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Osteotome sinus floor elevation with and without grafting material in the severely atrophic maxilla. A 1-year prospective randomized controlled ~~pilot~~ study.

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Running title

Sinus elevation in atrophic maxilla with and without grafting

ABSTRACT

Objectives: (1) To measure and compare endo-sinus bone levels around implants randomly placed with an osteotome sinus floor elevation (OSFE) procedure in grafted (control) and non-grafted (test) sinuses, (2) to evaluate the OSFE efficacy with short, tapered and chemically-modified hydrophilic surfaced implants in extremely atrophic maxilla, (3) to show that cortical merging may constitute a complication risk.

Materials & Methods: TE® SLActive 8 mm long implants (Straumann AG) were placed using OSFE procedure. Healing time before prosthetic rehabilitation was 10 weeks. One year after implant placement, bone levels were measured on standardized periapical radiographs.

Results: Thirty-seven (17 tests, 20 controls) implants were placed in 12 patients with a mean maxillary residual bone height (RBH) of 2.4±0.9 mm. Before loading, 2 control implants failed (RBH 1.4 and 1.2 mm); two others rotated at loading (1 test, RBH 0.9 mm; 1 control, RBH 1.5 mm) but were uneventfully loaded after 3 additional months of healing. These adverse events and complications occurred when implants were placed in merged corticals. Endo-sinus bone gain was 3.9 ± 1.0 and 5.0 ± 1.3 mm for the test and control groups (p=0.003). The 1-year success rate was 100% and 90%, respectively (p = 0.49).

Conclusion: Although more bone is gained when grafting material is used, this one may not be required to promote endo-sinus bone gain. The OSFE procedure with or without grafting material could be efficient when the RBH is ≤ 4 mm. However, when both corticals merged, the risk of complication could increase.

INTRODUCTION

Rehabilitation of the posterior atrophic maxilla is challenging because of limited maxillary residual bone height (RBH) and low bone density. An augmentation procedure is often indicated in this area. Sinus elevation with a lateral window approach is the most common one; however, it is complex, invasive and time consuming (Fugazotto 2003, Brägger et al. 2004, Toffler 2004). Therefore, numerous studies aimed at simplifying the augmentation procedures in the atrophic posterior maxilla (Deporter et al. 2000, Toffler 2004, 2006, Nedir et al. 2006, 2009b).

The osteotome sinus floor elevation procedure (OSFE), introduced by Summers (1994a, 1994b), is less invasive, less time-consuming and reduces post-operative discomfort to the patient. However, some complications like benign paroxysmal positional vertigo can occur during this procedure because of percussive forces (Di Girolamo et al. 2005, Penarrocha et al. 2001). The OSFE procedure improves implant primary stability and bone-to-implant contact (Zitzmann & Schärer 1998). Recent meta-analyses showed that it was highly predictable in short- and long-term studies (Emmerich et al. 2005; Shalabi et al. 2007, Tan et al. 2008, Esposito et al. 2010). Some authors reported lower survival rates when implants are placed in reduced RBH (Toffler 2004, Rosen 1999), while others documented RBH sites < 5 mm to be successfully treated with short implants (Nedir et al. 2006, 2009a). It seems, therefore, that rehabilitation of the atrophic posterior maxilla can be simplified by placing implants <10 mm in length (Nedir et al. 2004).

Primary stability in the severely resorbed maxilla is rather difficult to obtain with standard cylindrical implant designs. This is why tapered implants with a reduced pitch have been used in order to substantially improve primary stability (Nedir et al. 2009b). In addition, implants with a chemically enhanced rough hydrophilic surface

like the SLActive surface can improve bone regeneration and decrease healing time (Buser et al. 2004, Ferguson et al. 2006, Oates et al. 2007).

Peri-implant bone formation after sinus augmentation without grafting material has now been well documented (Bruschi et al. 1998, Winter et al. 2003, Lundgren et al. 2004, Nedir et al. 2006, 2009b, Lai et al. 2008, 2010, Pjetursson et al. 2009a, 2009b) but a prospective randomized controlled study, comparing the outcome of implants placed with and without a grafting material into the sinus and the behavior of bone around these implants, is still lacking. The current study was therefore set-up to compare, 1 year after implant placement, the efficacy of the OSFE technique carried out with vs. without grafting material in terms of implant success rate. More specifically, the aims of this study were:

1) to measure and compare radiologically bone level changes - mainly endo-sinus bone gain and crestal bone loss - around implants placed using the OSFE procedures with and without grafting, 2) to evaluate the success rates of the short tapered SLActive implants placed in sites of RBH ≤ 4 mm using the OSFE procedures with and without grafting material, 3) to show that crestal bone and sinus cortical bone merging can constitute a complication risk.

MATERIAL AND METHODS

Ethics Committees and patient's entry

This study was approved by the Ethics Committees of the University Hospitals of Geneva and Lausanne (Switzerland) for human research under respective protocol reference numbers 06-089 and 245/06. An informed consent was obtained from every subject before entering the study. Conduct of this research followed the principles outlined in the Declaration of Helsinki (2002) and the guidelines set forth by

the Ethics Committees. Patients attending a private practice (Ardentis Clinique Dentaire, Vevey, Switzerland) were recruited over a 12-month period.

At the initial screening appointment, the medical and dental histories of the subjects were reviewed and inclusion criteria were confirmed (Fig. 1). Patients requiring 1 to 2 implants per sinus in the atrophic posterior maxilla with RBH ≤ 4 mm were enrolled. An orthopantomograph was performed to determine the RBH.

A random allocation sequence was generated using an open generator (http://biostat.med.univ-tours.fr). For each patient, one sinus was randomized by allocation of a sealed independently prepared envelope containing the procedure characteristics; this conferred an equal probability of either receiving grafting material (control group) or not (test group). If both sinuses met the enrollment requirements, the right side was treated according to the procedure attributed by randomization, whereas the left side was treated with the other procedure. A single surgeon (RN) enrolled the participants and assigned the surgeries.

Surgery and prosthetic procedures

The surgical procedures were performed under antibiotic prophylaxis initiated the day prior to surgery (Amoxi-Mepha, Mepha Pharma SA, Aesch Basel, Switzerland; 750 mg, 3 x / day during 6 days or Dalacin C, Pfizer, Zürich, Switzerland; 300 mg, 3 x / day during 5 days, in case of penicillin allergy). A mid-crestal incision was performed for flap elevation, without any vertical or periostal releasing incision. To get access to the sinus floor, the cortical bone was marked using round burs of increasing diameter (Ø 1.4-3.1 mm). Whatever bone density, a Ø 2.8 mm sinus floor elevation osteotome (Straumann AG, Basel, Switzerland) was first implemented. Careful light tapping with a mallet pushed the bony sinus floor into the sinus cavity; this elevated the Schneiderian membrane. The osteotomy site was then enlarged with the Ø 3.5 mm

osteotome; integrity of the membrane was controlled with an undersized Ø 2.1 mm depth gauge and by using the Valsalva manoeuver. When attributed to the control group, the elevated sinus was filled with 0.5 cm^3 (0.25 g) of Bio-Oss® (Geistlich Pharma AG, Wolhusen, Switzerland; granulometry 0.25-1 mm) and 1 or 2 TE® SLActive implants (Straumann AG, Basel, Switzerland; Ø 4.1/4.8 mm, length 8 mm) were placed without tapping. When implants were randomized to the test group, they were placed without grafting material and without tapping. All implants were seated in the osteotomy site until the rough surface limit was no longer visible on the mesial and distal sides; implant neck was protruding above the crest.

