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Prospective Multicenter Clinical Cohort Study of a Novel Macro Hybrid Implant in Maxillary Anterior Postextraction Sockets: 1-Year Results



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A prospective cohort clinical study was performed to evaluate the concept and design of a novel macro hybrid implant placed into maxillary anterior postextraction sockets. Thirty-three patients with an equal number of hybrid implants were used to replace nonrestorable single anterior teeth with immediate tooth replacement therapy (immediate implant placement and immediate provisional restoration). The macro features of this hybrid implant are unique in geometry, as it combines two different shapes—a cylindrical coronal and tapered apical portion—into a singular body design, each comprising roughly half of the implant length. The hybrid design of this platform-switched implant also has a subcrestal angle correction, or Co-Axis feature, that facilitates screw-retained restorations. Mean implant survival at 1 year relative to primary stability, labial bone plate thickness with socket grafting at two reference points (L1 and L2), tooth-to-implant interproximal bone crest thickness, and pink esthetic score (PES) were evaluated. A mean insertion torque value of 65 Ncm (range 45 to 100 Ncm) was reached with the use of the tapered apical half of the implant body. No implants failed during an average healing period of 1 year. A labial plate dimension between 1.8 and 2.1 mm was attained immediately posttreatment and remained stable over time. A toothto-implant interdental bone crest distance and dimension of 2.3 to 2.6 mm was reached; it was also sustained at the 1-year follow-up. The average PES was 12.5 (range 9.0 to 14.0), with nearly 90% of treated sites with an "almost perfect" score. This macro hybrid implant in concept and design may be useful in immediate tooth replacement therapy of maxillary anterior postextraction sockets to achieve successful implant survival and esthetic outcomes, specifically labial plate and papilla preservation without midfacial or interdental tissue loss and discoloration. Int J Periodontics Restorative Dent 2018;38(suppl):s17-s27. doi: 10.11607/prd.3987

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Immediate tooth replacement therapy (ITRT), ie, immediate implant placement and provisional restoration, for single teeth in the esthetic zone has become a viable treatment option since its introduction in the late 1990s.1-3 Even though osseointegration can be accomplished with implant survival rates equivalent to delayed therapy, achieving consistent esthetic outcomes remains the challenge and benchmark for success.⁴⁻⁸ Tissue discoloration can be a negative consequence of labial plate loss in both dimension and contour, which detracts from a pleasing smile (Figs 1a and 1b).^{9,10} In addition, loss of the interdental papilla in the smile as a result of poor implant placement in excessively close proximity to an adjacent natural tooth can also be an esthetic dilemma (Figs 2a and 2b).^{11,12} The above-mentioned visual situations can contribute to a low and unsatisfactory pink esthetic score (PES).^{13,14}

Adequate labial bone plate thickness and tooth-to-implant distance indicative of interproximal bone crest thickness equal to 1.5 to 2.0 mm have been suggested for the maintenance of facial and interdental bone, respectively, which leads to long-term stability of the ridge contour, interdental papillae, and ultimately esthetics.^{15–18} While smaller-diameter implants are recommended to maintain labial plate



Fig 1 Patient presents with (a) tissue discoloration associated with the maxillary right lateral incisor visible in the smile as a consequence of (b) labial plate and periimplant soft tissue loss. Note loss of labial bone plate clinically after flap reflection.







Fig 2 Patient presents with (a) interproximal papilla loss at the distal aspect of the maxillary right lateral incisor in the smile as a result of (b) implant placement too close to the adjacent canine tooth. The loss is subtle in that the facial papilla is absent due to the facial-distal placement and angulation of the lateral incisor implant, yet the palatal papilla is still intact.

and interproximal distance, achieving adequate primary stability can be a clinical challenge. Wider-diameter implants are effective in increasing primary stability but decrease the gap distance, with the potential risk of apical fenestration of the extraction socket (Fig 3a).¹⁹ Consequently, subcrestal angle correction (SAC) or Co-Axis implants have been utilized since the early 2000s to engage more palatal-apical bone, decrease the risk of labial plate fenestration, and increase the incidence of screwretained definitive restorations.^{20–23} This reduces the need for custom abutments with the possibility of undetected cement remnants in the peri-implant tissues.²⁴ However, SAC implants require an incisal path of insertion angle to engage the palatal-apical triangle of bone, effectively diminishing the facialcoronal gap distance (Fig 3b).

