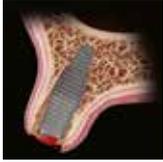




# Outcomes of a 1-Year Prospective Single-Arm Cohort Study Using a Novel Macro-Hybrid Implant Design in Extraction Sockets: Part 1



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A novel macro-hybrid design implant was introduced to afford high apical primary stability and more coronal space to preserve the circumferential extraction socket architecture. This study presents 1-year data from a prospective single-arm cohort study. The data was distilled based on the following criteria: (1) single-tooth immediate tooth replacement therapy (ITRT) in the maxillary anterior and premolar regions in intact (Type 1) extraction sockets that were (2) treated with the dual-zone grafting technique. The clinical and radiographic outcomes of 48 ITRT implants were evaluated. The mean  $\pm$  SD labial plate dimension changes were  $0.33 \pm 0.41$  mm at the implant abutment interface (L1) and  $0.34 \pm 0.40$  mm at 5.0 mm below (L2). The mean labial plate dimension (thickness) at the 1-year recall was  $2.27 \pm 0.88$  mm (L1) and  $1.95 \pm 0.95$  mm (L2). At ITRT, the ridge contour at the free gingival margin and 3.0 mm below it were  $7.54 \pm 0.93$  mm and  $9.44 \pm 2.36$  mm, respectively; after final restoration delivery, the corresponding values were  $7.45 \pm 0.95$  mm and  $10.23 \pm 2.30$  mm, respectively. The peri-implant soft tissue thickness (PISTT) at the time of implant-level impression-making was  $3.29 \pm 0.73$  mm, with an average Pink Esthetic Score of 12.79. A macro-hybrid design implant showed high levels of primary stability ( $\sim 60$  Ncm), stable ridge contour at 1 year, a labial plate dimension between 1.5 and 2.0 mm, and PISTT  $> 3.0$  mm, which may be a critical factor in providing stable, long-term esthetic outcomes. *Int J Periodontics Restorative Dent* 2021;41:xxx-xxx. doi: 10.11607/prd.5709

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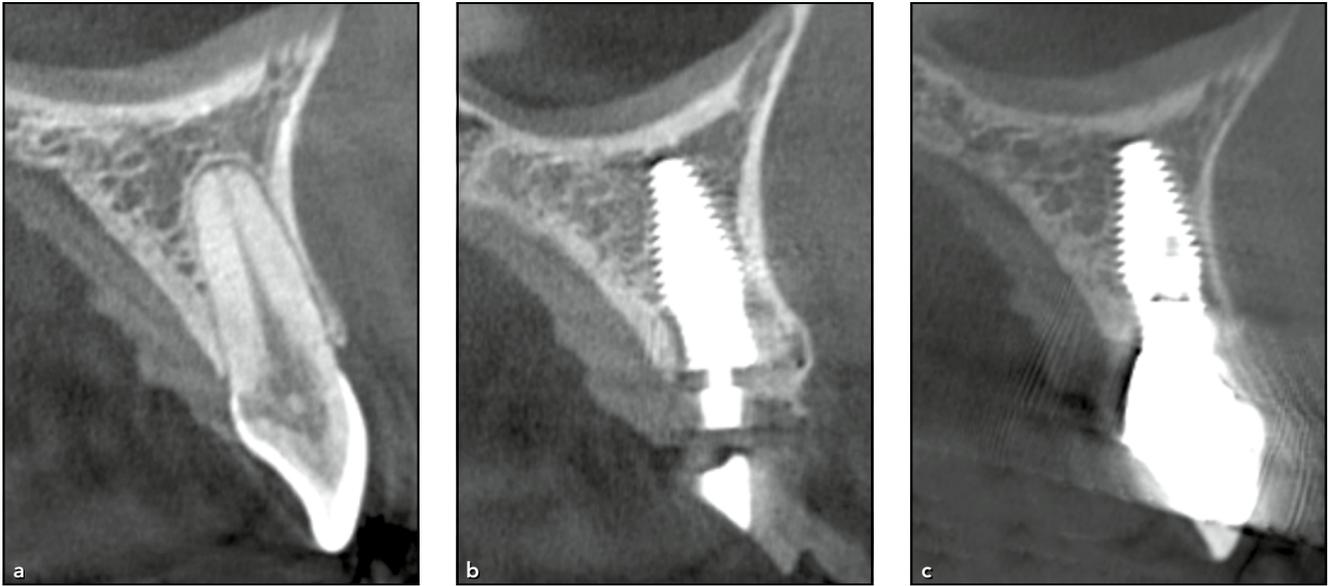
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One of the critical prerequisites for immediate tooth replacement therapy (ITRT) or implants placed immediately into extraction sockets with a provisional restoration is achieving adequate apical primary stability, whether for single- or multiple-unit restorations.<sup>1,2</sup> Extraction sockets present several clinical and anatomical challenges—including thin bony walls, limitations in socket dimension based upon tooth location, and concavities at the apex of the facial bone—that increase the potential incidence and risk of labial plate perforation.<sup>3,4</sup> Wide-diameter implants are often used to gain greater stability; however, increased width inherently compromises the distance between the facial bone walls and proximity to the adjacent natural teeth. Conversely, narrow-diameter implants provide greater coronal space for facial and interproximal bone formation; however, they lack the level of primary stability required to support an immediate provisional restoration, as the surface area of the implant in contact with the available apical bone may be limited.<sup>5,6</sup>

