Influence of the Size of the Microgap on Crestal Bone Changes Around Titanium Implants. A Histometric Evaluation of Unloaded Non-Submerged Implants in the Canine Mandible

Joachim S. Hermann,*† John D. Schoolfield,‡ Robert K. Schenk,§ Daniel Buser,§ and David L. Cochran*

Background: Endosseous implants can be placed according to a non-submerged or submerged approach and in 1- or 2-piece configurations. Recently, it was shown that peri-implant crestal bone changes differ significantly under such conditions and are dependent on a rough/smooth implant border in 1-piece implants and on the location of an interface (microgap) between the implant and abutment/restoration in 2-piece configurations. Several factors may influence the resultant level of the crestal bone under these conditions, including movements between implant components and the size of the microgap (interface) between the implant and abutment. However, no data are available on the impact of possible movements between these components or the impact of the size of the microgap (interface). The purpose of this study was to histometrically evaluate crestal bone changes around unloaded, 2-piece non-submerged titanium implants with 3 different microgap (interface) dimensions and between implants with components welded together or held together by a transocclusal screw.

Methods: A total of 60 titanium implants were randomly placed in edentulous mandibular areas of 5 hounds forming 6 different implant subgroups (A through F). In general, all implants had a relatively smooth, machined suprabony portion 1 mm long, as well as a rough, sandblasted, and acid-etched (SLA) endosseous portion, all placed with their interface (microgap) 1 mm above the bone crest level and having abutments connected at the time of first-stage surgery. Implant types A, B, and C had a microgap of <10 µm, ~50 µm, or ~100 µm between implant components as did types D, E, and F, respectively. As a major difference, however, abutments and implants of types A, B, and C were laser-welded together, not allowing for any movements between components, as opposed to types D, E, and F, where abutments and implants were held together by abutment screws. Three months after implant placement, all animals were sacrificed. Non-decalcified histology was analyzed histometrically by evaluating peri-implant crestal bone changes.

Results: For implants in the laser-welded group (A, B, and C), mean crestal bone levels were located at a distance from the interface (IF; microgap) to the first bone-to-implant contact (fBIC) of 1.06 ± 0.46 mm (standard deviation) for type A, 1.28 ± 0.47 mm for type B, and 1.17 ± 0.51 mm for type C. All implants of the non-welded group (D, E, and F) had significantly increased amounts of crestal bone loss, with 1.72 ± 0.49 mm for type D (P <0.01 compared to type A), 1.71 ± 0.43 mm for type E (P <0.02 compared to type B), and 1.65 ± 0.37 mm for type F (P <0.01 compared to type C).

Conclusions: These findings demonstrate, as evaluated by non-decalcified histology under unloaded conditions in the canine mandible, that crestal bone changes around 2-piece, non-submerged titanium implants are significantly influenced by possible movements between implants and abutments, but not by the size of the microgap (interface). Thus, significant crestal bone loss occurs in 2-piece implant configurations even with the smallest-sized microgaps (<10 µm) in combination with possible movements between implant components. *J Periodontol 2001;72:1372-1383.*

KEY WORDS

Alveolar bone/anatomy and histology; animal studies; dental implants, endosseous/methods; tooth movement; titanium; dental implants/anatomy and histology; follow-up studies.

* Department of Periodontics, Dental School, University of Texas Health Science Center at San Antonio, TX.
† Department of Preventive Dentistry, Periodontics, and Cariology, University of Zürich Dental School, Zürich, Switzerland.
‡ Statistical/Mathematical Consulting, Computing Resources, University of Texas Health Science Center at San Antonio.
§ Department of Oral Surgery, University of Bern School of Dental Medicine, Bern, Switzerland.

Endosseous implants have been placed and followed in patients for a period of more than 30 years. Early on, the major focus in implant dentistry was the rehabilitation of edentulous patients by placing 4 to 6 implants in the interforaminal area of the lower jaw. Providing implant-borne restorations, using a full bridge[1] or a bar-borne overdenture design,[2] tremendously increased patient comfort by adding to stability, providing better function, and improving phonetics. Excellent long-term results could be accomplished (for review see reference 3) by either using a submerged[4] or non-submerged technique.[5-7] It has been shown that a distinct crestal bone loss of about 2 mm will occur with the submerged, 2-piece approach, dependent on the location of the interface (microgap).[8-12] Using a non-submerged, 1-piece implant design, however, minimal to no resorption can be found when placing a rough/smooth border clinically at the bone crest level.[9-16] In an attempt to reduce the number of surgeries necessary to place an implant and to try and prevent crestal bone loss, 2-piece implants have also been placed according to a non-submerged technique.[17-23] In all these clinical as well as experimental studies, however, similar crestal bone loss patterns occurred as compared to the traditional 2-piece, submerged approach.[8] These results reinforced the experimental finding that the existence of an interface (microgap) within soft or hard peri-implant tissues, independent of the surgical approach used, will result in a distinct degree of crestal bone loss.[17-23] This suggests that this phenomenon is related to a predictable biological principle.[9-11,24] One of the conclusions of this experimental study material was that in all 2-piece implant configurations, the degree of crestal bone loss was significantly dependent on the location of the interface (microgap) in relation to the crest of the bone. Thus, it could be shown that the most severe loss of crestal bone and the most severe degree of peri-implant inflammation occurred if the interface (microgap) was placed 1 mm below the crest. Less bone loss and inflammation were observed if the 2-piece implants were placed with their microgap (interface) exactly at the bone crest level, and the least bone resorption/peri-implant inflammation occurring if the microgap (interface) was located 1 mm above the crest. One potential factor which could account for the observed crestal bone loss around 2-piece implants could be the size of the interface (microgap) between the implant components. Another possible factor are movements between the implant and the abutment. Several in vitro studies have shown that the dimension of the size of the interface (microgap) at the level between implant and abutment can be ~100 µm,[25] ~50 µm,[26,27] or <10 µm.[28] However, no data are available where different-sized microgaps (interfaces) have been investigated in a side-by-side comparison for effects of crestal hard and soft tissue changes.