A platform-switched macro hybrid implant with SAC (Inversa Co-Axis, Southern Implants) has been developed with the benefits of both a tapered and cylindrical design in a singular implant body, with prosthetic screw retention. This hybrid concept is unique because it possesses a "body shift" in diameter and shape, each comprising approximately half the implant length. The design concept provides the clinician the primary stability of a larger-diameter implant at the apex yet the gap distance of a smallerdiameter implant at the bone crest. Because the diameter of the coronal half of the implant is reduced

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Fig 3 (a) Straight implants placed with a cingulum angulation maintain coronal gap distance (green arrow) at the risk of apical fenestration (red arrow). (b) Subcrestal angle correction (SAC) or Co-Axis tapered implants reduce the risk of apical perforation (green arrow) at the expense of reduced coronal gap distance (red arrow).



Fig 4 (a) Less space is available for biomaterial with conventional tapered implant designs with SAC. (b) The Inversa Co-Axis hybrid implant allows a greater volume of graft material to be placed into the gap because of its reduced diameter (0.5 to 0.75 mm) and shape (cylindrical from tapered) in the coronal portion.

uniformly, the circumferential gap distance is increased, thereby creating a "bone chamber" for additional volume of hard tissue biomaterial in immediate extraction sockets over conventional tapered or other implant designs (Figs 4a and 4b).

Few studies have assessed the ability to achieve high insertion torque values in postextraction sockets with macro implant designs featuring SAC with only half the implant length. Also lacking is evaluation of the labial plate thickness and toothto-implant bone crest distance of implants placed immediately into intact extraction sockets with grafting, stability over time, and esthetic outcomes with this hybrid implant.13,25,26 Therefore, the purpose of this prospective clinical cohort study was to assess (1) primary stability and initial short-term survival, (2) labial bone plate thickness, (3) tooth-to-implant interproximal bone crest dimension (distance), and (4) PES using this novel macro hybrid implant design

in maxillary anterior postextraction sockets. Assessment was performed immediately posttreatment and at a 1-year recall.

Materials and Methods

Clinical Protocol

Thirty-three implants in the same number of patients requiring singletooth replacement in the maxillary anterior region were treated with ITRT in four different clinical sites. The study was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2000. All patients signed an informed consent form. All removed teeth were deemed hopeless, due to horizontal root fracture, endodontic failure, or root resorption, with the labial bone plate intact postextraction.

The inclusion criteria for implant placement was (1) good systemic health of the patient, (2) maxillary anterior teeth from canine to canine affected by coronal clinical crown fracture, (3) failed endodontic lesions that did not affect the integrity of the facial plate, (4) absence of periodontal disease or gingival recession, and (5) presence of adjacent teeth (Fig 5). Exclusion criteria were general medical or psychiatric contraindications, pregnancy, patients with local or generalized healing limitations, diabetes, smoking more than half a pack of cigarettes per day, type II and III extraction sockets, compromised soft tissue conditions at the surgical site, and poor patient compliance.

The surgical treatment protocol entailed flapless tooth extraction, thereby maintaining the periosteal blood supply to the interproximal and labial bone plate.²⁷ Sharp dissection of the supracrestal gingival fibers was performed with a 15c scalpel blade prior to tooth removal. The residual socket was thoroughly debrided, and an osteotomy was



Fig 5 Patients included in this study had a failing maxillary anterior tooth requiring immediate replacement predominantly due to end-odontic complication or horizontal root fracture.



Fig 6 A flapless tooth extraction protocol was used to maintain the periosteal blood supply to the residual labial bone plate. Thorough socket debridement was performed prior to implant site preparation.