Consequently, a novel macro-hybrid implant incorporating a prosthetic angle correction and body-shift feature (ie, variations in diameter, shape, and thread pattern in a singular body design) was introduced in 2018 to overcome these



**Fig 1** CBCT scans (a) of the preoperative condition, (b) at immediate implant placement with socket grafting and provisional restoration, and (c) at 1 year postsurgery with the definitive restoration in place.

dilemmas (Inverta, Southern Implants). The wider, apical, tapered-body form (roughly 60% the implant body length) allows the high initial apical primary stability that a wide diameter offers in ITRT while the narrower cylindrical coronal form (about 40% of the body length) provides more distance to the labial and interproximal bone, and therefore the architecture of the socket can be protected and preserved.<sup>1,4</sup> This also provides more coronal space for grafting biomaterials that further maintain circumferential bone integrity of the labial plate<sup>7,8</sup> (Fig 1). Recent preclinical, clinical, and radiographic case series reported very high apical primary stability achieved by this unique design feature, which can lead to positive short-term esthetic results. However, a prospective cohort study was not investigated.<sup>1,4,7-9</sup>

Therefore, the aim of this study was to present 1-year data from a pro-

spective single-arm, multicentered study that correlated clinical, radiographic, and esthetic outcomes.

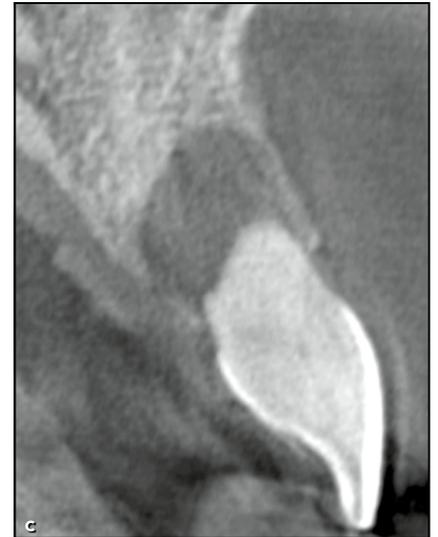
## Materials and Methods

The Inverta Data Registry is a secure repository used for a prospective single-arm, multicentered study using an implant design with an inverted body-shift and prosthetic angle correction (Inverta, Southern Implants). The registry was approved by the Western Institutional Review Board, and registered patients provided consent in accordance with the Declaration of Helsinki. Six calibrated study centers participated in the data collection. The data was extracted from the registry based upon the following criteria: (1) single-tooth immediate tooth replacement therapy in maxillary incisor, canine, and premolar teeth,

and (2) treated with the dual-zone grafting technique in Type 1 sockets.<sup>10,11</sup>