Therefore, the purpose of the present investigation was to evaluate crestal bone changes at the histological level around welded versus screw-retained 2-piece implant configurations with varying sized microgaps (interfaces).

MATERIALS AND METHODS

Implant Design and Surfaces

In this study, a full-body screw design was selected for 6 different cylindrical titanium implants (types A through F) made from cold-worked, grade IV commercially pure titanium‖ (Fig. 1). The total length of the implant, up to the level of the interface (microgap), was 7 mm; inner diameter = 3.5 mm; and outer diameter = 4.1 mm (thread tips). At the most coronal portion (the top 1 mm), the implants had a relatively smooth, machined suprabony titanium surface. The rough, endosseous apical part had a sandblasted (large-grit) and HCl/H_2SO_4 acid-etched surface (SLA). This surface had 2 levels of roughness, one at 20 to 40 µm peak to peak and a superimposed second level at 2 to 4 µm peak to peak. For type A, B, and C implants, 3 mm high abutments with a machined titanium surface were laser welded onto the implants with 4 small, 1 mm diameter spots (90° apart) prior to the experiment (Fig. 1). Therefore, movements were not possible; however, an interface (microgap) of <10 µm in size (type A), ~50 µm (type B), and ~100 µm (type C) was still present. Thus, implants of the laser-welded group were placed according to a non-submerged approach. Type D, E, and F implants were identical except that abutments were screwed onto the implants at the time of first-stage surgery resulting in a 2-piece, non-submerged approach. Thus, movements were possible between the 2 components (implants/abutments), with an interface (microgap) of <10 µm in size for type D implants, ~50 µm for type E, or ~100 µm for type F. Based upon results from another study (degree of crestal bone loss/peri-implant inflammation) by the same research team,[9-11,24] all implants in the present study were placed with their interface (microgap) 1 mm above the bone crest level and, consequently, the rough/smooth border was located at the level of the crest of the bone (Fig. 1).

Animals

This protocol was approved by the Institutional Animal Care and Use Committee of the University of Texas Health Science Center at San Antonio (UTHSCSA). Five lab-bred, male American hounds were used. At the beginning of the study, the dogs were approximately 2 years of age and had a body weight of about 30 to 35 kg each.

‖ Institut Straumann AG, Waldenburg, Switzerland.

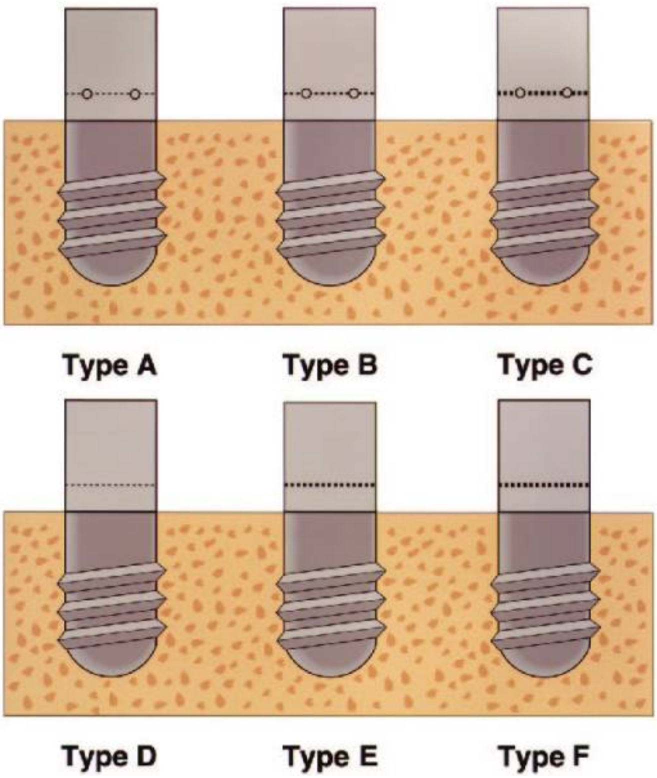

Figure 1.
Schematic (to scale) of implants type A through F at the time of implant placement in relation to the crest of the alveolar bone. The solid black line shows the border between the rough and smooth implant surface; dotted lines delineate the location of the interface (microgap). Small circles in types A, B, and C indicate where implants were laser welded to prevent movements between components. Microgap sizes: A and D, <10 µm; B and E, ~50 µm; C and F, ~100 µm.

Surgeries

Extraction. Extractions were carried out in an operating room under general anesthesia and sterile conditions utilizing 4% thiopenthal-Na solution I.V.¶ (0.4 ml/kg body weight) for premeditation purposes (Fig. 2). The dogs were placed on a heating pad, intubated, administered 1.5% to 2% isoflurane,# and monitored with an electrocardiogram during the surgery. The surgical site was first disinfected with 10% povidone-iodine solution/1% titratable iodine;** consequently, 2% lidocaine HCl with epinephrine 1:100,000 was given as local anesthetic,†† and all 4 mandibular premolars (P_1-P_4) and the first molar (M_1) were extracted bilaterally. Before extraction, all teeth had been scaled and cleaned, and P_2-M_1 was sectioned to help prevent tooth fracture. Finally, interrupted sutures were used allowing for an approximation of the wound margins.

