Three-Dimensional Evaluation of Peri-implant Soft Tissue When Tapered Implants Are Placed: Pilot Study with Implants Placed Immediately or Early Following Tooth Extraction

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Purpose: This study examined a new 3D volumetric analysis method for the assessment of baseline-to-12-month changes of the soft tissue volume at early and immediately placed tapered implants after loading with ceramic single crowns.

Materials and Methods: Eligible patients with one incisor, canine, or premolar to be extracted were included. The patients were divided randomly into early-placement or immediate-placement groups. Tapered implants (BLT, Institut Straumann) were placed after the extractions. In the early-placement group, the implants were placed 8 weeks after extraction. In the immediate-placement group, the implants were placed immediately after the extraction. All implants healed transmucosally, and the final crowns were inserted after healing (baseline). Impressions were made at screening, baseline, and 12 months after crown insertion (Permadyne, 3M). The casts were scanned (Imetric 4D) and aligned, and a superimposed area of interest (AOI) (labial/buccal aspects) was defined to assess the volumetric changes (GOM Inspect). Specific software (3Matic, Materialise NV) was used for volumetric analysis. The vertical mucosal recession was measured at each time point. Repeated-measures one-way analysis of variance and the Tukey method were used for statistical analysis (SPSS 22, IBM).

Results: Twenty tapered implants (16 regular and four narrow) were placed in 20 patients (12 men and 8 women) in the early-placement (EP; n = 10) and immediate-placement (IP; n = 10) groups, respectively. Three-dimensional volumetric analysis revealed soft tissue volume loss in both groups of 10.0 ± 16.5 mm³ (EP) and 24.3 ± 21.3 mm³ (IP) between baseline and 12 months (P = .6). The analysis also revealed local differences in the changes, displaying both localized gain and loss in both groups. Conclusion: With this novel 3D analysis method, true volumetric soft tissue differences, ie, both localized gain and loss, were specified between the treatment groups. Int J Oral Maxillofac Implants 2020;35:1037–1044. doi: 10.11607/jomi.7879

Keywords: dental implants, early placement, immediate placement, soft tissue changes, volumetric analysis

The success of treatment with implant-supported reconstructions is not only defined by good survival rates but also by esthetics. Among the various clinical parameters, analysis of the facial soft tissue is a major factor in an evaluation of esthetics. The facial soft tissue has been evaluated widely through the pink esthetic score or measurements of vertical mucosal recession.¹⁻⁴ Using these methods, 2D information regarding gingival recession could be described.

On the other hand, a 3D assessment is desirable for the comprehensive analysis of peri-implant soft tissues. Several studies have presented methods to assess the volumetric changes in the peri-implant soft tissues. The Moiré method was used to compare the soft tissue changes, but it required specialized equipment and considerable effort to perform.⁵⁻⁶ Recently, the volumetric changes in the alveolar bone were tested. CBCT images were made to construct 3D models of a bone to calculate the volumetric changes.⁷⁻¹³ Purely digitalized volumetric analyses of soft tissues were used to assess the volumetric changes at the pontic sites. The extraction sites were analyzed after different alveolar ridge preservation methods.¹⁴⁻¹⁵ Digital 3D volume analysis of the soft tissues around the implant-supported reconstructions were also presented.¹⁶ The investigators acquired digital data of the surfaces at two different time points and measured the...
volume changes between the two different surfaces by analyzing the volume changes indirectly. The means of multiple 2D distances per unit area between the two different superimposed surfaces were calculated to become volumetric changes. The calculated overall mean volume changes in these studies did not differentiate between volume gain and loss.15

To evaluate the precise volumetric changes to the soft tissues around the implant-supported reconstructions at two different time points, the detailed volume gain and volume loss per area should be distinguished to calculate the net volume change. Furthermore, the area of volume gain and volume loss should be visualized to evaluate the esthetic outcomes. To the best of the authors’ knowledge, there are no reports on the detailed digital 3D volumetric analysis of soft tissues around implant reconstructions, considering the aforementioned method.

Therefore, this study used a new 3D virtual analysis method to assess the detailed 3D volumetric outcomes of soft tissues around tapered single implants (BLT implants, Institut Straumann), supporting ceramic implant crowns, including a group of patients who had received early or immediate implant placement.