Flaps were sutured around the implant neck. Implants were left to heal transgingivally; the sites were kept prosthesis-free over the whole healing period. After 8 weeks, clinical stability was manually assessed by finger pressure exerted on the implant as well as RFA measurements (Osstell® apparatus, Integration Diagnostics AB, Gothenburg, Sweden). When stable, an impression was taken and the classical prosthetic steps were conducted. Ten weeks after surgery, abutments were tightened with a 15 Ncm torque, screw-retained porcelain-fused-to-gold single crowns were screwed into the implants and functionally loaded. At the 1-year post implant placement control, prostheses were further tightened with a 35 Ncm torque.

Success criteria

Implants were controlled at 1 week, 8 weeks i.e. at impression time, 10 weeks i.e. at prosthetic delivery, 12 weeks and then 1 year after implant placement. The success criteria proposed by Buser et al. (1997) and Cochran et al. (2002) were followed. They include: 1) no clinically detectable implant mobility, 2) no pain or any subjective

sensation, 3) no recurrent peri-implant infection, 4) no continuous radiolucency around the implant.

Radiographic analysis

Radiographic analysis was performed by one investigator not involved in the surgical procedure. Periapical radiographs taken immediately after surgery, at 8 weeks and 1 year were standardized. For standardization, the same film holder-beam device was applied. The radiographs were taken with the film placed parallel to the implants and the X-ray beam directed perpendicular to the implants. For better reproducibility, indentations of the incisal edges of the implant suprastructure and whenever possible of the neighboring teeth was taken with impression material. A small amount put around the film holder resulted in a custom made bite block to improve reproducible repositioning. Implant placement served as the baseline. Internal calibration was realized on each radiograph by measuring 3 inter-thread distances (2.4 mm). The following parameters were recorded at the mesial and distal implant sides: implant protrusion into the sinus, peri-apical endo-sinus bone level, grafted bone height above the implant dome when the site was grafted, peri-implant crestal bone level. Figure 2 details the radiographic landmarks.

Statistical analysis

The implant was the unit of analysis. The following hypotheses were set forth:

1: The bone height gained with a grafting material is at least equal to the bone height gained without grafting one year after implant placement.

2: All implant show endo-sinus bone gain at the one-year control on the radiographs.

3. At least 90% of implants supporting single crowns are stable and functional one year after implant placement.

4: Complications occur when corticals are merged.

Differences between the endo-sinus bone gain measured at the test and the control implants were chosen as the primary outcome. Sample-size calculations were performed using a web calculator (http://www.dssresearch.com/KnowledgeCenter). Previous studies have shown that the 1-year bone gain amounted 2.5 ± 1.7 mm for tapered implants placed without grafting (Nedir 2009b) whereas between 3 and 4 mm of bone gain was expected when biomaterials were used (Nkenke et al. 2002, Toffler 2004, Brägger et al. 2004). For sample size calculation, a value of 3.5 ± 2 mm was used for the control group. Therefore, to detect a true difference of at least 1.0 mm with a standard deviation of 2 mm between the test and control groups in this study designed with 80% power, it has been planned to place at least 43 implants per group. With each patient needing 1 to 2 implants per sinus, the recruitment of at least 22 patients was expected.

Bone level measurements obtained from radiographic measurements included each implant side. Descriptive statistics - mean, standard deviation (SD), median value and range - were performed. Because some patients had several implants, and each implant was measured on 2 sides, the observations were not independent. Data were analyzed using mixed linear models that included a random effect (random intercept) for each patient, and a fixed effect for the treatment group. The comparison of success rates was tested by means of a Fisher test. The threshold value for statistical significance was set at $p < 0.05$.

RESULTS

Despite extension of the screening period from 12 to 20 months (June 2007 - February 2009), enrollment rate was much slower than expected. Deviation from the original protocol in terms of the planned number of patients was necessary. After 20 months, twelve patients (9 women and 3 men, 57.6 ± 4.7 years) were treated; seven patients needed treatment of both sinuses (bilateral sites) and five patients one sinus. Thirty-seven sites (32 molars and 5 premolars, 19 sinuses) with RBH ≤ 4 mm (mean 2.4 ± 0.9 mm, range 0.9-4.0 mm) met the inclusion criteria.

Nine of the 12 patients lost their maxillary molars and premolars because of periodontal disease history. Through randomization, 17 implants were assigned to the test group (9 patients, 9 sinuses) and 20 implants (10 patients, 10 sinuses) to the control one. The mean RBH of the test and control groups were 2.6 ± 0.9 mm and 2.2 ± 0.8 mm, respectively (Tab. 1). The mean RBH of the two groups were similar ($p = 0.14$).

During surgery, no perforation of the sinus membrane occurred; six patients complained about typical post-operative events without consequences. At 8 weeks, before impression, two control implants were clinically mobile; on the periapical radiographs, they appeared as having moved coronally. RBH was 1.2 and 1.4 mm for these implants sites. After removal, only one implant was later replaced, without further augmentation material.

At the 10-week milestone, while applying the 15 Ncm screw abutment tightening of the final crown, two implants rotated in a single patient (1 test implant, RBH 0.9 mm; 1 control implant, RBH 1.5 mm). After three additional months of healing, these implants resisted tightening and were successfully rehabilitated. The adverse events and complications (implant failure and mobility) occurred when implants were placed in merged corticals ($p = 0.021$). The mean healing time, including rotated implants,

was 2.6 ± 0.9 months. At the 1-year control, 35 out of 37 (94.6 %) implants were clinically stable with their definitive prosthesis in function. Success rate of the test and control groups was 100% and 90%, respectively; the difference was not statistically significant ($p = 0.49$). Figure 3 shows the clinical and radiographic follow-up of the test and control implants before and after surgery, and at the one-year control after implant placement with prosthesis in place. Table 1 displays the measured bone data.

Mean crestal bone loss was 0.6 ± 0.8 mm for the test group and 0.4 ± 0.7 mm for the control; the difference was not statistically significant ($p =0.29$). Endo-sinus bone height increased at all implant sides; the difference between post-operative and the one-year data was statistically significant ($p \leq 0.001$). Mean bone gain was 3.9 ± 1.0 mm and 5.0 ± 1.3 mm for the test and control groups, respectively. The difference was statistically significant ($p = 0.003$). Peri-implant bone within the sinus appeared denser on the control implant radiographs because of superposition of Bio-Oss® and the newly formed bone. Thirteen implants of the control group (72.2%) were completely embedded in peri-implant bone; the mean bone gain above the apex of these 13 implants was 1.2 ± 0.8 mm. In the test group, only two implants (11.8%) were completely embedded; the mean bone gain above the apex of these two implants was 0.9 ± 0.7 mm.