At the day of surgery, the animals were given 20 mg of the analgesic nalbuphine s.c. b.i.d. (10 mg/ml).‡‡ In addition, the hounds received 3 ml of the antibiotic benzathine penicillin (150,000 I.U.) combined with procaine penicillin G (150,000 I.U.) s.c. s.i.d. every 48 hours for 7 to 10 days.§§ The animals were then briefly anesthetized with a combination (1.1 ml/15 kg body weight) of xylazine (7.1 mg/ml),‖‖ acepromazine (2.1 mg/ml),¶¶ atropine (0.1 mg/ml),## and ketamine (50.0 mg/ml) i.v.*** After anesthesia, sutures were removed following disinfection of the wound site with a 0.12% chlorhexidine digluconate-soaked gauze.†††

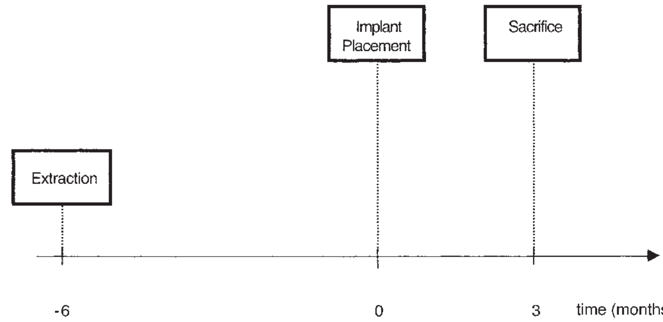

Figure 2.
Study design.

Implant placement. After a healing period of 6 months (Fig. 2), all implants were placed according to a non-submerged approach under the same surgical conditions as the tooth extractions (operating room, anesthesia, sterility). A crestal incision was performed to maximize keratinized tissue on each side of the incision. Consequently, mucoperiosteal flaps were reflected on the lingual and buccal aspect. Foramina mentalia were dissected and exposed. A Boley gauge was used to help distribute 6 test implants on each side of the mandible. Implant site preparations were carried out with torque reduction rotary instruments at 500 rpm using chilled saline. Starting with a stepdrill (diameter 10 mm) and a center bolt (inner implant diameter 3.5 mm), the edentulous osseous ridge was carefully flattened, combined with copious irrigation and chilled sterile physiologic saline.

The peri-implant crestal bone was carefully leveled at a 90° angulation to the future implant long axis in a circular area 3 mm outside the center implant osteotomy site. In addition, an O-ring (height 1.0 mm; diameter 10 mm) was used during implant placement to more precisely align the interface (microgap) for implant types A, B, and C or the top of implant types D, E, and F 1 mm above the peri-implant crestal bone level. Thus, the rough/smooth border clinically could

¶ Pentothal, Abbott Laboratories, North Chicago, IL.
\# Ærane, Ohmeda Carbide Inc., Liberty Corner, NJ.
** Clinidine, Clinipad Co., Guilford, CT.
†† Henry Schein Inc., Port Washington, NY.
‡‡ Nubain, Astra Pharmaceutical Products Inc., Westborough, MA.
§§ Pen-B, Pfizer Inc., Lee's Summit, MO.
‖‖ Miles Inc., Shawnee Mission, KS.
¶¶ Burns Veterinary Supply, Oakland, CA.
\## Burns Veterinary Supply, Rockville Center, NY.
*** Fort Dodge Laboratories Inc., Fort Dodge, IA.
††† Peridex, Procter & Gamble Co., Cincinnati, OH.

be placed at the bone crest level with high precision. Welded implants A, B, and C were inserted with abutments already being rigidly connected to the implant itself (Fig. 1), and non-welded implants and abutments (types D, E, and F) were screwed together at first-stage surgery (Fig. 1), resulting in a non-submerged approach for all implants placed. One of each test implant type was inserted per side in a randomized fashion so that no implant type had a biased position in the arch.

If indicated, periosteal relieving and contouring incisions were carried out on the buccal and lingual aspects of each implant to obtain tension-free adaptation of the wound margins for close adaptation of the gingiva to the transgingival portion of the implants. The animals received 20 mg of the analgesic nalbuphine s.c. b.i.d. (10 mg/ml) at the day of surgery. Three ml of the antibiotic benzathine penicillin (150,000 I.U.) with procaine penicillin G (150,000 I.U.) were given s.c. s.i.d. every 48 hours for 14 days. On day 1, 100 mg of the antibiotic gentamicin was given s.c. b.i.d., and the same amount s.i.d. from day 2 to 10 (50 mg/ml).[‡‡‡] Animals received 2 ml of the anti-inflammatory dexamethasone i.m. s.i.d. day 1 and day 4 (2 mg/ml).[§§§] Suture removal was performed after 7 to 10 days as described above. The dogs were fed a softened diet to minimize loading. Mechanical and chemical plaque control was carried out 3 times a week utilizing a soft toothbrush and a soft sponge in combination with a 0.2% chlorhexidine gel.[‖‖‖]

Follow-Up Period

Abutment loosening. To imitate clinically as well as biologically important and relevant steps[9-12,29] during implant treatment such as the placement of another cover screw/healing abutment and mounting of the impression cylinder, as well as the delivery of the temporary/final prosthetic component, abutments of the 2-piece implants (D, E, and F) were disconnected and immediately tightened afterwards at 4, 8, and 10 weeks after first-stage surgery.

Sacrifice. Three months after first-stage surgery, all animals were sacrificed (Fig. 2). Euthanasia was carried out with an overdose of pentobarbital sodium i.v. (0.2 ml = 65 mg/kg body weight).[¶¶¶] Block-resection of the mandibles was performed using an oscillating autopsy saw.[###] The recovered segments with the implants were immersed in a solution of 4% formaldehyde combined with 1% $CaCl_2$ for histologic preparation and analysis.[30]

Non-Decalcified Histologic Analysis

Preparation. Each implant with surrounding tissues was prepared for non-decalcified histology. Specimens were carefully dehydrated and embedded in methyl methacrylate. One well-centered mesio-distal section was cut with a diamond saw;[****] the 2 remaining blocks were then glued together with an interposed plastic spacer (cyanoacrylate)[††††] and subsequently sectioned in an orofacial direction. All sections were ground to a final thickness of approximately 80 µm and superficially stained with toluidine blue and basic fuchsin.

Histometry. Histometric quantification was carried out using a light microscope at different magnifications (×40 to ×200) to best locate anatomical reference points.[‡‡‡‡] The microscope was connected to a high-resolution video camera[§§§§] and interfaced to a monitor[‖‖‖‖] and personal computer.[¶¶¶¶] This optical system was associated with a digitizing pad and a bone histometry software package with image capturing capabilities.[####] Consequently, the distance between the interface (IF; microgap) and the first bone-to implant contact (fBIC) was measured at each implant site (Fig. 3).