**MATERIALS AND METHODS**

**3D Volumetric Analysis Method and Step-by-Step Procedure**

The new 3D volumetric analysis method was based on precise alignment, superimposition, selection, and several modeling functions, such as “Extrusion” and “Boolean subtraction” using two 3D software programs (GOM Inspect 2017; and Materialise 3-matic). Compared with previously published methods,14–16 the present method allowed for detailed analysis of the individual site-specific volumetric changes, ie, the regions of volume gain and volume loss in detail.

The systematic procedures for volumetric analysis of the soft tissues around the implants in two STL files from different time points are as follows:

1. Superimposition of two STL files by the best-fit algorithm focusing on the area of implant restoration using 3D software (GOM Inspect 2017) (Fig 1a).
2. Aligning the superimposed files with the x-, y-, and z-axes by each surface of the restoration of the implant (Fig 1b).
3. A curved line was drawn to define the AOI on the surface of the baseline according to the schematic diagram (Fig 2). The line was then projected to the other surface through the y-axis (Fig 1c). Once the AOI was defined on the surface of the baseline, it was projected to any new surface, which would be acquired through continuous follow-up.
4. The remaining part of only the selected area of two different surfaces was reimported into reverse engineering software (Materialise 3-matic). Orange represents the surface of the baseline, and blue represents the surface 12 months after the baseline (Fig 1d).
5. Solid objects (files) were constructed by moving the surfaces through the y-axis in the same direction. The object “baseline” was subtracted from the object “12-month,” and the unnecessary volume outside of the AOI was deleted. The volume differences, ie, gain or loss, can be obtained. The volume gain and loss can be distinguished and measured by performing the opposite subtractive procedure (Figs 1e and 1f).

The above procedure was performed on areas A and B and as a total of the analyzed surfaces at the point of screening, baseline, and 12 months (Fig 2).
As mentioned earlier, area A represents the soft tissue supported by the reconstruction, and area B shows the area supported by bone and bone substitutes. The net volume change was calculated from the difference between the volume gain and loss. The net volume change was zero when the volume gain and loss were the same.

One well-trained examiner (H.L.) performed all measurements using the same procedure, and the names of the files were coded to blind the information.

**Subject Inclusion for the Validation of the Method**

Twenty patients (12 men, 8 women) who required the extraction of a single tooth (central or lateral incisor, canine, or premolar) and who received a tapered implant as part of an ongoing randomized controlled clinical trial were enrolled in the present study.

The ongoing randomized controlled clinical trial compared the outcomes of immediate versus early implant placement, and of monolithic lithium disilicate and zirconia single crowns, and included a total of 60 patients.

The patient cases selected for the present investigation had randomly received either an immediate implant (n = 10) or an early implant (n = 10) supporting a monolithic all-ceramic single crown (lithium disilicate, zirconia), and had passed the 12-month follow-up visit.

The inclusion criteria were established in the clinical record form:

- ≥ 22 years of age
- Patient in good general health
- Adequate bone quality and quantity for one-stage implant placement
- Patient with physical status PS1 and PS2 (according to Physical Status Classification System of the American Society of Anesthesiologists)
- Adequate bone height that was at least 1 mm longer than the length of the study implant

**Surgical and Prosthetic Protocol**

In the present pilot study of volumetric analysis, 20 patients with 20 tapered implants of this initial pool were included (16 regular- and 4 narrow-diameter; BLT, Roxolid, SLActive, Institut Straumann). The implants in the early placement group (EP) were placed 8 weeks after extraction, and the implants in the immediate placement group (IP) were placed immediately after extraction. In situations with hard or soft tissue deficiencies, augmentation procedures were performed using evidence-based methods and materials (Bio-Oss, Bio-Gide, Geistlich; autologous palatal connective tissue). Before the definitive reconstruction, the patients were restored with removable provisional prostheses. Eight weeks after placing the transmucosally healed implants, impressions were taken, and the definitive reconstructions were completed.

