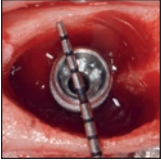


Evaluation of an Innovative Hybrid Macrogeometry Dental Implant in Immediate Extraction Sockets: A Histomorphometric Pilot Study in Foxhound Dogs



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A preclinical pilot study was performed to evaluate the safety, efficacy, primary stability, and wound healing of a hybrid dental implant with a unique macrogeometry design in which the coronal section is narrower and cylinder-shaped followed by a wider, tapered apical portion, each comprising approximately one half the length of the implant. Eighteen hybrid macrogeometry-designed dental implants were placed bilaterally into three foxhounds in the mandibular third and fourth premolar and first molar (P3, P4, and M1, respectively) extraction sockets of different dimensions immediately following full periosteal flap elevation and removal of teeth without socket grafting. Bone plate thickness, implant position and depth, gap distance, and insertion torque values were measured following implant installation. Surgical sites were healed uneventfully for 3 months, and then samples of soft and hard tissues surrounding the implants were retrieved to perform light microscopic and histomorphometric analyses. All 18 implants were stable and osseointegrated both clinically and radiographically. The analyses revealed that the amount of hard tissue alteration and bone fill that occurred during the healing period was significantly influenced by the thickness of the bone plate, the size of the horizontal buccal gap, and the implant diameter, position, and depth within the extraction socket. The P3 and P4 hybrid implants placed approximately 1.0 mm subcrestal from the interproximal height of bone with less gap distance (≤ 1.0 mm) exhibited minor to modest (1.5 to 2.0 mm) crestal bone remodeling relative to the implant platform. Conversely, M1 implants positioned with greater depth (≥ 2.0 mm) and gap distance (≥ 2.0 mm) that were evaluated in a buccal-lingual dimension exhibited minimal crestal change with first bone-to-implant contact within 1.0 mm (range: 0.00 to 0.89 mm) of the machined-collar surface. The thicker lingual bone plate on all M1 implants was relatively maintained and unaffected. The apical half of the implant provided high initial stability (range: 65 to 100 Ncm). The mean percentage of bone-to-implant contact was 56.34% (range: 40.15% to 72.04%). This preclinical study provided clinical and histologic evidence to support the safety and efficacy of a new hybrid macrogeometry implant design that achieved excellent primary and secondary stability in immediate extraction sockets without grafting. *Int J Periodontics Restorative Dent* 2019;39:29–37. doi: 10.11607/prd.3848

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A cylinder-shaped dental implant design, introduced by the late Professor Per-Ingvar Brånemark, experienced historic long-term clinical survival and success.¹ Although this design was the decades-long industry standard for a wide variety of clinical applications, new designs continued to emerge, and innovations in both implant macrogeometry and microsurface technology gave birth to the tapered dental implant. This design has been adopted by both clinical and research communities alike and is popular due to its enhanced primary stability, especially in poor-quality bone.^{2–5} Both success and survival rates of tapered or conical implants are comparable to that of conventional parallel-wall or cylindrical implant designs.^{6–12}

Tapered dental implants are usually divergent in shape: the width is greatest at the coronal portion and gradually decreases towards the apical portion. This tapered design has also been favored in immediate extraction sockets where achieving initial stability can be challenging due to the limited engagement of residual socket walls.^{13–15} Increasing implant diameter is also an effective means of enhancing primary stability in extraction sockets; however, this treatment strategy can compromise gap distance at the crest, thereby reducing the potential for osseointegration and labial plate reformation.^{16–18}

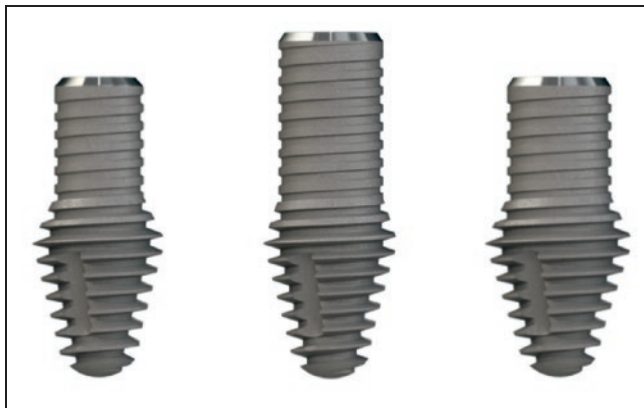


Fig 1 *Inverta DC30-4510 (left) and DC35-4511 (middle) hybrid implants were placed into third- and fourth-premolar extraction sockets. DC35-5010 (right) implants were placed into first-molar extraction sockets. Insertion torque values ranged from 65 to 100 Ncm. Note the hybrid macrogeometry design with cylindrical coronal and tapered apical portions, each comprising roughly half the length of the implant, with a 0.3-mm machined collar.*

Longer and more narrow implants can also be used to increase primary stability, though there are anatomic risks and limitations (ie, adjacent roots, floor of the nasal cavity) with increasing implant length.