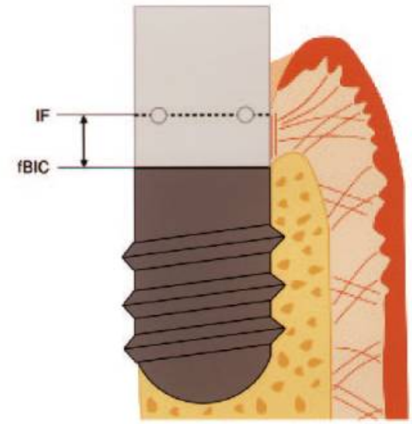

Figure 3.
Composite schematic (not to scale) showing histometric evaluation analyzing the distance between the interface (IF; microgap) to the first bone-to-implant contact (fBIC).

Statistical Analysis

To verify that the measurements of the distance from the interface to the first bone-to-implant contact (fBIC) obtained from the histologic sections were not subject to examiner bias, the primary examiner made a second set of observations for each site within one implant selected from each of the 6 implant types. Using this selection criterion, examiner verification was performed on 39 sites, 10.9% of the total number of sites with

‡‡‡ Gentocin, Schering-Plough Animal Health Corp., Kenilworth, NJ.
§§§ Dexaject, Burns Veterinary Supply, Oakland, CA.
‖‖‖ PlakOut Gel, Hawe-Neos AG, Bioggio, Switzerland.
¶¶¶ Euthanasia-5 Solution, Henry Schein Inc.
Stryker Co., Kalamazoo, MI.
**** Vari/Cut VC-50, Leco Corporation, St. Joseph, MI.
†††† Miocoll, Migros Company, Zürich, Switzerland.
‡‡‡‡ Vanox-T, Olympus, Tokyo, Japan.
§§§§ CCD-Iris Color Video Camera, Sony Corp., Fujisawa, Japan.
‖‖‖‖ Multisync XV17+, NEC, Itasca, IL.
¶¶¶¶ Vectra VL, Hewlett Packard, Palo Alto, CA.
Image-Pro Plus, Media Cybernetics, Silver Spring, MD.

observable fBICs. A secondary examiner also measured the same 39 sites, performing 2 independent sets of observations. For the primary examiner, the 2 readings differed by less than 0.10 mm for all 39 (100%) of the sites, and the maximum difference was 0.07 mm. For the second examiner, the 2 readings differed by less than 0.10 mm for 38 (97.4%) of the sites, and the maximum difference was 0.11 mm. When all 4 readings were collectively compared, 25 differed by less than 0.10 mm (64.1%) and 35 (89.7%) by less than 0.30 mm, and the maximum difference was 0.54 mm.

For the purposes of determining the effect of the size/stability of the microgap (interface), the principal measure of interest was the distance of the interface (IF; microgap) to the first bone-to-implant contact (fBIC). Each implant had 2 to 4 sections with 2 sites each for which histometric data were collected, resulting in a total of 444 sites. After excluding 86 (19.4%) of the sites for which the distance of IF:fBIC was unreadable, a mean value of IF:fBIC was calculated for each implant. The fBIC for buccal sites tended to be lower than that for lingual, mesial, or distal sites, regardless of implant type. In fact, the mean distance between the interface of the implant and the fBIC was significantly greater for buccal sites compared to the other 3 sites for all implants combined ($P<0.001$ for Bonferroni-adjusted paired Student t test). These differences were also seen histometrically, as buccal sites had distances that exceeded lingual sites by an average of 0.42 mm per implant and both mesial and distal sites by an average of 0.36 mm per implant. As a result, buccal sites were excluded from the analysis. The mean implant measures were then analyzed using a mixed-model analysis of variance (ANOVA) to determine if implant types differed in a consistent fashion for each dog. The mixed-model ANOVA tested the main effects of welded/non-welded and microgap (interface) size as well as the interaction between these 2 effects, with all results adjusted for any dog effect. If any of the F-tests were significant ($P<0.05$), then relevant pairwise comparison, using unpaired Student t tests adjusted for any dog effect, was performed to identify differences across all implant types.

RESULTS

Clinical Data

In this study, all 60 implants were successfully placed. Clinical stability was achieved and no complications occurred during healing or during the follow-up period. The same data set, based on monthly radiographic evaluations, demonstrated that no peri-implant radiolucencies were found around any of the implants (unpublished data). Thus, these implants achieved excellent hard tissue integration as assessed by clinical and radiographic means. Although both meticulous mechanical and chemical plaque control was carried out 3 times per week, different degrees of peri-implant inflammation could be detected. In general, type A through C implants (welded group) presented with no or minimal clinical signs of peri-implant inflammation (Fig. 4), whereas types D through F (non-welded group) exhibited moderate to severe degrees (Fig. 5).

Histometric and Statistical Data

Light microscopic evaluation of the bone-to-implant contact indicated that hard tissue integration of the implants was achieved as well (Figs. 6 through 11). In all implant types, intimate contact of bone was found directly adjacent to the sandblasted and acid-etched (SLA) surface. As expected, dense cortical bone had large areas of bone-to-implant contact compared to cancellous bone areas, where more marrow space was found.

Ten type A implants were analyzed measuring 37 implant sites (Table 1, Fig. 1). At the completion of the study, the mean distance from the interface (microgap) of the implant to the fBIC was 1.06 ± 0.46 mm (Table 1, Fig. 12). This indicated that the fBIC was found approximately at the rough/smooth border which had

Figure 4.
Clinical appearance of a type B implant (laser welded; interface/microgap ~50 μm) immediately before sacrifice. Peri-implant soft tissues show no detectable signs of inflammation (also see Figure 7). Four grooves on the top of the implant show the location of the laser-welded spots at the level of the interface (microgap) for alignment purposes during implant placement surgery (also see Figures 1, 3, and 12).

