Guided Tissue Preservation: Clinical Application of a New Provisional Restoration Design to Preserve Soft Tissue Contours for Single-Tooth Immediate Implant Restorations in the Esthetic Area

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This article aims to evaluate the effect of anatomically designed, single-unit provisional restorations on soft tissue preservation following immediate implant placement. Patients in need of a single-tooth replacement in the esthetic area were recruited for this study. An immediate provisional restoration with a transmucosal area anatomically designed to support the soft tissue was used for every patient. The horizontal volumetric tissue changes and the presence and amount of vertical recession were measured at baseline (T0) and after 1 month (T1), 3 months (T2), and 6 months (T3). Sixty-three patients received 66 implants that were placed into fresh extraction sites. The average follow-up time was 48 months (range: 24 to 60 months). All implant restorations were successful, and the cumulative implant survival rate and success of restorations was 100%. After 6 months, the mean horizontal ridge measured midbuccally had increased by 0.10 ± 0.10 mm at 1 mm from the free gingival margin, had decreased by 0.09 ± 0.10 mm at 3 mm, and had decreased by 0.20 ± 0.10 mm at 5 mm. In addition, the mean recession at the midbuccal surfaces was 0.04 ± 0.37 mm. Measurements were made clinically and compared to measurements made on the casts. According to the results of this study, the use of customized anatomically designed immediate provisional restorations following single-tooth extraction and immediate implant placement appeared to minimize the loss of tissue volume that results from postextraction bone remodeling, thus optimizing the final esthetic result. Int J Periodontics Restorative Dent 2020;40:869–879. doi: 10.11607/prd.4692

Treatment with dental implants is a well-established technique for the replacement of missing or hopeless teeth. After dental extraction, a bone remodeling process takes place that leads to reduction of tissue volume. It is well known that bone remodeling results in a dimensional change that frequently compromises esthetic outcomes. The delayed or two-stage technique proposed by Brånemark in 1977 has been considered the standard procedure. Although it has been considered safe, it requires three separate surgical interventions: (1) extraction of the tooth; (2) insertion of the implant; (3) and uncovering to connect a healing abutment. Several studies have demonstrated that the immediate loading with a provisional prosthesis that provides proper occlusal schemes does not disturb the implant osseo-integration process if the loading forces are well-oriented and the implant has satisfactory primary stability upon insertion. Presently, the application of this procedure has been extended to partially edentulous patients and for single-tooth replacements to reduce treatment time and optimize esthetics. This procedure replaces the tooth and avoids additional surgeries, thereby reducing treatment time and patient discomfort and offers the opportunity to rehabilitate patients.
avoiding the need for a removable prosthesis.\textsuperscript{8,10,16}

There is supportive evidence that the success rates of immediately loaded implants are comparable to those with deferred loading if the insertion torque is adequate.\textsuperscript{17,18} However, variable results have been reported for tissue volume stability and final esthetic outcome.\textsuperscript{19,20} The aim of this study was to evaluate the effectiveness of individually customized anatomical single-unit provisional restorations with respect to tissue preservation following immediate implant insertion and loading in the esthetic zone using the flapless technique. Primary outcomes include dimensional changes of the buccopalatal and corono-apical aspects of the transmucosal area corresponding to the implant-supported crown.

**Materials and Methods**

Patients (> 20 years old) in need of extraction and replacement of a single maxillary or mandibular anterior tooth (central incisor to second premolar) were consecutively recruited to participate in a clinical study between March 2014 and June 2017. All subjects were thoroughly informed about the risks and benefits associated with the procedure and signed an informed consent form in accordance with the Declaration of Helsinki for investigations in human subjects. The main inclusion requirement was presence of an intact alveolar facial plate and absence of periodontal disease in the tooth to be extracted (the reasons for extraction included caries, fracture, or endodontic failure, as seen in Fig 1). All other teeth had to be in satisfactory periodontal condition; complete intraoral examinations were provided to each patient. Smoking was not considered to be an exclusion criterion, nor was the presence of a periapical lesion. However, implant placement was postponed if any one of the following occurrences existed: an abscess, draining fistula, pus, or exudate. Uncontrolled diabetes or any other systemic condition that was a contraindication to surgery was also considered an exclusion criterion, as was the presence of pathology involving the adjacent teeth. CBCT scans were obtained and used for 3D analysis of the alveolar sites and of the tooth anatomy (Fig 2). Surgical templates and provisional restorations were fabricated with the aid of diagnostic wax patterns.

