

Human Histologic Evaluations of Implants with a Unique Triangular Neck Design



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The goal of the present study was to evaluate human histologic healing of dental implants with a unique triangular neck design that is narrower than the implant body. Four patients in need of full-mouth reconstruction were recruited and received several implants to support a full-arch prosthesis. In each patient, two additional customized reduced-diameter implants were placed, designated to be harvested after 6 months of submerged healing. The eight harvested implants were all placed in healed edentulous maxillary or mandibular ridges. These implants were $\text{Ø } 3.5 \times 8 \text{ mm}$ in size, and the final osteotomy drill allowed for the creation of a gap up to 0.2 mm in size between the coronal aspect of the triangular implant neck and the surrounding bone. At the end of the healing period, the implants were retrieved with the surrounding bone. Microcomputed tomography (μCT) was performed before processing the biopsy samples for undecalcified histologic examination. Bone-to-implant contact (BIC) was measured from the μCT data and from buccolingual/buccopalatal and mesiodistal central histologic sections. All implant gaps were filled by mature remodeled bone. The mean BICs of the BL/BP and MD sections were $64.45\% \pm 6.86\%$ and $65.39\% \pm 10.44\%$, respectively, with no statistically significant difference. The mean 360-degree 3D BIC measured all over the implant surface was $68.58\% \pm 3.76\%$. The difference between the BIC measured on the μCT and on the histologic sections was not statistically significant. The positive histologic results of the study confirmed the efficacy of this uniquely designed dental implant. *Int J Periodontics Restorative Dent* 2020;40:657–664. doi: 10.11607/prd.4982

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Presently, implant therapy is commonly preferred over alternative removable and fixed prosthetic options because dental implant-supported restorations offer a satisfactory solution to achieve functional mastication, esthetics, and phonetics. The implant industry continues to reevaluate and advance the macro- and microdesign features in the quest to enhance osseointegration as well as hard and soft tissue harmony and stability. Diverse considerations have been given for the implant collar design to minimize crestal bone loss and to optimize the overlying soft tissue profile.¹ Several modifications have been introduced, from smooth to rough surfaces, microthreads to laser microtexturing, and macrogeometric changes such as tapering and scalloping of the implant neck.²

Most dental implants have a cylindrical collar where the diameter of the neck portion is typically analogous to that of the implant body. Recently, this common implant design has been challenged by an innovative modification conceived by a dental implant company (V3, MIS Implants Technologies). The coronal part of the implant has a triangular neck design with three flat areas. When seated at the crestal bone level, the flat areas of the triangular shape do not come in contact with the cortical bone, but instead leave

a gap between the implant neck and the surrounding bone. The diameter of the V3 implant system varies from 3.3 to 5.0 mm; accordingly, 27% to 29% of the implant collar perimeter contacts the adjacent supporting bone, leaving a 0.1- to 0.5-mm gap space. The rationale behind this design is to reduce the stresses and strains exerted at the bone crest during insertion, thus preventing marginal bone resorption.³⁻⁶ These gaps serve as a reservoir for blood pooling and formation of blood clots to facilitate natural bone growth. At implant placement, these spaces provide additional room for new bone formation; this is particularly advantageous when one of the gaps is located in buccal position.

Human histologic studies of immediate implants showed that when the gap was 2 mm or less, the degree of bone-to-implant contact (BIC) was comparable to that of conventional implants without the use of a barrier membrane or grafting materials.^{7,8} However, no human histologic data on delayed implant placement with intentionally created gaps are available. Human histologic evidence of successfully osseointegrated implants is extremely rare in the literature because there are not many opportunities to retrieve them in humans.^{9,10} The present research strategy provided an opportunity for individuals requiring dental implants who otherwise could not afford the ideal treatment: The study participants received all dental treatments at no cost in exchange for retrieval of two customized dental implants, either in the

maxilla or mandible. The retrieval of histologic samples from successfully osseointegrated implants is an accurate, irrefutable, and confirmatory methodology that generates valuable knowledge regarding BIC and thus the predictability of the product.⁹

In addition to histologic assessments, microcomputed tomography (μ CT) is a nondestructive technique that provides 3D evaluation of bone quantification, structure, and mineralization around an implant. BIC assessment aided by μ CT can provide a good correlation with values obtained from light microscopic histology.¹¹

The objective of this study was to provide a short-term observation of the unique triangular-neck dental implants placed into localized or completely edentulous healed alveolar ridges in humans. The goal was to evaluate the BIC of implants placed in humans and verify the natural bone filling of the gaps created at the coronal aspect in order to demonstrate the safety and efficacy of the implant design.