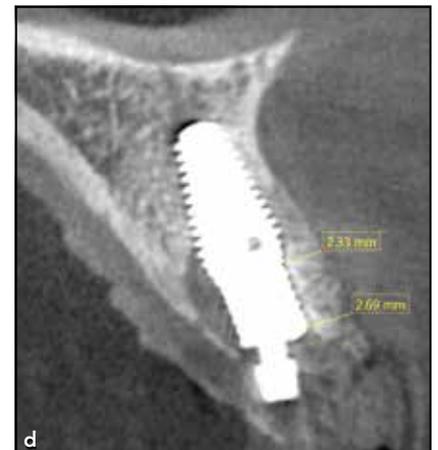
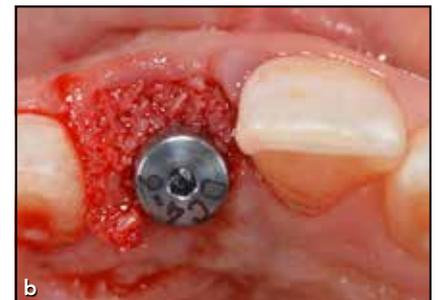
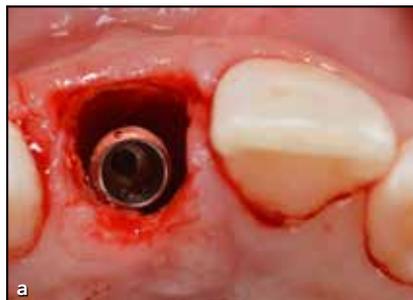
## Clinical Procedure

The surgical treatment protocol included atraumatic tooth extraction, thorough debridement of the residual socket, and an osteotomy sized to receive the inverted body shift (INV) implant of choice, placed 3.0 to 4.0 mm apical from the free gingival margin (FGM; Figs 2 and 3a). A minimum primary stability of 35 Ncm was required to facilitate immediate full-contoured provisional restorations in nonocclusion. The circumferential gap was filled with a small-particle mineralized bone allograft (Puros Cancellous Particulate Autograft, Zimmer Biomet), and screw-retained provisional restorations were fabricated in infraocclusion (Figs 3b to 3d). A minimum of



**Fig 2** Patient 1. (a) Preoperative clinical view of a 23-year-old woman with a prior dental history of trauma to tooth 11 (FDI tooth numbering system) and a slight distal-incisal edge fracture of tooth 21. The patient's chief complaint was discoloration of tooth 11 and pain on percussion. The midfacial FGM on tooth 11 was slightly coronal to tooth 21. (b) Preoperative periapical radiograph showing significant root resorption of tooth 11 due to trauma and nontreatment. (c) CBCT scan of tooth 11 showing a significant amount of root resorption and a compromised socket dimension due to the apical resorption, pulpal atrophy, and periapical pathology.

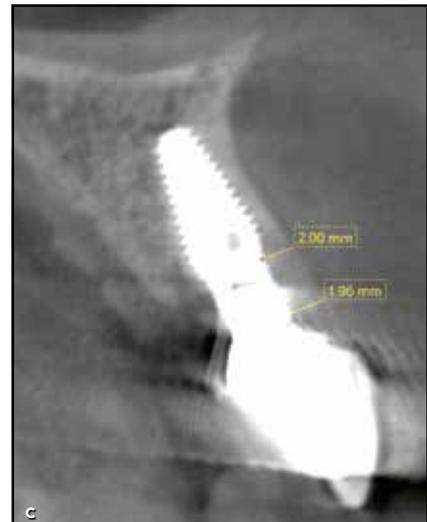
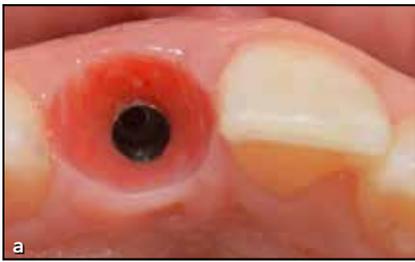
**Fig 3** Patient 1. (a) Implant placement after flapless tooth removal and thorough socket debridement. Note the substantial circumferential gap around the reduced-diameter implant neck that allows more space for graft biomaterial. This implant was placed with an insertion torque value of 80 Ncm. (b) A healing abutment was placed to allow dual-zone grafting with a small-particle mineralized cancellous allograft (Puros). The graft was brought to the level of the FGM to thicken the soft tissue zone in lieu of a subepithelial connective tissue graft. (c) An anatomical contoured provisional restoration was made, and the prosthetic socket seal technique was used to contain and protect the graft material for a minimum of 4 months. (d) A CBCT scan was immediately taken following implant placement, socket grafting, and placement of the temporary restoration. The labial plate dimension was recorded at L1 and L2 with values  $> 2.0$  mm immediately postsurgery.