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**Figs 1 to 1g**

- (d) Retain only the selected area for analysis. Orange is the baseline, and blue is 12 months.
- (e) Move the surfaces through the y-axis to construct the solid object.
- (f) Perform subtraction twice to obtain each volume gain and loss.
- (g) Green represents the situation after 12 months.
prostheses were fabricated. The subgingival contour of the restoration was controlled to have a concave shape.

Follow-up Examinations
When the patients were screened, alginate impressions were made (Alginoplast, Kulzer) and poured with stone (Elite Ortho, Zhermack) at the baseline (delivery of the definitive reconstruction) and at the 12-month follow-up visit. These stone casts were scanned using a highly precise laboratory scanner (IScan D104, Imetric), and STL files of each situation were obtained.

To focus exclusively on the volumetric changes to the labial soft tissue around the implant, the outline of the AOI was defined virtually between the interproximal contact zones horizontally, and between the line 0.5 mm below the gingival margin and the line 5 mm vertically below that line (Fig 2). The upper 3 mm of the AOI was designated as area A, which represents soft tissue without the support of bone. The lower 2 mm of the AOI was labeled area B, which represents the soft tissue with the support of bone or bone substitutes.

Statistical Analysis
The data of the EP and IP groups were acquired. Before statistical analysis, the distribution of data was tested for normality. Repeated-measures one-way analysis of variance and the Tukey method were carried out to assess the statistical significance among the groups using the SPSS statistical package (version 22, IBM).

RESULTS
Volumetric Changes of the Peri-implant Soft Tissues
A trend for the 3D soft tissue volume changes was noted for the different time points and AOIs (Figs 3 to 5).

The AOI on 3 mm of marginal soft tissue supported by the reconstruction was selected as AOI A, and the apical 2 mm of soft tissue was defined as AOI B (Fig 2). Table 1 lists the detailed results according to various variables. Interesting results were obtained from this novel volumetric analysis. AOI A showed 13.5 mm$^3$ volume loss between the baseline (delivery of the definitive reconstruction) and 12 months on IP, whereas 5.4 mm$^3$ of volume loss was noted on EP.

Focusing on EP and AOI A, the 5.4 mm$^3$ volume loss between the baseline and 12-month follow-up examination indicated the net volume loss resulting from 2.1 mm$^3$ of volume gain and 7.5 mm$^3$ of volume loss. The total volume change, if not divided into “gain” and “loss,” was 9.6 mm$^3$ for the same group and same time points.

Figure 6 shows the detailed 3D volumetric “gain and loss” analysis for each case. Volume gain and loss were colored in blue and orange, respectively, which shows the overall, individual, and intuitive visualization simultaneously. Although the number of patients was insufficient to determine statistical significance among the groups, it provided adequate visualized information.
**DISCUSSION**

The new method for 3D volumetric analysis allowed detailed regional evaluations of the soft tissue volume changes around implants supporting single crowns. In this pilot study, the AOI was defined to evaluate the clinically important buccal area of implant reconstruction. They were divided into a reconstruction-based supported marginal area as AOI A and a bone-based supported apical area as AOI B. One of the main features of this method is that the result can reveal the volume and 3D visualized images. From this, overall
Table 1: Mean ± SD Volumetric Changes (mm$^3$) Between Each Period According to Early and Immediate Placement

<table>
<thead>
<tr>
<th>Placement</th>
<th>Screening–baseline</th>
<th>Baseline–12 mo</th>
<th>Screening–12 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Area A</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IP</td>
<td>–3.80 ± 12.11</td>
<td>–13.45 ± 11.83</td>
<td>–12.90 ± 15.84</td>
</tr>
<tr>
<td><strong>Area B</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EP</td>
<td>7.89 ± 9.96</td>
<td>–4.58 ± 8.72</td>
<td>2.76 ± 15.14</td>
</tr>
<tr>
<td>IP</td>
<td>6.75 ± 14.48</td>
<td>–10.50 ± 10.78</td>
<td>–0.76 ± 13.61</td>
</tr>
<tr>
<td><strong>Area total</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IP</td>
<td>2.54 ± 24.19</td>
<td>–24.25 ± 21.34</td>
<td>–14.95 ± 27.70</td>
</tr>
</tbody>
</table>

G = gain; L = loss, EP = early placement; IP = immediate placement.