Fig 7 Osteotomy site preparation sequence and protocol for the Inversa Co-Axis hybrid implant. An incisal path of drilling, with the use of a (shown from left) spade, 2.0-mm twist, 3.3-mm twist, and final sizing-shaping drill of 4.5 or 5.0 mm, is recommended for (right) the 13.0- or 15.0-mm implants employed in the study.

made with an incisal orientation for the placement of a 12-degree SAC hybrid implant (Fig 6). The osteotomy was stepwise enlarged to the final shaping-drill diameter in accordance with the manufacturer's recommendations (Fig 7). Implants with a "body shift" in diameter of 1.0 to 1.5 mm (ie, 5.0-mm tapered apical portion and 4.0-mm cylindrical coronal portion), a length of 13.0 or 15.0 mm, and an external or deep conical connection were used (Fig 8). The "body shift" in diameter and shape of the macro hybrid design creates a circumferential coronal bone chamber that allows additional hard tissue graft material to be placed into the "gap" between the labial and interproximal surface of the implant and the residual plate of bone. The hybrid implant was placed, engaging the palatal-apical bone, and hand torqued into the correct rotational orientation for a screw-retained provisional restoration (Figs 9). Primary stability was obtained from the implant macrothread design, predominantly at the apical third to half of the extraction socket walls, and was confirmed by hand torque with a minimum of 45 Ncm to facilitate immediate

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Fig 8 From left to right: Inversa Co-Axis hybrid implants were used with a "body shift" in diameter of 1.0 to 1.5 mm (ie, 5.0-mm tapered apical portion and 4.0-mm cylindrical coronal portion), lengths of 15.0 and 13.0 mm, and an external or deep conical connection (IV-DC3512D-5013). Note the variation in platform shift dimension at the direct midfacial aspect of the implant equivalent to 0.86 mm (far right).



Fig 9 Note the tapered apical and cylindrical coronal portion design of the Inversa Co-Axis hybrid implant. Hybrid implants are preconnected to the implant mount with labial and palatal orientation for screw retention.



Fig 10 The midfacial aspect of the implant is denoted with a labial marker (dot) in the implant mount with placement depth lines of 3.0 mm from the midfacial free gingival margin.



Fig 11 A screw-retained provisional restoration was fabricated with a preformed gingival former shell attached to a PEEK temporary cylinder. The reduced coronal diameter of the implant allows easier seating of provisional prosthetic components during the fabrication process.

non-occlusally loaded provisional restorations. The platform-shift implant shoulder was placed about 3.0 mm apical to the midfacial free gingival margin (Fig 10).

The restorations were fabricated using polyether-ether-ketone (PEEK) temporary cylinders with an internal deep conical or external hex connection. Preformed submergenceprofile root-form shells (i-Shell, Vulcan Dental Labs) were luted with autopolymerizing acrylic resin (Super-T, American Consolidated) (Fig 11). The provisional restorations possessed subgingival contours that conformed to the pre-extraction state of the tooth root cervix to support the soft tissue submergence profile and to help protect the blood clot and contain the bone graft particles (Fig 12).²⁸ The labial and interproximal residual gap into the soft tissues was filled with one of the following biomaterials: small-particle (250 to 500 μ m) mineralized bone allograft (Puros, Zimmer Dental); prehydrated collagenated corticocancellous porcine bone xenograft (mp3, OsteoBiol, Tecnoss Dental); or alloplast biomaterial (EthOss, Ethoss Regeneration) at the time of implant placement, with approximately 50%

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Fig 12 The provisional restoration (left: labial view; right: proximal view) was properly contoured relative to the implant position, polished, and steam cleaned prior to insertion.



Fig 13 The dual-zone grafting technique was used to maintain ridge dimension and enhance peri-implant soft tissue thickness at the time of tooth replacement.



Fig 14 The provisional restoration is seated to contain and protect the biomaterial during the healing phase of ITRT.