Consequently, a hybrid macrogeometry implant (Inverta, Southern Implants) was developed to potentially maximize the advantages of both the cylindrical and tapered implant designs. This macrogeometry hybrid concept is unique in dimension and shape, as it combines two different implants in a singular body design, each comprising roughly one-half the length of the implant. The coronal portion is cylinder-shaped and narrower than the tapered apical portion. The apical portion potentially allows higher primary stability while eliminating stress at the crestal region of the bone in immediate extraction sockets and healed ridges. In addition, this novel design could have great benefits with extraction sockets in the esthetic zone because (1) gap distance could be enhanced over existing tapered (divergent) or wider implant designs by creating a

coronal 'compartment' or 'chamber' between the implant surface and remaining socket walls, and (2) creating a default gap distance would allow the blood clot to form new bone, eliminating the convention of placing an implant too close to the facial or interproximal wall.^{19–24}

Therefore, the purpose of this preclinical pilot study, in addition to gauging safety and efficacy, was to evaluate primary stability and wound healing of this novel hybrid macrogeometry implant design in immediate extraction sockets of varying dimensions without socket grafting.

Materials and Methods

Study Animals and Dental Implants

The study protocol was approved by the Institutional Animal Care and Use Committee at PARF (Pine Acres Rabbitry Farm) in Massachusetts, USA. Three female foxhounds (age: 2 to 3 years; weight: 20 to 24 kg), which were bred exclusively for biomedical research purposes, were

obtained from a licensed vendor. They were acclimated for 2 weeks prior to the research commencement and were fed an appropriate diet with ad libitum access to water. The following implant randomization was allocated for premolar and molar extraction sockets (Fig 1).

Third and fourth premolar (P3 and P4, respectively) extraction sockets: Twelve sites received either DC30-4510 (4.5 mm apex diameter / 3.0 mm coronal diameter × 10.0 mm length) or DC35-4511 hybrid implants (4.5 mm apex diameter / 3.5 mm coronal diameter × 11.0 mm length).

First molar (M1) extraction sockets: Six sites received DC35-5010 hybrid implants (5.0 mm apex diameter / 3.5 mm coronal diameter × 10.0 mm length).

All implants were made of cold-worked titanium grade 4 (manufactured according to ASTM F67, UTS > 920 MPa) and large-particle (110 μm at 72 psi) alumina-blasted surface (1.43 Ra/Sa value) with a prosthetic internal connection (deep conical) and 0.3-mm machined collar below the implant platform.

General and Local Anesthesia

All surgical procedures were performed under general and local anesthesia in sterile conditions. Initial intramuscular administration of xylazine hydrochloride (2.2 mg/kg) and tiletamine hydrochloride/zolazepam hydrochloride (10 mg/kg) was followed by inhalation of 1.5% to 2% isoflurane as a general anesthesia for the duration of the procedure. Local anesthesia (2% lidocaine with 1:100,000 epinephrine) was provided at the surgical sites.

Surgical Teeth Extraction and Immediate Implant Placement

The bilateral mandibular P3, P4, and M1 were extracted following full periosteal flap elevation. After careful socket debridement, site preparation was performed in accordance with the manufacturer's armamentarium and recommended drilling sequence. Subsequently, dental implants with three different dimensions were placed into postextraction sockets (Fig 2). P3 and P4 implants were placed 0.5 to 1.0 mm subcrestal relative to the interproximal height of bone and supracrestal from the midfacial bone crest (Fig 3). M1 implants were placed 2.0 to 3.0 mm subcrestal from the midfacial bone crest (Fig 4). The rationale in placing implants at various depths was to evaluate the effect of bone thickness on first bone-to-implant contact and osseointegration. The occlusal-cervical portion of the implant body and threads did not contact bone circumferentially

