Factors Affecting Soft and Hard Tissues Around Two-Piece Transmucosal Implants: A 3-Year Prospective Cohort Study

Carlo Prati, MD, DDS, PhD1/Fausto Zamparini, DDS, MEndo, PhD2/Luigi Canullo, DDS3/
Chiara Pirani, DDS, MEndo, PhD4/Daniele Botticelli, DDS, PhD4/Maria Giovanna Gandolfi, DBiol, MBIol, PhD5

Purpose: This 3-year study aimed to evaluate hard and soft tissue modification around a two-piece implant characterized by a transmucosal hyperbolic neck in healthy consecutive patients with a need for single-tooth replacement. Materials and Methods: Two-piece implants (n = 66) were placed with a flapless technique in 56 patients (27 men; 29 women; mean age 55 ± 9 years): 16 immediately after root extraction (immediate group), 20 after 8 to 12 weeks (early group), and 30 after 10 or more months (delayed group). The transmucosal hyperbolic neck was exposed 1 to 1.5 mm above gingival level. Customized abutments were positioned 3 months later with the implant-abutment connection located approximately 1 to 1.5 mm above soft tissue level. Provisional cemented resin crowns were designed with the finishing line at the hyperbolic neck and then positioned to avoid excessive compression of soft tissue, to guide gingival contours. Twenty days later, a definitive metal-ceramic crown was cemented. In all patients, the gingival biotype (thin or thick) was also evaluated. The primary outcomes were as follows: 36-month implant survival rate, peri-implant marginal bone level (MBL, in mm) changes observed in single-blind on radiographs at 1, 3, 6, 12, 24, and 36 months (T1, T3, T6, T12, T24, and T36), and pink esthetic score (PES) at T6, T12, and T36. Results: The survival rate was 100%. The dropout rate was 1.79%. No infections, mucositis, or peri-implantitis were reported. Implants placed in thick-biotype tissues showed a statistically different lower bone loss at 36 months with respect to the thin biotype (P < .05). At 36 months, the early group showed lower bone loss compared with the delayed group (P < .05). Multilevel mixed logistic regression revealed that gingival biotype was the parameter that was most related to MBL variations (P = .025). The PES value (mean ± SD) at T6 was 10.76 ± 1.19 (median: 11; range: 8 to 13; IQR: 10 to 12). The values statistically increased at T12 and T36, where the mean values were 11.76 ± 1.10 (median: 12; range: 9 to 13; IQR: 11 to 12) and 11.83 ± 1.03 (median: 12; range: 9 to 14; IQR: 11 to 13). Conclusion: MBL and soft tissue clinical parameters measured around two-piece hyperbolic-neck implants were stable during the 3-year follow-up and free from complications. The exposure of the hyperbolic neck for 1.0 to 1.5 mm allowed a flapless one-stage surgery, which supported fast adaptation of the soft tissues, evidenced by high PES values and low percentages of BOP. The results from the study imply a new simple approach in the clinical management of gingival and bone tissue. Int J Oral Maxillofac Implants 2020;35:1022–1036. doi: 10.11607/jomi.7778

Keywords: flapless procedure, hyperbolic neck, prospective cohort study, single implant, transmucosal placement

The morphology and the healing phases of tissues around implants are important biologic conditions for function and esthetics.1,2 To achieve fast stability of hard and soft tissue, different factors should be considered in the early healing stage after implant placement, such as implant placement timing and bone quality,3,4 surgical procedures (ie, flapless implant insertion), implant exposure and superinfection, implant micro-movements, early occlusal loads,5–7 and cleansability of the implant restorations.8,9 Implant-abutment connection is another important biologic condition for post-loading crestal bone remodeling processes.10,11 Bacteria infiltration of the microgap,12 chronic trauma, and stress at the implant-abutment level and repetitive motions of the abutment provide risks for soft tissue damage and
gingival esthetic alterations, critical bone remodeling, and failures.13

Transmucosal implants have been proposed in many clinical studies, as they require only a one-stage technique compared with the submerged two-stage technique5,14–17 and provide good performances in terms of peri-implant bone preservation.17 The transmucosal one-stage technique may reduce surgical trauma and reduce any further surgical manipulation of gingival tissue before and during prosthetic procedures. Better control of impressions and less discomfort for patients are additional advantages.15

Innovative clinical strategies, such as one-piece implants with a flapless technique18–21 or the use of transmucosal/transgingival healing screws in the early phases after implant insertion at the crestal bone level,5,15,22,23 have been proposed in clinical studies to try to overcome the limits of two-stage techniques, which require a second surgical step to expose the submerged implant.

