Clinical Outcomes of Maxillary Anterior Postextraction Socket Implants with Immediate Provisional Restorations Using a Novel Macro-Hybrid Implant Design: An 18- to 24-Month Single-Cohort Prospective Study

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Extraction and immediate implant placement/restoration in the esthetic zone is clinically challenging; benefits include fewer surgical appointments and maintenance of peri-implant soft tissues throughout the treatment period, and limitations include gingival recession and bone dehiscence during surgery. Macro-hybrid implants (large-diameter apical/narrow-diameter occlusal) were placed in 19 patients immediately following the extraction of hopeless maxillary anterior teeth. Immediate restorations were fabricated without occlusal contacts. Pre- and postplacement cone beam computed tomography (CBCT) scans were taken. Nineteen implants were available for recall 13 to 25 months postoperatively. The overall implant cumulative survival rate was 100% (range: 13 to 25 months, mean: 19 months), and mean insertion torque value was 65 Ncm. Mean Pink Esthetic Score was 12.63 at 6 months, and was 13 at the 18- to 24-month follow-up. Mean mesial and distal tooth-to-implant distances immediately after implant placement were 2.55 ± 1.29 mm and 2.29 ± 0.82 mm, respectively. Interproximal bone crest width, distance, and height were maintained at implant platforms, mesially and distally, 18 to 24 months postoperatively. The results of this study indicated that the macro-hybrid implant geometry for this immediate surgical/restorative protocol provided excellent and stable 2-year results relative to implant survival (100%), labial plate thickness via CBCT evaluations, tooth-to-implant distances immediately post-implant placement, PES, and interproximal bone crest width, distance, and heights, which were maintained at the implant platforms. Int J Periodontics Restorative Dent 2020;40:355–363. doi: 10.11607/prd.4467

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restorations then functioned as prosthetic socket seals. Studies employing these treatment strategies have demonstrated reduced ridge collapse and peri-implant soft tissue recession, measured in tenths of millimeters instead of millimeters. Improved esthetic outcomes have been reported.\textsuperscript{13,14,16}

No surgical treatment is without limitations; care must be taken when immediate implant placement in anterior extraction sites is considered. This has been especially true when using straight implant designs, where the probability of apical socket perforation is high (82\%) due to the inherent anatomy of the premaxilla.\textsuperscript{17–20} Kan et al concluded that understanding the clinical relevance of sagittal root position provided adjunct data for treatment planning with immediate implant placement and provisional restorations in anterior maxillae. They proposed a classification system to improve interdisciplinary communication in treatment planning for implant-based therapy in anterior maxillae.\textsuperscript{17} Delayed implant placement, cement-retained restorations, angulated screw channel abutments, dynamic or static surgical guides, and subcrestal angle correction implants have been proposed as solutions to avoid this potential problem.\textsuperscript{20}

From a biologic perspective, avascular labial bone 1.0 mm or less in thickness can survive around natural teeth because the adjacent periodontal ligament is vascular and provides nourishment to this area and to the overlying periosteum.\textsuperscript{21–23} Bone surrounding implants after placement is of equal importance and must have adequate thickness. For long-term stability, studies suggest the importance of alveolar bone 1.5 to 2.0 mm thick.\textsuperscript{24,25} It has also been suggested that, if inadequate bone ($\leq 1.5$ mm) supports implants after placement, the peri-implant bone may not survive and fail secondary to avascular necrosis, since endosteum or marrow is absent. Also, changes associated with craniofacial growth and development may cause esthetic issues around implants in the long term.\textsuperscript{26}

One potential clinical solution involves the use of narrow implants even though they have been less effective in obtaining primary stability when compared to wider-diameter implants.\textsuperscript{27–29} Implant length is another consideration when there is adequate apical bone beyond the extraction socket prior to impacting the nasal floor,\textsuperscript{18} though implant diameter has been shown to be more effective than length in achieving primary stability. This has been important in soft bone where undersizing osteotomies has been an essential and useful clinical approach.\textsuperscript{27}