Materials and Methods

Implant Surgery

Four patients were enrolled and signed an informed consent form based on the Helsinki Declaration of 1975, as revised in 2000. Pre- and postsurgical clinical examinations were performed in concert with an evaluation of oral hygiene during each patient visit. All implant surgeries were performed as suggested

by the manufacturer (MIS Implants Technologies) under local anesthesia in sterile conditions. The implants to be restored were standard 3.75- and 4.2-mm-diameter implants that ranged from 8 to 13 mm in length (C1, MIS Implants Technologies). The implants designated for biopsy samples were customized 3.5 \times 8-mm V3 implants with a triangular neck that allowed for a 0.2-mm gap between the implant flat surfaces and the surrounding bone in three areas (Fig 1). Four study implants were placed in the mandible and four in the maxilla (Fig 2). All implants were allowed to heal under soft tissues.

Second-Stage Surgery and Biopsy

The second-stage procedure was performed 6 months after initial implant placement (Fig 3). All procedures performed were routine, with the exception of an en bloc removal of two study implants from each patient. The biopsy sample sites were reconstructed with bone replacement grafts and resorbable collagen membranes. The harvested implants were immediately immersed in a fixative solution.

μ CT Analysis

Prior to undergoing the histologic process, the fixed biopsy samples were scanned using a high μ CT system (SkyScan 1276, Bruker) in which the sample remains immobile while the radiation source and the de-

Fig 1 Customized V3 implant. (a) The triangular-neck implant had a dimension of 3.5×8 mm. (b) Determining the bony voids surrounding the implants using the shape of the final drill (blue) and the placement of the V3 implant (yellow). The gap between the external diameter of the final drill and the flat surface of the neck is up to 0.2 mm.

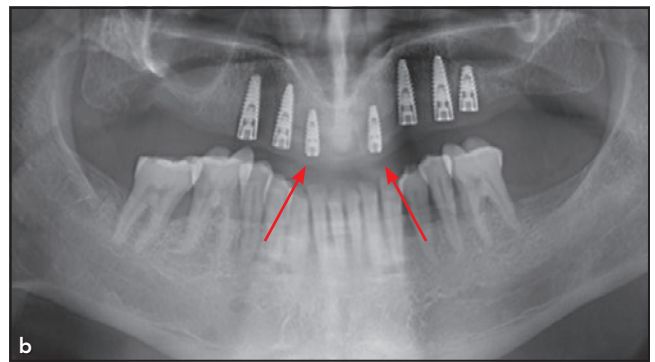
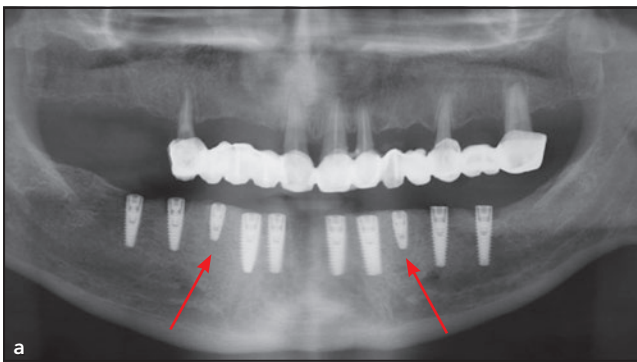
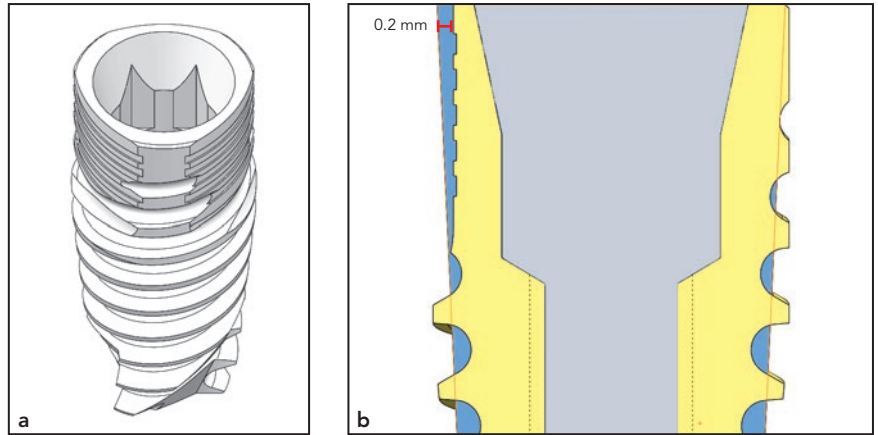