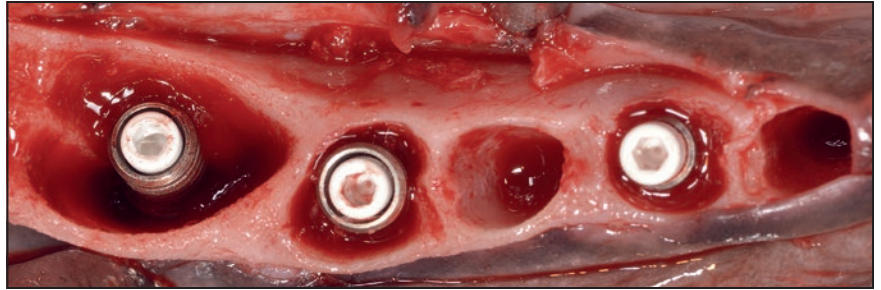


Fig 2 In each foxhound included in the study, the lingual bone plate was thicker than the buccal plate. A circumferential gap distance encompassed the cylindrical coronal portion of the hybrid implant in all sockets, and grafting was intentionally not performed. First-molar implants had gap distances ≥ 2.0 mm while those at third- and fourth-premolar sites were ≤ 1.0 mm. Polyether ether ketone healing abutments were placed on several implants (83%) in combination with titanium surgical cover screws.

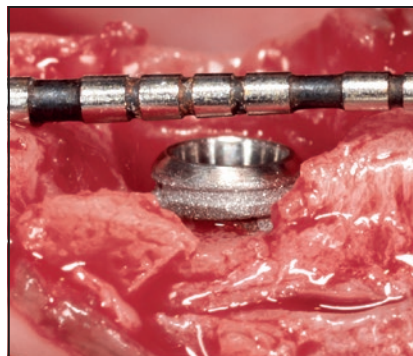


Fig 3 Third- and fourth-premolar implants were placed 0.5 to 1.0 mm subcrestally, relative to the interproximal height of bone.

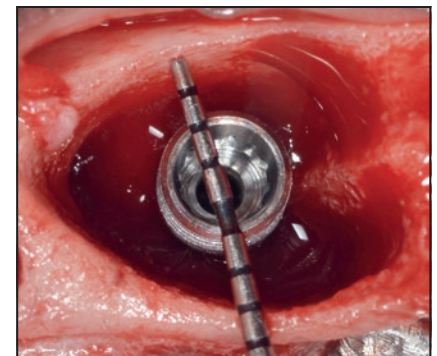
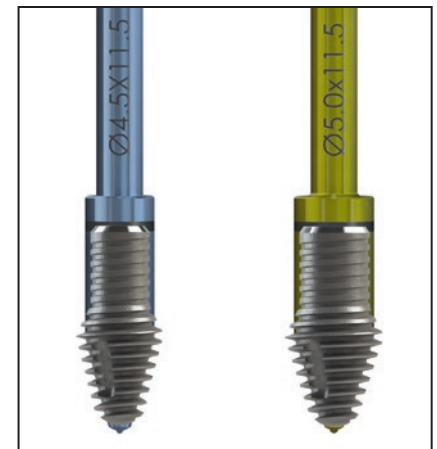


Fig 4 DC35-5010 Inverta hybrid implants were placed centrally in first-molar sockets and about 2.0 to 3.0 mm from the midfacial bone crest. Note the thin buccal and thick lingual bone plates, as well as the large gap distance [mean ≥ 2.0 mm] surrounding the cylindrical portion of the implant.

Fig 5 Final osteotomy sizing drill superimposed with Inverta DC35-4511 (left) and DC35-5010 (right) hybrid implants. Note the narrower coronal portion of both implant diameter combinations, comprising approximately half the implant length, with an aggressive apical thread pattern to maximize primary stability. This relieves stress on the crestal bone following implant placement and provides a coronal compartment for the blood clot.



upon implant delivery (Figs 2 and 5). No grafting was performed to fill

the gap between the implant and the extraction socket walls. Three

titanium surgical cover screws and 15 medical-grade polyether ether keytone (PEEK) healing abutments were placed; 83% of M1 (5/6) and P3 and P4 sites (10/12) received low-profile PEEK healing abutments that were ≤ 1.0 mm in height. Tension-free primary flap closure was achieved by periosteal releasing incisions with interrupted and continuous sutures. Insertion torque was recorded for each implant. Implant depth, bone plate thickness (buccal and lingual), and gap distance after implant installation were measured with a periodontal probe (Williams Probe, Hu-Friedy). The animals received standard postsurgical infection and pain control, consisting of cefazolin sodium (20 mg/kg) and buprenorphine HCL (0.02 mg/kg), both administered intramuscularly. The animals were fed a soft diet during the entire healing period and treatment phase.

