Contour Changes Following Implant Placement and Concomitant Soft Tissue Augmentation Applying a Volume-Stable Collagen Matrix

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The objective of this study was to assess volumetric and linear changes of buccal mucosal thickness at implant sites following soft tissue augmentation with a volume-stable collagen matrix (VCMX). Soft tissue augmentation using a VCMX was performed in 12 patients at the time of implant placement. Hydrocolloid impressions were taken prior to surgery and at 1 and 6 months postsurgery. Stone cast models were scanned, and stereolithography (STL) files from the three time points were uploaded to an image-analysis software. At all time points, linear and volumetric measurements of the contour changes up to 3 mm apical to the mucosal margin were performed and were analyzed statistically. At 1 mm apical to the mucosal margin, the change in soft tissue thickness between presurgery (T1) and 1 month (T2) amounted to 0.21 ± 1.22 mm, and the change between T1 and 6 months (T3) was 0.08 ± 1.47 mm. At 3 mm apical to the mucosal margin, the change in soft tissue thickness was 1.92 ± 1.70 mm between T1 and T2 and 0.31 ± 1.26 mm between T1 and T3. Contour (volumetric) changes revealed an increase of 0.58 ± 0.73 mm between T1 and T2 and an overall gain of 0.55 ± 0.73 mm between T1 and T3. Soft tissue augmentation with VCMX increased the ridge profile. The increase in ridge width was greater at 3 mm below the ridge crest than at 1 mm below the ridge crest. Remodeling processes during healing showed a decrease in the ridge contour between 1 and 6 months. Int J Periodontics Restorative Dent 2022;42:515–522. doi: 10.11607/prd.5840

Soft tissue volume augmentation procedures are frequently performed at implant sites and can be considered an integral part of implant surgery in both the anterior and posterior zones.1 Specific indications include an increase in mucosa thickness to minimize marginal bone level changes,2,3 to prevent soft tissue recession,4,5 and to positively affect probing depth values and inflammatory parameters.6

The autologous subepithelial connective tissue graft (SCTG) is most frequently used to increase the mucosal thickness and is considered to be the gold standard.7-12

In a systematic review and meta-analysis13 that was adopted in a consensus report,14 soft tissue grafting procedures using autologous graft transplantations to gain keratinized mucosal height have resulted in more favorable peri-implant health by improving bleeding indices and gaining mucosal thickness with significantly less marginal bone loss.

Disadvantages, however, include increased patient morbidity due to the second surgical site and individual anatomical variations with a limited amount of soft tissue available at the donor site. In order to overcome these limitations, soft tissue substitutes of various origins were developed and evaluated.15

Different soft tissue grafting substitutes were examined and com-

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pared to an autogenous source. A recent narrative review, which was followed by a systematic and meta-analysis on the peri-implant soft tissue phenotype modification and its impact on peri-implant health, disclosed that in addition to autogenous grafts, nonautogenous biomaterials (such as collagen or acellular dermal matrices) could result in a significant increase in mucosal thickness compared to nonaugmented sites. Further, the collagen matrix showed beneficial effects on marginal bone level stability. These soft tissue scaffolds showed an effective contribution in soft tissue augmentation at periodontal and peri-implant sites. However, as these materials are devoid of cells and cellular signaling molecules, they might promote soft tissue volume but not keratinized tissue neo-genesiss.

In a systematic review and meta-analysis of randomized controlled trials, surgical procedures to increase soft tissue thickness at implant sites (via SCTG or volume-stable collagen matrix [VCMX]) were evaluated. Out of 2,119 studies, only 14 RCTs met their inclusion criteria. Two studies showed improved soft tissue thickness with xenogeneic collagen matrix augmentation compared to no augmentation at the implant sites before prosthetic treatment. However, both studies were considered as having a high risk of bias. In comparison, other systematic reviews and consensus reports concluded that a VCMX demonstrated outcomes that were not inferior to SCTGs for a variety of indications.

Mucogingival surgeries to augment soft tissue volume can be performed at various times during implant therapy: before, during, and after implant placement, and even after insertion of the final restorations. Based on a recent systematic review, the time of intervention (soft tissue augmentation) does not significantly influence the outcomes. However, the same review stated that for some time points, insufficient data are available. Clinically, soft tissue augmentation should be combined with another mandatory surgical intervention to reduce morbidity, overall treatment time, and costs. In case of delayed implant placement without simultaneous hard tissue augmentation, soft tissue augmentation can be performed concomitantly. Clinical data for such a combined treatment, however, are scarce for autologous grafts or lacking completely for newly developed soft tissue substitutes.

