Three-Dimensional Volumetric Changes After Socket Augmentation with Deproteinized Bovine Bone and Collagen Matrix

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Purpose: Socket augmentation decreases the magnitude of alveolar ridge resorption, but the literature is limited in respect to quantifying soft tissue remodeling. The aim of this study was to determine the volumetric and linear dimensional changes at the buccal surface for both hard and soft tissues after socket augmentation treated with a xenogeneic collagen matrix in combination with bone grafting. Materials and Methods: Twenty-four individuals indicated for tooth extraction were enrolled in this investigation. Each participant was randomly assigned to one of two groups: (1) deproteinized bovine bone + collagen plug, or (2) deproteinized bovine bone + xenogeneic collagen matrix. A cone beam computed tomography scan was taken prior to extraction and at 6 months postextraction. Intraoral scanning images were taken at baseline, 3 months, and 6 months postextraction. Hard and soft tissue analyses were performed to compare linear ridge remodeling and volumetric changes by noncontact reverse-engineering software. Results: Both groups showed bone and soft tissue remodeling. For hard tissue remodeling, there was no significant difference between the collagen plug and collagen matrix groups. For soft tissue remodeling, the collagen matrix group showed a reduced soft tissue loss compared with the collagen plug group. The volumetric analysis demonstrated that the mean buccal soft tissue volume loss for the collagen matrix group was 68.6 mm³ compared with 87.6 mm³ found in the collagen plug group (P = .009) over a 6-month period. Conclusion: This clinical investigation provides early evidence of using the total tissue volume to compare soft and hard tissue remodeling after socket augmentation. The results of this study demonstrated that the use of a xenogeneic collagen matrix reduced the buccal soft tissue loss after tooth extraction, but additional studies are necessary to evaluate the clinical significance of soft tissue augmentation after tooth extraction. Int J Oral Maxillofac Implants 2020;35:566–575. doi: 10.11607/jomi.7961

Keywords: 3D, biomaterials, bone graft, bone substitute, randomized controlled clinical trial

Alveolar bone formation after tooth extraction is a natural healing event that occurs based on the surrounding alveolar walls.1,2 However, the loss in hard and soft tissue volume may compromise esthetic rehabilitation and impair proper implant placement. Several techniques have been proposed aiming at reduction of the magnitude of the alveolar crest resorption that occurs after tooth extraction.3–6 Minimizing extraction trauma and limiting flap elevation are among these procedures.7 The usage of bone fillers in socket augmentation also assists in preserving the remaining hard and soft tissues after tooth extractions and assists in decreasing additional bone grafting procedures for future implant placement.3,8,9 However, the literature is limited in quantifying soft tissue healing after socket augmentation protocols.

Resorbable and nonresorbable barrier membranes have been used for the preservation of the alveolar bone dimensions after tooth extraction and have demonstrated clinical advantages when combined with xenograft and allograft bone substitutes.9 The use of a collagen plug as an adjunct to cover the bone grafting material during socket augmentation is commonly used in clinical practice. Unlike barrier membranes, the clinical implication of the collagen plug is to seal the site, prevent loss of the bone grafting material, and to aid in clot formation and platelet aggregation.10 However, due to material limitations, the use of the collagen

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Submitted July 22, 2019; accepted October 9, 2019.
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plug offers a minimal advantage regarding the modulation of wound healing. Three-dimensional (3D) xenogeneic collagen matrix has been used over mineralized bone graft after minimally invasive tooth extraction in order to preserve hard and soft tissue volume for future implant placement. The application of such a xenogeneic collagen matrix appears to favor immediate blood clot stabilization, leading to early vascularization, to facilitate soft tissue cell ingrowth; and to enable excellent integration of the xenogeneic matrix within the surrounding tissues. While it is straightforward to demonstrate these characteristics in vitro and in very controlled wound healing models, it is more difficult to measure the clinical effects in human subjects.

