Guided Tissue Healing by Preformed Anatomical Healing Caps in the Edentulous Ridge: A 2-Year Retrospective Case-Control Study

The present study evaluated the 2-year changes in soft tissue width after implant placement in healed sites, using two different methodologies to obtain tissue healing: preformed and anatomical abutment caps for customized healing (test) vs conventional healing abutments (control). The null hypothesis was that there would be no difference between the test group and the control group. Patients who suffered from a single-tooth edentulous area in the premolar/molar region were included. Both the standard abutments and the preformed and anatomical abutment caps were immediately screwed on the implants. The final crown restoration was fabricated 3 months later. Primary outcomes (changes in the alveolar soft tissue ridge) and secondary outcomes (testing adverse events and measuring implant/prosthesis survival) were evaluated.

Thirty-nine patients (24 women) with a mean age of 57.7 ± 7.1 years (range: 42.6 to 72.8 years) were included. Alveolar widths in both groups showed significant increases from baseline to the 3-month follow-up, with augmentations of 3.6 ± 0.7 mm for the test group and 1.1 ± 0.9 mm for the control group. The gain in soft tissue appeared to be statistically different between the two groups (P < .0001). Contrarily, any subsequent change in width from 3 months to 2 years was negligible and insignificant (< 0.33 mm for both groups). The technique described in the present study encourages the potential for alternative healing based on the guided soft tissue concept, as it either eliminated the need for second-stage surgery or it reduced step-by-step peri-implant soft tissue conditioning, obtaining a tissue contour immediately very similar to that of a final prosthesis.


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Submitted September 27, 2021; accepted December 31, 2021.
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methods. Moreover, clinicians do not have any guide or tool available to help them identify the most proper shape, dimension, and orientation of the implant emergence profile in an objective, fast, and easy way.

New, preformed anatomical caps have been made available. The most striking feature is that the caps are cheap and easy to change in order to obtain proper anatomical gingival profiles.

Thus, the primary aim of this study was to evaluate 2-year changes in soft tissue width after implant placement in healed sites, using two different methodologies to obtain tissue healing: preformed and anatomical abutment caps for customized healing vs conventional healing abutments. The secondary purpose was to compare the clinical outcomes of the two groups.

Materials and Methods

Patient Selection

The present study retrospectively analyzed case sheets belonging to patients who were treated by a single oral surgeon and one prosthodontist from 2015 to 2017 at the Tuscan Stomatologic Institute and had signed an explicit consent for the use of their clinical information. Patients were followed up at the Complex Operating Unit of Maxillo-Facial Surgery of Pisa. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments.

Inclusion and Exclusion Criteria

The inclusion criteria for this study were as follows: (1) aged 18 years old or older and signed an informed consent form; (2) received delayed implant placement in long-standing healed site; (3) had one single edentulous site prosthetically rehabilitated with either immediate preformed healing abutment caps (test group) or conventional immediate healing abutments (control group); (4) the provisional implant loading lasted ~3 months; (5) the follow-up period extended up to 2 years from the first surgery; and (6) three-dimensional laser scans of preoperative and postoperative model casts were available.

Patients were excluded if there was at least one unreadable or corrupted file in the set of virtual plaster models, or if medical records attested any of the following: (1) a history of chronic and systemic diseases (uncontrolled diabetes, coagulation disorders); (2) long-term nonsteroidal anti-inflammatory drug therapy; (3) oral or intravenous administration of bisphosphonate drugs; (4) heavy smoking habit (> 10 cigarettes/day); (5) alcohol or drug abuse; (6) poor oral hygiene; and (7) the presence of parafunctional habits (bruxism, clenching).

Surgical Procedure

Patients were administered 1 g of amoxicillin (Zimox, Pfizer) 1 hour before surgery, then 1 g twice daily for 1 week. The intervention was performed under local anesthesia (optocaine 20 mg/mL with adrenaline 1:80,000; Molteni). A partial-thickness flap was raised after making a midcrestal incision. The implant bed was prepared according to the manufacturer’s recommendations, using standard drills set for a single implant system (progressive thread design; titanium, plasma-sprayed rough body; short, smooth, 0.5-mm collar; external hex) and unique design (Perfect, Avenir). The implant platform was placed in an equicrestal position.