Histologic Staining and Histomorphometric Analysis

The animals were sacrificed 3 months after implant placement, and surrounding tissue samples were fixed in 10% formalin and submitted for histologic analysis. Fixed samples were dehydrated in a graded series of ethanol (60%, 80%, 96%, and absolute ethanol) using a dehydration system with agitation and a vacuum. The blocks were infiltrated with Kulzer Technovit 7200 VLC-resin. Infiltrated specimens were placed into embedding molds, and polymerization was performed under blue and white light. Poly-

merized blocks of several P3 and P4 implants were sectioned in a mesio-distal direction, parallel to the long axis of P3 and P4 implants, while most M1 implants were sectioned in a buccolingual direction, parallel to the long axis of P4 and M1 implants. The slices were reduced by microgrinding and polishing using an Exakt grinding unit to an even thickness of 30 to 40 μm . Sections were stained with Sanderson's Rapid Bone Stain, counter-stained with acid fuchsin, and examined using both a Leica MZ16 stereomicroscope and a Leica 6000DRB light microscope. Histomorphometric measurements were performed by using ImageAccess software (Image) to calculate the surface of bone-to-implant contact.

Results

No adverse events were observed during the implant healing phase. All 18 implants appeared to be stable with clinical and radiographic osseointegration.

The unique hybrid macrogeometry implant design allowed for extremely high primary stability at implant placement, thus indicating it could be ideal in achieving initial stability in immediate extraction sockets. Mean insertion torque values were 70 Ncm (range 65 to 90 Ncm) for M1 and 90 Ncm (range 80 to 100 Ncm) for P3 and P4 implants, solely accomplished with the wider, tapered apical half of the implant body.

Light microscopic evaluation of extraction socket configurations

in the present study revealed tight contact between all apical implant threads and the surrounding bone, indicating successful osseointegration with a high insertion torque.

The buccal plate thickness in all extraction sockets was ≤ 1.0 mm (thin) while the mean lingual plate thickness was ≥ 2.0 mm (thick; range: 2.0 to 4.0 mm) upon implant installation (Fig 2).

In P3 and P4 sites, there was a 0.5- to 1.0-mm circumferential gap distance after implant placement. The majority of M1 sites had a gap distance ≥ 2.0 mm on both buccal and lingual aspects of the implant and 0.25 to 4.0 mm mesiodistally.

Both light microscopic and histomorphometric analyses revealed that (1) the thickness of the bone plate, (2) the implant diameter, position, and depth within the extraction socket, and (3) the size of the horizontal buccal gap significantly influenced the amount of hard tissue alteration and bone fill that occurred during the 3-month healing period. Bone-crest remodeling was observed on the interproximal aspect of P3 and P4 hybrid implants, and first bone-to-implant contact was about 1.0 to 1.5 mm more apical than M1 sites (Fig 6). Conversely, first bone-to-implant contact was observed more coronal on the buccal aspect of 80% of M1 implants and within 1.0 mm (range 0.00 to 0.89 mm) of the machined-collar surface compared to P3 and P4 sites (Figs 7 to 11). The thicker lingual bone plate on all implants was relatively unaffected and maintained throughout the healing process (Figs 7, 8, and 10). Light microscopy