It should also be noted that when wider-diameter, tapered implants (divergent wider coronal portion) have been used, labial/buccal gaps between implants and osteotomy walls may be reduced. Wide-diameter implant designs also may reduce tooth-to-implant distances, and this may lead to interdental papilla loss in extraction sockets. The horizontal dimension associated with biologic width (even with platform-switched designs) and/or pressure necrosis of crestal bone can also be causative factors in loss of interdental papillae.\textsuperscript{28–31} The requirements of modern-day implants for biologic and esthetic needs are no longer the same as those in the 1980s, when P. I. Brånemark first introduced the concept of osseointegration to North America.\textsuperscript{32}

Recent preclinical and clinical studies on a new macro-hybrid implant design (Inverta, Southern Implants) have been reported.\textsuperscript{33,34} This unique “body-shift” concept for diameter and shape includes a tapered apical portion and a cylindrical coronal portion (Fig 1). The overall configuration of the implant is inverted; these implants “converge” toward the implant-abutment interface, where bone is thinnest and avascular or divergent, as in traditional implant designs (Fig 2). Conversely, the tapered apical portion is wider where bone has the greatest volume and vascularity. By reducing the coronal portion of the implant with this body-shift design, pressure is not exerted on the thin, avascular crestal bone circumferentially. In addition, greater space is generated and allows more graft material to be placed both labially and interproximally between implants and interproximal bone. This creates a net increase in bone dimension (Figs 3 to 6).

A preclinical animal study showed no evidence of apical pressure necrosis with consistent insertion torque values (ITVs) of 100 Ncm on roughly three-quarters of the implants placed.\textsuperscript{33} The results of this histomorphometric study showed that a 100-Ncm ITV did not cause pressure necrosis. This was important since the apical portion of an extraction socket has the
greatest bone volume and is rich in marrow, with a greater potential for improved wound healing. The initial clinical study on 33 implants (33 patients) demonstrated labial bone dimensions of 1.6 to 2.0 mm, interdental distances of 2.4 to 2.6 mm, and a mean PES\textsuperscript{34} of 12.5 at 1-year follow-up visits.

Therefore, the purpose of this prospective clinical cohort study was to assess (1) implant survival, (2) labial bone plate thickness, (3) tooth-to-implant interproximal bone crest dimension (distance), and (4) PES using the novel macrohybrid implant design in maxillary anterior postextraction sockets with immediate restorations. Assessment was performed immediately posttreatment, at 6 months, and at 18 to 24 months.

Materials and Methods

Nineteen consecutive patients (11 females, 8 males) participated in this single-cohort prospective study, selected from patients in Part \textsuperscript{134} of this study who reached 18 to 24 months of follow-up; all patients had a treatment plan consisting of immediate placement of implants into fresh extraction sockets using

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**Fig 1** (left) The maxillary left central incisor was carefully extracted without flap elevation.

**Fig 2** (right) Drills used for preparation of the osteotomy. Dedicated extending solid shank drills were used for each implant apical diameter (Southern Implants).

**Fig 3** (left) The inverted body-shift implant was placed into the extraction socket. Note the change in shape and diameter of the macro-hybrid implant design.

**Fig 4** (right) Implant temporary cylinder in place. The gap between the implant and labial bone was grafted with allograft.

**Fig 5** (left) Provisional restoration was fabricated with i-Shell prefabricated gingival sleeves (Vulcan Custom Dental). Preexisting tooth emergence profiles were replicated. The restoration did not have centric or eccentric contacts.

**Fig 6** (right) Clinical image 12 weeks after implant placement, following first removal of the provisional restoration. Note the maintained labial and palatal alveolar width.
screw-retained implant-supported provisional crowns in the maxillary esthetic zone with nonocclusal loading. Nineteen macro-hybrid implants were placed. The implants were manufactured from Grade 4 titanium; surfaces were blasted with alumina particles (110 µm with an Sa value of 1.4) then cleaned with inert solvents to remove residual alumina (Appendix Table 1; all Appendix Tables can be found in the online version of this article at www.quintpub.com). Presurgical radiographic examinations were made using orthopantomograms and intraoral radiographs.