4 months of healing was observed before the first removal (disconnection) of the provisional restoration

(Fig 4a). Subsequently, implant-level impressions were made, and the final restorations were fabricated and

delivered within 4 to 6 weeks after impression-making (Figs 4b and 4c). Further details of the clinical



**Fig 4** Patient 1. (a) A healing period of 10 months was observed due to uncontrollable circumstances. Note the good health and shape of the ridge and soft tissue profile at the first disconnection and impression-making. (b) A final metal-ceramic screw-retained restoration was delivered 1 year postsurgery. Note the esthetic harmony and integration, with no change in the midfacial soft tissue and papilla heights equivalent to the adjacent natural tooth 21. The distal-incisal chip on tooth 21 was repaired with a direct composite-resin restoration. (c) CBCT scan taken at 1 year postoperative shows a slight LPD change at L1 and L2 with a net width of about 2.0 mm at both reference points.



**Fig 5** Patient 2. (a) Preoperative clinical view of a 28-year-old Caucasian woman with a prior dental history of trauma to tooth 12. (b) A periapical radiograph of tooth 12 shows external root resorption at the distal aspect.

procedure were previously described<sup>10,12</sup> (Figs 5 to 7).

#### Data Collection

The following data were evaluated for the study. Mean values and SDs were calculated for each category.

#### Clinical evaluation

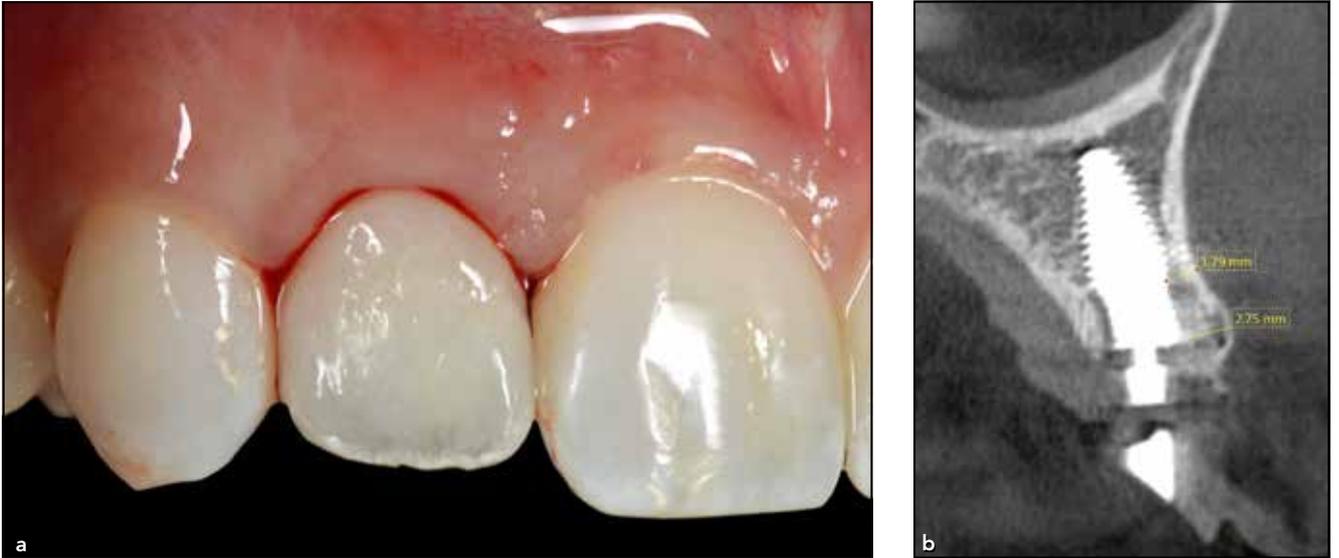
##### Implant primary stability

The insertion torque values were recorded in Newton centimeters (Ncm) at the time of implant placement using an electric handpiece.