Fig 15 A minimum of 4 months of healing was given prior to first disconnection and implant-level impression making.

of sites receiving the xenograft (Fig 13).²⁹ Once this was accomplished, the provisional restorations were steam cleaned or disinfected prior to insertion with hand torque, and maintenance of the periodontal architecture was ensured immediately postoperatively (Fig 14).³⁰

All patients received antibiotic premedication that was continued through postsurgery and an analgesic as needed. They were seen 7 to 14 days postoperatively for follow-up. A minimum healing time of 4 months was given before the first removal (disconnection) of the provisional restoration prior to impression making (Fig 15). Implantlevel impressions were made with a monophasic impression material (Flexitime, Kulzer) or intraoral scanning (3Shape) (Fig 16). The dental laboratory fabricated a soft tissue cast (G-Mask, GC America) that allowed screw-retained all-ceramic crowns to be fabricated and delivered approximately 2 to 3 months after final impression making (Fig 17). All definitive crowns were screw retained, seated, and torqued to the manufacturer's recommendation of 35 Ncm (Fig 18). After final restoration delivery, patients were placed on 6-month-interval recall visits.

Labial Plate Measurement

Cone beam computed tomography ([CBCT], 3D Accuitomo 170, J. Morita) was performed pre-extraction, immediately after implant placement with gap grafting (day 0), and at 1 year postsurgery healing. Measurements

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The International Journal of Periodontics & Restorative Dentistry
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Fig 16 An implant-level scan body or analog impression coping was used for impression making.



Fig 17 All-ceramic screw-retained definitive restorations with titanium bases were fabricated.

were taken at two levels, as previously described by Lee et al²⁵ and Sarnachiaro et al³¹: L1 = coronal level and L2 = middle level at the time of implant placement and 1 year posttreatment. The apical measurement (L3) was omitted, since Sarnachiaro and coworkers showed insignificant change over a 6- to 8-month healing period in this region. The coronal level (L1) corresponded to the implant-abutment interface equivalent to the midfacial labial bone crest, and the middle measurement (L2) to the implant body roughly 4.5 to 5.5 mm from the bony crest, coinciding with the upper portion of the hybrid implant transition zone where the body diameter shifts from a tapered to cylindrical form roughly one-half 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



Fig 18 Definitive all-ceramic screw-retained restoration seated intraorally. PES was 12.0.

in millimeters using bundled CBCT digital imaging software (i-Dixel, J. Morita), and the bone plate thickness was recorded at day 0 and 1-year posthealing (Table 1; Fig 19).

Interproximal Bone Crest Measurement

Digital periapical radiographs were taken pre-extraction, immediately after implant placement with gap grafting (day 0), and at 1 year postsurgery healing. The mesial and distal implant-to-tooth distance was measured from the height of the implant-abutment interface proximally and perpendicular to the interseptal bone using digital imaging software (Image J, NIH.org) (Fig 20). The width of the interproximal bone crest from the implant platform perpendicular to the adjacent tooth was measured at day 0 and at the 1-year follow-up (Table 2).

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Volume 38, Supplement, 2018



Fig 19 (a) Labial plate dimension pre-extraction, (b) immediate post-implant placement with gap grafting, and (c) 1-year postoperative CBCTs. Change in radiographic labial plate dimension at two points of reference, L1 (implant platform) and L2 (4.5 to 5.5 mm from implant platform), respectively, was calculated (Table 1).

Table 1	Distance Between the Exte Plate and the Facial Surface	ernal Surface of th e of the Implant at	e Labial Bone t Day 0 and 1 Year
CBCT	Day 0 (mm)	1 y (mm)	Change (mm)
L1	2.11 ± 0.73	2.04 ± 0.63	0.07
L2	1.78 ± 0.74	1.64 ± 0.73	0.14

L1 = labial plate thickness measured from the implant platform; L2 = labial plate thickness measured 4.5 to 5.5 mm from the implant platform.



Fig 20 (a) Pretreatment, (b) tooth-to-implant distance immediately post-implant placement, and (c) 1-year follow-up periapical radiographs. Change in interproximal bone crest width and distance, both mesial (M) and distal (D), was calculated (Table 2).