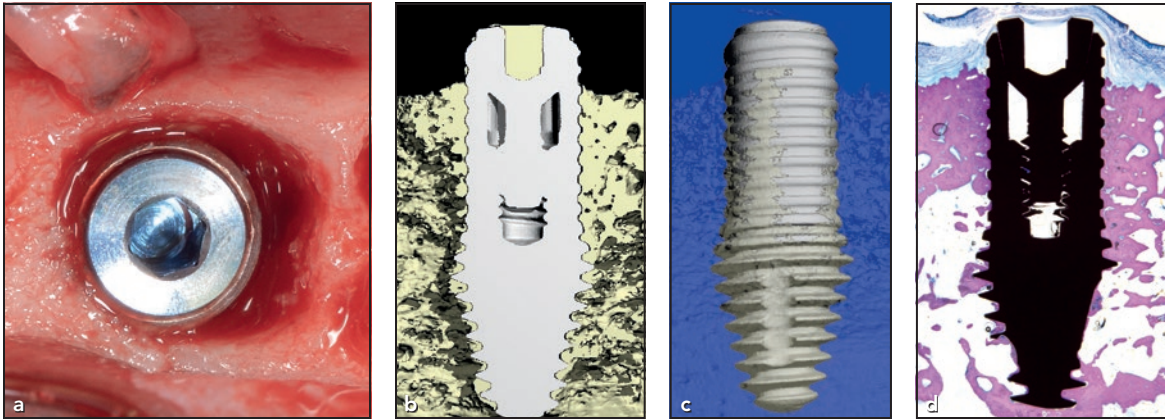


Fig 6 (a) Clinical image, (b, c) microtomography scans, and (d) histologic section of an Inverta DC35-4511 hybrid implant placed into a third- and fourth-premolar site without socket grafting (mesial-distal section). Robust bone-to-implant contact is seen with some crestal remodeling. A mean of 90 Ncm ITV was achieved upon hybrid implant installation for third and fourth premolar sites.

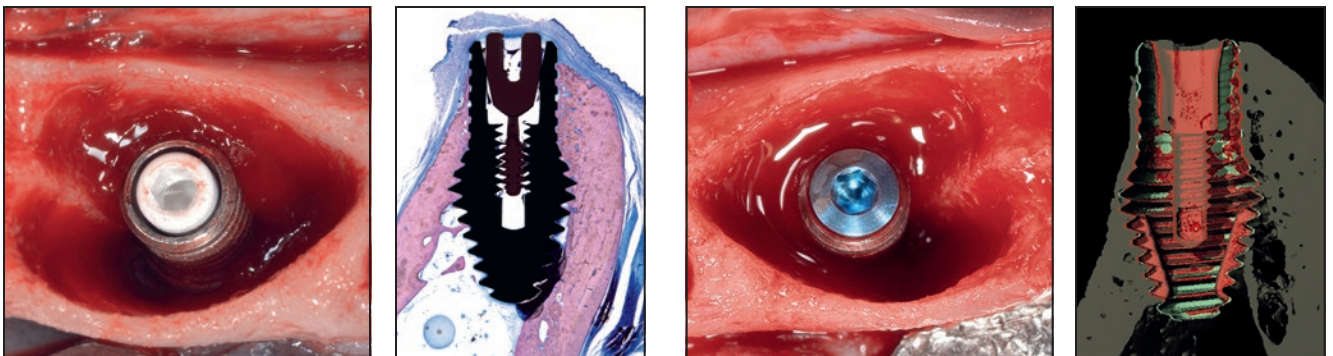
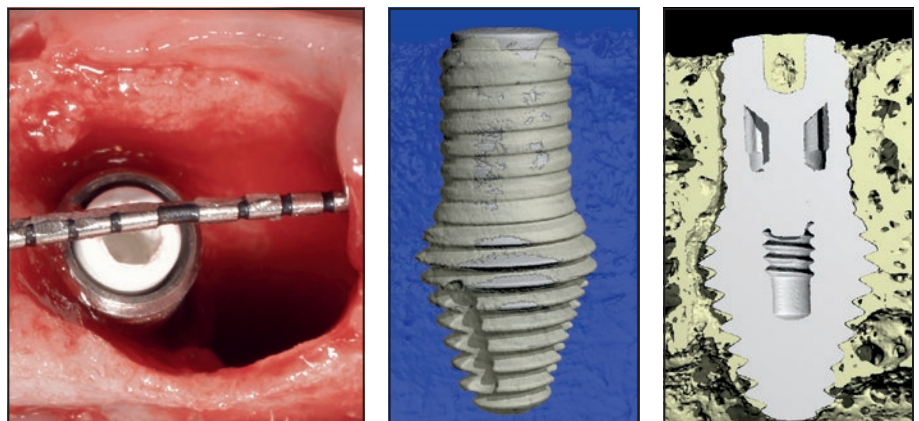


Fig 7 Clinical image (left) and corresponding histologic section (right) of an Inverta DC35-5010 hybrid implant placed into a first-molar socket (buccal = left bottom of left image) sectioned in a buccolingual direction. First bone-to-implant contact is present within 0.5 to 1.0 mm of the implant platform on both the buccal and lingual sides, without socket grafting. The thicker lingual bone plate was less affected by resorption. Excellent bone-to-implant percentage is noted at the tapered apical area of the implant, with a mean insertion torque value of 70 Ncm.