An accurate and reliable clinical quantification of hard and soft tissue volumetric changes has remained technically challenging. The use of cone beam computed tomography (CBCT) has been used and developed into a reliable measurement tool. However, this method also has several issues, including the limitation for linear measurement analysis, the scattering effect that can affect the analysis, and the additional exposure to radiation of the patient for comparative analysis. The use of digital intraoral optical scanning (IOS) and assessment methods were introduced to measure volume changes of oral tissues over time and provided a new perspective to measure and quantify soft tissue volume longitudinally after reconstruction or regenerative periodontal procedures.

The aim of the present investigation was to determine the volumetric and linear changes at the buccal surface for both hard and soft tissues after socket augmentation treated with a xenogeneic collagen matrix using CBCT- and IOS-generated models. To accomplish this, a novel 3D analysis using noncontact reverse-engineering software was developed and is described along with the outcomes.

**MATERIALS AND METHODS**

This randomized controlled clinical trial enrolled 24 participants who were in need of tooth extraction and future implant placement. The study protocol was approved by the University of North Carolina at Chapel Hill human subjects internal review board. All recruited participants were previously treatment planned for extraction + implant placement by nonstudy personnel to avoid any potential conflict of interest. Participants were randomized by sealed envelopes containing one of the two assigned treatment groups: (1) collagen plug group: extraction and socket augmentation treated with deproteinized bovine bone (Bio-Oss Collagen, Geistlich Pharma) + collagen plug (HeliPlug, Integra Milteex), or (2) collagen matrix group: Extraction treated with deproteinized bovine bone (Bio-Oss Collagen, Geistlich Pharma) + xenogeneic collagen matrix (Mucograft Seal, Geistlich Pharma). Participants who required antibiotic prophylaxis prior to dental treatment or those with medical contraindication to dental treatment were excluded. To be eligible for the study, participants had to be men or women ages 18 to 80 years of age, having a maxillary premolar, canine, lateral incisor, or central incisor with a restorative or periodontal hopeless prognosis, in which a dental implant was indicated without any anticipated guided bone regeneration or sinus grafting required. In addition, all participants must be in a stable periodontal condition prior to the implant surgery. Participants with uncontrolled diabetes (HbA1c > 7%) within 3 months prior to screening examination, with a history of intravenous bisphosphonates, current smokers, or currently taking anticoagulant medications, high-dose corticosteroids, radiation therapy, or chemotherapy were excluded from this study. Women who were known to be pregnant, breastfeeding, or planning to become pregnant within 6 months were also excluded from the study. Participants with dehisced, fenestrated, or discontinuous labial/buccal alveolar bone plates determined after baseline CBCT prior to extraction, or after tooth extraction where more than 50% of the buccal bone height was not present, were treated with guided bone regeneration and immediately excluded from the study. At the initial examination, all participants completed a full-mouth clinical examination including probing pocket depth, clinical attachment level, bleeding on probing, and Gingival Index on all teeth by a calibrated examiner. This randomized clinical trial was registered at the NIH Clinical Trials Registry (Clinical Trial Registration No. NCT02844569).

**Surgical Procedure**

Within 2 weeks of the initial examination, the predetermined hopeless tooth was extracted, using a minimally traumatic approach. Facial and lingual intrasulcular incisions were made only at the tooth requiring extraction. A periotome was used in the interproximal spaces to sever subcrestal periodontal attachment fibers and expand the periodontal ligament space. If needed to facilitate periotome insertion, a fine long diamond bur was used to minimally remove interproximal bone alongside the tooth. An elevator was used to mobilize the tooth, and forceps were used to deliver the tooth. The socket was curetted to remove all granulomatous tissue, and the site was irrigated with sterile isotonic saline solution.