In the test group, preformed and anatomical abutment caps (GTH, Guided Tissue Healing, Kalodon) with an emergence profile mimicking that of the natural teeth were screwed on the implants to support the mucosa of the treated sites during healing. If the cap dimension did not fit the pristine tooth emergence profile, it could be adjusted correctly. If the cap was too small, a photopolymeric material was added to fit the gingival margin position, then cured and polished with a rubber wheel. If the cap was too wide, an inverted cone bur (Integra Miltex) was used to create a buccal orientation, and the cap was then smoothed and slightly rounded around all margins (Fig 1).

In the control group, a standard healing abutment was screwed on...
the implant, and then the gingival flaps were secured around the abutment (Fig 2).

Prosthetic Procedures

Three months after implant placement, the shape of the emergence profile was transferred to the definitive plaster cast by an addition-reaction silicone elastomer. The master cast was then fabricated according to the restorative treatment plan. Proper final abutments and restorations (cement- or screw-retained) were fabricated.

In the test group, a conventional commercially available healing abutment was immediately screwed on the implant. Impressions were taken, and the final restoration was performed 3 months later.

In the control group, following Proussaef’s immediate guided soft tissue healing procedure, a temporary preformed anatomical abutment cap (ie, with a soft tissue emergence profile mimicking the forthcoming definitive rehabilitation) was used to modify the mucosa before prosthetic finalization.

Variables

The primary predictors were as follows: test group, preformed customized abutment caps for immediate guided soft tissue; control group, immediate conventional healing abutments. Accordingly, the secondary predictors were: tooth site, premolar vs molar; and arch, maxilla vs mandible.

Outcomes

Primary outcomes
Optical variables

The master plaster casts were retrieved from the records of prosthodontic rehabilitation and prosthodontic storage. Generally, the present conventional impression-taking method consisted of a one-step process on two viscosities of addition-reaction silicone elastomer (Flexitime Heavy Tray with Correct Flow or Light Flow, Heraeus Kulzer). Master casts were...
acquired by a three-dimensional scanner with a laser system (25-µm precision; 3D scanner with DWOS, Dental Wings), and obtained data were saved as standard tessellation language (STL) files. Then, MatLab (version 7.11, MathWorks) used a best-fit algorithm to align the acquired virtual arches until the occlusal planes were superimposable. The virtual arches were voxelized through conversion from stereolithography to a DICOM (Digital Imaging and Communications in Medicine) file format with the following settings: 300-µm isotropic voxel, 84-mm field of view, and 16 bit. Superimposable virtual casts underwent examination by SimPlant software (version 11.04, Materialise). A blind collector (P.T.) who was not involved in the treatment, survey, or healthcare maintenance of patients performed all analyses (Fig 3). Computerized cross-sections were selected at the midpoint of the edentulous ridge. The crestal width (CW) was measured in each of the superimposable images, and it was defined as the distance from the most protruding buccal point to the most palatal one, 1 mm below the coronal level of the preoperative contour. CWs were recorded before implant placement (preoperative/baseline) and at 3 months and 2 years after immediate cap placement (postoperative).

Papilla positions between the adjacent teeth and the surgical area were scored on virtual casts (Fig 4) according to Jemt’s Papilla Index (PI): 0 = no papilla; 1 = less than 50% of the papilla height; 2 = at least 50% of the papilla height, but not all of the interproximal space; 3 = papilla filling the interproximal space with a favorable gingival contour; 4 = hyperplastic papilla and unfavorable gingival contour. To evaluate PI in the present study, the reference point for each papilla was the line through the zenith of the implant restoration to that of the adjacent tooth.
**Clinical variables**

To assess gingival morphologic changes, peri-implant probing depths (PPDs) were recorded using a periodontal probe (PGF/GFS, Hu-Friedy) with a standardized pressure of ~0.2 N, and values were rounded to the nearest millimeter. PPDs and bleeding on probing (BOP) were measured at four points per implant (mesiobuccal, midbuccal, distobuccal, and midlingual), and an average was calculated. The following criteria were considered as implant failure: the presence of implant mobility, a radiolucent area close to the implant surface, suppurative mucosa, and associated pain (either spontaneous or due to the application of external strength).