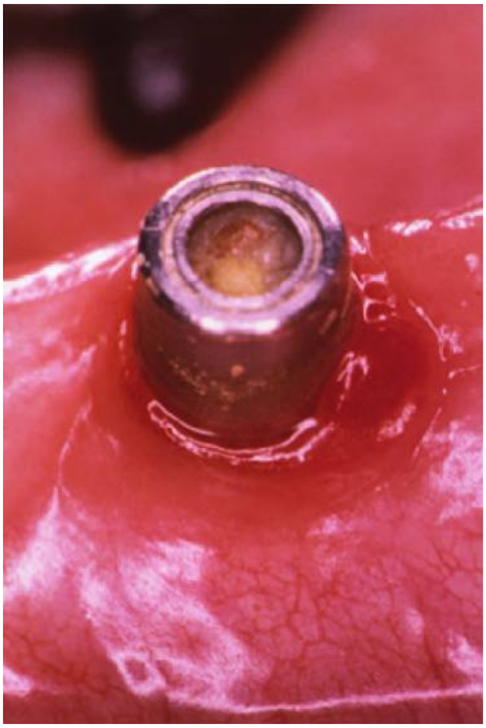

Figure 5.
Clinical appearance of a type E implant (2-piece implant; interface/microgap ~50 μm) immediately before sacrifice. Peri-implant soft tissues show minimal to moderate signs of inflammation (also see Figure 10).

been placed clinically as close to the alveolar crest as possible. Ten type B implants were measured evaluating 42 implant sites (Table 1, Fig. 1). At the end of the study, the mean distance from the IF to the fBIC was 1.28 ± 0.47 mm (Table 1, Fig. 12). This showed that also in this group, the fBIC was found approximately at the rough/smooth border. Ten type C implants were investigated at 43 implant sites (Table 1, Fig. 1). At the time of sacrifice, the mean distance from the IF to the fBIC was 1.17 ± 0.51 mm (Table 1, Fig. 12). These implants also had the fBIC close to the rough/smooth border.

Ten type D implants were studied evaluating 42 implant sites (Table 1, Fig. 1). At the completion of the study, the mean distance from the IF to the fBIC was 1.72 ± 0.49 mm (Table 1, Fig. 12). This showed that the fBIC was located significantly below the rough/smooth border. Ten type E implants were examined measuring 44 implant sites (Table 1, Fig. 1). The mean distance from the IF to the fBIC was 1.71 ± 0.43 mm (Table 1, Fig. 12). This revealed that the fBIC was located significantly below the rough/smooth border. Ten type F implants were investigated analyzing 32 implant sites (Table 1, Fig. 1). The mean distance from the IF to the fBIC was 1.65 ± 0.37 mm (Table 1, Fig. 12). This showed that the fBIC was found at a level significantly below the rough/smooth border.

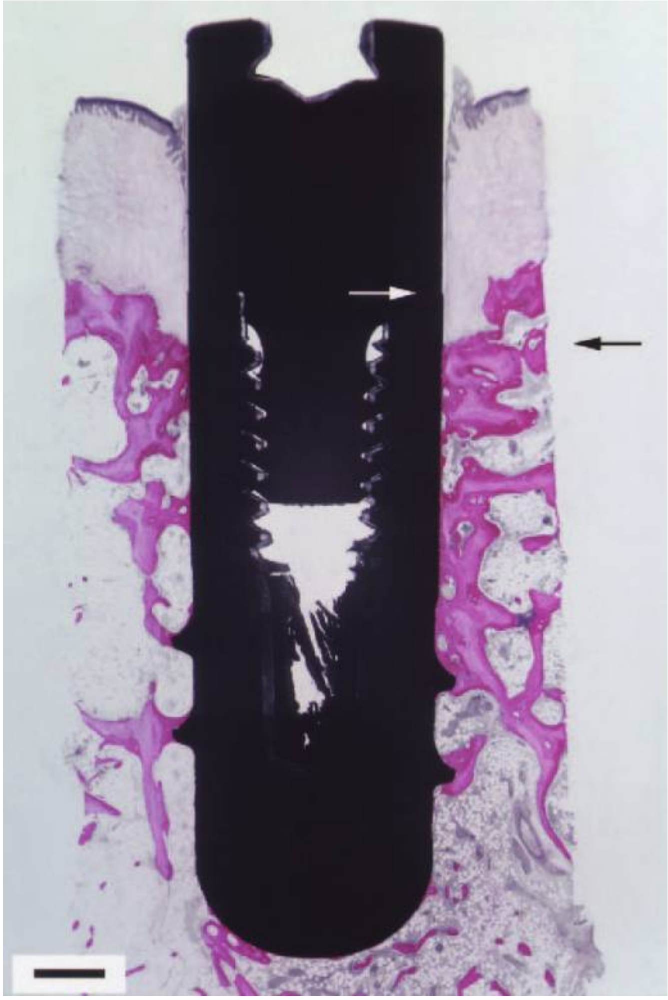

Figure 6.
Mesio-distal section of a type A implant/abutment (laser welded; interface/microgap <10 μm). White arrow shows the location of the interface (microgap); black arrow indicates the level of the first bone-to-implant contact (fBIC). (Non-decalcified histologic section; toluidine blue and basic fuchsin stain; original magnification × 2.5; original inner/outer implant diameter = 3.5 mm/4.1 mm; black bar = 1.0 mm).