Fig 8 Clinical image (left) and microtomography scan (right) of a first-molar hybrid implant sectioned in a buccolingual direction. Even in the presence of anticipated buccal resorption, excellent first bone-to-implant contact is attained with a buccal gap distance ≥ 2.0 mm, without socket grafting.

Fig 9 Clinical image (left) and microtomography scans (middle, right) of an Inverta DC35-5010 hybrid implant placed into a first-molar socket with a large distal gap distance ≥ 4.0 mm (mesial-distal section). Coronal first bone-to-implant contact and percentage of contact to the implant platform were achieved interproximally, without socket grafting.



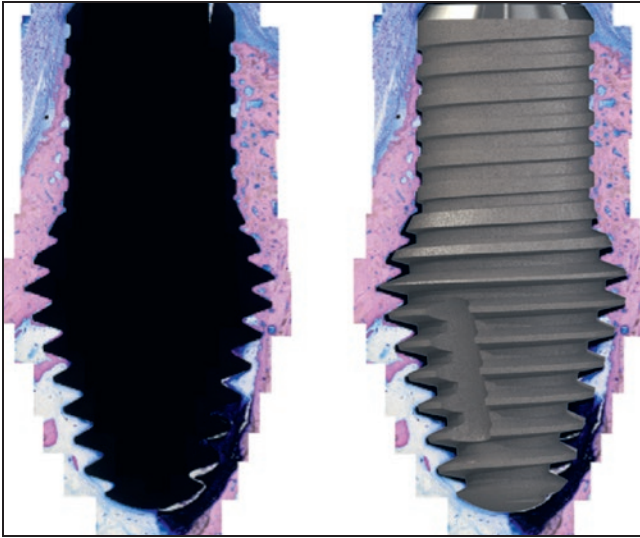


Fig 10 Silhouette (left) and superimposed implant image (right) of an Inverta DC35-5010 hybrid implant placed into a first-molar extraction socket. Even in the presence of buccal bone resorption, first bone-to-implant contact is achieved at a coronal level within 0.5 mm of the machined collar. The hybrid implant design creates a 'body-shift' in diameter and shape, thereby creating a coronal circumferential compartment for new bone formation and/or graft material. Increased implant depth and gap distance relative to fixture position were key factors in first bone-to-implant contact.

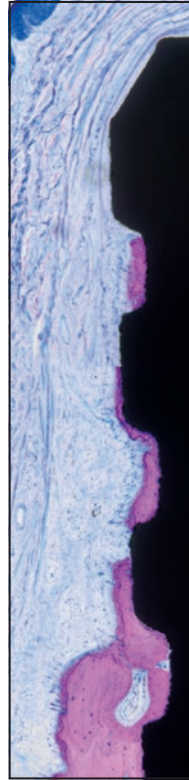


Fig 11 Magnified view of the buccal aspect of a first-molar hybrid implant. First bone-to-implant contact is present 0.39 mm from the machined collar as a consequence of implant depth and position in the presence of a thin bone plate.

revealed an excellent percentage of bone-to-implant contact for all implants (mean: 56.34%; range: 40.15% to 72.04%). The use of PEEK healing abutments on most hybrid implants appeared to have a compatible soft tissue response with no adverse reactions.

Discussion

Although microspheres play a role in the secondary phase of healing through completion of osseointegration, the macrogeometry of an implant body is important in achieving primary stability and facilitating provisional restoration. The primary stability of a dental implant has been

accepted as a necessity for longevity and subsequent long-term success of osseointegrated implants.^{13,14}