Fig 2 Placement of the standard (C1) and biopsy sample implants (V3). (a) Placement of the sample implants in the mandibular left and right premolar regions (arrows). (b) Placement of the sample implants in the maxillary anterior region (arrows). (c) Sample implant in the maxilla. Note the pooling of blood around the implant collar due to intentionally creating a gap between the implant surface and the osteotomy site.

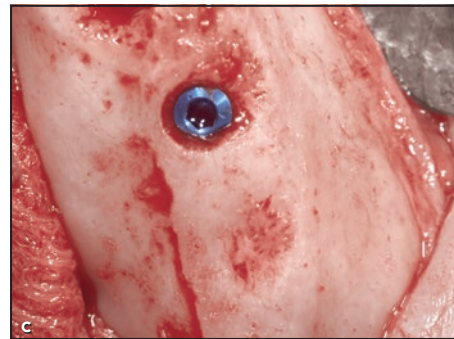
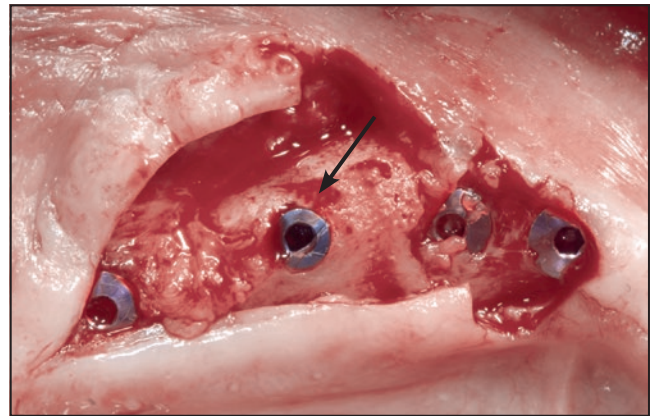


Fig 3 Second-stage implant surgery. Note the three standard C1 implants with purple cover screws and the V3 biopsy sample implant (arrow) with the blue cover screw.