**Secondary outcomes**

Changes in the alveolar ridge width ($\Delta CW$) after the implant restoration were calculated by equation 1, as follows:

$$\Delta CW = CW_{\text{postoperative}} - CW_{\text{preoperative}}$$

Changes in probing depth ($\Delta PPD$) were measured by equation 2, as follows:

$$\Delta PPD = PPD_{\text{postoperative}} - PPD_{\text{preoperative}}$$

**Statistical Analysis**

All statistical evaluations were performed with a specific software (Statistics Toolbox, MatLab). The null hypothesis was that there would be no difference between the test group (customized healing abutment cap) and the control group (conventional healing abutment). Homoscedasticity was verified by Brown-Forsythe test. Gaussian distribution was not confirmed by Shapiro-Wilk analysis. Nonparametric two-way analysis of variance (Friedman ANOVA test) was used to study the effect of tooth position and arch on $CW$, and then post hoc tests were applied. Measurements repeated in time (preoperative and postoperative) were matched data; each pairwise comparison was performed by Wilcoxon signed-rank test. For unmatched data, Wilcoxon rank-sum test was applied. Variables are described as mean ± standard deviation (rounded to the nearest decimal). The level of significance was set at .01.

**Results**

Thirty-nine patients (24 women, 15 men) with a mean age of 57.7 ± 7.1 years (range: 42.6 to 72.8 years) were selected for the present retrospective analysis.

After a follow-up of 2 years, none of the included patients showed implant failure (100% survival). Minor inflammation of gingival mucosa occurred during the first 1 to 2 days postsurgery, and neither mucositis nor flap dehiscences with suppuration were seen. Neither pain nor final prosthesis mobility was found in the patient records for up to 2 years.

Statistically significant differences ($P < .0001$) were detected when the alveolar ridge widths of both groups were compared to each other at 3 months (10.4 ± 1.4 mm and 7.8 ± 1.9 mm for test and control groups, respectively) and 2 years (10.1 ± 1.5 mm and 7.7 ± 1.7 mm for test and control...
groups, respectively) postsurgery, as reported in Appendix Table 1 (available in the online version of this article at quintpub.com/journals) and Fig 4. In both groups, the CWs showed significant augmentations from baseline to the 3-month follow-up, with increases of 3.6 ± 0.7 mm for the test group and 1.1 ± 0.9 mm for the control group. The soft tissue gain appeared to be statistically significantly different between the two groups ($P < .0001$; Appendix Table 1). Contrarily, any subsequent change in width (ie, from 3 months to 2 years) was negligible for both groups (< 0.33 mm) but statistically significant for the test group ($P = .0063$).

At 2 years, mean PPD was 3.0 ± 0.4 mm for the test group and 2.9 ± 0.4 mm for the control group; there were no significant changes except for a slight but significant ($P = .0066$) increase in PPD (0.4 ± 0.5 mm) in the control group from 3 months to 2 years. No differences were encountered in BOP between the two groups nor between the postoperative times (Appendix Table 1). Jemt’s PI showed a significant increase from baseline to 3 months in both groups ($P \leq .0003$). Final PIs appeared very similar between the test (1.6 ± 0.4) and control (1.8 ± 0.6) groups, in spite of the fact that the 3-month results seemed much better for the test group than the control group ($P = .0035$).

When secondary predictors (tooth positions and arches) were analyzed, no significant differences were found between the two groups regarding alveolar ridge width changes (neither for premolars vs molars nor for maxilla vs mandible).

**Discussion**

The present clinical study with a three-dimensional optical investigation aimed to reveal the most effective treatment method—customized abutment caps vs conventional abutments—for soft tissue rehabilitation with a transmucosal healing protocol.