The results of the mixed-model ANOVA indicated that the main effect of welded/non-welded was significant (P <0.001), while the main effect of microgap size (P >0.70) and the interaction between welded/non-welded and microgap size (P >0.50) were both non-significant, indicating that differences were observed only for welded versus non-welded regardless of microgap size. This result indicates that the combination of the welded implant types (A, B, and C) had a significantly shorter mean distance of IF to the fBIC as compared to the combination of the non-welded implant types (D, E, and F), revealing that the fBIC was located more apically in non-welded implants as compared to welded implants. When comparing welded versus non-welded implant types with corresponding microgap

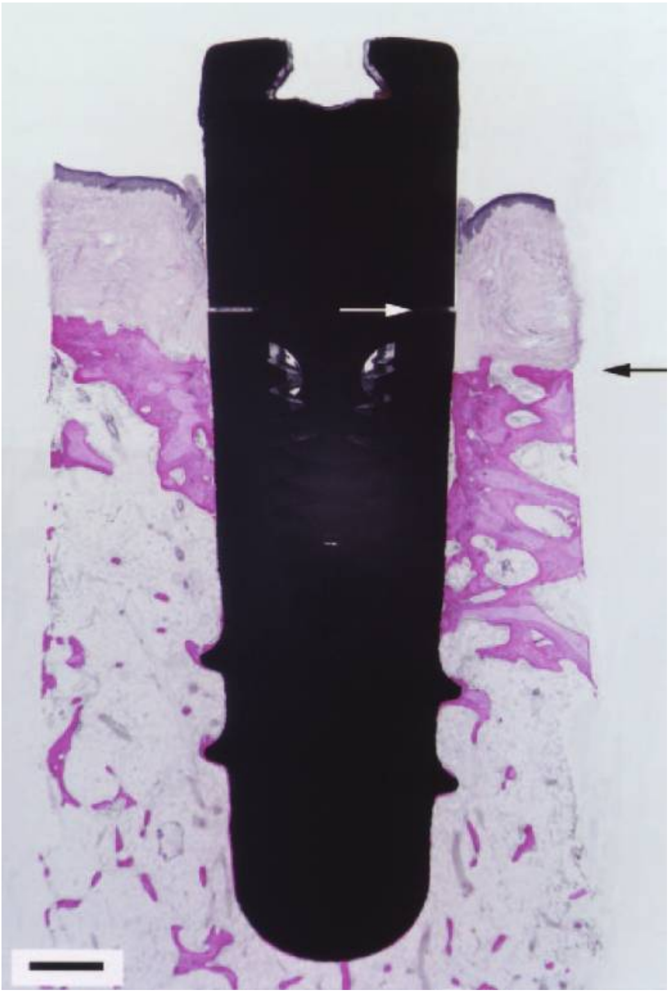

Figure 7.
Mesio-distal section of a type B implant/abutment (laser welded; interface/microgap ~50 μm). White arrow delineates the location of the interface (microgap); black arrow indicates the level of the first bone-to-implant contact (fBIC). (Non-decalcified histologic section; toluidine blue and basic fuchsin stain; original magnification ×2.5; original inner/outer implant diameter = 3.5 mm/4.1 mm; black bar = 1.0 mm).

Figure 8.
Mesio-distal section of a type C implant/abutment (laser welded; interface/microgap ~100 μm). White arrow shows the location of the interface (microgap); black arrow shows the level of the first bone-to-implant contact (fBIC). (Non-decalcified histologic section; toluidine blue and basic fuchsin stain; original magnification ×2.5; original inner/outer implant diameter = 3.5 mm/4.1 mm; black bar = 1.0 mm.)

sizes using unpaired Student *t* tests, the results corresponded to the F-tests from the mixed-model ANOVA, with type A significantly shorter than type D ($P<0.01$), type B shorter than type E ($P<0.02$), and type C shorter than type F ($P<0.01$).

DISCUSSION

In this study, welded and non-welded 2-piece implants with different microgaps (interfaces) were compared histometrically with one another in the canine mandible under unloaded conditions. The microgaps (interfaces) ranged from ~10 μm to ~100 μm, which have been shown to be clinically relevant.[25-28] All implants were placed according to a non-submerged approach with the interface (microgap) located 1 mm above the bone crest level. In the laser-welded group (types A, B, and C), all implants showed undetectable or minimal signs of crestal bone loss, while implants with non-welded abutments (types D, E, and F) exhibited significantly increased amounts of crestal bone resorption.

Implants were originally used predominantly in areas of no esthetic concern either using a fixed bridge[1] or a bar-borne overdenture[2] design. Encouraged by the significant success using such approaches and due to increased patient expectations, implants are now more frequently used in areas of esthetic concern and in the partially edentulous patient. In esthetic implant-borne restorations, crown margins are placed below the gingival margin. It has been suggested that implants be placed with their top (interface/microgap) a few millimeters below the bone crest level[31-34] to minimize

Figure 9.
Mesio-distal section of a type D implant/abutment (2-piece implant; interface/microgap <10 μm). White arrow represents the location of the microgap (interface); black arrow defines the level of the first bone-to-implant contact (f BIC). Note significantly increased dimension for crestal bone loss (cBL) in relation to the interface (microgap) as compared to type A implants (P <0.01; also see Table 1 and Figures 3 and 12). (Non-decalcified histologic section; toluidine blue and basic fuchsin stain; original magnification ×2.5; original inner/outer implant diameter = 3.5 mm/4.1 mm; black bar = 1.0 mm).