Recent immunohistochemical studies demonstrated that transmucosal implants applied with the one-stage technique showed gingival tissues with similar immune cell population and response to submerged implants.24

Scanning electron microscopy (SEM) analysis of the exposed abutments of human transmucosal implants showed the presence of a “clear zone” free from any biofilm connected with peri-implant mucosa, acting as a protective functional barrier.25,26

Histologic studies in animal models demonstrated that transmucosal implants showed less marginal bone loss and a lower degree of gingival inflammation than submerged implants10,27,28

A transmucosal implant with an innovative hyperbolic neck may represent a further approach in line with the concept to create the clinical-biologic conditions to induce early gingival adaptation and healing and to minimize soft tissue trauma by avoiding secondary surgeries to expose the implant.

The two-piece hyperbolic-neck implant was designed to keep 1 to 1.5 mm of the neck exposed after flapless surgical placement.29

This neck may allow transmucosal placement, relocating the implant-abutment junction above the tissue levels and consequently distant from crestal bone and gingival margins. To date, little information about the use of the hyperbolic-neck implant is present.30–32

The purpose of the present investigation was to study the hard and soft tissue modifications of a novel transmucosal two-piece implant with the hyperbolic neck exposed above tissue levels in a cohort of patients followed for at least 3 years.

Primary outcome measures were implant survival rate, crestal marginal bone level changes (MBL), and pink esthetic score (PES) up to 36 months.

Secondary outcomes were plaque score and bleeding on probing (BOP), measured around the implant neck.

MATERIALS AND METHODS

Study Design and Patient Enrollment

The clinical investigation was settled as a single-blinded longitudinal prospective cohort study on patients with requirement for rehabilitation with a single-tooth implant. Radiographic and clinical indicators were measured in the time of the settled study.

The investigation was performed in a university endodontic clinical department and in two private clinics in the same geographic area. Surgeries were performed by the same operator (C.Pr.) trained in flapless surgery. Recruitment of patients started in September 2014 and ended in February 2016. Follow-up was performed between October 2014 and March 2019 by the same clinical team included as authors.

Subjects included in this investigation were treated according to the principles established by the Declaration of Helsinki as modified in 2013.33 Patients were delivered written and oral information before recruitment into the study and signing the consent form. The document was prepared according to the Consolidated Standards of Reporting trials guidelines for reporting clinical trials34 and complied with the guidelines previously published by Dodson in 2007.35

Patient Allocation

Inclusion criteria were as follows:

- Age between 18 and 75 years
- Presence of a compromised unrestorable tooth with presence of both adjacent teeth
- Acceptance of a 3-year hygiene recall program and implant follow-up
- Smoking less than 10 cigarettes per day

Exclusion criteria were as follows:

- ASA score ≥ 3
- Lack of motivation and poor oral hygiene
- Pocket probing depth > 4 mm and positive BOP in the natural dentition, expressing active periodontal disease
- Smoking 10 or more cigarettes per day
- Uncontrolled type 2 diabetes
- Local and/or systemic diseases, which possibly compromise postoperative healing and osseointegration
- Substance abuse, such as alcohol or drugs
- Pregnancy or lactation status
• Occlusal disorders, including bruxism, or other malocclusions
• Any use of bisphosphonate drugs

Clinical criteria for extraction, postextraction healing, and implant placement timing were defined by an experienced senior university medical dentist (C.Pr.). Immediate, early, or delayed placement criteria\(^3\) were selected following clinical parameters for the best clinical practice (judgmental allocation).\(^36\) The defined placement timing groups were as follows:

• Immediate postextraction group\(^3\): Placement of implant into socket immediately after extraction of seriously compromised hopeless teeth free from infection or of teeth affected by granuloma.
• Early group\(^3\): Implant insertion was achieved in healed bone 8 to 12 weeks after extraction of teeth affected by acute endodontic abscess or periapical infection and severe symptoms.
• Delayed group\(^3\): Implant placement was performed in edentulous mature bone 10 to 12 months after teeth removal.

**Environmental Scanning Electron Microscopy of the Implant Neck**
Morphologic microanalyses of the transmucosal hyperbolic neck surface were performed using an environmental scanning electron microscope (ESEM; Zeiss EVO 50, Carl Zeiss).

The implant was examined without any previous treatment (the sample was not coated) following a previously published protocol.\(^37\) Operative parameters were as follows: accelerating voltage of 20 kV, low vacuum (100 Pascal), with working distance of 8.5 mm. The detection level was 0.5 wt%, while the resolution was 133 eV, and the amplification time was 100 µs.\(^37\)

**Presurgical Protocol**
Each patient received an oral antibiotic (1 g amoxilin/clavulanic) tablet 24 and 12 hours before scheduled surgery. Chlorhexidine digluconate 0.12% gel (Corsodyl Gel, GlaxoSmithKline) was prescribed: three applications per day. Antibiotic administration was scheduled for 5 postoperative days.

**Implant Surgery**
All implant placements were performed by one senior operator (C.P.). Mepivacaine chlorhydrate 30 mg/mL (Carboplyina, Dentsply Italia srl) was used as local anesthesia.