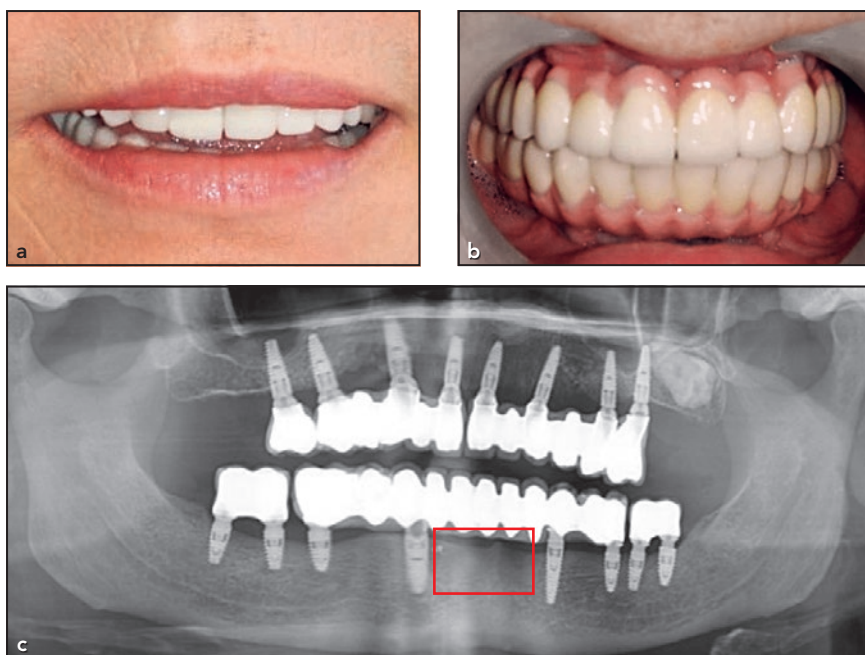


Fig 4 Follow-up at 6 months after prosthetic loading. (a and b) Clinical healing was uneventful following reconstruction, and successful prosthetic reconstruction of the maxilla and mandible is been demonstrated. The patient was satisfied with the esthetic result. (c) Radiographic view after full-mouth rehabilitation with dental implants. The red box indicates the successfully reconstructed area where two sample implants were harvested 6 months prior.

tectors rotate around it. A special sample holder was designed in order to maintain the long axis of the implants perpendicular to the x-ray source. Scan parameters were the following: 80-kV x-ray source voltage combined with an Al/Cu filter, 65- μ A source current, 2,700-ms exposure time/projection, acquiring 2 projections/position, and voxel size of 12 μ m. The scanning was performed over a 360-degree rotation acquiring images every 0.25 degrees. The images were reconstructed using the NRecon software (Bruker) and evaluated with the DataViewer software (Bruker). The reconstructed images were analyzed with the CTAn software (Bruker) using adaptive local threshold methods and setting the best threshold

parameters for the analysis. According to the bone structure at the bone-implant interface, a threshold of 29 or 34 was selected. The volume of interest (VOI) was set at 5 pixels around the implant surface, and the BIC was measured using the method described by the Bruker Academy method note of 2015 (manual).

Histologic and Histomorphometric Analyses

After μ CT analysis, the harvested implants with the surrounding hard tissue were dehydrated in a graded series of ethanol solutions and embedded in a light-curing resin (Technovit 7200 VLC; Heraeus Kul-

zer). The polymerized blocks were first sectioned along the long axis of each implant to obtain a central buccolingual (mandible) or buccopalatal (maxilla) (BL/BP) section and then remounted; mesiodistal sections were prepared afterwards. The sections were then thinned down to approximately 50 microns and stained following the Lévai-Laczkó method.¹² Images were captured using a motorized light microscope and a digital camera connected to a PC-based image capture system (BX51 and DP71 configuration, Olympus). Histomorphometric measurements were performed using an image-analysis program (cellSens Dimension, Olympus) to calculate the percentage of mineralized bone along the BIC surface.

Results

Clinical Observations

All implants were successfully placed and achieved clinical osseointegration with no signs of adverse events. Twenty-eight C1 implants placed in four patients were restored, and the biopsy sample sites were reconstructed (Fig 4). At the end of the treatment (after restoration of the implants), all patients verbally expressed improved esthetics and masticatory function.