For the collagen plug group, deproteinized bovine bone was placed into the debrided socket in the necessary amount to successfully fill the extraction socket. The bone substitute material was rehydrated...
with the subject’s blood and/or sterile saline solution. Subsequently, a collagen plug was placed to cover the grafted extraction socket and sutured with a resorbable suture (5-0 Chromic Gut, Ethicon) to stabilize the wound (Fig 1). For the collagen matrix group, the same deproteinized bovine bone was placed into the debrided socket in the necessary amount to successfully fill the extraction socket to the level of bone. The bone substitute material was similarly rehydrated with the subject’s blood and/or sterile saline solution. A xenogeneic collagen matrix was used to cover the grafted extraction socket and sutured with a nonresorbable suture (6-0 Prolene, Ethicon) and resorbable suture to stabilize the collagen matrix over the extraction socket and maximize direct contact between the matrix and soft tissue of the socket opening (Fig 2).

Medications prescribed to all participants included 500 mg amoxicillin (7 days) or 250 mg azithromycin (4 days) for participants who reported allergy to amoxicillin, and 600 mg ibuprofen (7 days). All participants were instructed to rinse with 0.12% chlorhexidine gluconate for 30 seconds twice daily, and to avoid brushing or touching the surgical site for 2 weeks. Sutures were removed 2 weeks following the surgical appointment. Participants were recalled at 1, 2, 4, 12, and 24 weeks for monitoring of the healing process. Participants were permitted to wear a provisional removable prosthesis to replace the missing tooth. All removable prostheses were adjusted to remove any direct contact with the extraction site, minimizing any direct effect of the prosthesis into the soft tissue healing.

**Radiographic Analysis**

CBCT scans (New Tom 5G; 110 kV; 2 mA) were taken following the screening visit and at 6 months post–tooth extraction. To evaluate radiographic linear and volumetric changes from baseline to 6 months, data were converted to Digital Imaging and Communications in Medicine (DICOM) format and imported into InVesalius 3 software. Maxillary surface mesh models were generated using CBCT data creating stereolithography (STL) files that were later analyzed using noncontact reverse-engineering software (Geomagic Control, 3D Systems). All radiographic data were analyzed by one calibrated examiner (E.M.).

**Soft Tissue Analysis**

Soft tissue linear and volumetric analyses were performed to compare the soft tissue remodeling between the collagen matrix and collagen plug groups. IOS images captured with an intraoral digital scanner (Trios 3, 3Shape) were collected at baseline, 1 week, 2 weeks, 4 weeks, 3 months, and 6 months. To evaluate soft tissue linear and volumetric changes, data were converted to STL files and analyzed by noncontact reverse-engineering software. Linear and volumetric changes were calculated based on the data measured at baseline, 3-month, and 6-month visits.

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**Fig 1** Clinical images of the procedure performed for the collagen plug group. (a) Buccal view prior to the extraction of the maxillary left central incisor. (b) Occlusal view. (c) Extraction socket after minimally invasive extraction. (d) Extraction socket grafted with deproteinized bovine bone and covered with collagen plug. (e) Occlusal view 6 months postextraction. (f) Buccal view 6 months postextraction.
Linear and Volumetric Assessments
For each participant, presurgical and 6-month postsurgical radiographic models, and presurgical, 3-, and 6-month postsurgical IOS models were superimposed. The superimposition technique included the selection of the same three teeth in each model. The software was then able to perform an automatic alignment and superimposition of the two models (eg, presurgical and a follow-up model). The mean error in alignment of the two data sets was kept below 0.1 mm for all subjects. Prior to analysis, the presurgical model was selected as reference, while the postsurgical models were selected as the testing model against the reference. For each participant, to measure the volumetric remodeling, an area of interest at the buccal aspect of the extraction site was defined, and the volumetric remodeling at this area was measured. In addition, two-dimensional buccal-palatal cross sections were obtained in the center of the extraction site. Subsequently, the buccal linear remodeling between preoperative and postsurgical models was measured at 1, 3, and 5 mm below the crest for both radiographic and IOS models. Both linear and volumetric soft tissue analyses were performed by only one calibrated examiner (E.M.).

Statistical Analyses
Descriptive statistics (mean and standard deviations) were calculated for the pooled data sets for each treatment group. A power analysis was performed using a statistical power calculator (SAS Power Procedure). The sample size of 24 subjects, 12 in each of two groups, allowed 90% power ($\alpha = .05$) to detect a difference of 2.5 mm in the horizontal ridge width measured at 3 mm below the crest, assuming a standard deviation of 1.6 mm as determined by a previous study. This power calculation accounted for a 10% subject dropout rate. Differences were considered statistically significant at $P < .05$.