Inclusion criteria included: hopeless teeth in the maxillary esthetic zone (canine to canine); the presence of enough residual bone volume for long implants (at least 13.0 mm); and a consent form signed by the patient. Exclusion criteria were: aged younger than 18 years and having general contraindications for oral surgery. Patients were thoroughly informed about the treatment. The study was conducted in full accordance with ethical principles, including the World Medical Association Declaration of Helsinki. The labial bone thickness was measured after tooth extraction with a periodontal probe.

One hour before surgery, amoxicillin (Amimox, Meda; 2 g) and diazepam (Stesolid, Alpharma; 0.3 mg/kg body weight) were given to patients orally. The surgical sites were infiltrated with Xylocaine-Adrenaline (Dentsply Sirona), and teeth were carefully extracted without flap elevation (Fig 1). The sites and alveolar sockets were carefully evaluated with consideration of esthetic and biomechanical aspects to determine optimal implant positions engaging the maximum amount of apical-palatal bone. Bone quality and quantity were assessed according to Albrektsson et al.\textsuperscript{35} Implants were placed according to a diagnostic drill protocol\textsuperscript{13}; selection of the final drill size was based on bone quality for maximum initial stability (Fig 2). Dedicated, extending solid shank drills were used for each implant apical diameter. Final seating and orientation of the inverted body-shift macro-hybrid implants was performed, with subcrestal angulation of the implants (Fig 3). Insertion torque values were measured with a manual, calibrated torque wrench. A mean ITV of 65 Ncm was achieved for all implants (range: 40 to 80 Ncm). These implants were designed with aggressive apical threads for optimal bone/implant contact to achieve high primary stability at implant placement. Osteotomies were not undersized.

In this report, 12 patients, gaps between the implants and labial bone were grafted after implant placement using either cortico-cancellous heterologous bone mix (mp3, OsteoBiol, Tecnoss; n = 16) or allograft (Puros Cortico-Cancellous Particulate Allograft, Zimmer Biomet; n = 8) (Fig 4). Grafts were not warranted in 7 patients.

Patients were asked to gently rinse with chlorhexidine for 10 days postsurgery (0.1% twice per day) and to adopt a soft-food diet. Fixed provisional restorations were fabricated with either polyether ether ketone or titanium temporary cylinders and composite resin. The provisional restorations were fabricated without occlusal contacts in centric and eccentric positions. Preexisting tooth emergence profiles were replicated using either i-Shell prefabricated gingival sleeves (Vulcan Custom Dental) or reusing the existing teeth and crowns (Fig 5).

Twelve weeks after implant placement, the provisional restorations were removed and scan flags (Southern Implants) were placed onto the implant restorative interfaces (Fig 6). Intraoral digital impressions were made for screw-retained all-ceramic implant restorations (Fig 7), and the soft tissue contours and adjacent teeth were captured during intraoral scanning.
All patients participating in the study agreed to a strict and individually designed maintenance care program that included oral hygiene instruction and follow-up, stability of fixed restorations, soft tissue health, and function of the dentition. Immediately postsurgery, a cone beam computerized tomography (CBCT) scan was taken (Fig 8). Posttreatment follow-up examinations were scheduled for 3, 6, and 12 months. New CBCTs were taken after 1 and 2 years (Fig 9).

Implant survival was measured regarding the lack of mobility at any of the follow-up appointments.

Labial bone plate thickness was measured with CBCT scans at the time of implant placement and again at 18 and 24 months later.

Tooth-to-implant interproximal bone crest dimensions (distances) were measured immediately after implant placement with CBCT scans; the measurements were repeated on new CBCT scans taken 1 and 2 years after implant placement.

PES was measured clinically at 6 months post–implant placement (L1) and again at the 18- to 24-month follow-up visits (L2).

