Tapered Screw Implants With Different Machined Neck Designs: A 3-Year Split-Mouth Randomized Controlled Prospective Study

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INTRODUCTION

Marginal bone resorption (MBR) around osseointegrated dental implants is a multifactorial phenomenon that is not yet fully understood. The general consensus is that it is important to maintain stable bone levels and prevent excessive peri-implant bone loss. Implant design seems to play a critical role in influencing marginal bone remodelling.[1] In this respect, the evaluation of implant neck configurations on marginal bone stability is of utmost importance, because the bone remodeling process is most dominant at this level.[2,3] A close relationship was found between alveolar bone loss and the lengths of polished necks for various implant systems.[4] Some studies claim that implants with shorter polished smooth collars are more effective in decreasing MBR in animal models.[5] The same assumption has been confirmed in human studies evaluating the MBR around implants with different height configurations of the neck portion.[6,7] However, scarce information is available about the optimal height of the machined collar with respect to crestal bone level changes over time. Schwarz et al[8] investigated histomorphometrically the crestal bone changes at nonsubmerged implants with two machined collar lengths in a dog model, and observed higher bone loss at implants with a longer machined neck. To test the hypothesis that the longer the machined neck, the higher the bone resorption, the present prospective study aimed to evaluate radiographically in a standardized fashion the MBR around nonsubmerged implants with two machined neck configurations in humans.

MATERIALS AND METHODS

Patient selection

The present prospective study was performed as a monocentric study in a university setting. The study protocol was submitted to and approved by the responsible local ethical committee (reference number: PRK-3.002) in accordance with the ethical principles listed in the Helsinki Declaration for medical research involving human subjects. Each patient agreed to participate in the study and gave informed consent.

A sample of 9 healthy, nonsmoking patients was recruited according to the following inclusion criteria: 1) $\geq$18 years of age; 2) bilateral partial edentulism consisting of at least 2 missing teeth in the premolar/molar region of the mandible; 3) alveolar ridge healing period $>$4 months prior to implant placement; 4) no need for bone augmentation procedures; 5) presence of $>$2 mm of keratinized mucosa in a corono-apical dimension with respect to the mucogingival junction; and 6) opposing dentition present.

Study design

The patients were assigned to receive screw-type sandblasted and acid-etched titanium implants in a nonsubmerged healing procedure. The test group (CAM+) consisted of patients who received implants with a machined neck height of 0.4 mm (Promote Plus, Camlog Biotechnologies AG, Basel, Switzerland). The control group (CAM-) consisted of patients who received implants with a machined portion of 1.4 mm (Promote, Camlog Biotechnologies AG). In each patient, test implants were randomly allocated to the right or left mandibular premolar and molar regions according to a computer-generated randomization list. Following a split-mouth design, control implants were placed in the contralateral region. Allocation to the treatment was concealed by means of sealed envelopes until the time of implantation. The optimal diameter and length of the implants were selected to best fit the residual ridge dimensions.

The surgical procedures were performed on an outpatient basis by the same operator. A midcrestal horizontal incision and vertical releasing incisions were made to mobilize a full-thickness flap. A 2-mm diameter surgical guide was placed in the surgical area and serial osteotomies were performed according to the manufacturer's instructions to prepare the implant sites bilaterally. In both groups, implants were placed at the same sink depth, so that the implant shoulder was situated 0.4 mm above the alveolar crest. In the CAM- group, the interface between the machined neck and the rough

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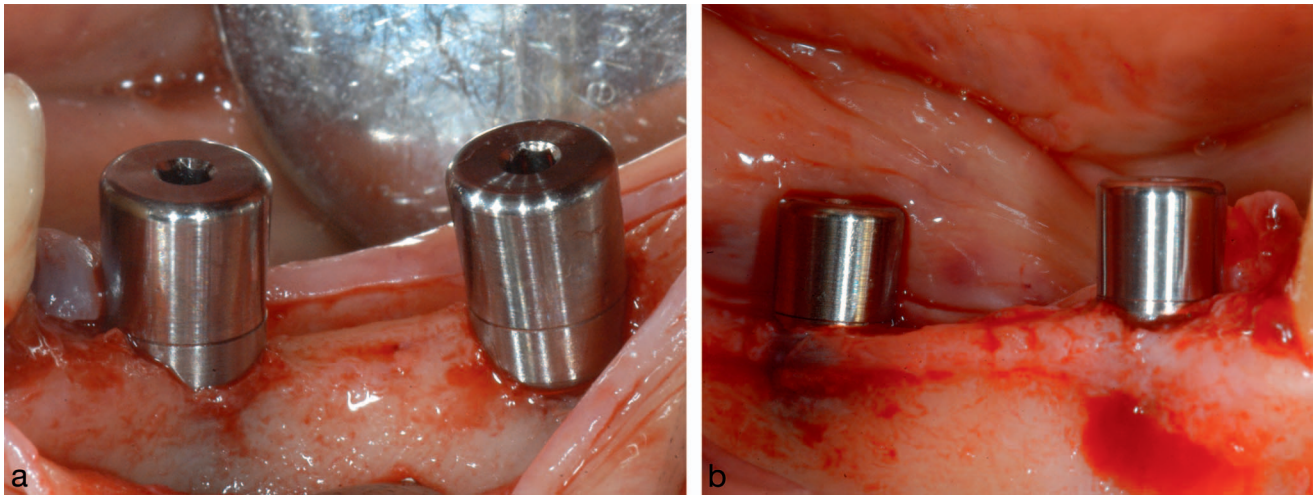