All implants were positioned with single-stage procedures and without the use of surgical guides.

**Immediate Implant Placement**
Teeth extractions were made with attention to prevent any trauma. A careful inspection of the socket was made followed by a radiographic evaluation. When present, the periapical tissue that presented a sign of granulation was removed with great attention from the socket apical portion and carefully inspected. A first drill (1.2 mm) working at 250 rpm under saline solution irrigation was used as a guide. The position and the inclination of palatal bone wall indicated the direction and the other position parameters. Calibrated drills (used at 225 rpm) were mounted on a low-speed handpiece (W&H Austria) to prepare the implant housing. The apical portion of the sockets was prepared to obtain a first anchorage for the implant. Usually 3.0 mm depth was enough to obtain stability.

Corticocancellous bone (OsteoBiol mp3, Tecnoss Dental) was inserted into the surgical site in four cases. The procedures were selected to replace the lack of bone tissues and to reduce the gap between the bony walls and the implant surface.

Acid-etched titanium implants (Prama, Sweden & Martina) with surfaces treated by zirconium oxide particle blasts were used in the study. Implants were characterized by a 2.8-mm anodized smooth machined long hyperbolic neck as illustrated in Figs 1 and 2.

All implants were surgically inserted to maintain the blasted surface at cortical crestal bone level and the smooth surface of the neck 1.0 to 1.2 mm above the gingival margin to achieve the transmucosal emergence of the neck. A sealing thin screw (height: 1.0 mm) was kept in place for the 3-month healing time. A eugenol-free surgical dressing (Coe-Pak, GC America) was placed on the area of implant placement and kept in position for 5 to 7 days.

**Early and Delayed Implant Insertion**
Similar surgical procedures were performed for both early and delayed groups. In these cases, no flaps were made before implant placement.

A first guide drill (diameter: 1.2 mm) was utilized to mark the position and to define the direction angle and depth of placement. The drill crossed the entire gingival thickness and the cortical and cancellous bone. All procedures were under saline solution irrigation. Calibrated drills working at 225 rpm were then utilized, creating a calibrated diameter for the implant site and a corrected depth.

The implants were positioned to achieve transmucosal healing. The rough implant surface was placed corresponding to crestal bone, and the smooth neck was calibrated at 1 to 1.2 mm above the surface of soft tissues (Fig 3). A thin screw (1.0-mm height) was kept in place to seal the connection for the next 3 months. The
Prati et al

surgical dressing was kept on the area of implant placement for 5 to 7 days.

Maryland Bridge Placement

A bonded Maryland bridge was applied when possible and used as the provisional prosthesis in 46 cases during the healing phase period. The enamel surfaces of teeth adjacent to the implant were acid etched (H₃PO₄ 3 gel, 3M ESPE) and water rinsed for 20 to 25 seconds. A single-component enamel/dentin adhesive (Scotchbond Universal Bonding, 3M ESPE) was brushed on the enamel surface. A dual cement (RelyX Ultimate, 3M ESPE) was mixed and positioned to bond and keep the Maryland bridge in place.
Postoperative Procedures
Instructions for patients included following a soft diet regimen for 1 week to prevent any trauma in the area. Chlorhexidine-based mouthwash (0.12%) was prescribed, and it was suggested to rinse three times/day for 3 weeks and to perform oral hygiene procedures on the surgical dressing for the first week and to continue for 2 weeks after surgical pack removal. Hence, brushing and flossing were permitted.

Prosthetic Rehabilitation
After 3 months, polyether impressions (Permadyne and Garant, 3M ESPE) were obtained using plastic customized trays. In all patients, the pickup impression technique was performed by two operators (F.Z., C.Pr.) to obtain gypsum models. Custom resin crowns were prepared as provisional prostheses. The gingival finishing line of crowns was designed to be in delicate contact with the gingival-papilla line to obtain a moderate compression of the peri-implant soft tissues. Customized titanium abutments were prepared and positioned after approximately 7 days from impression. The provisional resin crowns were placed and fixed with zinc-oxide temporary cement (Temp-Bond NE, Kerr). The connection between the implant and abutment was at 1 to 1.5 mm from the gingival external margin and, for this reason, completely covered by the crown. The application of the abutment increased the retention offered by the cement-crown monoblock.

Definitive metal-ceramic crowns were prepared on the same models. Both metal and ceramic finishing lines were designed and fabricated to fit corresponding to the implant hyperbolic neck. Definitive metal-ceramic crowns were fixed after 3 to 4 weeks using a radiopaque polycarboxylate powder/liquid cement (Heraeus Kulzer) with careful attention to prevent any cement overflowing and excess. Two experienced prostho-dentists (F.Z., C.Pr.) did all the laboratory and clinical prosthetic procedures.