μ CT Observations and 3D BIC Analysis

The μ CT provided simultaneous images of the sagittal, transverse, and

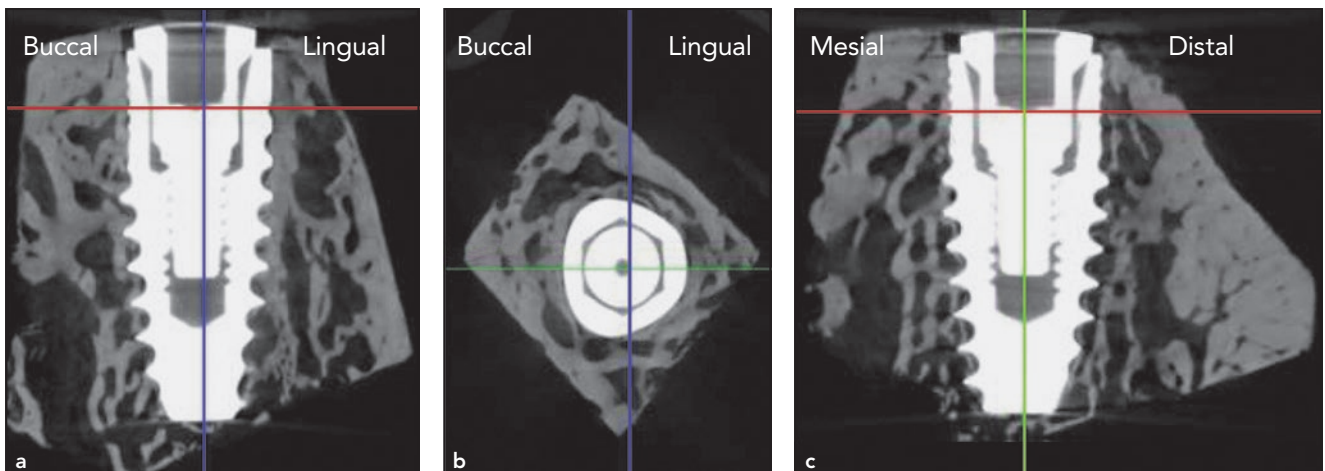


Fig 5 The (a) sagittal, (b) axial, and (c) frontal μ CT sections from a biopsy sample implant placed in the mandible. Note the bone apposition on the implant surface and the crestal bone level over the implant platform. The red lines in the sagittal and frontal views show the level of the axial section. (a) The axial view taken at the neck level shows close bone apposition at all three flat surfaces. (b) The sagittal section corresponds to the plan defined by the axial section's green line. (c) The frontal section corresponds to the plane defined by the axial section's blue line that intercepts two flat sides of the neck.

axial planes (Fig 5). In all cases, the gap left behind by the final drill was filled with bone (Fig 5). The mean 3D BIC was $70.31\% \pm 2.80\%$ for the maxillary implants and $66.84\% \pm 3.80\%$ for the mandibular implants, with no statistically significant difference ($P = .24$).

Histologic Observations and Histomorphometric Analysis

All gaps facing the flat surfaces of the triangular neck were filled by newly formed dense bone with marrow spaces and blood vessels that came into close contact with the implant surface (Figs 6 and 7). The mean BIC for all eight V3 implants was $65.06\% \pm 8.85\%$. In the maxilla, the mean BIC calculated for BL/BP and mesiodistal sections were $64.20\% \pm 9.62\%$ and $65.66\% \pm 12.25\%$, respectively ($P = .88$). The mean BIC for maxillary implants was $64.93\% \pm 12.03\%$. In the mandible,

the mean BIC calculated from buccolingual and mesiodistal sections were $64.70\% \pm 1.17\%$ and $65.68\% \pm 8.23\%$, respectively ($P = .85$). The mean BIC for mandibular implants was $65.19\% \pm 8.04\%$. There was no significant difference between the mean BICs of the mandibular and maxillary implants ($P = .95$).

Discussion

The special feature of the implant design investigated in this study is its unique triangular geometry at the neck region. The three flat surfaces of the triangular shape do not come in contact with the surrounding bone, and the final drill leaves a gap up to 0.2 mm wide (Figs 1b and 2c). This feature aims to reduce stress at the crestal bone level that might induce micro-cracks in the cortical bone⁴ and additional marginal bone loss.⁵ This confined space allows pooling of blood, and

bone apposition is better fostered when compared to the parts of the implant neck that come in direct contact with the implant surface.^{13,14}

A randomized controlled clinical trial¹⁵ showed that, while engaging only 29% of the circumference of the implant osteotomy at the bone crest, the implant was able to achieve a high primary stability in the posterior maxilla, with 45 Ncm as median insertion torque and 68.4 as mean ISQ value, which is compatible with immediate loading.

The exact time frame it takes to completely fill these three gaps needs further investigation. In a canine model, Sanz-Martín et al showed that after 4 weeks most gaps were filled by immature cortical bone, and by 12 weeks all gaps were completely closed with remodeled bone.¹⁶ The present study showed that all gaps in the maxilla and mandible were filled by 6 months, but these spaces were probably already fully occupied by