Results

Within the implants presented in Part 1 of this study,\textsuperscript{24} 19 implants were examined at a follow-up appointment 18 to 24 months postoperative. Preoperative periodontal phenotypes were classified as type 1 (thin), 2 (intermediate), or 3 (thick). Most of the implants in this study were placed into patients with type 2 phenotypes. All implants were placed into fresh extraction sockets classified as Type 1.\textsuperscript{36} None of the 19 implants failed. The overall cumulative survival rate for implants in the study was 100% after 13 to 25 months (mean follow-up: 19 months). Implant/abutment connections were either deep conical or external hex. Mean insertion torque value was 65 Ncm, ranging from 40 to 80 Ncm. Seventy percent of implants reached 60- to 80-Ncm ITV.

The mean labial plate thickness measured 1.82 ± 0.82 mm at L1 and 1.55 ± 0.82 mm at L2 on CBCTs taken after implant placement and gap grafting (Fig 10).
mean labial plate thickness at the 18- to 24-month follow-up was 1.82 ± 0.88 mm at L1 and 1.38 ± 0.74 mm at L2 (Appendix Table 2).

Mean tooth-to-implant distance immediately after implant placement was 2.55 ± 1.29 mm and 2.29 ± 0.82 mm at the mesial and distal aspects, respectively, from the implant platform to the adjacent tooth. The interproximal bone crest width, distance, and height were maintained at the implant platform, both mesially and distally, at 18- to 24-month follow-up visits (Appendix Table 3).

PES was measured at 6 months (L1) and at the 18- to 24-month follow-up (L2) (Appendix Table 4). Mean PES was 12.63 (including one case without the score for texture, which may decrease the mean for this follow-up) at 6 months and was 13 at the 18- to 24-month follow-up.

When the comparisons were made regarding preoperative gingival phenotype and PES/marginal peri-implant soft tissue, all preoperative intermediate and thick phenotype cases showed stability over a minimum period of 18 months (Appendix Table 5).

A potential limitation of this study protocol was interpreting the cross-sectional CBCT scans. It was sometimes difficult to distinguish between bone and bone graft. At times there was scatter from metallic restorations. All CBCT scans were read by independent clinicians (P.O.O. and S.C.). The authors have never experienced a clinical situation in which less bone was clinically evident at final follow-up when compared with preoperative CBCT scans.

**Discussion**

The design elements of the macro-hybrid implant evaluated in this study had two distinctive features: a wider, tapered apical portion for high primary stability; and a narrower, cylindrical coronal portion that provided increased gap distances and space for graft material in immediate tooth-replacement therapy. Implant primary stability has been associated with improved implant survival, especially in immediate extraction sockets where engagement of residual peripheral socket walls and apical bone is minimal. With this protocol, it was noted that potential violation to the buccal plate secondary to osteotomy preparation exists; the design of the apical portion of this implant and the angle correction feature of this hybrid design reduced this risk.

The results of this 18- to 24-month follow-up study demonstrated labial bone plate thicknesses of 1.82 ± 0.88 mm at L1 and 1.38 ± 0.74 mm at L2, with a mean PES of 13. Interestingly, when compared to the thickness measured immediately postoperative (1.82 ± 0.82 mm at L1 and 1.55 ± 0.82 mm at L2), L1 exhibited better stability, though it was not clinically significant. This could be due to the macro-hybrid implant design of a narrower cylindrical coronal portion that provided increased gap distances. It has been shown that labial-palatal ridge stability improves and peri-implant soft tissue thickness increases when greater gap distances are present.37

Most of the implants in this study were placed in patients with Type 2 phenotypes. Cook et al8 performed an in vivo radiographic study that evaluated differences in labial plate thickness in patients identified with thin vs thick/average periodontal phenotypes. They concluded that periodontal phenotype was significantly related to labial plate thickness, alveolar crest position, keratinized tissue width, gingival architecture, and probe visibility but unrelated to gingival recession. The grafting protocol used by Cook et al minimized labial plate resorption and contributed to achieving at least 3.0 mm of buccal peri-implant soft tissue thickness at the 2-year follow-up, regardless of gingival phenotype.