Figure 1. (a) Implant placement in the control group (CAM-). (b) Implant placement in the test group (CAM+).

portion was located approximately 1 mm subcrestally (Figure 1a), whereas at CAM+ implants with a rough/smooth interface were located at the bone crest level (Figure 1b).[8] Healing abutments were screwed to the implants, and the flaps were finally adapted around the healing caps to obtain a transmucosal healing (Figure 2a and b).

Both groups were left to heal for 12 weeks. Impression copings equipped with repositioning caps were screwed to the implants and implant impressions were taken with a customized closed-tray. After 2 weeks, temporary acrylic resin prostheses were delivered to the patient. After 6 months, definitive ceramic crowns were cemented to definitive abutments.

Radiological assessment

The delivery of the temporary prostheses was considered as the baseline time point (T_0) for the evaluation of the peri-implant MBR. During the same appointment, customized film holders (Rinn XCP, Dentsply Sirona Italia, Rome, Italy) were made using acrylic resin positioned on the bite block of the film holders. Intraoral radiographs were taken using the long-cone paralleling technique at T_0, and at 6, 12, 24, and 36 months thereafter. The images were digitalized with a scanner (Perfection V800 Photo, Epson, Suwa, Japan) in a resolution of 1200 dpi. The MBR, calculated as the distance in mm between the implant shoulder and the first visible bone-to-implant contact, was measured at the mesial and distal aspects of each implant with a ×10–15 magnification using an image analysis program (Image J, US National Institutes of Health, Bethesda, Md). To adjust each radiograph for distortion, the images were calibrated by a reference structure, which was the well-known implant length. Marginal bone level changes were assessed by two independent clinicians blinded to the type of treatment.

Statistical analysis

The methodology and the statistical analysis were reviewed and performed by an independent statistician. Inter-rater reliability of MBR measures between the two independent clinicians was assessed with intraclass correlation coefficient (ICC) according to Fleiss.[9] The patient was considered as the

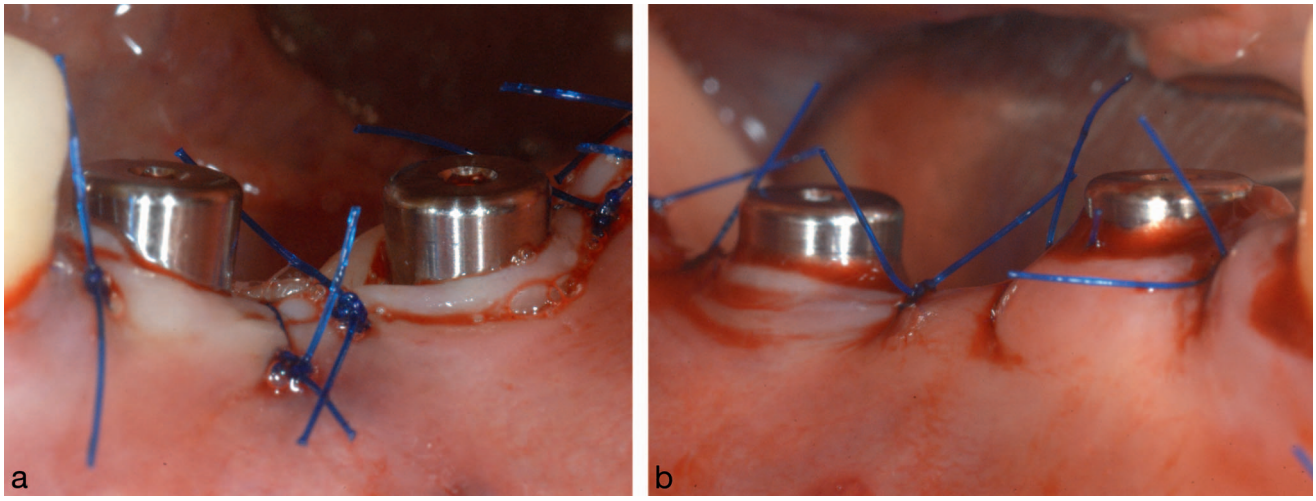

Figure 2. (a) Healing abutments screwed to the control implants (CAM-). (b) Healing abutments screwed to the test implants (CAM+).