Regarding the management of gingival tissues to obtain the best esthetics, the abutment emergence profile form is of utmost importance. Despite the variability of tooth and implant features, the soft tissue surrounding and supporting either the teeth or the implant might exhibit a similar contour pattern and comparable shapes. The position and angle of the placed implant; the soft tissue management before, during, and after surgery; and the level of the gingival margin over the
buccal surface of the implant showed complex and interdependent influences on functional and esthetic outcomes when tooth restorations were compared to adjacent natural teeth. According to the guided soft tissue concept, a preformed anatomical cap allows clinicians to form a soft tissue emergence profile very similar to that of the final prosthesis, allowing the definitive prosthesis to be inserted without pressure, or under very light contact pressure, on the surrounding soft tissue. This low contact force and minimal placement pressure on the definitive prosthesis could lead to good long-term stability of bone and soft tissue. In standard implant rehabilitations, the ability to model soft tissues and achieve a correct emergence profile often requires continuous tissue conditioning, using progressively modified provisional restorations during the temporary crown phase. The provisional restoration stage consists of a series of sessions, which extends the treatment time and increases final costs through induction of minor but progressive mechanical injuries, that allow tissues to fit a prosthesis very similar to that of natural teeth. According to the guided soft tissue concept, a preformed anatomical cap allows clinicians to form a soft tissue emergence profile very similar to that of the final prosthesis, allowing the definitive prosthesis to be inserted without pressure, or under very light contact pressure, on the surrounding soft tissue. This low contact force and minimal placement pressure on the definitive prosthesis could lead to good long-term stability of bone and soft tissue. In standard implant rehabilitations, the ability to model soft tissues and achieve a correct emergence profile often requires continuous tissue conditioning, using progressively modified provisional restorations during the temporary crown phase. 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The provisional restoration stage consists of a series of sessions, which extends the treatment time and increases final costs through induction of minor but progressive mechanical injuries, that allow tissues to fit a prosthesis very similar to that of natural teeth.

Conclusions

The technique described in the present study encourages the potential for alternative healing based on the guided soft tissue concept, as it either eliminated the need for second-stage surgery or it reduced step-by-step peri-implant soft tissue conditioning, obtaining a tissue contour immediately very similar to that of a final prosthesis.

Acknowledgments

The authors declare no conflicts of interest.