In the test group, at the proximal facing sides of two adjacent implants, the mean endo-sinus bone gain was 4.9 ± 0.9 mm compared to 3.1 ± 1.2 mm at the non-facing sides. The difference in bone gain was statistically significant ($p \leq 0.001$). In the control group with grafting material, the difference in bone gain between the facing and non-facing sides, 5.3 ± 1.6 mm and 4.7 ± 1.4 mm respectively, was not statistically significant ($p = 0.26$).

Immediately after surgery, implants placed without grafting material were protruding into the sinus by 5.0 ± 1.2 mm in average (range 3.1-7.0 mm); at the 1-year control, this average dropped down to 1.0 ± 0.8 mm (range 0.0-3.2 mm). In the control group, the mean height of the dome formed by the grafting material above the implants was 1.4 ± 1.0 mm (range 0.0-4.3 mm) after implant placement; it dropped down to 0.9 ± 0.9 mm (range 0-2.7 mm) after 1 year. At 1 year, the available bone height reached 6.5 ± 1.0 mm (range 4.6-8.2 mm) (C in Fig. 2) for the test group and 8.2 ± 1.5 mm (range 5.4-10.3 mm) (C+E in Fig. 2) for the control group. The difference was statistically significant ($p<0.01$).

DISCUSSION

The purpose of this investigation was to evaluate and compare the performance of implants placed by the mean of an OSFE with and without grafting material in the extremely atrophic maxilla (RBH ≤ 4 mm). Although a lower than expected number of implants was placed, the study hypotheses were validated. The bone gain difference obtained hereby of 1.1 ± 1.3 mm was statistically higher than the expected difference of 1.0 ± 2.0 mm. Thus the post-hoc power of the study was 89.6%. This means that the numbers are sufficient to provide a robust power supporting the conclusion of the study. It is noteworthy that, at the 1-year control, the success rate of both implant groups treated by an OSFE procedure was high in the following extreme conditions of this study: 1) the RBH was systematically lower than the accepted RBH limits of 5 to 6 mm, despite notice of possible lower survival rates observed for lower RBHs (Jensen et al. 1998, Rosen et al. 1999, Toffler 2004), 2) sinus augmentation was performed without grafting material, a procedure still subject to controversy (Esposito et al. 2010), 3) short implants, 8 mm long, were placed, although some authors

associated them with a lower predictability (Jemt & Lekolm 1995, Bahat 2000), particularly in the maxillary posterior region of poor bone quality and limited bone height, 4) healing time was reduced to 10 weeks for definitive rehabilitations, despite recommendation of longer healing times in such a limited RBH (Jensen et al. 1998, Cochran et al. 2002), 5) no provisional rehabilitation was placed for progressive loading, 6) single crowns served for rehabilitation, in spite of being considered less predictable than splinted ones which share and distribute better the load (Guichet et al. 2002). The selected procedure went contrary to classical recommendations for posterior maxillae rehabilitation; hence, the high success rates obtained in these extreme conditions should open the path for further studies and scientific debate.

The test group performed somewhat better (100 % vs. 90 %). Failures and adverse events were not related to the presence or lack of grafting material; from the limited sample size, one can only conclude that the lack of grafting material was not detrimental to the success rate of the OSFE procedure in the atrophic maxilla. The RBH of both failed implants was <1.5 mm; in this situation, the bone crest and the cortical bone of the sinus floor fuse together and implant primary stability was difficult to achieve, even with the tapered conical implant. When the cortexes were discernable on periapical radiographs, they provided two distinct spots of bone support; these enhanced primary stability and consequently implant success. Reliability of the OSFE procedure in this low RBH might be attributed to the implant tapered shape that provided sufficient primary stability (Nedir et al. 2009b).

The present study replicated two similar 1-year investigations (Tab. 2). In the first one (Nedir et al. 2006), endo-sinus bone gain was 2.5 ± 1.2 mm, while the mean RBH was 5.4 ± 2.3 mm, treated with cylindrical Straumann SLA implants placed without grafting material. Primary stability was difficult to achieve with those standard

implants. Implant placement deeper than usual was necessary to bring the flared implant neck resting on the crestal bone, beyond the smooth-rough boundary. As expected (Hämmerle et al. 1996), this resulted in more crestal bone loss and a lower average net bone gain of 1.3 ± 1.1 mm. In the second report (Nedir et al. 2009b), the mean RBH was lower, 3.8 ± 1.2 mm, and tapered cylindro-conical SLA implants were used to achieve a better primary stability. Endo-sinus bone gain was 2.5 ± 1.7 mm; crestal bone loss was reduced to 0.2 ± 0.6 mm because implant smooth-rough boundary could be leveled with crestal bone; the net bone gain 2.3 ± 1.8 mm in average was higher (Tab. 1). In the present randomized study, the mean RBH of the sites treated without grafting material was 2.2 ± 0.9 mm, lower than in the previous patient cohorts. Mean bone gain was higher, 3.9 ± 1.0 mm, and crestal bone loss was lower; average net bone gain was 3.3 ± 1.5 mm. This enlarged endo-sinus gain might be linked to a previously established correlation between increased endo-sinus bone gain and higher protrusion into the sinus (Nedir et al. 2010). Implementation of the SLActive surface could also contribute in explaining the high values of endo-sinus bone gain presented in this study. By using this surface, osseointegration events might have been modified or accelerated (Oates et al. 2007, Roccuzzo & Wilson 2009, Rossi et al. 2010, Schwarz et al. 2007, 2010a, 2010b).

Interestingly, endo-sinus bone gain measured between the facing sides of 2 adjacent implants was higher than the one measured at the non-facing sides. A more efficient local tenting effect of the Schneiderian membrane was probably responsible for this observation.

Sul et al. (2008) reported that bone gain without grafting could not exceed 3.2 mm. In the current study, mean implant protrusion into the sinus was 5.0 ± 1.2 mm immediately after placement; it dropped down to 1.0 ± 0.8 mm after 1 year. By that

time, the bone height available for implant anchorage averaged 6.4 ± 1.0 mm; but it appeared enough to efficiently distribute the load exerted on the single crowns. With time elapsing, the neo-formed bone should not shrink as it was previously documented in a 3- and 5-year survey (Nedir et al. 2006, 2010). In contrast, the grafted area above the implant dome shrunk after 1 year from 1.4 ± 1.0 mm in average at surgery, down to 0.9 ± 0.8 mm, in line with other studies (Brägger et al. 2004, Hatano et al. 2004, Zijderveld et al. 2009). With the grafting material, the mean available bone height was 8.2 ± 1.5 mm and most of 8 mm long implants remained embedded in a bony envelop. Yet, the utility of complet implant bone coverage by adding a graft material into the sinus might be questioned. First, because no correlation between partial bone coverage and implant failure was found (Peleg et al. 1999, Hatano et al. 2004); second, because the present test group showed that 6.4 mm of bone anchorage might be sufficient to ensure implant function in the posterior area at the 1-year follow-up. Furthermore, the bone tissue existent above the implant (dome) might not contribute to implant anchorage into the maxilla; only the bone in contact with the implant surface is responsible to the implant integration process.