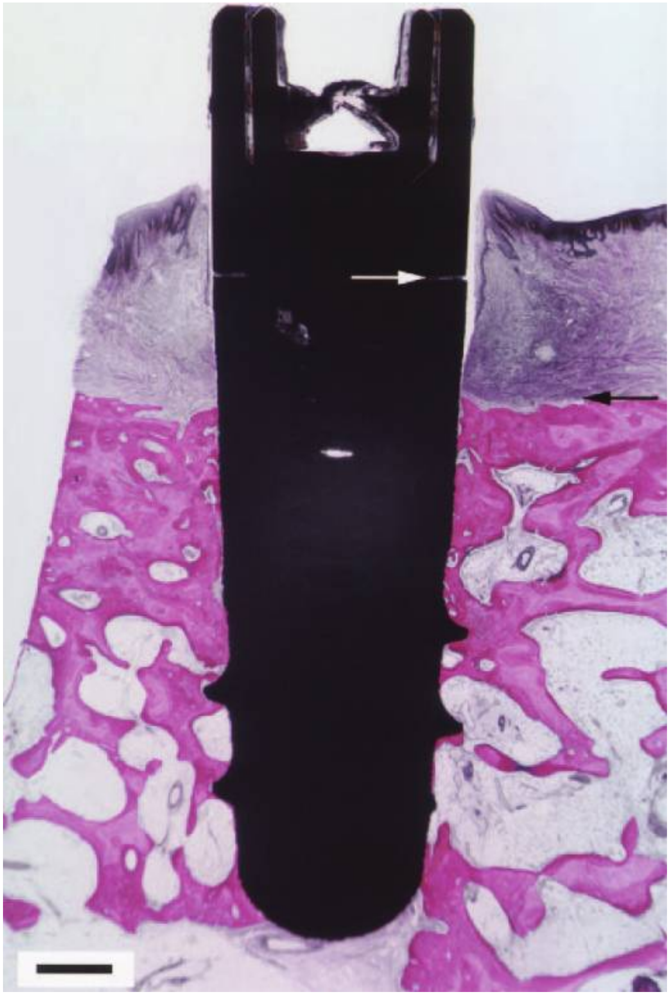

Figure 10.
Mesio-distal section of a type E implant/abutment (2-piece implant; interface/microgap ~50 μm). White arrow depicts the location of the interface (microgap); black arrow is located at the level of the first bone-to-implant contact (fBIC). Note significantly enhanced dimension for crestal bone loss (cBL) in relation to the interface (microgap) in comparison with type B implants (P <0.05; also see Table 1 and Figures 3 and 12). (Non-decalcified histologic section; toluidine blue and basic fuchsin stain; original magnification ×2.5; original inner/outer implant diameter = 3.5 mm/4.1 mm; black bar = 1.0 mm).

the risk of metal exposure of the top of the implant (interface/microgap) or the abutment and to allow for enough space in a vertical dimension to develop a harmonious emergence profile.

Recent data from experimental studies have shown, however, that such placement resulted in a severe degree of crestal bone loss[9,10,12] as well as significant peri-implant inflammation,[11,24] as compared to locating an interface (microgap) at or 1 mm above the bone crest level or when no microgap (interface) existed,[14,16] with the latter scenario exhibiting no crestal bone loss or peri-implant clinical inflammation. Based upon the same data set,[11] as well as another experimental study,[29] it was also shown that the gingival margin of the soft tissues, as well as the crestal bone levels, significantly migrated in an apical direction. These findings support the principle of the biologic width as it has been described both around natural teeth[35,36] and endosseous 1- and 2-piece titanium implants.[14,16,29]

These data taken together suggest that implants, when placed in an area where crestal bone loss is to be minimized (low residual bone height below the sinus or above the mandibular canal), should either be of a 1-piece design or have its microgap (interface) 1 to 2 mm coronal to the alveolar crest. Placing an implant

Figure 11.
Mesio-distal section of a type F implant/abutment (2-piece implant; interface/microgap ~100 μm). White arrow displays the location of the interface (microgap); black arrow shows the level of the first bone-to-implant contact (fBIC). Note significantly magnified dimension for crestal bone loss (cBL) in relation to the interface (microgap) as related to type C implants (P <0.03; also see Table 1 and Figures 3 and 12). (Non-decalcified histologic section; toluidine blue and basic fuchsin stain; original magnification ×2.5; original inner/outer implant diameter = 3.5 mm/4.1 mm; black bar = 1.0 mm).

with its microgap (interface) 1 mm above the bone crest level in one study, however, still caused significant crestal bone loss.[9-12] One hypothesis to explain crestal bone loss could be possible movements between components, i.e., the implant and the abutment. Furthermore, the bone loss could also be dependent on the size of the microgap (interface). Therefore, 3 clinically relevant-sized microgaps (interfaces) were chosen in the present study, attempting to determine if a threshold value occurs whereby crestal bone loss would not occur. The results of implants in groups D, E, and F showed, however, that this could not be achieved even with the smallest-sized microgap (interface) tested. The results of the 2-way ANOVA showed that there was no significant difference in the amount of crestal bone loss that could be attributed to the size of the microgap (interface). A significant difference (P <0.001) in the amount of crestal bone loss was found in non-welded 2-piece implants as compared to welded implants. This same trend occurred when comparing implants with corresponding microgap (interface) sizes. All 6 implant types were identical, except that laser welding prevented possible movements of the implant/abutment interface (microgap) for types A, B, and C. Interestingly, no crestal bone loss occurred beyond the rough/smooth border in this implant group. These findings support earlier studies where the rough/smooth implant border defined the level of the first bone-to-implant contact.[9-16]

Some contradictory reports can be found in the literature regarding the amount of crestal bone loss and, consequently, the extent of apical migration of the gingival margin in 2-piece implant configurations.[9-12,29,37-39] Some of these studies stated that crestal bone loss patterns and, consequently, the location of the gingival margin are more or less identical using either 1-piece or 2-piece implant configurations.[37-39] However, in these experiments, abutments were never loosened which is an important and relevant procedure that imitates the exchange of the cover screw/healing abutment, mounting of the impression cylinder, and placement of the temporary/final restoration which occur in actual clinical situations. In a study by the same authors, using the same animal model, however, significant crestal bone loss combined with an apical migration of the gingival margin did occur once abutments had been loosened during the course of the study.[29] The data in the present study reinforce these findings and suggest, even in the case of very small interfaces (microgaps), that movement between the implant components can result in significant crestal bone loss. Thus, it is evident that loosening of the abutments (causing movement between components) is a crucial step when evaluating peri-implant crestal bone as well as gingival margin levels in experimental studies.