Therefore, the aim of the present study was to assess volumetric and linear changes of implant sites following soft tissue augmentation with a VCMX. Soft tissue contour and periodic volume changes were recorded. The null hypothesis was that mucosal thickness would be obtained at the sites grafted with VCMX.

Materials and Methods

Study Design

In 12 periodontally healthy patients who had periodontal indices in good standing (plaque control record and bleeding on probing both < 25%), soft tissue augmentation was performed in prospective implant sites at the crestal and buccal aspects of the edentulous areas. The study was performed at the postgraduate periodontic/prosthodontic clinic at the School of Dental Medicine of Tel Aviv University. The Ethical Committee of the university approved the study. Patients received a detailed explanation of the treatment course and the rationale for the procedure, and patients who agreed to participate signed an informed consent form.

Only nonsmoking patients who were considered in good general health (ASA 1 or 2 according to the American Society of Anesthesiologists) were included in the study. Future implant reconstruction sites with a concaved labial profile and/or thin soft tissue phenotype were noted and were considered for the soft tissue augmentation procedure. Cases with a comprised clinical ridge concavity in a partial edentulous site where thin mucosal thickness was evident were included. Surgical soft tissue thickness procedures were applied only at single, labial, concaved implant sites, although multiple implant reconstruction cases were involved too. No distal extensions were considered. The indication for the surgical sites was independently allocated by two examiners (Z.A. and U.R.).

Surgical Procedure

Prior to soft augmentation procedure (T1), an elastic hydrocolloid
impression was taken (Hydrogum 5 alginate, Zhermack) of the designated implant site and the peripheral anatomical surroundings. Local anesthetic (2% lidocaine hydrochloric acid with norepinephrine 1:100,000) was infiltrated labially and lingually at the anticipated implant site (Fig 1a). Full buccal and lingual muco-periosteal flaps were elevated. An extension of a dissected soft tissue pouch was followed on the labial aspect. Then, the soft tissue was augmented using VCMX (Fibro-Gide, Geistlich) trimmed according to the designated recipient bed. The VCMX was stabilized to the inner aspect of the buccal flap using a horizontal internal 5-0 coated polyglactin 910 suture (Vicryl, Ethicon, Johnson & Johnson). Implants were then placed (Fig 1b).

Conical implants with an internal-hex connection (Alpha Bio-Tec) were placed via the two-stage approach (ie, the traditional Brånemark protocol). Primary soft tissue closure

Fig 1 (a) Occlusal view of partially edentulous maxillary left central incisor with buccal volume deficiency. (b) An implant is placed, and (c) VCMX is then applied to augment the mucosal thickness. (d) Primary wound closure is obtained. (e) Occlusal view following implant healing and superstructure connection. (f) Facial view of the final restored maxillary left central incisor. Note the final outcome of the buccal mucosal volume, which cannot be differentiated between the single implant restoration and the neighboring natural dentition.
was then obtained via coronally advanced flaps and/or lingual/palatal coronal flap manipulation techniques25 (Fig 1c). Postoperative instructions and medication were then administered. At 1 month post-augmentation (T2) (Figs 1d and 1e), a second hydrocolloid impression was performed; this was repeated at 6 months post-augmentation (T3), prior to abutment connection (Fig 1f).

Outcome Measures

The unit of analysis was the patient. Inclusion criteria were at least one implant site. In some patients, more than one implant was placed in the same area. In such cases, one implant site was randomly chosen for analysis (the more mesial or the one in the center).

Impressions

Stone casts (Lab Stone, Talladium) were produced from all impressions taken at T1, T2, and T3. Casts were assessed for irregularities (porous areas, undefined mucosal margins, an undefined vestibulum). Only suitable casts without irregularities were further analyzed.

Stereolithography Image Acquisition and Data Matching

All suitable cast models were scanned (MS Scan & Design, 7Series, Dental Wings) and STL (stereolithography) files from the three time points (T1, T2, and T3) uploaded to an image analysis software (Swissmeda). The software automatically superimposed the digital casts (Fig 2). Manual adjustments were done if needed using adjacent teeth as reference points.