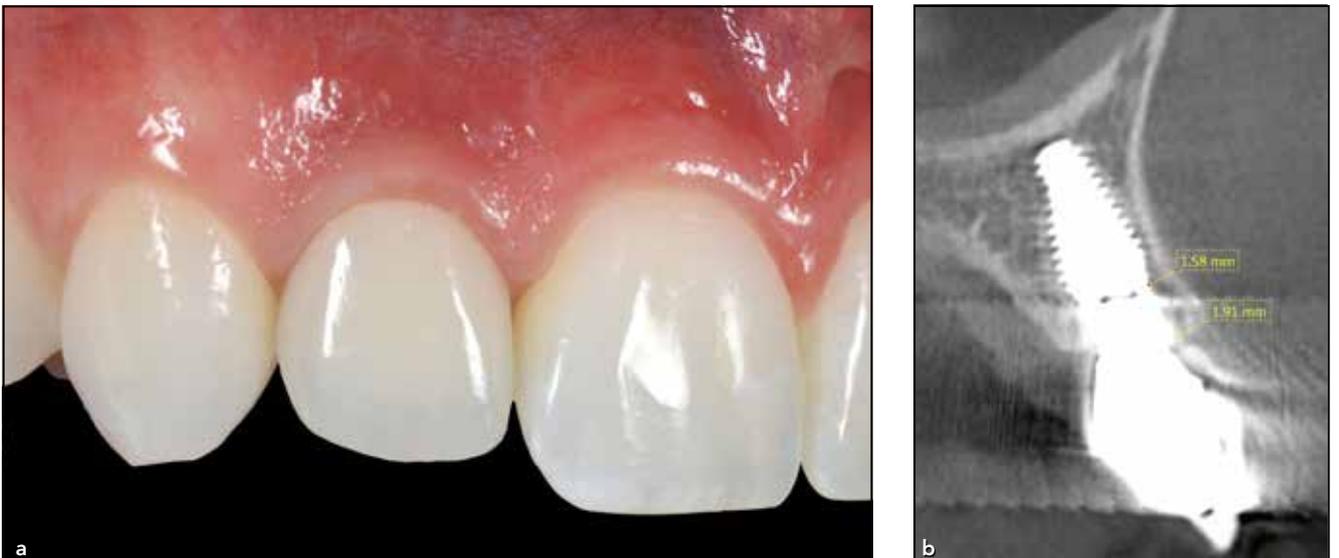
##### Buccolingual ridge dimension

Buccolingual ridge dimension was measured at two reference points,

at the FGM and 3.0 mm below, from digitally scanned models or STL files (TRIOS, 3Shape) taken preoperatively and after final restoration delivery. Computer subtraction analysis was performed using the manufacturer's software to obtain the difference in buccolingual dimension.



**Fig 6** Patient 2. (a) The provisional restoration seated after ITRT and dual-zone grafting. The implant was placed with an insertion torque value of 70 Ncm. (b) CBCT scan taken immediately posttreatment showing 1.5 to 2.8 mm of LPD.



**Fig 7** Patient 2. (a) A final metal-ceramic screw-retained restoration was delivered 1 year postsurgery. Note the integration of esthetics, including color matching and a good Pink Esthetic Score with no change in midfacial soft tissue height nor papillae relationships. (b) A CBCT scan taken at the time of delivery of the final restoration shows 1.6 to 2.9 mm of LPD.

#### *Pink Esthetic Score (PES)*

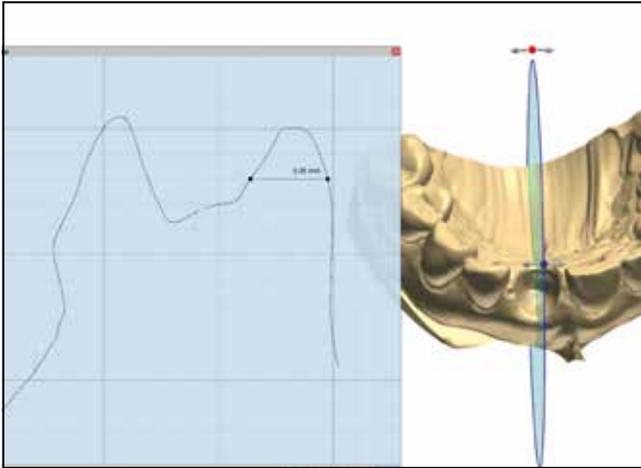
High-resolution images were captured using a digital single-lens reflex camera with a 105-mm macro-lens and wireless twin (spot) flash system (D3200, R1C1, Nikon) at a 1:1 ratio. Images were rated by

a single observer (S.J.C.), and all measurements were made twice, at least 24 hours apart. The intra-examiner error was calculated by comparing the first and second measurements with paired t test at a significance level of 5%. No statis-