Despite limited RBH, a healing time of 2.6 ± 0.9 months was effective. This is shorter than the healing periods of 3.1 ± 0.4 and 4.2 ± 6 months allotted in the above-mentioned studies with higher RBHs (Nedir et al. 2006, 2009b). Implant rotation (or so called spinners) was recorded at the 12-weeks milestone only when RBH was < 2.5 mm. It did not further influence implant function (Roccuzzo et al. 2001, Cochran et al. 2002). However, to avoid this adverse event in such a low RBH, healing time could be extended to at least 4 months. This is still less than the time of 4-6 months otherwise required for maturation of the autograft placed through a lateral window

approach (Jensen et al. 1998) and for subsequent implant osseointegration obtained after an additional 3-4 months, i.e. 7-10 months of treatment.

In most practices, patients with RBH ≤ 4mm are offered the lateral approach with delayed implant placement as recommended (Jensen et al. 1998, Davarpanah et al. 2008). A systematic review by Wallace & Froum (2003) showed that the mean survival rate of implants placed in conjunction with sinus floor elevation involving the lateral approach was 91.8% (range 61.7% - 100%). Pjetursson et al. (2008) reported a mean 3-year implant survival of 90.1%, including an annual failure rate of 3.5% for implants inserted with the same procedure. These authors concluded that survival rates compared favorably with implants placed in the non-grafted maxilla. However, because of greater financial burden and treatment length, patients can reject this implant treatment. The mean survival rate of the present study was 94.6%, in line with the data obtained for the classical technique of sinus elevation. Offering the present simplified crestal approach to the patient should increase acceptance of implant treatment because it is less invasive, faster and less expensive than the traditional technique.

In conclusion, this paper reports the first prospective randomized study comparing implants placed with the OSFE technique with and without a grafting material. Although results must be completed with long-term data, both procedures were efficient in the severely atrophic maxilla with a RBH ≤ 4 mm after 1-year of follow-up; however, the presence of merged corticals could represent a risk factor. Implant success rate was overall 94.6%; no implant failed in the test group. The data confirmed that grafting is not a pre-requisite to achieve a neo-bone formation that could reach 3.9±1.0 mm in average after 1 year. More bone was gained when the grafting material was inserted; most implants in the control group were completely

embedded in bone. But, the latter proved not to be necessary in the test group, at least at the 1 year after implant placement milestone. On the condition of being replicated by other groups and with longer follow-up, the OSFE procedure with immediate implant placement in reduced RBH, while technically sensitive, might in the future be considered as a predictable and efficient alternative care of the atrophic maxilla. Advantage would be to provide a shorter, less invasive and more affordable implant treatment.

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References

Bahat, O. (2000) Brånemark system implants in the posterior maxilla: clinical study of 660 implants followed for 5 to 12 years. *The International Journal of Oral & Maxillofacial Implants* **15**: 646-653.

Brägger, U., Gerber, C., Joss, A., Haenni, S., Meier, A., Hashorva, E. & Lang, N.P. (2004) Patterns of tissue remodeling after placement of ITI® dental implants using an osteotome technique: a longitudinal radiographic case cohort study. Clinical Oral Implants Research **15**: 158-166.

Bruschi, G.B., Scipioni, A., Celesini, G. & Bruschi E. (1998) Localized management of sinus floor with simultaneous implant placement. A clinical report. *The International Journal of Oral & Maxillofacial Implant* **13**: 219-226.

Buser, D., Mericske-Stern, R., Bernard, J.P., Behneke, A., Behneke, N., Hirt, H.P., Belser, U.C. & Lang, N.P. (1997) Long-term evaluation of nonsubmerged ITI

implants. Part 1: 8-year life table analysis of a prospective multi-center study with 2359 implants. *Clinical Oral Implants Research* **8**: 161-172.

Buser, D., Broggini, N., Wieland, M., Schenk, R.K., Denzer, A.J., Cochran, D.L., Hoffmann, B., Lussi, A. & Steinemann, S.G. (2004) Enhanced bone apposition to a chemically modified SLA titanium surface. *Journal of Dental Research* **83**:529-33.

Cochran, D., Buser, D., ten Bruggenkate, C., Weingart, D., Taylor, T., Bernard, J.P., Peters, F. & Simpson, J. (2002) The use of reduced healing times on ITI implants with a sandblasted and acid-etched (SLA) surface. *Clinical Oral Implants Research* **13**: 144-153.

Davarpanah, M., Szmukler-Moncler, S., Khoury, P.M., Martinez, H. (2008) Traitement implantaire du secteur postérieur. In: Davarpanah, M., Szmukler-Moncler, S., Khoury, P.M., Jakibowicz-Kohen, B., Martinez, H. Manuel d'Implantologie clinique. Concepts, protocoles et innovations récentes, 2e éd. Paris, p. 367-416. CdP Editions.

Deporter, D., Todescan, R., Caudry, S. (2000) Simplifying management of the posterior maxilla using short, porous-surfaced dental implants and simultaneous indirect sinus elevation. The International Journal of Periodontics & Restorative Dentistry **20**: 476-485.

Di Girolamo, M., Napolitano, B., Arullani, C.A., Bruno, E., Di Girolamo, S. (2005) Paroxysmal positional vertigo as a complication of osteotome sinus floor elevation. *European Archives of Oto-Rhino-Laryngology* **262(8):** 631-633.

Emmerich, D., Att, W. & Stappert, C. (2005) Sinus floor elevation using osteotomes: a systematic review and meta-analysis. *Journal of Periodontology* **76**: 1237-1251.

Esposito, M., Grusovin, M.G., Rees, J., Karasoulos, D., Felice, P., Alissa, R., Worthington, H.V. & Coulthard, P. (2010) Interventions for replacing missing teeth: augmentation procedures of the maxillary sinus. *Cochrane Database of Systematic Reviews* **3**: CD008397.

Ferguson, S.J., Broghgini, N., Wieland, M., De Wild, M., Rupp, F., Geis-Gerstorfer, J., Cochran, D. & Buser, D. (2006) Biomechanical evaluation of the interfacial strength of a chemically modified sandblasted and acid etched titanium surface. *Journal of Biomedical Material Research A* **78**: 291-297.

Fugazzotto, P. (2003) Augmentation of the posterior maxilla: A proposed hierarchy of treatment selection. *Journal of Periodontoly* **74**: 1682-1691.