Implant Clinical Evaluation and Patient Follow-up
Instruction in oral hygiene practice and motivation were verbally discussed with the patients. Scaling and root planing was performed every 6 months or more frequently when modest plaque and calculus was observed and still present after the follow-up clinical control.

Hard and Soft Tissue Evaluation

MBL. Periapical radiographs were taken using a paralleling technique with Rinn holders and analog films (Kodak Ektaspeed Plus) after implant insertion and at 1 (T1), 3 (T3), 6 (T6), 12 (T12), 24 (T24), and 36 (T36) months after implant placement.

Periapical radiographs were performed following an accurate standardization carried out before the study. The following radiographic parameters were used:

- Fig 3 (a to d) Surgical phases of Prama implant insertion on a healed ridge using a flapless technique. (e) Extraction was performed 3 months before for tooth fracture. (f) Please note that the cylindrical machined portion is positioned with a minimal invasive surgery at the hard-soft tissue interface, while the hyperbolic neck was partially exposed above tissue level (1.0 to 1.5 mm), which avoids a two-stage surgery before prosthetic procedures.
target-film distance was approximately 30 cm, exposure time was 0.41 seconds, 70-kV voltage, and 8-mA intensity. Radiographic development was performed in a developer unit (Euromax) at standard room temperature (25°C) with 12-second developing and 25-second fixing time, following the manufacturer indications. When not fulfilling the parameters, patients were asked to get a new radiograph. All periapical radiographs were then scanned with a scanner with the following acquisition parameters: resolution 96 dpi and ×20 magnification factor.

The morphology of peri-implant marginal bone was carefully examined. MBL was assessed at the distal and mesial sides, calculating the distance from the implant platform (reference point) to the most coronal bone-to-implant contact. A 0.1-mm step scale was used to perform the measurements, according to previous studies, corrected according to the implant diameter and length of each implant.43

One additional examiner (Ch.P.) performed the single-blinded radiographic evaluation. A preliminary careful calibration was performed using reference radiographs with various peri-implant marginal bone level measures and defined instructions.

**PES.** The evaluation was made after 6, 12, and 36 months according to a previous investigation.40

The photographs were analyzed twice by a blinded trained examiner (Ch.P.) at an interval of 4 weeks. The photographs were reevaluated in the reverse order at the second assessment. A total of seven variables were evaluated and compared with a natural reference tooth: mesial papilla, distal papilla, soft tissue level, soft tissue contour, alveolar process deficiency, soft tissue color, and soft tissue texture. A 0-1-2 scoring system was used (0 was defined as the lowest; 2 was the highest value). In this way, the maximum rate of PES was 14.

**Peri-implant Soft Tissue Thickness.** Soft tissue thickness around implants and the corresponding mesial/distal neighboring teeth was defined. Buccal gingival soft tissues were pierced at 3 mm apical to the margin by using an endodontic instrument (K-File #20, Dentsply Maillefer). According to previous studies, soft tissue morphology was defined as thick (thickness > 2 mm) or thin (thickness ≤ 2 mm).41–43

**Plaque Score.** The plaque score around the implant crown was evaluated at four sites (distal, mesial, palatal, and vestibular) at T12 and T36. Dichotomous scores were defined (0 = absence of visible plaque at the soft tissue margin; 1 = visible plaque at the soft tissue margin).44

**BOP.** BOP around the implant crown was defined at four sites (distal, mesial, palatal, and vestibular) at T12 and T36. Dichotomous scores were defined (0 = negative bleeding; 1 = positive bleeding).44

## Results

**ESEM Micromorphologic Evaluation of the Implant Neck**

The surface of the hyperbolic neck and body of the implant was observed using ESEM.

Analysis at low magnification (approximately 90×) was performed to observe the neck geometry and the implant-abutment connection (Fig 1).

The morphology of the neck (2.8 mm) was characterized by two distinct areas: a 2.0-mm hyperbolic neck and 0.8-mm cylindrical portion. ESEM images at high magnification (1,000×) revealed an anodized machined micromorphology with regular microgrooves, ranging from 10 to 25 µm. The microgrooved morphology was detected over all the 2.8-mm transmucosal neck and ended corresponding to the first implant thread. In this area, the machined pit transition zone was detected.

The implant connection was an internal hexagon with a small internal collar, designed to distribute the occlusal load and to provide greater stability (Fig 2).
Study Population and Demographic Data
Fifty-six patients (27 men, 29 women; mean age: 55 ± 9 years) with a total of 66 implant rehabilitations were included. The survival rate was 100%. One patient failed to comply with the follow-up visits (dropout was 1.7%). No biologic complications, including wound infections, osteitis, or bone graft sequestration, occurred during the entire follow-up. Two screw loosenings were observed at 20 and 24 months from insertion. Crowns were gently removed, and a new connection screw was provided and tightened in the same session. No other complications or loosening occurred.