It is interesting to compare results from this current study addressing microgap sizes (implant types identified below in *italics*) with earlier work by the same research team which addressed the impact and the location of the microgap[9-12] (implant types in **bold face**). A conclusion from these location studies showed that the rough/smooth border defines the level of the first bone-to-implant contact (fBIC) for 1-piece, non-submerged implants **(types A and B)**. However, when examining 2-piece implants, whether placed according to a submerged **(types D through F)** or a non-submerged approach **(type C)**, about 1.5 to 2.0 mm of crestal bone loss occurred, depending on the location of the microgap (interface) in relation to the crest

Table 1.

Histometric Data for Implant Groups A-C (Welded Group) in Comparison to Groups D-F (Non-Welded Group) at Time of Sacrifice (mean values ± SD, mm; $[n_i]$ = N measured implants; $[n_{is}]$ = N measured implant sites)

Variables	Group A	$[n_i]$	$[n_{is}]$	Group B	$[n_i]$	$[n_{is}]$	Group C	$[n_i]$	$[n_{is}]$
IF : fBIC	1.06 ± 0.46	[10]	{37} *	1.28 ± 0.47	[10]	{42} †	1.17 ± 0.51	[10]	{43} ‡
	Group D	$[n_i]$	$[n_{is}]$	Group E	$[n_i]$	$[n_{is}]$	Group F	$[n_i]$	$[n_{is}]$
IF : fBIC	1.72 ± 0.49	[10]	{42}	1.71 ± 0.43	[10]	{44}	1.65 ± 0.37	[10]	{32}

* $P<0.01$.
† $P<0.02$.
‡ $P<0.01$.

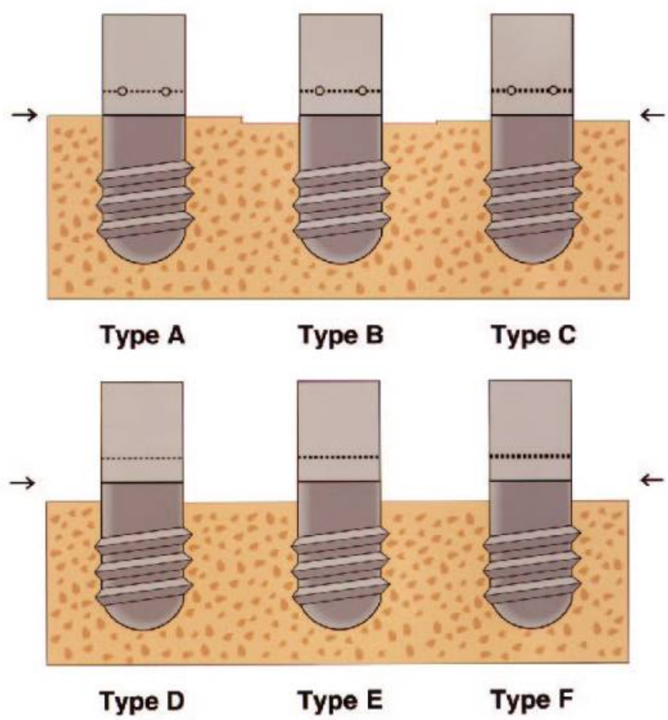

Figure 12.
In all laser-welded implants (types A, B, and C) the first bone-to-implant contact (fBIC) remodeled to about the level of the rough/smooth border irrespective of the appropriate size of the interface (microgap; also see Table 1). In all 2-piece implants (types D, E, and F), the first bone-to-implant contact (fBIC) remodeled beyond the level of the rough/smooth border irrespective of the distinct size of the interface (microgap; also see Table 1). Arrows depict the level of the crest of the bone at the time of implant placement.

of the bone. **Type F** implants were placed with their microgap (interface) 1 mm below the bone crest level, with the rough/smooth border 0.5 mm below the microgap (interface). Nevertheless, crestal bone levels remodeled significantly beyond the rough/smooth border, indicating that the influence of the microgap (interface) in this situation was greater when compared to that of the rough/smooth border. For **type E** implants (2-piece, submerged), crestal bone levels remodeled to the level of the rough/smooth border, which was about 2.5 mm away from the microgap (interface). The microgap (interface) in this case was located 1 mm above the crest at the time of implant placement. In this scenario, the effect of the rough/smooth border was greater than that of the microgap (interface). These findings may indicate that there could be a threshold value, between 1.5 to 2.0 mm at a distance from the microgap (interface), where these 2 effects become greater one than the other and vice versa. In other words, if the rough/smooth border is greater than 1.5 to 2.0 mm from the microgap (interface), the influence of the rough/smooth border may become greater. If the distance of the rough/smooth border to the microgap (interface) is less than 1.5 to 2.0 mm, however, a distinct degree of crestal bone loss will occur independent of the existence of the rough/smooth border. In *type E* implants of the present study, the size of the microgap (interface) was identical to **type E** implants of the other studies with a dimension of about 50 µm, also placed in a 2-piece implant/abutment configuration. Both type E implants were placed with their microgap (interface) 1 mm above the bone crest level. The only difference between the 2 type E implants was the level of the rough/smooth border in relation to the location of the microgap (interface) and the crestal bone. In the present study, where the rough/smooth border was located at the alveolar crest, less crestal bone loss occurred for *type E* implants compared to the situation of **type E** implants where the rough/smooth border was located 1 mm below the crestal bone level, which would support the above-mentioned assumption.

In conclusion, 6 different welded (types A, B, and C) and non-welded (types D, E, and F) 2-piece implant designs with different sized microgaps were investigated in this study in the canine mandible in a side-by-side comparison. The results demonstrate that significantly increased amounts of crestal bone loss occurred for all non-welded 2-piece implant configurations, which were independent of the size of the microgap (interface). This suggests that even with the most precise fit between implant components (<10 μm), crestal bone loss cannot be prevented in 2-piece implant configurations in combination with possible movements between the implant and the abutment.

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Send reprint requests to: Dr. David L. Cochran, University of Texas Health Science Center at San Antonio Dental School, Department of Periodontics, 7703 Floyd Curl Dr., San Antonio, TX 78284-7894. Fax: 210/567-3643; e-mail: cochran@uthscsa.edu.

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