Table 2 Distance from the Implant Platform to the Adjacent Tooth Surface (Day 0) and the Interproximal Bone Crest Width to the Adjacent Tooth from the Height of the Implant Platform (1 Year)					
Periapical radiograph	Day 0 (mm)	1 y (mm)	Change (mm)		
Mesial	2.57 ± 1.14	2.59 ± 1.15	0.02		
Distal	2.34 ± 0.74	2.37 ± 0.75	0.03		

Pink Esthetic Score

High-resolution images were captured at the 1-year follow-up using a digital single lens reflex (DSLR) camera with a 105-mm macro lens and wireless twin (spot) flash system (D3200, R1C1, Nikon), rated by a single observer.³²

Results

Maxillary central (61%) and lateral (39%) incisors were treated in this study. Fifty-eight percent of the patients possessed an intermediate periodontal phenotype, with twothirds of extraction sockets having type III-IV quality bone identified at implant insertion. Twenty-nine percent of implants employed a deep conical connection, with the remaining using an external hexagon.

Mean insertion torque values for the macro hybrid implants was 65 Ncm (range 45 to 100 Ncm). All definitive restorations were screw retained with the Co-Axis implantabutment interface. Short-term survival rate (1 year) was 100% for all implants placed.

The CBCT mean immediate posttreatment labial plate thickness following implant placement and gap grafting was 2.11 \pm 0.73 mm at L1 and 1.78 \pm 0.74 mm at L2, respectively. The CBCT mean labial bone plate thickness at the 1-year follow-up was 2.04 \pm 0.63 mm at L1 and 1.64 \pm 0.73 mm at L2, with a mean change of 0.07 mm at L1 and 0.14 mm at L2 (Table 1).

Mean tooth-to-implant distance immediately post-implant

The International Journal of Periodontics & Restorative Dentistry

placement was 2.57 ± 1.14 mm at the mesial aspect from the implant platform to the adjacent tooth and 2.34 ± 0.74 mm at the distal aspect (Table 2). The interproximal bone crest width, distance, and height were maintained at the implant platform, both mesial and distal, 1-year posthealing as shown on periapical radiographs. The mean PES for the 33 single-tooth hybrid implants was 12.5 out of a possible high score of 14.0, with a range of 9.0 to 14.0. Eighty-eight percent of the implant sites had a mean PES approximating 13.0, with the remainder having an average score of 10.3 and only one patient with a score of 9.0. The mean PES subset rating was 1.9 (2.0 maximum) for the mesial papilla, 1.8 for the distal papilla, and 1.9 for the level (midfacial) of the soft tissue (gingival) margin.

Discussion

The design elements of the macro hybrid implant evaluated in this study provide the best of both worlds—a larger tapered apical portion for high primary stability and a narrower cylindrical coronal portion for maintaining gap distance and space for graft material in ITRT. Primary stability of implants has been associated with implant survival, especially in immediate extraction sockets, where engagement of residual peripheral socket walls and apical bone is at a premium. While the potential violation to the buccal plate still exists, the use of the angle correction feature of the hybrid implant can reduce this risk. Hybrid implants in this study achieved a mean primary stability and insertion torque value (ITV) significantly above the minimum threshold value of 25 Ncm, with the range achieving a minimum of 45 Ncm up to an extremely high ITV of 100 Ncm without buccal plate contact.^{7,8} The apical half of the implant body has aggressive threads for increasing cutting capability and enhanced primary stability. A thread depth of 0.5 mm, angle of 35 degrees, and pitch of 0.6 mm creates an aggressive design that resulted in the measured high primary stability in this study. Values in this range are consistent with a prior publication showing high insertion torque values of hybrid implants placed in foxhounds with absence of apical pressure necrosis.33 Khayat et al also showed no radiographic evidence of pressure necrosis of crestal bone around implants placed in healed edentulous ridges with high vs normal ITV surrounded by adequate bone thickness and volume.³⁴ However, pressure necrosis both labially and interproximally may be a phenomenon associated with thin crestal bone (Fig 2). Another factor in interproximal attachment loss could be the reformation of the horizontal component of biologic width, which is about 0.6 mm for platformswitched implant designs.³⁵ This can be a factor when an implant is placed too close to the adjacent tooth. The coronal portion of the hybrid implant is circumferentially reduced to eliminate the potential of both of the aforementioned risk factors.