Guichet, D.L., Yoshinobu, D. & Caputo, A.A. (2002) Effect of splinting and interproximal contact tightness on load transfer by implant restorations. *The Journal of Prosthetic Dentistry* **87**: 528-535.

Hämmerle, C.H., Brägger, U., Bürgin, W. & Lang, N.P. (1996) The effect of subcrestal placement of the polished surface of ITI implants on marginal soft and hard tissues. *Clinical Oral Implants Research* **7**:111-119.

Hatano, N., Shimizu, Y. & Ooya, K. (2004) A clinical long-term radiographic evaluation of graft height changes after maxillary sinus floor augmentation with a 2:1 autogenous bone/xenograft mixture and simultaneous placement of dental implants. *Clinical Oral Implants Research* **15**: 339-345.

Jemt, T. & Lekholm, U. (1995) Implant treatment in edentulous maxillae: A 5-year follow-up report on patients with different degrees of jaw resorption. *The International Journal of Oral & Maxillofacial Implant* **10**: 303-311.

Jensen, O.T., Shulman, L.B., Block, M.S. & Iacono, V.J. (1998) Report of the sinus consensus conference of 1996. *The International Journal of Oral & Maxillofacial Implants* **13(suppl)**: 11–32.

Lai, H.C., Zhang, Z.Y., Wang, F., Zhuang, L.F. & Liu, X. (2008) Resonance frequency analysis of stability on ITI implants with osteotome sinus floor elevation technique without grafting: a 5-month prospective study. *Clinical Oral Implants Research* **19**: 469-475.

Lai, H.C., Zhuang, L.F., Lv, X.F., Zhang, Z.Y., Zhang, Y.X. & Zhang, Z.Y. (2010) Osteotome sinus floor elevation with or without grafting: a preliminary clinical trial. *Clinical Oral Implants Research* **21**: 520-526.

Lundgren, S., Andersson, S., Gualini, F. & Sennerby, L. (2004) Bone reformation with sinus membrane elevation: a new surgical technique for maxillary sinus floor augmentation. *Clinical Implant Dentistry and Related Research* **6**: 165-173.

Nedir, R., Bischof, M., Briaux, J.M., Beyer, S., Szmukler-Moncler, S. & Bernard, J.P. (2004) A 7-year life table analysis from a prospective study on ITI implants with special emphasis on the use of short implants. Results from a private practice. *Clinical Oral Implants Research* **15**: 150-157.

Nedir, R., Bischof,M., Vazquez, L., Szmukler-Moncler, S. & Bernard, J.P. (2006) Osteotome sinus floor elevation without grafting material: a 1-year prospective pilot study with ITI implants. *Clinical Oral Implants Research* **17**: 679-686.

Nedir, R., Bischof, M., Vazquez, L., Nurdin, N., Szmukler- Moncler, S. & Bernard J-P. (2009a) Osteotome sinus floor elevation technique without grafting material: 3-year results of a prospective pilot study. *Clinical Oral Implants Research* **20**: 701-707.

Nedir, R., Nurdin, N., Szmukler- Moncler, S. & Bischof, M. (2009b) Placement of tapered implants using an osteotome sinus floor elevation technique without grafting material: 1-year results. *The International Journal of Oral & Maxillofacial Implants* **24**: 727-733.

Nedir, R., Nurdin, N., Vazquez, L., Szmukler-Moncler, S., Bischof,M. & Bernard, J.P. (2010) Osteotome sinus floor elevation technique without grafting: A five-year prospective study. *Journal of Clinical Periodontology* **37**: 1023-1028.

Nkenke, E., Schlegel, A., Schultze-Mosgau, S., Neukam, F.W. & Wiltfang, J. (2002) The endoscopically controlled osteotome sinus floor elevation: a preliminary prospective study. *The International Journal of Oral & Maxillofacial Implants*. **17**:557-566.

Oates, T.W., Valderrama, P., Bischof, M., Nedir, R., Jones, A., Simpson, J., Toutenburg, H. & Cochran, D.L. (2007) Enhanced implant stability with a chemically modified SLA surface: A randomized controlled clinical trial. *The International Journal of Oral & Maxillofacial Implants* **22**:755-760.

Peleg, M., Chaushu, G., Mazor, Z., Ardekian, L. & Bakoon, M. (1999) Radiological findings of the post-sinus lift maxillary sinus: a computerized tomography follow-up. *Journal of Periodontology* **70**: 1564-1573.

Penarrocha, M., Perez, H., Garcia, A. & Guarinos, J. (2001) Benign paroxysmal positional vertigo as a complication of osteotome expansion of the maxillary alveolar ridge. *Journal of Oral and Maxillofacial Surgery* **59**: 106-107.

Pjetursson, B.E., Tan, W.C., Zwahlen, M. & Lang, N.P. (2008) A systematic review of the success of sinus floor elevation and survival of implants inserted in combination with sinus floor elevation. Part I: Lateral approach. *Journal of Clinical Periodontology* **35(Suppl. 8)**: 216–240.

Pjetursson, B.E., Rast, C., Brägger, U., Schmidlin, K., Zwahlen, M. & Lang, N.P. (2009a) Maxillary sinus floor elevation using the (transalveolar) osteotome technique with or without grafting material. Part I: implant survival and patients' perception. *Clinical Oral Implants Research* **20**: 667–676.

Pjetursson, B.E., Ignjatovi, D., Matuliene, G., Brägger, U., Schmidlin, K. & Lang, N.P. (2009b) Transalveolar maxillary sinus floor elevation using osteotomes with or without grafting material. Part II: radiographic tissue remodeling. *Clinical Oral Implants Research* **20**: 677-683.

Roccuzzo, M., Bunino, M., Prioglio, F. & Bianchi, S.D. (2001) Early loading of sandblasted and acid-etched (SLA) implants: A prospective split-mouth comparative study. *Clinical Oral Implants Research* **12**:572-578.

Roccuzzo, M. & Wilson, TG Jr. (2009) A prospective study of 3 weeks' loading of chemically modified titanium implants in the maxillary molar region: 1-year results. *The International Journal of Oral & Maxillofacial Implants* **24**: 65-72.

Rosen, P.S., Summers, R., Mellado, J.R., Salkin, L.M., Shanaman, R.H., Marks, M.H. & Fugazzotto, P.A. (1999) The bone-added osteotome sinus floor elevation technique: multicenter retrospective report of consecutively treated patients. *International Journal of Oral & Maxillofacial Implants* **14**: 853–858.

Rossi, F., Ricci, E., Marchetti, C., Lang, N.P. & Botticelli, D. (2010) Early loading of single crowns supported by 6-mm-long implants with a moderately rough surface: a prospective 2-year follow-up cohort study. *Clinical Oral Implants Research* **21**: 937–943.

Schwarz, F., Herten, M., Sager, M., Wieland, M., Dard, M., Becker, J. (2007) Bone regeneration in dehiscence-type defects at chemically modified SLActive and

conventional SLA titanium implants: a pilot study in dogs. *Journal of Clinical Periodontology* **34**:78-86.