**Anatomical Provisional Fabrication**

Several steps were performed to create the anatomically designed provisional restorations. Alginate (Jeltrate Fast Set, Dentsply Sirona) impressions and occlusal registrations (Ramitec, 3M ESPE) were acquired 1 week before surgery and poured within 1 hour with orthodontic gypsum (Selenor, Zeta) to develop study casts, which were mounted on an articulator. The mesiodistal and buccolingual diameters of the defective tooth were

*Fig 1 Preoperative facial view of the maxillary left central incisor.*
measured using 3D radiography with CBCT at the cementoenamel junction, up to 4 mm apically (Fig 2). These data were transferred to the lab technician. Knowing the exact shape and size in the transmucosal area allowed the technician to fabricate a provisional with the same anatomy of the natural tooth to be extracted and replaced. In fact, the transmucosal area of the temporary restoration will be built up, verifying the correct mesiodistal and buccolingual diameter by the use of an electronic caliper in order to match the CBCT data transmitted previously by the dentist (Fig 3). The shape and size of the natural tooth anatomy in the transmucosal area served to replicate the exact subgingival dimension in the provisional restorations for soft tissue support; provisional restorations were fabricated as exact replicas of the original tooth with respect to the supragingival and subgingival areas (Fig 4). The master cast was carved out in similar correspondence to the transmucosal area of the tooth to be extracted in order to collocate the provisional restoration and verify the correct emergence profile (Fig 5). This technique aids in reestablishing the proper mechanical support to the soft tissue in the transmucosal area once the tooth is extracted. As a result, the original width and height of the alveolar tissue is preserved for an optimal esthetic result.

Surgery

Full-mouth scaling was performed 48 hours before the scheduled surgery. Antibiotic prophylaxis (1 g of amoxicillin, twice daily for 6 days)
was started 12 hours before surgery. Local anesthesia was induced with articaine (4% with adrenaline 1:100,000) in the vestibular and lingual areas. A flapless approach was used, and each tooth was extracted atraumatically to preserve the alveolar plates (Fig 6). Then, thorough debridement of the alveolus was carried out with an alveolar curette.

The osteotomy was prepared in accordance with the manufacturer’s protocol for immediately placed implants, using a vacuum shell surgical template (with a hole in the cingulum area for incisors and canines) in the central fossa for the premolars for precise implant placement.

In order to achieve adequate insertion torque (> 50 Ncm) for improvement in primary stability, the osteotomies were undersized using a final drill with the same diameter as the implant but one size shorter than the actual implant length. All implants were tapered screw-vent (TSV Implant, Zimmer Biomet) and inserted using a motor unit. The final seating was obtained with a calibrated torque hand ratchet (Indicating Ratchet Wrench, Zimmer Biomet) in order to evaluate and record the final insertion torque value. All the implants were placed 3 to 4 mm apical to the midfacial gingival margin, leaving a minimum 1.5-mm facial gap (Fig 7a). The buccal gap present between the implant and the buccal ridge was always grafted (Fig 7b). The graft consisted of a 50:50 mixture of autogenous bone chips collected during the osteotomy combined with anorganic bovine bone granules (Endobon, Zimmer Biomet). Sutures were not required as a consequence of the flapless technique.

In all cases, a temporary abutment (PreFormance Temporary Cylinder, Zimmer Biomet) was connected to the implant (Fig 8a). Temporary cylinders that were smaller than the 5-mm implant diameter were utilized (platform-switching). The
anatomically designed provisional crown was luted to the temporary cylinder using low-viscosity composite resin (Tetric EvoFlow, Ivoclar Vivadent) that was light-cured (Figs 8b and 8c). The provisional crown was then removed, refined, polished, and reinserted; the abutment screw was then torqued to 20 Ncm using the Indicating Ratchet Wrench. All provisional crowns were screw-retained and left out of occlusion (Fig 9). A final radiograph was taken to record the marginal bone level (baseline; Fig 10). Patients were instructed to consume a liquid diet for the first week after surgery and to refrain from chewing on the im-
plant crown for 8 to 10 weeks. They were also requested to use a 20% chlorhexidine rinse three times a day for 2 weeks. Periodontal maintenance visits occurred the first week and once a month thereafter for the first 6 months following surgery.