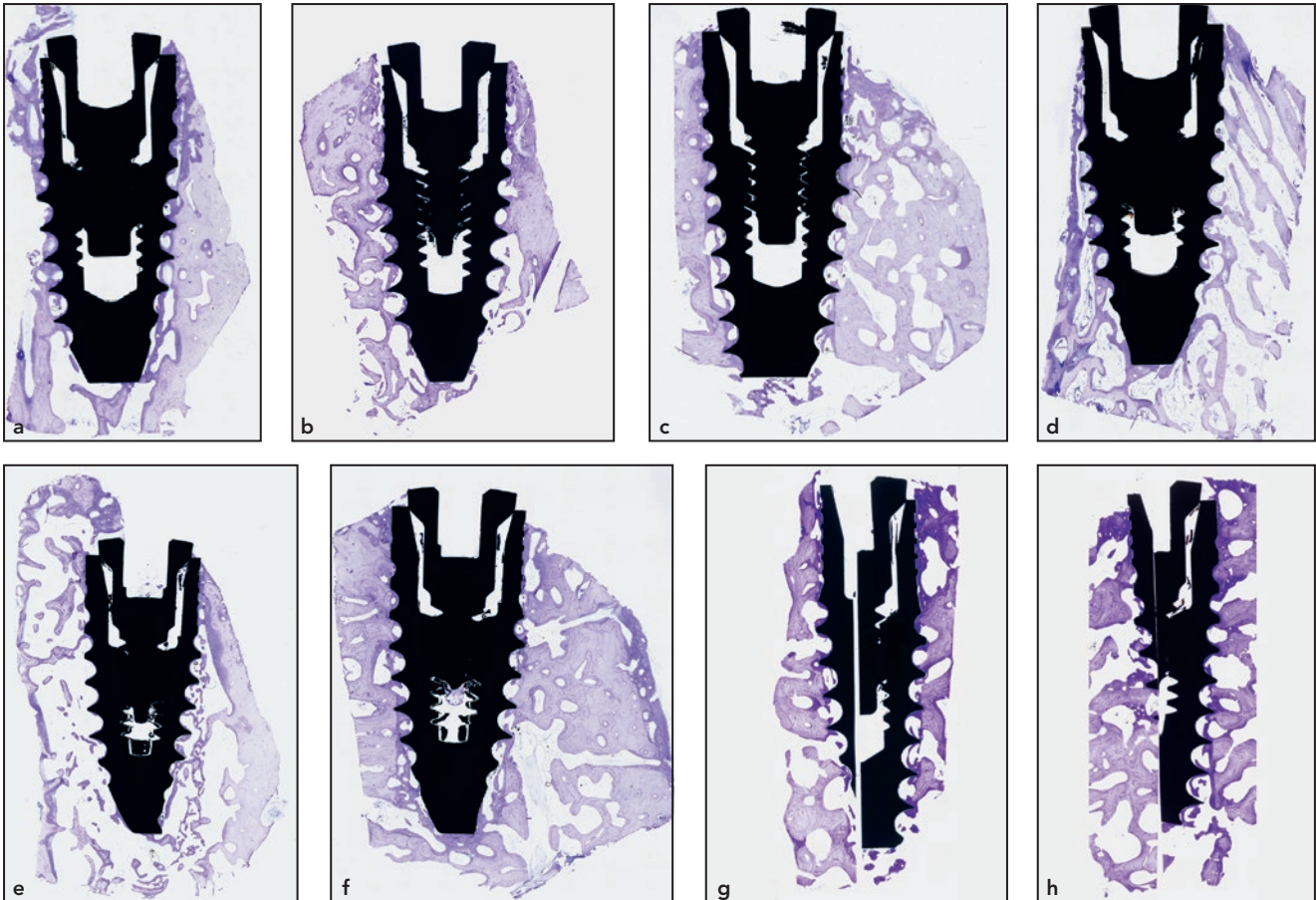


Fig 6 Examples of (a to f) buccolingual/buccopalatal and (g and h) mesiodistal histologic sections from the biopsy sample implants. All specimens demonstrated significant BIC. Newly formed bone was found in contact with the implant surfaces, with normal bone marrow spaces and blood vessels. The crestal bone level exceeded the first thread on most specimens.