Schwarz, F., Sager, M., Kadelka, I., Ferrari, D., Becker, J. (2010a) Influence of titanium implant surface characteristics on bone regeneration in dehiscence-type defects: an experimental study in dogs. *Journal of Clinical Periodontology* **37**:466-73.

Schwarz, F., Jung, RE., Fienitz, T., Wieland, M., Becker, J., Sager, M. (2010b) Impact of guided bone regeneration and defect dimension on wound healing at chemically modified hydrophilic titanium implant surfaces: an experimental study in dogs. *Journal of Clinical Periodontology* **37**:474-85.

Shalabi, M.M., Manders, P., Mulder, J., Jansen, J.A. & Creugers, N.H.J. (2007) A meta-analysis of clinical studies to estimate the 4.5-year survival rate of implants placed with the osteotome technique. *The International Journal of Oral & Maxillofacial Implants* **22**: 110-116.

Sul, S.H., Choi, B.H., Li, J., Jeong, S.M. & Xuan, F. (2008) Effects of sinus membrane elevation on bone formation around implants placed in the maxillary sinus cavity: an experimental study. *Oral Surgery Oral Medicine Oral Pathology Oral Radiology and Endodontics* **105**: 684-687.

Summers, R.B. (1994a) A new concept in maxillary implant surgery: the osteotome technique. *Compendium of Continuous Education in Dentistry* **15**: 152-160.

Summers, R.B. (1994b) The osteotome technique. Part 3. Less invasive methods in elevation of the sinus floor. *Compendium of Continuous Education in Dentistry* **15**: 698-708.

Tan, W.C., Lang, N.P., Zwahlen, M., Pjetursson, B.E. (2008) A systematic review of the success of sinus floor elevation and survival of implants inserted in

combination with sinus floor elevation. Part II: transalveolar technique. *Journal of Clinical Periodontology* **35**(8 Suppl): 241-54.

Toffler, M. (2004) Osteotome-mediated sinus floor elevation: a clinical report. *The International Journal of Oral & Maxillofacial Implants* **19**: 266-73.

Toffler, M (2006). The clinical and practical benefits of combining short implants with minimally invasive osteotome sinus floor elevation in the treatment of the atrophic posterior maxilla. *Practical Procedures & Aesthetic Dentistry* **18**: 185-192.

Wallace, S.S. & Froum S.J. (2003) Effect of maxillary sinus augmentation on the survival of endosseous dental implants. A systematic review. *Annals of Periodontoogy* **8**: 328-43.

Winter, A.A., Pollack, A.S. & Odrich, R.B. (2003) Sinus/alveolar crest tenting (SACT): a new technique for implant placement in atrophic maxillary ridges without bone grafts or membranes. *International Journal of Periodontics and Restorative Dentistry* **23**: 557-565.

Zijderveld, S.A., Schulten, E.A., Aartman, I.H. & ten Bruggenkate, C.M. (2009) Long-term changes in graft height after maxillary sinus floor elevation with different grafting materials: radiographic evaluation with a minimum follow-up of 4.5 years. *Clinical oral Implants Research* **20**: 691-700.

Zitzmann, N.U. & Schärer, P. (1998) Sinus elevation procedures in the resorbed posterior maxilla. Comparison of the crestal and lateral approaches. *Oral Surgery Oral Medicine Oral Pathology Oral Radiology and Endodontics* **85**: 8-17.

Figure legends

Fig. 1: Inclusion criteria of the present study.

Fig. 2: Radiographic measurements.

Crestal bone loss: The **distance A** parallel to the implant axis, between the most apical implant thread and the most coronal bone-implant contact, was measured on both sides of each implant; it was then averaged. A decrease in this mean value on consecutive radiographs, taken immediately after implant surgery and 1 year after implant placement, was indicative of a crestal bone loss.

Endo-sinus bone gain: The **distance B** between a reference coronal implant thread and the most apical implant-bone contact was measured on both sides of each implant; it was then averaged. An increase of this mean value on consecutive radiographs, taken immediately after implant surgery and 1 year after implant placement, was indicative of endo-sinus bone gain.

Height of protrusion into the sinus: The **D distance** was measured and averaged on both sides of each test implant on radiographs taken immediately after surgery and 1 year after implant placement.

Apical grafted dome height: **E distance**, measured at the control group, along the implant axis on radiographs taken immediately after surgery and 1 year after implant placement.

Available bone height at 1 year: The **C distance** was measured and averaged on both sides of each implant, on radiographs taken 1 year after implant placement. For the test implants, it expresses the available bone height after 1 year. **C + E** expresses the available bone height at the control implants.

Fig. 3: Pre-operative, post-operative, and 1-year clinical photographs and radiographs.

■ Implants test (without grafting) □ Implants control (with grafting).

Table legends

Tab. 1: Measured bone data of the present study (mean, standard deviation, median value and range).

Tab. 2: Bone data and success rates of replicated studies recorded 1 year after implant placement (Nedir et al. 2006, 2009b, present study).

Net bone gain is: endo-sinus bone gain – crestal bone loss. Endo-sinus bone gain and net bone gain were highest when lowest RBH and SLActive implants were combined.

Patient inclusion criteria

a. Patient requires implant treatment in the posterior maxilla.

b. Teeth extractions at the implant sites were performed at least 4 months before surgery.

c. Residual bone height between the alveolar bone crest and the sinus floor, measured on panoramic radiograph at each implant site, is ≤ 4 mm.

d. The osteotome sinus floor elevation procedure will be performed with or without grafting material according to the randomization process.

e. TE® SLActive implants, 4.1/4.8 mm in diameter and 8 mm in length (Straumann AG, Basel, Switzerland) will be placed.

f. Patient agrees to avoid wearing a removable prosthesis at the implants site during the healing period.

g. Absence of medical history of acute or chronic sinusitis.

h. Absence of active periodontal disease, diabetis and metabolic bone disease.

Fig. 1: Inclusion criteria of the present study.