Assessment of Volumetric Changes

All measurements of volumetric change26 were done by a calibrated examiner (D.S.T.) not involved in surgical procedures and patient treatment. At all time points, the following measurements were performed:

Linear measurements: A longitudinal slice was selected in the center of the augmented site, and a line was drawn parallel to the tooth axis of the neighboring teeth. The distance between this line and the buccal soft tissue contour was assessed at 1 and 3 mm apical to the mucosal margin, and changes in thickness were evaluated ($\Delta T_{1\text{mm}}$ and $\Delta T_{3\text{mm}}$, respectfully).

Fig 2 To analyze volumetric changes, scans of the casts at baseline (before soft tissue augmentation; T1) were superimposed with scans of the casts at the 1-month (T2) and 6-month (T3) follow-up appointments. The blue area is the region of interest. Yellow line = vertical cut of the T1 model; green line = sagittal cut of the T2 model; gray line = sagittal cut of the T3 model; vertical blue line = reference for linear measurements.
Volumetric measurements: A region of interest (ROI) was individually selected in each site. The ROI was bordered by the transition between the crestal and buccal aspects of the ridge and by the mesial and distal line angles, extended 3 to 6 mm apically. Contour changes were then calculated by the software (measured in millimeters) and corresponded to the mean distance between two surfaces (eg, between two time points: T1 vs T2 and T1 vs T3).

Statistical Analysis

Means, SDs, medians, and interquartile ranges were calculated using a statistical software (Microsoft Excel). Due to the limited number of cases and the case series design, only descriptive statistics were applied.

Results

All patients responded well, with no side effects and/or complications recorded. No detectable signs of inflammation or change in tissue color were seen during healing. Clinically, a buccal thickening of the labial mucosal tissue was noted but relatively subsided in a later stage. No changes were observed in keratinized mucosal height nor mucogingival line location.

All implants were placed, followed by the restorative phase. The ridge contour and profile (Figs 1d and 1e) increased due to the surgical procedure. Subsequently, the augmented ridge area demonstrated some remodeling with a greater increase at 3 mm below the ridge crest than at 1 mm below.

Table 1 Volumetric Results

<table>
<thead>
<tr>
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<th>T1 to T2</th>
<th>T1 to T3</th>
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<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Median (IQR 1, IQR 3)</td>
</tr>
<tr>
<td>ΔTT_1mm</td>
<td>0.21 ± 1.22</td>
<td>–0.04 (–0.28; 0.6)</td>
</tr>
<tr>
<td>ΔTT_3mm</td>
<td>1.92 ± 1.70</td>
<td>1.32 (0.94; 2.65)</td>
</tr>
<tr>
<td>CC</td>
<td>0.58 ± 0.73</td>
<td>0.52 (–0.32; 0.73)</td>
</tr>
</tbody>
</table>

ΔTT_1mm = changes in tissue thickness at 1 mm apical to the mucosal margin; ΔTT_3mm = changes in tissue thickness at 3 mm apical to the mucosal margin; CC = contour changes; IQR = interquartile. Values are presented in millimeters.

Contour (volumetric) changes revealed an increase of 0.58 ± 0.73 mm between T1 and T2 and an overall gain of 0.55 ± 0.73 mm between T1 and T3.

Discussion

The present clinical study assessed volumetric changes following soft tissue augmentation with VCMX at implant placement with a follow-up of 6 months. The ridge contour and profile increased by 0.21 ± 1.22 mm due to the surgical procedure. Subsequently, the augmented ridge area demonstrated some remodeling with a greater increase at 3 mm below the ridge crest than at 1 mm below.

Surgical interventions are frequently performed to enhance the quantity and quality of soft tissues at implant sites. Esthetics, cleanliness of restorations, and maintenance of peri-implant health are some of the suggested indications for these procedures. Based on clinical studies comparing implant sites with and without soft tissue volume augmentation, esthetic outcomes are in favor of sites having received...
an autogenous connective tissue graft.\textsuperscript{27} Ever since the introduction of soft tissue substitutes with a proposed indication for mucosal thickness gains, an increasing number of studies have been performed documenting various indications and treatment protocols.\textsuperscript{16,22}

Aside from the choice of either autologous or xenogeneic materials for soft tissue augmentation, one dilemma is choosing the time of intervention. Several protocols exist that use different time points: at implant placement, at the time of second-stage surgery, and delayed augmentation. In a recent systematic review with 23 studies included in the network meta-analysis, no significant association was observed with regard to the timing of soft tissue augmentation when mucosal thickness was analyzed as an independent parameter.\textsuperscript{16} The changes in mucosal thickness compared to baseline were 0.17 mm (95% CI: \(-0.04, 0.38; P = .16\)) at the second stage and 0.34 mm (95% CI: \(-0.03, 0.73; P = .15\)) for delayed treatment protocol.\textsuperscript{16} As such, performing soft tissue grafting simultaneously with implant placement reduces the need for an additional intervention.