References


## Appendix Table 1 Descriptive Clinical Parameters at Three Time Points with Statistical Analyses

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Size</th>
<th>Time vs time</th>
<th>Baseline</th>
<th>3 mo</th>
<th>2 y</th>
<th>Baseline to 3 mo</th>
<th>3 mo to 2 y</th>
</tr>
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<tbody>
<tr>
<td><strong>Test</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CW, mm</td>
<td>21</td>
<td>vs 3 mo</td>
<td>6.8 ± 1.3</td>
<td>10.4 ± 1.4</td>
<td>10.1 ± 1.5</td>
<td>3.6 ± 0.7</td>
<td>-0.3 ± 0.4</td>
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<tr>
<td></td>
<td></td>
<td>(5.3 to 9.6)</td>
<td>(7.8 to 13.4)</td>
<td>(7.9 to 13.3)</td>
<td>(1.9 to 4.6)</td>
<td>(-0.8 to 0.5)</td>
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<tr>
<td></td>
<td></td>
<td>vs 2 y</td>
<td>&lt; .0001^b</td>
<td>.0063^b</td>
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<td></td>
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<td>&lt; .0001^b</td>
<td>.0063^b</td>
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<tr>
<td>PI, score</td>
<td>21</td>
<td>vs 3 mo</td>
<td>0.5 ± 0.3</td>
<td>1.8 ± 0.4</td>
<td>1.6 ± 0.4</td>
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<tr>
<td></td>
<td></td>
<td>vs 3 mo</td>
<td>(0 to 1)</td>
<td>(1 to 2)</td>
<td>(1 to 2)</td>
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<tr>
<td></td>
<td></td>
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<td>&lt; .0001^b</td>
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<td>&lt; .0001^b</td>
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<tr>
<td>PPD, mm</td>
<td>21</td>
<td></td>
<td>2.8 ± 0.4</td>
<td>3.0 ± 0.4</td>
<td>0.2 ± 0.7</td>
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<tr>
<td></td>
<td></td>
<td>vs 3 mo</td>
<td>(2 to 3.25)</td>
<td>(2.25 to 4)</td>
<td>(-1.25 to 1)</td>
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<td></td>
<td></td>
<td></td>
<td>&lt; .0001^b</td>
<td>.2458^b</td>
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<tr>
<td>BOP, %</td>
<td>21</td>
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<td>20 ± 18</td>
<td>21 ± 20</td>
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<td></td>
<td></td>
<td>vs 3 mo</td>
<td>&lt; .0001^b</td>
<td>.2896^c</td>
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<td>Control</td>
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<tr>
<td>CW, mm</td>
<td>18</td>
<td>vs 3 mo</td>
<td>6.8 ± 1.6</td>
<td>7.8 ± 1.9</td>
<td>7.7 ± 1.7</td>
<td>1.1 ± 0.9</td>
<td>-0.1 ± 0.5</td>
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<td></td>
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<td>vs 3 mo</td>
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<td>(4.7 to 12.2)</td>
<td>(5.2 to 11.5)</td>
<td>(-0.5 to 2.5)</td>
<td>(-0.9 to 0.5)</td>
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<td></td>
<td></td>
<td>vs 2 y</td>
<td>&lt; .0001^b</td>
<td>.2458^b</td>
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<tr>
<td>PI, score</td>
<td>18</td>
<td>vs 3 mo</td>
<td>0.5 ± 0.4</td>
<td>1.4 ± 0.4</td>
<td>1.8 ± 0.6</td>
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<td>&lt; .0001^b</td>
<td>.0146^b</td>
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<td>PPD, mm</td>
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<td>2.6 ± 0.4</td>
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<td>vs 3 mo</td>
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<td>(2.35 to 3.5)</td>
<td>(-1 to 0.5)</td>
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<td>BOP, %</td>
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<td>24 ± 23</td>
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<td>&lt; .0001^c</td>
<td>&lt; .0001^c</td>
<td>.2896^c</td>
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**Test vs control (P values)**

- CW = crestal width; PI = Jemt’s Papilla Index (0 = no papilla; 1 = < 50% of papilla height; 2 = at least 50% of papilla height, but not all interproximal space; 3 = papilla fills the interproximal space with a favorable gingival contour; 4 = hyperplastic papilla and unfavorable gingival contour); PPD = peri-implant probing depth; BOP = bleeding on probing; Size = sample size (n).
- Data are presented as mean ± SD (range). P values in the test and control sections pertain to intragroup comparisons. Statistically significant P values (< .01; two-tailed) are bolded.
- aIntragroup comparison.
- bWilcoxon signed-rank test.
- cWilcoxon rank-sum test.

Homoscedasticity assumption and results of Brown-Forsythe test for the outcomes: CW: F = 2.4667, df1 = 5, df2 = 111, P = .0369; PPD: F = 0.9297, df1 = 3, df2 = 74, P = .4308; BOP: F = 0.8483, df1 = 3, df2 = 74, P = .4719; PI: F = 1.5226, df1 = 5, df2 = 111, P = .4688. Analysis of variance and results of Friedman’s test for the outcomes of changes in CW (∆CW) between baseline (bsl), 3-month (3mo), and 2-year (2y) time points: ∆CWbsl–3mo (tooth interaction): df = 1, MS = 9, chi-square = 0.3164, P = .5738; ∆CWbsl–3mo (arch interaction): df = 1, MS = 24.5, chi-square = 1.0833, P = .2980; ∆CW3mo–2y (tooth interaction): df = 1, MS = 53.77, chi-square = 1.9017, P = .1679; ∆CW3mo–2y (arch interaction): df = 1, MS = 52.53, chi-square = 2.333, P = .1267.