**Final Prosthesis Fabrication**

A final impression was made 6 months after implant placement using a custom tray, a pick-up coping (Zimmer Biomet) that was customized to replicate the transmucosal area of the provisional (Fig 11), and low-viscosity polyether impression material (Impregum Penta, 3M ESPE). Gold UCLA definitive abutments (Zimmer Biomet) were connected to all implants. All of the definitive restorations were screw-retained with the abutments screw-torqued to 20 Ncm for internal connection implants and 32 Ncm for external connection (Fig 12). Follow-up visits occurred every 6 months after delivery of the definitive restoration. At each recall appointment, alginate impressions and photographs were obtained to document any gingival margin change, and periapical radiographs were taken to detect any bone loss (Fig 13). Implants were considered well-integrated in the absence of mobility and < 1 mm of bone loss. A successful restoration was determined when there was no shrinkage of the papillae and < 1 mm of recession. Healthy patients showed no signs or symptoms of inflammation.
To evaluate the horizontal volumetric tissue changes during healing, a cast was developed by pouring white orthodontic gypsum (Selenor) onto alginate impressions taken from each treated site.

Measurements were acquired before tooth extraction (T0) and at 1-month (T1), 3-month (T2), and 6-month follow-ups (T3). Measuring levels were marked on the study casts at 1, 3, and 5 mm apical to the free gingival margin on the buccal and palatal sides using millimeter-calibrated paper stickers (Fig 14a).

The distance between the buccal and palatal marks at each of the three levels on the casts was measured to a tenth of a millimeter using an electronic digital caliper (Aura-Dental) for each patient and time point (Fig 14b). At each study site, one operator measured the patient’s cast using ×2.5 magnification optical loupes (EyeMag Pro S, Zeiss). The designated operators were calibrated for the method of measurement, and the digital caliper was calibrated prior to each measurement of every cast. Measurements were taken three times, and mean values and SDs were calculated for each reference point.

Results
A total of 63 patients (23 men and 40 women) were recruited to participate in the study. Most patients (n = 60) received one implant, whereas three patients received two implants at separate sites. Details of the implant distribution (See Appendix Table 1 in the online version of
ful, and the cumulative implant sur-
rection torque (Appendix Table 2) are
presented for all implants (n = 66).
After 6 months, the mean ho-
izontal ridge had increased by 0.10 ± 0.10 mm at 1 mm from the free gingival margin, decreased by 0.09 ± 0.10 mm at 3 mm, and diminished by 0.20 ± 0.10 mm at 5 mm. The av-
average horizontal ridge reduction at
the three measured levels and time
points following implant insertion
and loading with provisional resto-
rations is presented in Appendix
Tables 3 to 5 and Appendix Fig 1.
Vertical volumetric tissue changes
during healing (1-, 3-, and 6-month
follow-ups) were compared to T0
measurements. The height at the
midbuccal point from the free ging-
vival margin was noted by in sev-
eral cases at 6 months (Fig 12). All
implant restorations were success-
ful, and the cumulative implant sur-
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measurement vs follow-up time
changes significantly by location, as
depicted in Appendix Table 5.

Discussion

Immediate implant placement in
fresh extraction sites was initially in-
roduced to quickly rehabilitate the
patient and avoid multiple surger-
ies. Implant survival rates report-
ed for immediate provisionalization
were comparable to the standard
delayed approach. However, esthetic
results were controversial in terms of
tissue stability and final ginv-
aval esthetic outcomes, indicating
variable outcomes for this tech-
nique.

Currently, five main factors are
thought to influence an optimal
esthetic result: (1) integrity of the
alveolar; (2) minimally invasive ap-
proach to preserve the blood sup-
ply for the alveolar plates; (3) precise
prosthetic-driven implant position;
(4) the use of a graft material buccal
to the implant to provide space, vol-
ume, and scaffolding for new bone
formation; and (5) adequate support
for the soft tissue in the transmu-
cosal area, both buccally and inter-
proximally.

Optimal conditions of the alve-
olar facial plate without periodontal
bone loss are essential for a predict-
able esthetic result, as a compro-
mised alveolar integrity predisposes
the site to recession upon healing.
Flap elevation has also been sug-
gested to play a relevant role in soft
tissue dimensional changes. The
flapless surgery preserves the blood
supply from the periosteum to the

Statistical Methods and
Assumptions

Data from 63 subjects were collect-
ed, for which the measurements at
1, 3, and 5 mm apical to the free ginv-
vival margin were recorded at 0, 1,
3, and 6 months. The analysis aimed
to verify how the measurements
changed at the follow-up time and
location (1, 3, or 5 mm). A repeated-
tures of variance (ANO-
VA) using the mixed-effects models
framework and a post hoc analysis
were used in this regard. R (version
4.0.0, R Core Team) and G*Power
(version 3.1) software were used
for the analysis, as well as the fol-
lowing R packages: emmeans and
lme4. Significance was assessed
using the following type I error level;
α = .05. The implied minimum de-
tectable effect size has been retro-
spectively estimated equal to f =
0.20, assuming the aforementioned
a, total sample size, and a required
power of 80%.