Fig 6: Three-dimensional view of the volume change between baseline and 12 months. Blue means volume gain, and orange means volume loss.
information on what happened regarding soft tissue changes among each group can be obtained. A single section of 2D measurements would be insufficient to show real 3D changes of soft tissue between different time points.

Within the limited number of patients, pilot measurements were taken, and a trend for smaller changes in the soft tissue volume, ie, loss, was observed between baseline and 12 months of function compared with the IP group. In both groups, similar volume loss occurred in the B regions (supported by bone or bone substitute) to that in the A regions (supported by reconstruction).

These observations are in accordance with other investigations. More favorable soft tissue outcomes at the implants placed following the EP protocol have been reported. Using the present method, however, the detailed gain and loss of soft tissues could be distinguished at the AOI and visualized for each time point before the net volume change was calculated.

In the era of digital dentistry, the volumetric changes after soft tissue augmentation or implant surgery have been investigated. These studies used different types of digital analysis methods, using STL files for surface comparisons and measurements of the 2D distances for 3D volume calculations.

Superimposition is one of the important steps to compare two different surfaces. In many software programs, the surface-matching algorithm is generally used to superimpose two surfaces. An accurate superimposition of the STL files of the scanned surfaces of different time points, eg, baseline (delivery of the reconstruction) and at the 12-month follow-up, is essential for evaluating the soft tissue changes around an implant. Errors can occur due to moving, fracturing, extrusion of reference teeth, or changes in the soft tissue, which may cause an inaccurate superimposition of the files’ AOI. For this reason, in the present methodology, a defined surface on the implant restoration was used as a reference to superimposition in the different scans. The surface of the implant restoration, which was fixed firmly onto the implant, was judged to be the most reliable and unchangeable reference. Therefore, a localized area that would be the same at two STL files served as the reference for the superimposition in this study.

The features of the volume changes separated into gain and loss were visualized in a standardized way for each case. No significant differences in the net volume changes in the AOI were observed between the regions supported by the reconstruction (A) and those supported by hard tissues (B) in the present pilot pool of patients. The more stable and thick soft tissue in the EP group might affect the results, but a larger number of patient cases would be needed to acquire statistical significance. Future studies will be needed involving more patients with the currently compared time points for implant placement (IP and EP) to deliver more statistical power. In the present study, the focus was on the novel 3D volumetric analysis method, which was very useful for the detailed analysis of soft tissue outcomes around implant reconstructions.

The labial soft tissues around the implant reconstruction, particularly those close to the marginal area, play a major role in the pink esthetics of the implant reconstruction. Therefore, it is important to define an AOI focusing on the labial surface. The AOI was extended toward the interproximal papilla. Information on the papilla is difficult to acquire because of alginate tearing during removal of the reconstruction, or due to bubbles on the cast or artifacts caused by saliva, causing errors.

CONCLUSIONS

This study evaluated a new 3D method for the virtual analysis of soft tissue volumetric changes at implant-supported reconstructions. The method allowed a detailed analysis of the changes according to areas closer to the mucosal margin and apical to the margin. Therefore, this new method delivered important information for prediction and evaluation of soft tissue esthetic outcomes of implant reconstructions. On the other hand, the number of patients in each group was small, and significant differences were not observed despite the normality of the data and trends between the groups. The final evaluation of all patient cases in both the EP and IP groups of the original randomized controlled clinical trial will allow for more detailed outcomes. Furthermore, the alginate impression might have placed some pressure on the soft tissue, which might have disturbed the standardization. In future research, intraoral optical scanners should be used to obtain accurate information on the soft tissue outlines.

The limitation of this study was that the analysis method was complex. On the other hand, it could be applied to assess the changes in soft tissue in daily practice as the software evolves in the future. A meaningful result may be obtained in a further study using this method and a sufficient number of patients.

ACKNOWLEDGMENTS

The authors wish to thank the ITI Foundation for the ITI scholarship that enabled the first author to perform this research at the University of Geneva. Furthermore, the authors thank Institut Straumann AG for the financial support of this study and the support with implants and abutments. The authors reported no conflicts of interest related to this study.
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