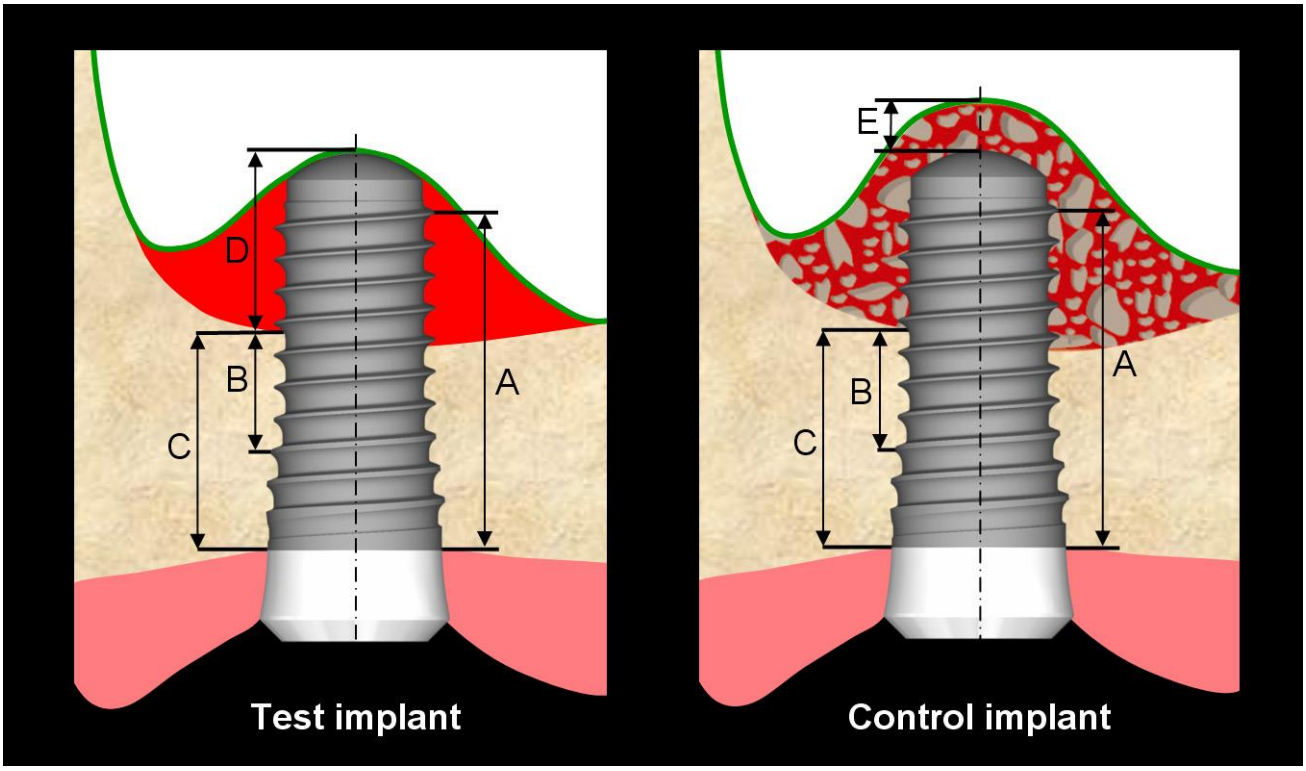

Fig. 2: Radiographic measurements.

Crestal bone loss: The **distance A** parallel to the implant axis, between the most apical implant thread and the most coronal bone-implant contact, was measured on both sides of each implant; it was then averaged. A decrease in this mean value on consecutive radiographs, taken immediately after implant surgery and 1 year after implant placement, was indicative of a crestal bone loss.

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Apical grafted dome height: **E distance**, measured at the control group, along the implant axis on radiographs taken immediately after surgery and 1 year after implant placement.

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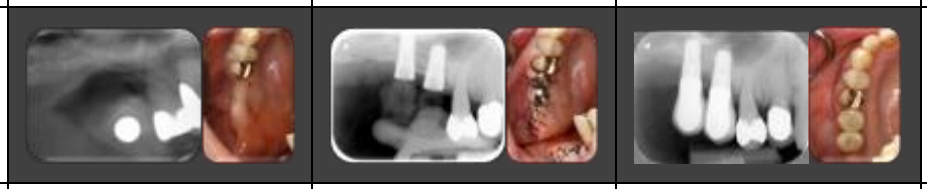
	Right maxilla			Left maxilla		
	Pre-operative	**Post-operative**	**1 year**	**Pre-operative**	**Post-operative**	**1 year**
1						
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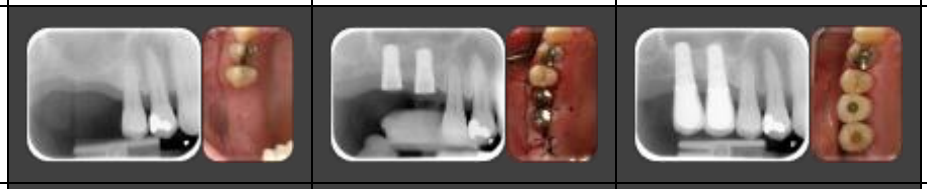
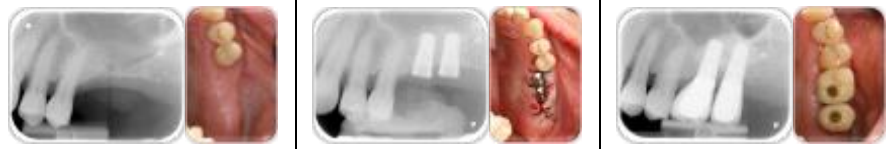
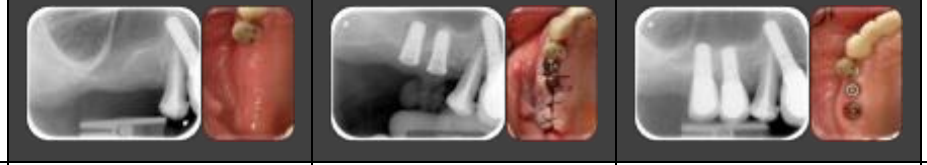
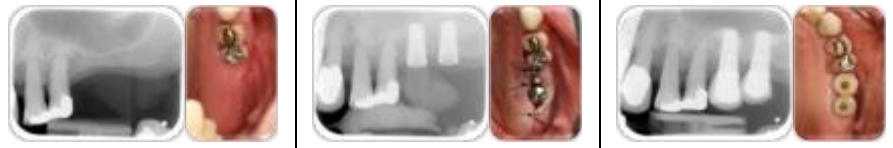
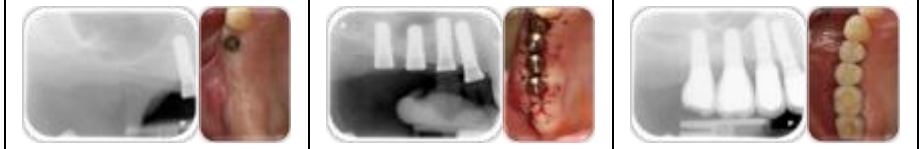
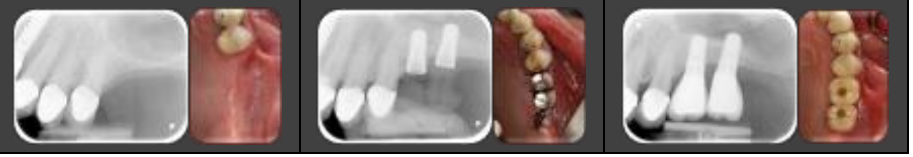
3						
4						
5						
6						