Impact of Follow-up Time and
Location

The inferential analysis (ANOVA P
values) indicates that all main effects
and interaction are significant. Thus,
alveolar buccal plate, leading to faster healing and minor bone resorption.\textsuperscript{31,32} Precise implant placement is probably the most important feature of the whole procedure; excessive facial angulation of the implant would compromise the final esthetic result, leading to recession and/or an unesthetic, gray appearance of the soft tissue.\textsuperscript{19,20} While grafting extraction sockets does not prevent alveolar bone remodeling, it does appear to minimize buccal bone collapse.\textsuperscript{14,15} Araújo et al stated that the use of graft material in fresh extraction sockets does not eliminate bone crest resorption but can significantly influence the volumetric reduction of the alveolar tissue.\textsuperscript{33}

The use of a provisional prosthesis to support the soft tissue is crucial in achieving an optimal esthetic result. In addition, the immediate connection of a provisional prosthesis has been demonstrated to maintain peri-implant tissue volume and serve as a barrier for blood clot containment, which is essential for postsurgical healing.\textsuperscript{13,14,32}

The most important feature of the provisional prosthesis is the transmucosal area that creates an emergence profile responsible for the final esthetic result.\textsuperscript{15} Saito et al suggested that the surface topography of the acrylic provisional restoration and/or abutment can function as a substratum for cellular adhesion and may serve an important role in supporting peri-implant mucosa at the time of immediate implant placement.\textsuperscript{34} The same group stated that the use of anatomically contoured provisional restorations may provide a platform to promote peri-implant soft tissue healing and minimize remodeling of the buccopalatal ridge dimension.\textsuperscript{35} Ross et al suggested that the use of a customized provisional abutment can reduce the amount and frequency of recession.\textsuperscript{36} Kan et al demonstrated that immediate placement and single-unit provisionalization of anterior implants can optimize peri-implant esthetics by maintaining the existing hard and soft tissue architecture of the replaced tooth.\textsuperscript{19} In 2016, a study group concluded that immediate placement and provisionalization of implants resulted in a high survival rate, minimum peri-implant bone loss, very good esthetics, and satisfied patients after a mean follow-up period of 4 years.\textsuperscript{37}

Combining connective tissue graft and immediate provisionalization has also been advocated to compensate for recession in patients with a thin periodontal biotype.\textsuperscript{38,39} Recent studies have demonstrated that the use of an immediate provisional in combination with particulate graft material can minimize volumetric horizontal changes. In fact, changes less than 0.3 mm have been reported.\textsuperscript{14,15} The use of an adequately designed provisional to support the transmucosal area can further improve these results.

The authors of the present study report on the preservation of the horizontal tissue and coronal gingival height by immediate provisionalization with an anatomically designed single-tooth crown. Designing the subgingival area of the provisional as an exact replica of the natural tooth to be replaced is the element of this technique. Preoperative analysis of the natural tooth anatomy based on CBCT measurements allows for precise fabrication of the customized immediate provisional. The goal is to support the soft tissue both in the midfacial and interproximal areas in order to avoid any tissue shrinkage or volumetric change.

In patients with a very thin soft tissue phenotype, it could be an advantage to insert a connective tissue graft facially in order to convert the biotype, allow for better graft protection, and maintain the long-term stability of the tissue level.\textsuperscript{34,35}

Conclusions

Results from the present study indicate minimal soft tissue changes in the horizontal and vertical dimensions at single-tooth immediate implant placement and provisionalization in fresh extraction sites in the esthetic zone. The techniques employed to achieve this result included flapless and atraumatic tooth removal, immediate implant placement with bone grafting, and immediate provisional prosthetic insertion using an anatomically designed crown.

Patients in need of single-tooth replacement in the esthetic area can be treated according to the protocol outlined in the present study to promote an optimal esthetic result. More studies and larger samples are needed to further validate this conclusion.


Acknowledgments

The authors declare no conflicts of interest.