In this report, all implants were placed into Type 1 extraction sockets; Elian et al36 classified Type 1 extraction sockets as follows:
sockets as the easiest and most predictable to treat. This type of socket is present when the facial soft tissue and buccal plate of bone are at normal levels relative to the cemento-enamel junction of the pre-extracted tooth; the soft tissue and labial plate remain intact after extraction. An additional benefit illustrated in this report’s protocol was the fabrication of immediate, nonocclusally loaded, provisional restorations, which allowed for maintenance of soft tissue contours instead of having to re-establish them after socket healing.¹⁰

Kan et al⁵ reported favorable implant success rates and peri-implant tissue responses with immediate implant placement and provisionalization of single implants in the esthetic zone. They also noted that, over the 2- to 8-year period, recession continued relative to the facial gingival tissues around implants; however, the sites were not grafted. Kan et al reported that the effect of gingival phenotype on peri-implant tissue response seemed to be limited only to facial gingival recession and did not influence interproximal papilla or proximal marginal bone levels. Peri-implant gingival responses were not measured in the present study; this characteristic is worthy of further study with the present implant design and surgical protocol.

It is interesting to note that Cosyn et al’s clinical research reported advanced midfacial recession (> 1.0 mm) in 2 out of 25 patients (8%) at 3 years posttreatment.⁶ It should also be noted that Cosyn et al’s patients originally presented with thick gingival biotypes, ideal gingival levels/contours, and intact socket walls at the time of tooth extraction. Grafting was accomplished in the spaces around the placed straight implants. Cosyn et al also reported PES. Five cases (21%) were classified as esthetic failures (PES < 8), and another 5 cases showed almost perfect esthetic outcomes (PES ≥ 12). The remaining restorations (14/24; 58%) demonstrated acceptable esthetic results.

Cosyn et al³⁸ also reported 5-year results regarding clinical and esthetic outcomes of single immediate implants in the esthetic zone. Twenty-two patients were originally treated; 17 returned for the 5-year recall visits. Teeth were removed, the sockets were grafted, and implants/restorations were placed in one visit. Single immediate implants showed high implant survival (21/22) and limited long-term marginal bone loss (0.19 mm at 5 years). However, after 1 year, midfacial recession increased (0.48 mm at 1 year; 0.53 mm at 5 years) and deterioration was seen in the midfacial contour and alveolar process thickness. Esthetic complications were reported for 8 of 17 well-selected patients (thick gingival biotype, intact buccal bone walls, both adjacent teeth present) who had been treated by experienced clinicians. Cosyn et al concluded that type 1 socket/implant placement may not be recommended for daily practice. The implant design of the straight implants used by Cosyn et al may have affected the results in comparison to the present study; the implants used presently had larger diameters in the apical portions of the sockets (where there typically is less bone available).

**Conclusions**

The results of this study indicate that this macro-hybrid implant geometry for immediate-placement surgical/restorative protocols provided excellent and stable 2-year results relative to implant survival (100%), minimal loss of labial plate thickness via CBCT evaluation in the coronal (−0.1 mm) and middle (−0.2 mm) thirds of the implants, and increased labial plate thickness (+0.1 mm) in the apical portion of the labial plates. Mean tooth-to-implant distances immediately after implant placement were 2.55 ± 1.29 mm and 2.29 ± 0.82 mm at the mesial and distal aspects, respectively, from implant platforms to adjacent teeth. The interproximal bone crest width, distance, and heights were maintained at the implant platforms, mesially and distally, at 18- to 24-month follow-up visits. The mean PES was 12.63 and 13 at 6-month and 18- to 24-month follow-up visits.

Further long-term research is needed to validate this implant design regarding labial plate thickness, mean tooth-to-implant distance, PES scores, and interproximal bone crest width, distance, and heights.