The evidence is clear that implants placed in extraction sites do not alter the wound healing and remodeling process of the socket, so the scheme of reducing implant diameter and palatal position is a prudent treatment strategy.^{36,37} The coronal portion of the hybrid implant was not in contact with the surrounding socket walls, which allowed graft material to be placed into the gap circumferentially. Historic data, whether direct or via CBCT measurement, has shown the labial bone plate of maxillary anterior teeth to be thin, with 90% of patients having a thickness \leq 1.0 mm and two-thirds having ≤ 0.5 mm, regardless of periodontal phenotype or biotype.37,38 Hence socket grafting the gap between the implant body and internal aspect of the labial bone plate is recommended to maintain ridge dimension and volume for esthetics.²⁶

The results of this 1-year prospective study demonstrate that labial bone plate thickness between 1.8 and 2.1 mm with \leq 0.14-mm change over the healing period can be achieved at the implantabutment interface and up to 4.5 to 5.5 mm from the connection. Comparing these values to preoperative values of thin and thick biotype patients on CBCT, mean preoperative labial plate thickness of central and lateral incisors at L1 is roughly 0.6 mm and at L2 about 0.9 mm.³⁸ These values, when compared to 1-year posttreatment values in this study, equate to a difference and gain of 1.5 mm at L1 and 0.9 mm at L2. This is clinically significant, since it is roughly at least twice the amount of labial plate thickness from the preoperative condition of 1.0 mm. In addition, there was not significant radiographic remodeling

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Volume 38, Supplement, 2018

of the labial plate and interdental bone crest over the 1-year healing period consistent and within the range values of prior studies.²⁵

Authors have suggested that a minimum of 1.8 mm thickness of the labial bone plate must be attained for long-term stability since this threshold dimension possesses medullary bone important for sustainability.^{15,16} This same minimum distance holds true for the maintenance of both the mesial and distal papillae adjacent to natural teeth.^{12,18} The attachment level on the adjacent natural tooth determines its presence when the threshold distance of 1.5 mm between tooth and implant is not violated.³⁹ It was observed in the present study that the toothto-tooth distances between central incisors and central-lateral incisors varied consistently, with less distance between the latter tooth groups and thus reflected in Table 2. This pretreatment condition can potentially bias implant placement in postextraction sockets toward the side of least interproximal and facial bone.

These two factors can affect esthetic outcomes, since facial ridge collapse with concomitant tissue discoloration and loss of interdental papillae height is frequently deemed unattractive. Cosyn et al found that a PES between 8.0 and 12.0 was considered clinically satisfactory, with a score of \geq 12.0 being deemed above average and "almost perfect."14 Most of the implant sites in this study (~90%) had an average PES of 12.8 with a range of 12.0 to 14.0. Only about 10% of patients had a mean score < 12.0 (average score of 10.3; range 9.0 to 11.0). The

robust PES subcategory rating of the mesial papilla, distal papilla, and gingival margin indicates that little or no recession occurred in these areas at the 1-year follow-up. Consequently, ITRT may lend to consistent esthetic outcomes employing the advantages of a macro hybrid implant design.

Further research is needed to evaluate long-term radiographic and clinical esthetic maintenance outcomes longitudinally. Comparative studies on conventional tapered shape vs macro hybrid implants with equivalent apical diameters are also needed.

Conclusions

The hybrid implant evaluated in this prospective short-term study employs a "body shift" design concept with SAC that maximizes the benefit of a larger-diameter implant apically yet a smaller one coronally in postextraction sockets. These hybrid implants were able to achieve not only robust insertion torque values with prosthetic screw retention in immediate tooth replacement therapy, but also implant survival over a short-term period of 1 year. The apical half of the implant body provided mean insertion torque values of 65 Ncm (range 45 to 100 Ncm). A mean value of 1.5 to 2.0 mm was attained in labial plate thickness, with L1 (2.0 mm) being greater than L2 (1.6 mm) values, thereby suggesting greater resistance to midfacial recession. Interproximal tooth-toimplant and bone crest distances of 2.5 mm, for both the mesial and distal aspects, were achieved with this novel implant design, suggesting papillae height maintenance over time. A cumulative average PES of 12.5 was achieved, suggesting a correlation between hard and soft tissue outcomes and esthetic results.

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