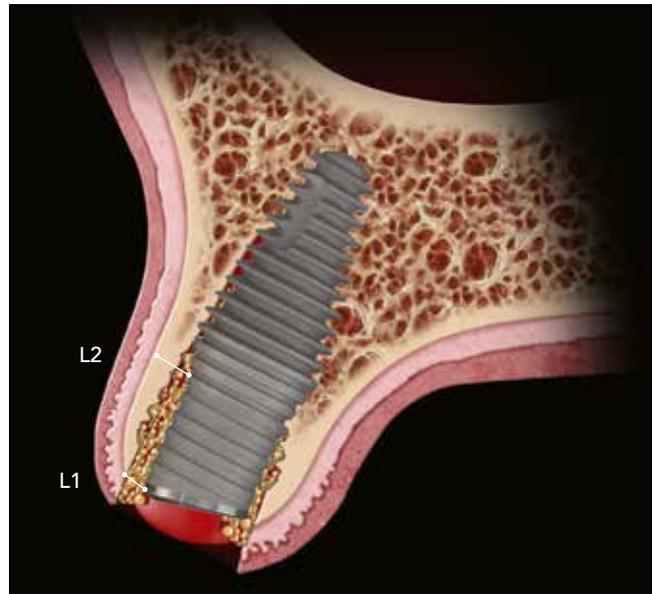
tically significant values were calculated between the values.

#### *Peri-implant soft tissue thickness*

The labial peri-implant soft tissue thickness (PISTT) was measured at 2.0 mm below the FGM using



**Fig 8** Example of a PISTT measurement 2.0 mm from the FGM using digital scanning software (TRIOS).



**Fig 9** Diagram representative of measurement reference points L1 and L2 on a CBCT. L1 corresponds to the implant-abutment interface (IAI) equivalent to the midfacial labial plate bone crest. L2 is roughly 5.0 mm from the bone crest, coincident with the upper portion of the inverted body shift design (INV) implant transition zone where the diameter shifts from a tapered to a cylindrical form.

either an intraoral scanner (TRIOS) or a scanned model from the final impression (Fig 8).

## Radiographic evaluation

### Labial plate dimension

Changes in labial plate dimension (LPD) were measured on the CBCT images taken immediately after implant placement and provisional restoration, and at 1-year after ITRT (Figs 1, 3d, and 4c). Measurements were taken (in millimeters) at two levels, L1 and L2, as previously described by Chu et al<sup>9</sup> (Fig 9). L1 corresponded to the implant-abutment interface (IAI) equivalent to the midfacial labial plate bone crest; L2 corresponded to the implant body roughly 5.0 mm from the IAI and bone crest, coincident with the upper portion of the INV implant tran-

sition zone where the diameter and shape shift from a tapered to a cylindrical form (roughly 40% the implant length). At each level, two reference points were identified: (1) the outermost aspect of labial bone plate, and (2) the first radiographic bone-to-implant contact point connected by a straight line perpendicular to the implant body. The distance between the two points at each level was measured using bundled CBCT digital imaging software (i-Dixel, J. Morita).

## Results

Forty-eight maxillary single-tooth implants were included based on the criteria earlier described. The mean patient age was 58.1 years

(range: 25 to 87 years), with 20 men and 28 women. Of the included implants, 54% (n = 26) were central incisors, 18.8% (n = 9) were lateral incisors, 16.7% (n = 8) were premolars, and 12.5% (n = 5) were canines. The reasons for the extraction included tooth fracture, endodontic complication with periapical pathology, and/or internal resorption. Twenty-one patients were categorized as having a thin gingival phenotype. The buccal gap space was grafted with small-particle (250 to 500  $\mu$ m) mineralized cancellous bone allograft (Puros). During the course of the study, one complication was reported (provisional restoration fracture). The definitive restoration was delivered 4 to 8 weeks after final impression-making, and more than 90% of the definitive restorations