**Acknowledgments**

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References


Appendix

### Appendix Table 1 Implant Properties

<table>
<thead>
<tr>
<th>Name</th>
<th>Site (tooth no.)</th>
<th>No. placed</th>
<th>Length, mm (n)</th>
<th>Apical diameter, mm (n)</th>
<th>Coronal diameter, mm (n)</th>
<th>Abutment connection (n)</th>
<th>Material (ASTM F67)</th>
</tr>
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<tbody>
<tr>
<td>Inverta 12</td>
<td>13 (2)</td>
<td>2</td>
<td>4.5 (1) 5 (1)</td>
<td>3.5 (1) 4.2 (1)</td>
<td>Ext hex (2)</td>
<td>Grade 4 titanium</td>
<td></td>
</tr>
<tr>
<td>Inverta 11</td>
<td>13 (1) 14 (1) 15 (4)</td>
<td>6</td>
<td>4.5 (1) 5 (5)</td>
<td>3.5 (2) 4 (1) 4.2 (3)</td>
<td>Ext hex (5); deep conical (1)</td>
<td>Grade 4 titanium</td>
<td></td>
</tr>
<tr>
<td>Inverta 21</td>
<td>13 (1) 15 (3)</td>
<td>4</td>
<td>5 (4)</td>
<td>3.5 (1) 4 (1) 4.2 (2)</td>
<td>Ext hex (3); deep conical (1)</td>
<td>Grade 4 titanium</td>
<td></td>
</tr>
<tr>
<td>Inverta 22</td>
<td>13 (2) 15 (5)</td>
<td>7</td>
<td>4.5 (5) 5 (2)</td>
<td>3.5 (7)</td>
<td>Ext hex (5); deep conical (2)</td>
<td>Grade 4 titanium</td>
<td></td>
</tr>
</tbody>
</table>

Ext hex = external hexagon.
Properties listed according to catalog descriptions.
*FDI system.

### Appendix Table 2 Mean ± SD Labial Bone Plate Thickness

<table>
<thead>
<tr>
<th>CBCT</th>
<th>Day 0, mm</th>
<th>18–24 mo, mm</th>
<th>Change, mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>L1</td>
<td>1.82 ± 0.82</td>
<td>1.82 ± 0.88</td>
<td>0</td>
</tr>
<tr>
<td>L2</td>
<td>1.55 ± 0.82</td>
<td>1.38 ± 0.74</td>
<td>0.17</td>
</tr>
</tbody>
</table>

SD = standard deviation; labial bone plate thickness = distance between the external surface of the labial bone plate and the facial surface; CBCT = cone beam computed tomography; L1 = time of implant placement; L2 = follow-up appointment at 18 to 24 months.

### Appendix Table 3 Mean ± SD Tooth-to-Implant Distance

<table>
<thead>
<tr>
<th>Periapical radiograph</th>
<th>Day 0, mm</th>
<th>18–24 mo, mm</th>
<th>Change, mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesial</td>
<td>2.55 ± 1.29</td>
<td>2.63 ± 1.25</td>
<td>0.08</td>
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<tr>
<td>Distal</td>
<td>2.29 ± 0.82</td>
<td>2.26 ± 0.78</td>
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</tbody>
</table>

SD = standard deviation; Day 0 = distance from the implant platform to the adjacent tooth surface; 18–24 mo = interproximal bone crest width to the adjacent tooth from the height of the implant platform.
### Appendix Table 4  PES Measured at 6-Month and 18- to 24-Month Follow-up Visits

<table>
<thead>
<tr>
<th>Site</th>
<th>6 mo</th>
<th>18–24 mo</th>
</tr>
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<tr>
<td></td>
<td>Mesial papilla</td>
<td>Distal papilla</td>
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<td>19</td>
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</tr>
</tbody>
</table>

PES = Pink Esthetic Score.

### Appendix Table 5  Mean PES and Marginal Stability of Preoperative Gingival Phenotypes at 6-Month and 18- to 24-Month Follow-up Visits

<table>
<thead>
<tr>
<th>Preoperative periodontal phenotype</th>
<th>Thin</th>
<th>Intermediate</th>
<th>Thick</th>
</tr>
</thead>
<tbody>
<tr>
<td>PES, 6 mo</td>
<td>13</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td>Marginal stability, 6 mo</td>
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<td>2</td>
<td>2</td>
</tr>
<tr>
<td>PES, 18–24 mo</td>
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<td>13</td>
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<tr>
<td>Marginal stability, 18–24 mo</td>
<td>1</td>
<td>2</td>
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</tbody>
</table>

PES = Pink Esthetic Score.