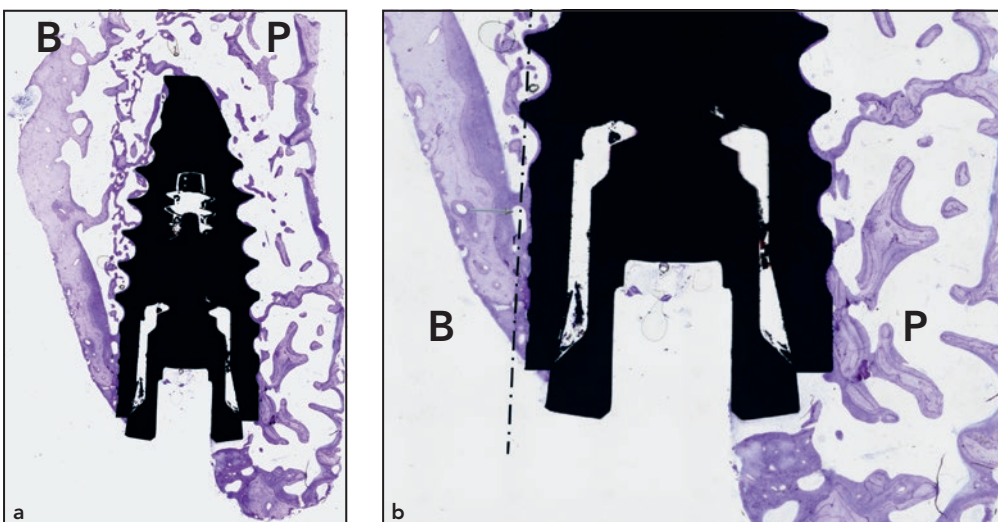


Fig 7 Histologic sections from a biopsy sample implant placed in the maxilla. (a) General view of the buccolingual/buccopalatal with the flat surface on the buccal side. Note that the implant was placed in very poor-quality type IV bone. (b) Magnification of the coronal aspect, showing that the gap was filled by remodeled bone. The line on the buccal side shows the amplitude of the gap created by the final drill. B = buccal side; P = palatal side.

bone at an earlier time, potentially 45 days (as suggested by Eshkol-Yogev et al¹⁵).

The BIC observed histologically in humans in the present study further supported the implant's efficacy. Indeed, the average BIC (65.06% \pm 8.85%) observed was quite remarkable, considering that the reported BIC for unloaded implants in other studies had an average of 54.07% \pm 23.20%.^{17,18} Interestingly, the BIC between maxillary and mandibular implants did not have a significant difference in the present study, which indicated the clinical efficacy of this implant across bone types II to IV. Furthermore, in most of the specimen, the BIC extended coronally to the implant neck. Standard 2D histomorphometry measurements performed under light microscopy are usually limited to one histologic slice per implant, mostly a central one in the BL/BP direction; subsequently, they provide only a partial assessment of the overall bone apposition on an implant surface. To get a better appreciation of the osseointegration of the study implants and, more specifically, of the flat surfaces of the triangular neck, mesiodistal sections were added as well as a 3D, 360-degree BIC analysis obtained by μ CT. The BICs of the BL/BP and mesiodistal sections were not statistically different. In addition, the mean 3D BICs for the maxillary and mandibular implants (70.31% \pm 2.80% and 66.84% \pm 3.80%, respectively) were similar to those obtained with histology (64.93% \pm 12.03% and 65.19% \pm 8.04%, respectively), with no statistical significance ($P = .45$ for

maxilla; $P = .62$ for mandible). These results corroborated with previously published studies by other research groups.^{13,19} However, it must be noted that 3D BIC calculated by μ CT can differ significantly depending on settings used during image retrieval and the parameters set for morphometric analysis. In the present study, thresholds of 29 and 34 and a VOI of 5 pixels were employed for the maxillary and mandibular samples.

There are two major limitations in the present study. First, the small sample size ($n = 8$) did not allow for a proper comparison between histologic and μ CT analysis. Second, all implants were placed according to a submerged protocol, and the biopsy specimens were not prosthetically loaded. Nevertheless, taken together with the successful restorative outcome of the V3 implant,²⁰ the evidence provided by this histologic study empowers surgeons' optimistic clinical decision to use triangular-necked implants (as opposed to regular-neck implants) when questioned by the patient.

Conclusions

The results of this human histologic investigation confirm the osseointegration of the unique titanium implants with a triangular-shaped neck in patients. All specimens demonstrated robust BIC. Despite the initial gap between the osteotomy and the implant surface at the coronal portion, bone apposition was observed all around the implant neck.

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