The hybrid implant with a unique macrogeometry investigated in this pilot study has several special features because it combines both cylindrical and tapered shapes in a singular body design. At the middle portion of the implant, there is a 'body shift' in diameter and shape, at which point the coronal half sharply tapers to a wider apical half; the difference in width between the two sections is 1.0 to 1.5 mm. The narrower cylindrical body in the coronal portion creates a chamber between the implant surface and extraction socket wall, allowing blood-clot formation and avoid-

ing exerting excessive pressure in the dense bone and undermined osteotomy sites. The apical half of the implant body has aggressive threads for increased cutting capability and enhanced primary stability. A thread depth of 0.5 mm, angle of 35 degrees, and pitch of 0.6 mm created an aggressive design that resulted in the high primary stability measured in this study. The majority of hybrid implants placed in this preclinical study reached extremely high minimum insertion torque values (65 Ncm for M1 and 80 Ncm for P3 and P4 hybrid implants) with no histologic evidence of pressure necrosis at the apex.²⁵

It is well documented that there is no marrow when bone thickness

is less than 1.5 to 2.0 mm, making it highly susceptible to resorption, especially with flap elevation.²⁶ Placing a graft in the gap at implant installation was not performed in this study with the understanding and knowledge that horizontal resorption would have an unfavorable effect on crestal bone height and, consequently, osseointegration.^{27,28} This outcome was anticipated and concurs with prior studies that exhibited diminished osseointegration that was culminated from factors such as implant position, diameter, and depth in extraction sockets without grafting.^{19–24,29} The thicker lingual bone plate (mean: 2.1 mm; range: 1.5 to 4.0 mm) on all implants was relatively unaffected and maintained throughout the healing process. Supplementary grafting within the gap at the time of surgery would have helped maintain ridge shape and volume.^{30,31}

Of special interest was a thin layer of new bone formation that was located 0.39 mm from the machined-collar surface and was histologically evident on the coronal cylindrical portion of the hybrid implant, where the buccal bone plate was thin and the gap distance was ≥ 2.0 mm (Fig 11). Gap distance, as a function of implant diameter and position, is necessary to allow new bone-plate formation without socket grafting since a defined and measurable amount of resorption will occur. This phenomenon was evident and deduced in P3 and P4 sites where the resorption of the buccal plate both extended to and affected the height of interproximal bone crest.

It has been suggested in preclinical studies that a gap distance ≥ 1.4 mm should be filled with a graft material, as the blood clot alone is inadequate to predictably induce bone formation. Authors using machined-surfaced implants in simulated extraction sockets showed that increasing the gap distance resulted in a decreased amount of bone-to-implant contact and an apical shift of first bone contact.³² However, in M1 implants with an increased gap distance in the present preclinical study, the point of first bone-to-implant contact shifted coronally. Furthermore, hybrid implants in the present study possessed a micro-textured, sandblasted surface that could potentially lead to more consistent clot stabilization during initial healing compared to implants with a machined interface.³³ Botticelli et al showed newly formed bone filling the > 2.0 -mm marginal defect without grafting and also demonstrated that the bone remodeling process differs in fresh extraction sockets than in simulated defects.³⁴

For an M1 implant with a distal gap distance > 4.0 mm, it was observed that new bone was able to fill and form to the implant platform. The clinical implications of this are greater spans of tooth-to-implant and implant-to-implant contact and new interseptal bone formation through macrogeometry design alone (Fig 9).

Histologic evaluations of PEEK healing abutments showed no adverse tissue reactions in the present study, which is consistent with previous works that showed comparable outcomes with titanium.^{35,36}

Lastly, Albrektsson and Johanson suggested a minimum of 50% bone-to-implant contact to ensure implant survival and successful long-term loading of osseointegrated implants.³⁷ In the present preclinical study, the apical portion of the implant achieved high percentages of bone-to-implant contact in all extraction socket configurations.

It should be noted that there might be factors affecting the results of the current study. Full periosteal flap elevation was performed in the present study to allow access for measuring bone-plate thickness and circumferential gap distance at the time of surgery as well as to ensure the surgical sites were covered and protected during the healing phase. The findings in this preclinical pilot study suggest that bone remodeling and osseointegration are influenced by bone-plate thickness and spatial implant position.

Further research in the field of macrogeometry implant designs in extraction sockets and healed ridge is required.

Conclusions

This preclinical trial provided clinical and histologic evidence to support the safety and efficacy of a new hybrid macrogeometry implant design and its excellent primary and secondary stability in immediate extraction sockets. The percentage of bone-to-implant contact apical to the widest portion of the hybrid implant was robust, with mean insertion torque values of 70 to 90 Ncm. Bone-plate thickness and spatial

implant position may influence the amount of hard tissue change and osseointegration without socket grafting.

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