MBL Assessment
Table 1 reports the implant distribution and MBL (in mm, expressed as mean ± SD) according to the evaluated preoperative, intraoperative, and postoperative parameters. Early and immediate placement groups had a mean MBL of 0.16 ± 0.33 mm and 0.19 ± 0.23 mm at T6, both statistically different (P < .05) compared with the values of the delayed group, revealing a higher bone loss (mean MBL was 0.42 ± 0.26 mm).

This difference is reduced at T36, as the early implant group showed significantly lower bone loss values compared with the delayed implant group (P = .005). On the contrary, the immediate implant group revealed no statistical differences compared with both delayed (P = .16) and early implants (P = .28). The mean values were 0.81 ± 0.43 mm for delayed, 0.43 ± 0.44 mm for early, and 0.55 ± 0.42 mm for immediate implants.

A constant MBL during the healing time (T3), initial loading time (T6), and 12 months (T12) from the insertion (P > .05) was observed for thin-biotype implants, revealing a crestal bone stability during the healing phases and leading to stable MBL values at T24 and T36. On the contrary, thin-biotype implants revealed MBL variation up to T3, which increased until T24 and was stable at T36. Instead, delayed implants

### Table 1 MBL (Mean ± SD) of the Placed Implants According to Operative Parameters

<table>
<thead>
<tr>
<th>Implant location</th>
<th>Tn</th>
<th>T3</th>
<th>T6</th>
<th>T12</th>
<th>T24</th>
<th>T36</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxilla</td>
<td>52</td>
<td>0.16 ± 0.39Ba</td>
<td>0.24 ± 0.32Ba</td>
<td>0.40 ± 0.43Ca</td>
<td>0.60 ± 0.46Ca</td>
<td>0.53 ± 0.49Ca</td>
</tr>
<tr>
<td>Mandible</td>
<td>14</td>
<td>0.26 ± 0.35Ba</td>
<td>0.39 ± 0.25Ba</td>
<td>0.54 ± 0.41Ca</td>
<td>0.82 ± 0.46Da</td>
<td>0.85 ± 0.47Da</td>
</tr>
<tr>
<td>Anterior</td>
<td>17</td>
<td>0.11 ± 0.33Ba</td>
<td>0.19 ± 0.29Ba</td>
<td>0.26 ± 0.36Ba</td>
<td>0.57 ± 0.39Ca</td>
<td>0.46 ± 0.35Ca</td>
</tr>
<tr>
<td>Posterior</td>
<td>49</td>
<td>0.21 ± 0.36Ba</td>
<td>0.32 ± 0.33Ba</td>
<td>0.51 ± 0.41Cb</td>
<td>0.69 ± 0.48Ca</td>
<td>0.71 ± 0.43Ca</td>
</tr>
<tr>
<td>Male</td>
<td>29</td>
<td>0.23 ± 0.35Ba</td>
<td>0.29 ± 0.33Ba</td>
<td>0.41 ± 0.41Ca</td>
<td>0.62 ± 0.49Ca</td>
<td>0.64 ± 0.47Ca</td>
</tr>
<tr>
<td>Female</td>
<td>37</td>
<td>0.15 ± 0.36Ba</td>
<td>0.26 ± 0.32Ba</td>
<td>0.47 ± 0.42Ba</td>
<td>0.70 ± 0.49Ca</td>
<td>0.68 ± 0.48Ca</td>
</tr>
<tr>
<td>Endodontic adjacent teeth</td>
<td>No</td>
<td>0.24 ± 0.37Ba</td>
<td>0.31 ± 0.33Ba</td>
<td>0.46 ± 0.42Ca</td>
<td>0.68 ± 0.48Ca</td>
<td>0.65 ± 0.48Ca</td>
</tr>
<tr>
<td>Implant placement</td>
<td>Yes</td>
<td>0.15 ± 0.36Ba</td>
<td>0.26 ± 0.32Ba</td>
<td>0.43 ± 0.41Ca</td>
<td>0.64 ± 0.48Ca</td>
<td>0.68 ± 0.47Ca</td>
</tr>
<tr>
<td>Immediate</td>
<td>16</td>
<td>0.15 ± 0.34Ba</td>
<td>0.19 ± 0.23Ba</td>
<td>0.24 ± 0.30Ba</td>
<td>0.63 ± 0.32Ca</td>
<td>0.55 ± 0.42Cab</td>
</tr>
<tr>
<td>Early</td>
<td>20</td>
<td>0.13 ± 0.41Ba</td>
<td>0.16 ± 0.33Ba</td>
<td>0.27 ± 0.40Ca</td>
<td>0.40 ± 0.45Ca</td>
<td>0.43 ± 0.44Ca</td>
</tr>
<tr>
<td>Delayed</td>
<td>30</td>
<td>0.26 ± 0.33Ba</td>
<td>0.42 ± 0.26Cb</td>
<td>0.63 ± 0.38Db</td>
<td>0.84 ± 0.47Db</td>
<td>0.81 ± 0.43Db</td>
</tr>
</tbody>
</table>