Table

Marginal bone resorption (MBR) differences between the means of CAM- and CAM+ implants adjusted for the subject at each study period

Subject ID	No. of Implants per Group	Differences in MBR (mm)				
		T_0	6 mo	12 mo	24 mo	36 mo
1	2 - 2	0	0	−0.1	−0.15	−0.15
2	2 - 2	0	0.57	0.92	1.12	1.12
3	2 - 2	0	0.57	0.67	0.65	0.62
4	2 - 2	0	−0.6	−0.45	−0.5	−0.57
5	2 - 2	0	0.27	0.07	0.02	0
6	3 - 3	0	−0.16	−0.11	−0.16	−0.26
7	2 - 2	0	0.02	0	0	0
8	3 - 3	0	0.11	0.15	0.15	0.03
9	2 - 2	0	0.27	0	−0.1	−0.12

statistical unit. Data were collected at T_0, and at 6, 12, 24, and 36 months. In all patients the mean MBR values for test and control implants were registered independently and weighted on the number of implants inserted in each patient. The first measurement of MBR performed at T_0 was subtracted from the subsequent measurements registered after 6, 12, 24, and 36 months, in order to compensate for potential intrasurgical discrepancies in apico-coronal positioning of the implants. In this way, at T_0 all implants were considered as being placed uniformly at the same sink depth. Therefore, all the measures in the follow-up of MBR start from 0 mm. For each patient and at each follow-up, the mean of MBR values for control (CAM-) and test (CAM+) implants were considered. Subsequently, for each patient at each time, the difference between the mean values of MBR obtained between CAM- and CAM+ implants was calculated. For each study period, the total difference was weighted on the number of implants in each patient. Efficacy of CAM+ was considered at 36 months. Paired sample *t* test and 95% confidence interval (CI) of the mean difference were used to evaluate the mean difference of MBR at 36 months between CAM- and CAM+ implants. The significance threshold was set at $P < .05$. All statistical analyses were conducted using SAS version 9.2 (SAS Institute Inc, Cary, NC).

Results

Overall, 5 female and 4 male subjects receiving a total of 20 CAM+ and 20 CAM- implants were available for the statistical analysis. In 7 patients 2 implants were inserted in each side of the mandible, whereas 2 patients received 3 implants per side. The mean age was 54.56 years (age range: 33–70). Surgical and prosthetic phases proceeded without biological or technical complications, and no dropouts were registered during the observation period.

Considering the totality of measurements of MBR performed by the two independent clinicians, the inter-rater reliability analysis showed a concordance of ICC = 0.972.

The differences between the mean values of MBR recorded for CAM- and CAM+ implants in each patient at each follow-up visit are summarized in Table 1 and illustrated in Figure 3. A trend of increasing mean MBR differences could be observed within the first year of function. During the following recall visits, mean MBR differences tended to stabilize with a slight reduction at 36 months. At 3 years, the mean within subject of the difference between CAM- and CAM+ implants weighted for the number of implants was not significantly different from zero ($t = 0.523$; $df = 8$; $P = .65$). The overall difference within subjects weighted for the number of implants was 0.05 ± 0.47 mm (95% CI = −0.16; 0.27).

Discussion

The present study was designed to test whether the apico-coronal dimension of the machined portion of the implant neck was able to influence the MBR. To verify this hypothesis, in the CAM+ group the rough/smooth interface was placed at the bone crest level, whereas in the CAM- group the rough/smooth interface was located approximately 1 mm subcrestally.

The results indicated that bone remodeling is comparable around CAM+ and CAM- implants. At 36 months, the mean difference between CAM- and CAM+ implants was not different from 0 in a statistically significant way. Hence, the assumption that test implants were able to prevent crestal bone resorption in comparison with control implants could not be verified in up to 3 years of function.

There is certain evidence suggesting that a reduced turned neck portion decreases crestal bone resorption.[5,6] This emphasizes the influence of the location of the rough/smooth interface on the apico-coronal position of the peri-implant crestal hard tissue. The establishment of a biologic width dimension in close relationship with the rough/smooth interface, and the physiologic response to the microgap/interface at the connection to the superstructure might play an important role in this direction. As a matter of fact, implants positioned in a way that the microgap resulted above the bone crest, and thus with the inflammatory infiltrate distant from the alveolar bone, showed the least bone loss compared to implants placed more apically.[10] It is of importance to mention at this point that slight inflammatory cell infiltrate in the connective tissue adjacent to the microgap of both CAM- and CAM+ groups was found.[8] However, at 12 weeks, this inflammatory cell infiltrate was clearly separated from the implant supporting alveolar bone by a subepithelial connective tissue zone, and thus the microbial leakage might not

