 years after augmentation, whereas the subsequent changes were minimal resulting in 9-year cumulative survival rate of 94.2%. Similar pattern of graft resorption following OSFE was noticed in our study. We recorded significant graft shrinkage during the 2 years after augmentation, and this process was the most intensive during the first year which coincided with a period of significant remodeling activity. In multicenter study of Rosen and colleagues, a total of 174 machined, titanium plasma-sprayed, and hydroxyapatite implants were placed simultaneously with OSFE using autogenous bone, demineralized freeze-dried bone allograft, freeze-dried bone allograft, bovine-derived hydroxyapatite or DBB, and no bone graft was recognized to provide better results. A systematic review of Nkenke and Stelzle showed no superiority of one grafting material over another, and the use of combined grafting materials has been suggested. In our study, combined graft used for OSFE with simultaneous implant placement showed least volume reduction, whereas use of single grafting material resulted in the greatest volume loss. Interestingly, OSFE without bone graft was associated with lower loss of endo-sinus bone volume formed from coagulum, compared with either of the two grafting materials tested in the present study when they were solely used. Despite of significant resorption of endo-sinus bone in all tested groups, all implants remained successful after 2 years in function, regardless of whether the grafting material was used or not. These findings bring into question the necessity of the grafting material usage together with OSFE. Nedir and colleagues proved that even in severely atrophic posterior maxilla, OSFE procedure with or without grafting material might be efficient with 1-year success rate of 100% and 90%, respectively. Si and colleagues recorded
significantly higher endo-sinus bone gain 6 months following OSFE with grafting material, but after 2 years and significant shrinkage, peri-implant bone reached the same level of that without grafting. Authors found 3-year cumulative survival rate of 95.1% with insignificant difference between these two OSFE procedures. In contrast to these findings, Pjetursson and colleagues reported only limited bone gain and less predictable outcome for the OSFE performed without grafting. However, nonrandomized allocation of the tested procedures might affect such conclusion.

Results of our study are related to residual bone height of 6.59 ± 0.45 mm and should be extrapolated carefully to sites where less bone is present. Data regarding the correlation between residual bone height and endo-sinus bone gain are controversial.26,39 However, taking into account the resilience capacity of the Schneiderian membrane, there might be some concern of accidental membrane perforations in sites where extensive membrane elevation is required. It might jeopardize stability of the blood clot, and membrane collapse could reduce the space available for new bone.4 Further, our results are limited to healing period of 6 months prior to implant loading. However, data from literature encourage shorter healing time if sufficient implant stability might be confirmed.15

From the results of our study, it might be concluded that the usage of grafting materials does not improve significantly the primary stability of dental implants placed simultaneously with OSFE. Implants with hydrophilic and nanostructured SLActive surface placed after OSFE without grafting material could be as successfully osseointegrated as those inserted with grafting material. Grafting material is not prerequisite for osteogenesis following OSFE procedure. Endo-sinus bone gained after OSFE inevitably and significantly shrinks regardless of whether grafting material is applied or not. The usage of grafting material offers no significant advantage to clinical success of dental implants placed simultaneously with OSFE.

REFERENCES