### Intraoperative parameters

<table>
<thead>
<tr>
<th>Diameter (mm)</th>
<th>3.8</th>
<th>0.11 ± 0.23Ba</th>
<th>0.29 ± 0.36Ba</th>
<th>0.38 ± 0.32Aba</th>
<th>0.57 ± 0.41Ba</th>
<th>0.78 ± 0.46Cca</th>
<th>0.87 ± 0.49Ca</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.25</td>
<td>34</td>
<td>0.13 ± 0.36Ba</td>
<td>0.24 ± 0.32Ba</td>
<td>0.42 ± 0.41Ca</td>
<td>0.65 ± 0.48Ca</td>
<td>0.60 ± 0.47Ca</td>
<td></td>
</tr>
<tr>
<td>5.0</td>
<td>9</td>
<td>-0.05 ± 0.02Ba</td>
<td>0.16 ± 0.30Aa</td>
<td>0.25 ± 0.38Aba</td>
<td>0.37 ± 0.42Ba</td>
<td>0.48 ± 0.38Ba</td>
<td></td>
</tr>
</tbody>
</table>

### Postoperative parameters

Gingival thickness

| Thin | 40  | 0.26 ± 0.29Ba | 0.38 ± 0.25Ca | 0.60 ± 0.37Da | 0.82 ± 0.48Ca | 0.78 ± 0.46Ca |
| Thin | 26  | 0.08 ± 0.43Ba | 0.14 ± 0.39Bb | 0.24 ± 0.39Bb | 0.46 ± 0.44Cb | 0.51 ± 0.41Cb |

Total

| 66  | 0.24 ± 0.32Ba | 0.44 ± 0.36Cca | 0.66 ± 0.46Dca | 0.69 ± 0.49Dca |

Different superscript letters represent statistically significant differences in the same horizontal row (uppercase letters among times) or in the same column (lowercase letters for each parameter). P value was set at .05.
Fig 4  Box plot reporting MBL of (a) immediate, (b) early, and (c) delayed implants in the present investigation. Delayed group reports the widest distribution of values at 2 and 3 years from implant insertion (T24 and T36), also revealing a greater presence of negative outliers (indicating bone loss). Interestingly, the immediate group showed a larger distribution of MBL values at 3 months (T3), which was attributed to the alveolar bone remodeling processes of postextraction sockets.

Fig 5  Box plots depicting MBL of implants surrounded by a thin or a thick soft tissue biotype. (a) A larger distribution and a marked MBL variation is observed in the thin group. (b) A more stable MBL, in particular after 1 month (T1), 24 months (T24), and 36 months (T36), was observed in the thick biotype group.
showed the widest distribution of values at $T_{36}$, with negative outliers, defined by bone loss (Fig 4c).

Figure 5a reports a wider distribution and a consistent decrement of MBL values for implants surrounded by thin biotype. On the contrary, MBL of implants surrounded by a thick biotype showed higher stability (Fig 5b).

Multiple mixed logistic regression analysis exploring all factors associated with MBL at $T_{36}$ is shown in Table 2, corroborating that gingival biotype significantly influenced MBL results at $T_{36}$ ($P = .031$). Gingival biotype was the most significant parameter associated with MBL at $T_{36}$ ($P = .025$) after stepwise selection (Table 2).

PES, BOP, and Plaque Score Assessment
PES at $T_{6}$, $T_{12}$, and $T_{36}$ is illustrated in Fig 6. The mean 6-month PES was 10.76 ± 1.19 (median: 11; range: 8 to 13; IQR: 10 to 12). These values significantly increased at 12 and 36 months; the mean values were 11.76 ± 1.00 (median: 12; range: 9 to 13; IQR: 11 to 12) and 11.83 ± 1.03 (median: 12; range: 9 to 14; IQR: 11 to 13), respectively.

Mesial and distal papilla parameters improved after $T_{12}$, with slight modifications after final evaluation ($T_{36}$). No 0 scores were observed at both 12 months and 36 months.

Other soft tissue parameters increased to the highest score. Soft tissue texture and gingival color presented the highest score in 92% to 95% of the samples at $T_{36}$. The data proved the presence of healthy tissue free from inflammation and gingival discoloration. Soft tissue level and contour scores also increased during the observation time.

Plaque score and BOP are illustrated in Table 3. A low percent of BOP-positive sites were recorded at final $T_{36}$, while the plaque score index was positive at the mesial site (23.3%). Both values were lower than the $T_{12}$ values.

Two representative clinical cases are shown in Figs 7 and 8.