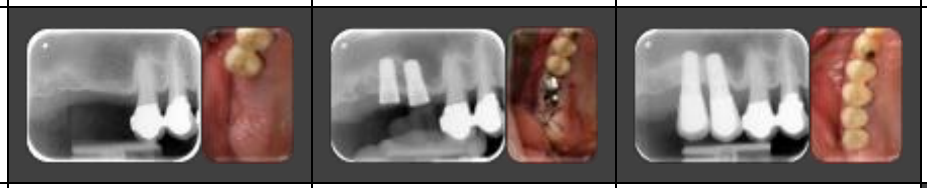
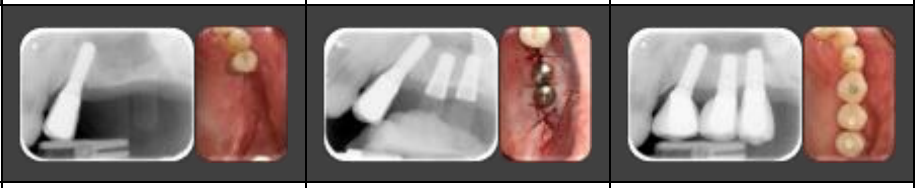
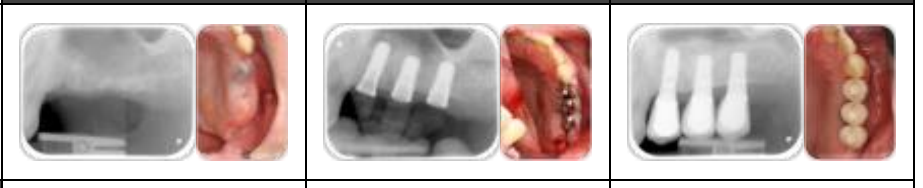
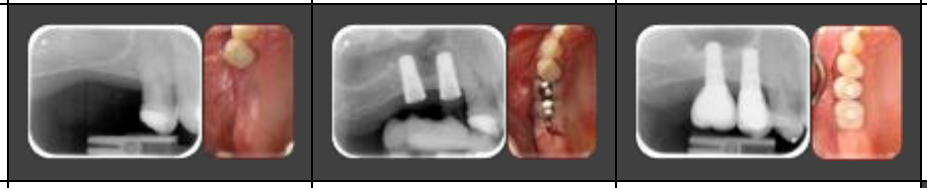
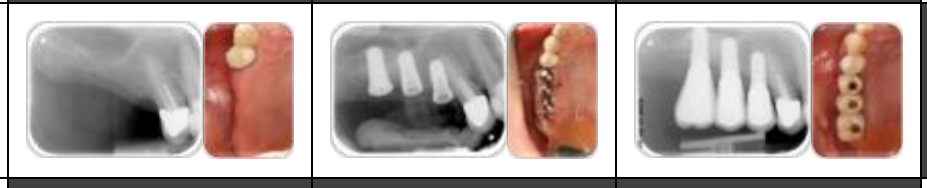
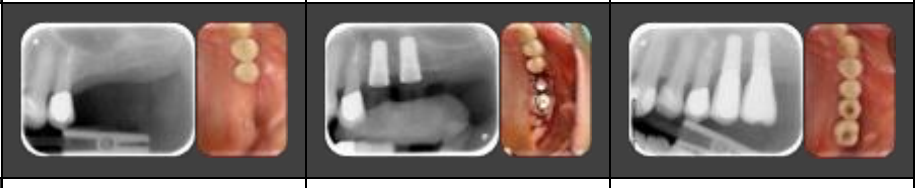
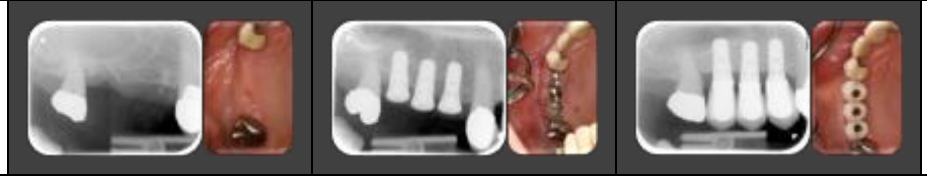
	Right maxilla			Left maxilla		
	Pre-operative	**Post-operative**	**1 year**	**Pre-operative**	**Post-operative**	**1 year**
7						
8						
9						
10						
11						
12						

Fig. 3: Pre-operative, post-operative, and 1-year clinical photographs and radiographs.

■ Implants test (without grafting) □ Implants control (with grafting).

Implant group	Test (no grafting material)	Control (with grafting material)	p*
Initial RBH	Mean ± SD 2.6 ± 0.9 mm median 2.5 mm range 0.9-4.0 mm	Mean ± SD 2.2 ± 0.8 mm median 2.1 mm range 0.9-3.8 mm	0.14
Endo-sinus bone gain	Mean ± SD 3.9 ± 1.0 mm median 4.1 mm range 1.8-6.2 mm	Mean ± SD 5.0 ± 1.3 mm median 5.1 mm range 2.9-6.7 mm	0.003
Crestal bone loss	Mean ± SD 0.6 ± 0.8 mm median 0.5 mm range 0-2.4 mm	Mean ± SD 0.4 ± 0.7 mm median 0.3 mm range 0-2.1 mm	0.29

Tab. 1: Bone data of the present study (mean, standard deviation (SD), median value and range).

* p value from mixed linear model including random effects for patients.

References	Nedir et al. 2006	Nedir et al. 2009b	Present study	
Elevation procedure	OSFE	OSFE	OSFE	
Implant type	Standard cylindrical implants 10 mm long (SLA)	Tapered implants 8 and 10 mm long (SLA)	Tapered implants with chemically-modified surface 8 mm long (SLActive)	
Grafting material	No	No	No	Yes
Mean initial RBH	5.4 ± 2.3 mm	3.8 ± 1.2 mm	2.6 ± 0.9 mm	2.2 ± 0.8 mm
Implant number	25	54	17	20
Healing time	3.1 ± 0.4 months	4.2 ± 2.6 months	2.6 ± 0.9 months	2.6 ± 0.9 months
Mean endo-sinus bone gain	2.5 ± 1.2 mm (median 2.3 mm)	2.5 ± 1.7 mm (median 2.3 mm)	3.9 ± 1.0 mm (median 4.1 mm)	5.0 ± 1.3 mm (median 5.1 mm)
Mean crestal bone loss	1.2 ± 0.7 mm (median 1.1 mm)	0.2 ± 0.8 mm (median 0.2 mm)	0.6 ± 0.8 mm (median 0.5 mm)	0.4 ± 0.7 mm (median 0.6 mm)
Net bone gain	1.3 ± 1.1 mm (median 1.4 mm)	2.3 ± 1.8 mm (median 2.3 mm)	3.3 ± 1.5 mm (median 3.3 mm)	4.6 ± 1.4 mm (median 5.1 mm)
Success rate	100.0%	100.0%	100.0%	90.0%

Tab. 2: Bone data and success rates of replicated studies recorded 1 year after implant placement (Nedir et al. 2006, 2009b, present study). Net bone gain is: endo-sinus bone gain – crestal bone loss. Endo-sinus bone gain and net bone gain were highest when lowest RBH and SLActive implants were combined.