**Table 1 Distances Between the External Surface of the Labial Bone Plate and the Facial Surface of the Implant Over Time**

CBCT	Day 0	1 y	Change
<b>L1</b>			
Mean $\pm$ SD, mm	2.81 $\pm$ 0.69	2.27 $\pm$ 0.88	0.33 $\pm$ 0.41
Range, mm	1.03–4.80	1.00–4.25	
<b>L2</b>			
Mean $\pm$ SD, mm	2.49 $\pm$ 0.76	1.95 $\pm$ 0.95	0.34 $\pm$ 0.40
Range, mm	1.67–4.47	0.6–4	

Day 0 = day of immediate tooth replacement therapy; L1 = the implant-abutment interface (IAI) equivalent to the midfacial labial plate bone crest; L2 = the implant body roughly 5.0 mm from the IAI and bone crest. Minimal change was noted over the healing period.

**Table 2 Buccolingual Ridge Dimension Over Time**

Digital scan	Day 0	1 y	Change
<b>At the FGM</b>			
Mean $\pm$ SD, mm	7.54 $\pm$ 0.93	7.45 $\pm$ 0.95	0.21 $\pm$ 1.03
Range, mm	5.89–9.19	4.61–9.77	
<b>3 mm below the FGM</b>			
Mean $\pm$ SD, mm	9.44 $\pm$ 2.36	10.23 $\pm$ 2.30	-0.42 $\pm$ 0.80
Range, mm	4.31–13.77	6.09–15.18	

Day 0 = day of immediate tooth replacement therapy. Minimal change was noted over the healing period.

were screw-retained ( $n = 44$ ) with either zirconia titanium-base restorations ( $n = 26$ ) or porcelain-fused-to-metal ( $n = 18$ ). The mean insertion torque value was 61.78 Ncm, with 83.3% of the cases exceeding 50 Ncm.

#### Radiographic Evaluation

Forty-two sets of CBCTs taken at the time of ITRT and delivery of the final restorations were available for radiographic evaluation.

The average LPD at L1 and L2 at the time of ITRT were 2.81  $\pm$

0.69 mm and 2.49  $\pm$  0.76 mm, respectively. At the 1-year follow-up, the L1 and L2 values were 2.27  $\pm$  0.88 mm and 1.95  $\pm$  0.95 mm, respectively. The average changes were 0.33  $\pm$  0.41 mm at L1 and 0.34  $\pm$  0.40 mm at L2 (Table 1).

#### Clinical Evaluation

The average ridge dimension at the FGM and 3.0 mm below FGM at the time of ITRT were 7.54  $\pm$  0.93 mm and 9.44  $\pm$  2.36 mm, respectively. After delivery of the final restoration, the ridge dimension was 7.45

$\pm$  0.95 mm at the FGM and 10.23  $\pm$  2.30 at 3.0 mm below the FGM. A slight increase of 0.79  $\pm$  1.03 mm was noted 3.0 mm below the FGM, but it was not statistically significant (Table 2).

The average PISTT at the time of impression-making for the final restoration was 3.29  $\pm$  0.73 mm. When divided by phenotype, the pretreatment thin-phenotype group exhibited 3.22  $\pm$  0.73 mm and the thick-phenotype group exhibited 3.34  $\pm$  0.77 mm.

The average PES was 12.79, with the following distribution: a score of 14 in 15 cases, a score of 13 in 16

cases, a score of 12 in 10 cases, a score of 11 in 6 cases, and a score of 10 in 1 case.

## Discussion

This is a first report of a prospective, single-arm, multicentered registry study of a novel hybrid-designed implant used in ITRT. Clinical and radiographic evaluations in this study revealed positive effects in functional and esthetic outcomes, which redefine parameters in ITRT.