**DISCUSSION**

The study investigated the use of implants designed with a long smooth hyperbolic neck placed in a transmucosal configuration in consecutive patients and their effectiveness on clinical parameters and MBL up to 3 years. The study demonstrated that neck exposure was free from complications such as gingivitis, mucositis, and implant failures during the healing time. MBL was stable in both the preloading and postloading time in accordance with the traditional accepted success criteria. Neck exposure during the healing time displayed limited plaque accumulation, as evidenced by low BOP and plaque score values.

The neck morphology and use of the transmucosal technique present some clinical advantages and some limitations identified in the study. The neck diameter was narrower than the implant diameter (Fig 1), and the hyperbolic configuration was partially positioned into the thickness of gingival tissues (Fig 3). The images obtained by the use of scanning microscopy illustrated

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Multilevel Mixed Logistic Regression Exploring Factor Associated with MBL at 36 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preoperative parameters</strong></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>$-0.350$</td>
</tr>
<tr>
<td>Position</td>
<td>$-0.044$</td>
</tr>
<tr>
<td>Location</td>
<td>$-0.019$</td>
</tr>
<tr>
<td>Implant placement group</td>
<td>$0.148$</td>
</tr>
<tr>
<td>Endodontic adjacent teeth</td>
<td>$0.888$</td>
</tr>
<tr>
<td><strong>Intraoperative parameters</strong></td>
<td></td>
</tr>
<tr>
<td>Implant diameter</td>
<td>$-0.125$</td>
</tr>
<tr>
<td>Implant length</td>
<td>$-0.081$</td>
</tr>
<tr>
<td><strong>Postoperative parameters</strong></td>
<td></td>
</tr>
<tr>
<td>Gingival biotype</td>
<td>$-0.296$</td>
</tr>
<tr>
<td><strong>After stepwise selection</strong></td>
<td></td>
</tr>
<tr>
<td>Implant placement group</td>
<td>$0.142$</td>
</tr>
<tr>
<td>Gingival biotype</td>
<td>$-0.304$</td>
</tr>
</tbody>
</table>

*Statistically significant difference ($P < .05$).
Fig 6  Graphs reporting PES scores at different times from insertion, namely, after (a) 6, (b) 12, and (c) 36 months. No zero scores were observed at 12 and 36 months from insertion. PES at 6 months was significantly different compared with the 12-month values (P < .05). On the contrary, no differences were observed between values at 12 months and 36 months (P > .05).
Table 3  Periodontal Parameters Around Implant Restorations After Definitive Load

<table>
<thead>
<tr>
<th></th>
<th>PS</th>
<th>BOP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T12</td>
<td>T36</td>
</tr>
<tr>
<td>Mesial</td>
<td>63.8%</td>
<td>36.2%</td>
</tr>
<tr>
<td>Distal</td>
<td>75.7%</td>
<td>24.3%</td>
</tr>
<tr>
<td>Vestibular</td>
<td>80.5%</td>
<td>19.5%</td>
</tr>
<tr>
<td>Palatal</td>
<td>75.7%</td>
<td>24.3%</td>
</tr>
</tbody>
</table>

PS = plaque score; BOP = bleeding on probing.
A null (0) value indicates no BOP or PS; a 1 value indicates positive BOP or PS.

As the emergence profile was exposed 1.0 to 1.5 mm above the gingival mucosa, a more coronal implant-abutment connection—more distant from the bone tissues—was obtained, avoiding secondary peri-implant tissue manipulation. The present concept is in accordance with Romanos et al, proposing the insertion of the definitive abutment immediately after implant insertion (“one-time abutment concept”) and avoiding further disconnections as a useful strategy to avoid bone loss in submerged or crestal-level implants, and also with Sanz et al, who used a healing screw to obtain transmucosal healing.

A more coronal neck-abutment connection eliminates the risks for bacterial leakage, described for crestal and subcrestal placement, where the connection between the implant and the abutment is located at bone level.
A further characteristic of a coronal/supragingival hyperbolic neck-abutment connection is the greater available space for metal and ceramic thickness of the crown.

The abutment increased the retention of crowns that are cemented on the neck and on the abutment surface. The relatively short hyperbolic neck represents a simplification to avoid the limit of true one-piece implants that present a high exposed abutment and require immediate provisional crown positioning.50

The positioning of the implant-abutment junction at the subcrestal level usually increases the risk for cement excess,51,52 while the presence of a deep mucosal tunnel may add further risks for peri-implant mucositis.20

The design and preparation for the provisional and definitive crowns were based on the so-called biological oriented preparation technique concept.53 Thus, each crown was designed to have gentle contact with the gingival margin with modest tissue compression and with the finishing line at neck level.

No tissue inflammation or peri-implantitis were observed after crown cementation. Temporary zinc-oxide eugenol-based cement was selected for provisional restorations, as enough retention on the hyperbolic neck was obtained (no provisional decemented crowns were reported). Radiopaque definitive polycarboxylate cement was selected for the ease of removal and for its adequate setting time (approximately 5 minutes).