References


### Appendix Table 1 Implant Distribution by Designated Tooth

<table>
<thead>
<tr>
<th>Location</th>
<th>Implants, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central incisor</td>
<td>9</td>
</tr>
<tr>
<td>Lateral incisor</td>
<td>12</td>
</tr>
<tr>
<td>Canine</td>
<td>8</td>
</tr>
<tr>
<td>Premolar</td>
<td>37</td>
</tr>
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</table>

### Appendix Table 2 Implant Insertion Torque

<table>
<thead>
<tr>
<th>Insertion torque</th>
<th>Implants, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 90 Ncm</td>
<td>31</td>
</tr>
<tr>
<td>70 to 90 Ncm</td>
<td>26</td>
</tr>
<tr>
<td>50 to &lt; 70 Ncm</td>
<td>5</td>
</tr>
<tr>
<td>&lt; 50 Ncm</td>
<td>4</td>
</tr>
</tbody>
</table>

### Appendix Table 3 Average Horizontal Dimensional Variation at Three Locations Over Time

<table>
<thead>
<tr>
<th>Measurement location</th>
<th>1 mo</th>
<th>3 mo</th>
<th>6 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 mm</td>
<td>+ 0.49 mm</td>
<td>+ 0.27 mm</td>
<td>+ 0.10 mm</td>
</tr>
<tr>
<td>3 mm</td>
<td>+ 0.23 mm</td>
<td>0.00 mm</td>
<td>−0.09 mm</td>
</tr>
<tr>
<td>5 mm</td>
<td>+ 0.24 mm</td>
<td>−0.03 mm</td>
<td>−0.20 mm</td>
</tr>
</tbody>
</table>

Locations were the respective distance apically from the free gingival margin.

### Appendix Table 4 Measurement vs Follow-up Time (by mm)

<table>
<thead>
<tr>
<th>Model term</th>
<th>df1</th>
<th>df2</th>
<th>$f$</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement</td>
<td>2</td>
<td>473</td>
<td>1295.687</td>
<td>.000</td>
</tr>
<tr>
<td>Follow-up time</td>
<td>3</td>
<td>473</td>
<td>10.895</td>
<td>.000</td>
</tr>
<tr>
<td>Measurement:follow-up</td>
<td>6</td>
<td>473</td>
<td>3.483</td>
<td>.002</td>
</tr>
</tbody>
</table>

$df_1 =$ degrees of freedom 1; $df_2 =$ degrees of freedom 2.
### Appendix Table 5  Measurement Statistics by Location and Follow-up Time

<table>
<thead>
<tr>
<th>Location</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>9.274</td>
<td>1.094</td>
</tr>
<tr>
<td>T1</td>
<td>9.852</td>
<td>1.100</td>
</tr>
<tr>
<td>T2</td>
<td>9.666</td>
<td>1.097</td>
</tr>
<tr>
<td>T3</td>
<td>9.600</td>
<td>1.091</td>
</tr>
<tr>
<td>3 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>11.113</td>
<td>1.434</td>
</tr>
<tr>
<td>T1</td>
<td>11.380</td>
<td>1.393</td>
</tr>
<tr>
<td>T2</td>
<td>11.199</td>
<td>1.399</td>
</tr>
<tr>
<td>T3</td>
<td>11.081</td>
<td>1.408</td>
</tr>
<tr>
<td>5 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>12.462</td>
<td>1.695</td>
</tr>
<tr>
<td>T1</td>
<td>12.544</td>
<td>1.683</td>
</tr>
<tr>
<td>T2</td>
<td>12.305</td>
<td>1.685</td>
</tr>
<tr>
<td>T3</td>
<td>12.150</td>
<td>1.652</td>
</tr>
</tbody>
</table>

T0 = baseline; T1 = 1 month; T2 = 3 months; T3 = 6 months. Locations were the respective distance apically from the free gingival margin. Each analysis comprised 63 implants.

### Appendix Table 6  Average Vertical Dimensional Variation at the Midbuccal Level at Each Follow-up

<table>
<thead>
<tr>
<th>Vertical change, mm</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
</tr>
</thead>
<tbody>
<tr>
<td>+0.18mm</td>
<td>+0.07mm</td>
<td>-0.04mm</td>
<td></td>
</tr>
</tbody>
</table>

T0 = baseline; T1 = 1 month; T2 = 3 months; T3 = 6 months.
Appendix Fig 1  Horizontal dimensional changes by follow-up time at (a) 1 mm, (b) 3 mm, and (c) 5 mm apically from the free gingival margin. T0 = baseline; T1 = 1 month; T2 = 3 months; T3 = 6 months.