The first prerequisite for ITRT is to achieve adequate apical primary stability that enables the placement of a provisional restoration.<sup>1,2,4</sup> Traditionally, wide-diameter implants are used to obtain primary stability in the postextraction socket, aiming to engage the implant in the bone apical to the socket. However, as the conventional tapered-body implant has its widest portion at the implant shoulder or at the most coronal portion of the body, the distance between implant shoulder and the labial bone plate and adjacent tooth attachment apparatus consequently becomes less favorable.<sup>13–15</sup> In addition, placing a uniaxial implant in the ideal prosthetic position (with the screw access hole aligned at the cingulum and adjacent teeth) poses the possible perforation of the apical part of the labial bony plate that is narrower and concave in shape.<sup>16,17</sup> The use of narrow-diameter implants has been proposed, as they provide greater space between the implant body and the surrounding bony architecture of the residual socket. However, there may not be ad-

equated primary implant stability for ITRT due to the limited surface area of the implant in bone.

A hybrid implant design with a wider, tapered apical portion that is 60% the implant body length achieves the desired levels of apical primary stability for immediate provisional restoration, and the narrow coronal half provides a larger gap that addresses the aforementioned negative dilemmas.

The placement of a bone graft or biomaterial into the gap has been recommended to compensate the remodeling of thin labial bone plate.<sup>18–20</sup> As a result of a larger space for grafting provided by the narrow coronal half of the INV implant body, stable buccolingual ridges and LPDs were seen in the present study at 1 year postsurgery for both L1 and L2. The labial bony plate thickness of  $\geq 2$  mm will facilitate a blood supply that supports stable long-term preservation.<sup>21–23</sup> This is in both healed ridge and extraction socket situations, with the latter being more challenging to achieve due to its finite dimension, as previously mentioned. Prior mid-term retrospective longitudinal studies by Kan et al and Degidi et al did not place a graft material into the gap and therefore reported collapse and gingival recession.<sup>24,25</sup> In fact, 20% of the patients in Degidi et al's study had no labial plate at the 7-year recall appointment.<sup>25</sup>

What is interesting to note is that the present study showed a gain in ridge contour instead of maintaining or losing dimension, which prior studies showed utilizing the same techniques. This gain

in ridge dimension may be attributed to the construction of an anatomically contoured screw-retained provisional restoration at the time of surgery that supports the soft tissues and acts as a prosthetic socket sealing device that contains and protects the graft material during healing.

Changes in macro-implant design, such as platform-switching and variable platform-switching, have been shown to increase peri-implant soft tissue dimension in combination with dual-zone grafting.<sup>12,26</sup> A robust gain in PISTT of about 1.5 to 2.0 mm, and above 3.0 mm at times, was reported in the present study; the combination of dual-zone grafting with the inverted body-shift design may enhance thickness, which may be more resistant to midfacial recession over time. Also in the present study, the average PES score of approximately 13 was reported, with a score of 12 being above average. PES, which consists of seven different variables, includes the evaluation of midfacial gingival levels and papilla heights. The cases from the registry were treated with the dual-zone grafting technique in which bone graft material was placed up to the level of the FGM. The anatomically contoured provisional restorations have been shown to help stabilize the buccolingual ridge dimension and peri-implant soft tissue thickness without a subepithelial connective tissue graft (SCTG).<sup>12,27</sup> The SCTG at the time of ITRT has been used to minimize the anticipated risk for midfacial recession that is expected in a thin gingival phenotype patient

(< 0.5 mm buccal bone thickness).<sup>28–30</sup> A recent systematic review reported 0.41 mm less midfacial recession after 12 to 24 months of follow-up when SCTG is in conjunction with ITRT, though long-term (> 10 years) stability of the peri-implant soft tissue with SCTG still remain unclear.<sup>31</sup>

The present study has certain limitations. First, it was conducted as a single-arm prospective cohort study without a comparison group. Although the reported parameters were favorable compared to the preoperative condition, a randomized controlled clinical trial is more desirable. Second, the study period was only up to 1 year after ITRT, and possible further remodeling of hard and soft tissues may occur longitudinally. Further research is required to assess the long-term outcomes of this macro-hybrid implant design with ITRT techniques.

## Conclusions

The macro-hybrid implant design evaluated in this study showed high levels of apical primary stability (~60 Ncm), stable ridge contour from the preoperative condition through final restoration at 1 year, LPD between 1.5 and 2.0 mm at both L1 and L2, and PISTT > 3.0 mm. Thicker hard and soft tissues may be critical in providing stable long-term esthetic outcomes.

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