A transmucosal one-piece implant with a smooth higher conical neck has been previously proposed by Hahn.54 Additional studies analyzed this implant in a number of clinical conditions with conflicting results. In particular, bone loss, recessions of the soft tissues, and high implant losses were reported by Ostman et al when placing these implants with immediate loading and in situ abutment customization.50

In the present study, selected significant parameters affecting MBL were analyzed.4,55,56 Gingival biotype was the parameter responsible for the most significant association with MBL. Implants positioned in patients with thick biotypes showed a more stable crestal MBL compared with thin biotypes. The study confirms that gingival thickness is one of the most important parameters affecting MBL during the peri-implant bone
remodeling, as demonstrated in several animal models\textsuperscript{2} and in some clinical studies.\textsuperscript{57,58} Establishment of a biologic barrier between the oral environment and the implant, leading to a more stable connective tissue, was observed around the transmucosal neck of implants with a thick biotype.\textsuperscript{26}

Immediate and early groups had a similar MBL progression trend up to 12 months from insertion. On the contrary, the delayed group exhibited a higher bone loss in the initial 6 months, significantly different from the other groups (\textit{P} < .005). Old mineralized mature cortical bone offers limited new bone formation, as observed in a recent histologic investigation.\textsuperscript{59,60} Oral bone density may be different in mature edentulous bone compared with healing alveolar sockets. In addition, mature edentulous cortical bone could be severely damaged by surgical procedures and may require additional bone-resorbing osteoclasts to completely remove cortical bone debris.\textsuperscript{39}

The use of PES offered the possibility to evaluate soft tissue modification during the clinical follow-up.\textsuperscript{40} The majority of the studies used PES only in the anterior region, which is the most aesthetic area.\textsuperscript{3,44,61,62} Only one clinical investigation proposed PES in the posterior region.\textsuperscript{63}

In the present clinical trial, PES showed important gingival improvement both in the anterior and posterior areas at 12 months from implant insertion, with a general stability at 3 years. Gingival soft tissue was sound and had a stable morphology in all groups. As an important element, a high number of samples exhibited the highest score value for parameter soft tissue texture, soft tissue color, and alveolar process deficiency at the 36-month evaluation. The results support the use of the adopted flapless technique with the novel implant neck design.

The ZirTi surface of the investigated implant was analyzed in several animal (dog) studies and presents favorable osseointegration data, as demonstrated by high bone-to-implant contact values.\textsuperscript{54,65} Implants with the same surface morphology, but different macromorphology of the neck, have been recently documented by clinical studies\textsuperscript{23,56} and by ESEM-EDX analysis on human histologic samples of retrieved implant biopsy specimens.\textsuperscript{66}

In the present study, 3.0% screw loosening was reported. This percentage was in line with a previously published review, taking into account studies conducted in a university setting, which revealed an estimated 3-year complication-free period of 97.6%.\textsuperscript{67} Other studies reported an annual loosening rate of approximately 2.29%, with a 4-year loosening rate of 8.5%.\textsuperscript{68,69} The two screw loosenings may be attributable to a technical operative error.

The implant-abutment connection differs from a traditional internal hexagon, as a small collar was designed to distribute the occlusal load and to provide greater stability.\textsuperscript{70} A previous finite element method study showed a 20% increase in structure loosening and deformation of the present connection compared with three other traditional implant-abutment connections, which was attributable to the presence of the internal collar.\textsuperscript{70}

Some limitations of the technique and implant design must be reported. The neck transmucosal profile cannot be altered after insertion into the bone. This means that the implant angulation needs to be carefully planned before surgery. A skilled operator must insert the implant in the right location, parallel to the adjacent roots, avoiding implant malposition that cannot be corrected by abutment angulation.\textsuperscript{71}

Provisional Maryland bridge restorations were cemented in a large number of cases and kept in position during the healing time. The bonded bridges may be necessary to avoid any esthetic disadvantage of transmucosal implant neck exposure, according to Tonetti et al.\textsuperscript{72}

Some limitations may be considered with the short-term follow-up. The preliminary findings of this study must be validated with a longer follow-up. Moreover, soft tissue morphology around the implants should be investigated by histologic studies, which are still lacking in the literature.

CONCLUSIONS

This 3-year study demonstrated the following: (1) novel two-piece implants with a transmucosal hyperbolic neck showed a low number of complications, stable MBL, and adequate PES in the anterior and posterior regions; (2) the transmucosal flapless one-stage technique allows soft tissue healing as shown by PES parameters after a short time and 3 years; (3) cement-retained crowns may be easily applied without cement excess and subsequent gingival inflammation; and (4) timing of implant placement and gingival biotype were the preoperative factors to be considered for the clinical results.

ACKNOWLEDGMENTS

The authors claim to have no financial interest, either directly or indirectly, in the products or information listed in the article.
REFERENCES