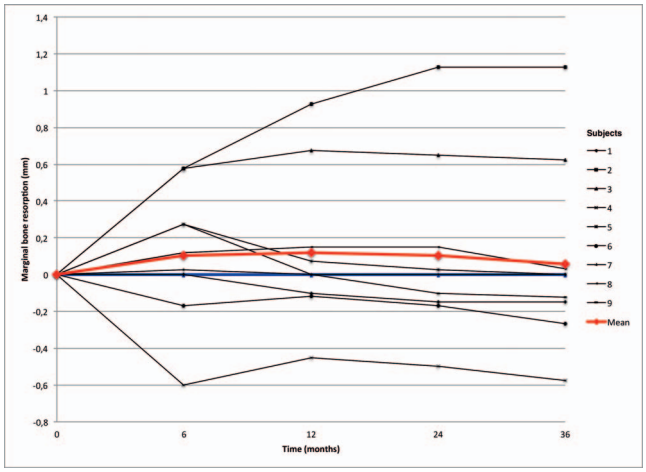

Figure 3. Marginal bone resorption differences between the means of the control (CAM-) and test (CAM+) implants adjusted for the subject from the delivery of the temporary prosthesis (T_0) to 36 months postloading. The red line illustrates the overall mean of the differences within subjects between CAM- and CAM+ implants weighted for the number of implants; the black lines represent the difference within subjects of the two mean values between CAM- and CAM+ implants in each subject.

contribute to the marginal bone resorption. This speculation may explain the results of the present study, characterized by no substantial changes in marginal bone levels at 3 years in both groups. This outcome complies favorably with other studies comparing implants with different collar lengths. Similarly to the present work, a clinical study was conducted to evaluate crestal bone level changes radiographically over a period of up to 3 years in humans around implants with a 2.8 mm machined coronal portion versus implants exhibiting a 1.8 mm machined coronal portion.[11] Bone remodeling did not significantly differ between the two types of implants over the entire observation period. With a comparable study design, another trial was performed to evaluate crestal bone level changes radiographically over a period of 12 months in humans for implants with a 0.7-mm machined collar versus implants with a 1.5-mm machined collar.[7] Results suggested that crestal bone level changes were similar at 12 months after placement, without statistically significant differences. These findings, taken together with the results of the current study, suggest that there is uncertain evidence of improved marginal bone level preservation for any particular length of the implant neck. This is consistent with a systematic review exploring the relationship between neck configuration and marginal bone resorption, which failed to prove substantial advantages when different collar lengths were used to preserve marginal bone levels.[12]

Another finding from the present study was that, for both neck configurations, after a remarkable bone loss observed during the first 12 months, MBR remained almost unchanged during the following intervals up to 3 years. According to other studies,[5,11] it might be stated that in both neck configurations, MBR inevitably proceeded along the polished neck to the smooth/root interface, stabilizing thereafter when the bone loss reached the roughened threaded area. It is worth mentioning that slightly lower MBR values were observed in the CAM+ group with a reduced machined portion, particularly during the early period of function. This is in accordance with recent systematic reviews stating that the use of rough collars promotes reduction in crestal bone resorption when compared to machined collars.[13,14] In this respect, it has been suggested that the smooth-rough border should at best coincide with the adjacent alveolar bone, or in other words, a subcrestal positioning of smooth implant parts should be avoided.[15] Irrespective of the configuration, however, our results support the fact that neck design might not be able to modify the formation of the biologic width intended as the distance between the top of the peri-implant mucosa to the first bone-to-implant contact.

The results obtained in the present study have to be interpreted with caution due to some limitations. The small number of patients included led to a reduced power to detect small differences. In addition, the sample of patients enrolled consisted of a conveniently sampled population that was treated in a university setting under a professional oral hygiene maintenance regimen. It must be noted that patients with a reduced compliance are more likely to develop peri-implant disease and therefore higher MBR.[16] All of these concerns recognize a lack of external validity and demand that the reported results should be interpreted with caution and should not be extrapolated to the general population.

Conclusion

In conclusion, in a conveniently sampled population, MBR was not influenced by the length of the machined collar around screw-type rough-surfaced implants placed in a nonsubmerged healing procedure in the posterior region of the mandible. This trend was maintained up to 3 years of prosthetic loading.

Abbreviations

CAM-: control group consisting of implants with a machined portion of 1.4 mm

CAM+: test group consisting of implants with a machined neck height of 0.4 mm

CI: confidence interval

ICC: intraclass correlation coefficient

MBR: marginal bone resorption

Note

The authors declare that there is no conflict of interests regarding the publication of this paper.

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