The application and efficacy of collagen matrices for augmenting soft tissue volume were reported in previous studies that compared VCMX and SCTG.\textsuperscript{21,28} Similar to the present study, linear volumetric changes were assessed by employing digital analyses of dental stone casts. It was reported that at 1 and 3 months after soft tissue augmentation with VCMX, buccal tissue thickness increased significantly (1.10 mm and 0.59 mm, respectively). The differences between VCMX and SCTG were not significantly different.\textsuperscript{21} Three years after augmentation with VCMX, the median change in mucosal thickness was 0.5 mm, with no significant difference compared to SCTG.\textsuperscript{28} It was concluded that SCTG, which is considered the gold standard for soft tissue augmentation, demonstrated negligible differences when compared with VCMX, and that both methods demonstrate stable outcomes at implant sites.

In the present study, the horizontal width increase was greatest 3 mm below the mucosal margin. This is in line with a preclinical study reporting the greatest mucosal thickness gain at 3.5 mm below the crest.\textsuperscript{29} Apart from preclinical data, clinical studies found the greatest horizontal ridge width gain below the mucosal margin, irrespective of whether soft tissue augmentation was performed as a separate procedure or in conjunction with implant placement and guided bone regeneration.\textsuperscript{21,30} In a case series, implant placement and guided bone regeneration were combined with soft tissue augmentation using a resorbable collagen matrix.\textsuperscript{27} The overall increase in tissue contour was most significant at 5 mm below the mucosal margin.\textsuperscript{30}

The increase of horizontal width in the present study was the largest at 1 month and decreased at the next follow-up appointments. This is in line with preclinical studies where soft tissue thickness gain, measured at the most coronal level, was the greatest after 1 month (2.1 ± 1.6 mm) and decreased at 6 months (0.2 ± 0.03 mm).\textsuperscript{29} Similar results were reported in serial preclinical studies in canines, assessing volume changes using optical scanning-based digital technologies and histologic analyses.\textsuperscript{31–33} During the study follow-up, the obtained gains in vertical and horizontal dimensions in the crestal area decreased to a level close to the presurgical situation, and it was reported that horizontal ridge augmentation can be expected more apically than 3 mm below the ridge zenith.\textsuperscript{28} A recent in vivo canine study that employed a different collagen matrix (originated from bovine tendon) showed increased soft tissue thickness and full degradation of the grafting material 12 weeks after the augmentation procedure.\textsuperscript{34}

In another clinical study, a collagen matrix was used to increase the soft tissue contour at implant sites. The reported soft tissue thickness gain was 0.9 ± 0.2 mm at 6 months.\textsuperscript{35} Even though the time of intervention (at implant uncovering) and the measurement methodology (an endodontic file 1 mm below the gingival margin only) in that study\textsuperscript{15} differ from the present study, the current results demonstrated a horizontal ridge width gain similar to preclinical data. Based on the above-mentioned preclinical and clinical studies, soft tissue augmentation is followed by a first phase of remodeling processes. Once tissue maturation takes place and final restorations are inserted, minimal tissue contour changes are reported.\textsuperscript{30,36} Even though the flap used in the present study was designed to avoid excessive
compression of the buccally augmented tissue, bleeding and swelling due to the surgical procedure resulted in some clinically visible anemia of the site in some cases, but it did not influence healing.

The outcomes of the present study are limited to some extent by the design (as it was not a randomized controlled clinical trial), the lack of a control group, and a limited number of patients and sites.

Conclusions

Soft tissue augmentation with VCMX at implant placement resulted in an increased ridge profile. Remodeling processes during healing resulted in a decrease in the ridge contour between 1 and 6 months. Moreover, the increase in ridge width was greater at 3 mm below the ridge crest than at 1 mm below.

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