For soft tissue analysis, the primary outcome was the within-participant difference between the linear and volume changes at the collagen matrix and collagen plug groups. These data were collected prior to surgery, as well as 3 and 6 months after surgery, leading to a series of three longitudinal differences for each participant. Linear mixed model was used to analyze the data longitudinally, in which the actual linear and volume measures were modeled as a function of time, treatment group, and the interaction of time and treatment, while accounting for the repeated measures on each participant with a random participant effect. Due to the exploratory nature of the analysis, no Bonferroni correction for multiple testing was applied. Statistical significance was defined as $P < .05$.

For hard tissue analysis, a two-sample equal variance Student $t$ test with a two-tailed distribution was performed comparing the two groups for each of the linear measurements as well as for the volumetric analysis. Statistical significance was defined as $P < .05$.
RESULTS

A total of 28 individuals were screened for study eligibility; of these, 24 met study inclusion criteria and were randomized between the two study groups. Demographic baseline characteristics of this cohort are described in Table 1. Each individual underwent a single tooth extraction. For the collagen plug group, seven extractions were performed in the anterior area and five in the premolar area. For the collagen matrix group, five extractions were performed in the anterior area and seven in the premolar region. All individuals completed the 6-month follow-up period, and the hard and soft tissue could be assessed in all preserved socket sites.

Data from horizontal linear soft tissue remodeling are demonstrated in Figs 3 and 4. Results showed that socket augmentation with the use of a deproteinized bovine bone + collagen plug showed a greater linear buccolingual loss of soft tissue at 1, 3, and 5 mm below the gingival margin at the 1-, 3-, and 6-month follow-ups. Both groups showed similar horizontal linear soft tissue loss, with most of the soft tissue loss concentrating 1 mm below the gingival margin. The linear analysis between collagen matrix and collagen plug was not statistically significant at any of the evaluated time points.

Data from horizontal linear hard tissue remodeling are demonstrated in Figs 5 and 6. Two collagen matrix group participants and four collagen plug group participants were excluded from the linear hard tissue analysis due to unacceptable discrepancies during

### Table 1: Study Demographics

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<tr>
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<th>Collagen matrix</th>
<th>Collagen plug</th>
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<tr>
<td>Female</td>
<td>7</td>
<td>7</td>
<td>NS</td>
</tr>
<tr>
<td>Male</td>
<td>5</td>
<td>5</td>
<td>NS</td>
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<tr>
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<td>9</td>
<td>NS</td>
</tr>
<tr>
<td>Noncaucasian</td>
<td>4</td>
<td>3</td>
<td>NS</td>
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<tr>
<td>Mean age, y (SD)</td>
<td>45.2 (11.4)</td>
<td>56.4 (12.2)</td>
<td>NS</td>
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NS = not significant.

Fig 3  Linear (mean, SE) soft tissue loss for xenogeneic collagen matrix (CMX) and collagen plug (CP) groups at 1, 3, and 5 mm from the gingival margin at the midbuccal of the extraction site at (a) 1, (b) 3, and (c) 6 months. No statistically significant difference between groups (P > .05).

Fig 4  (a) Three-dimensional superimposition of scanned images at baseline and 6 months from the collagen plug group. Colored scale represents the linear soft tissue loss (mm) at the buccal site. (b) Cross-sectional image of the midbuccal position at the maxillary left central incisor showing the linear soft tissue loss for both buccal and palatal sites. (c) Three-dimensional superimposed scanned images showing the linear loss in soft tissue at 1, 3, and 5 mm below the gingival margin. (d) Cross-sectional image at the midbuccal site of the maxillary left central incisor showing baseline (red) and 6-month (black) soft tissue and tooth contour.
the alignment of the baseline and 6-month CBCT data. Thus, a total of 10 datasets were used for the collagen matrix group, and eight for the collagen plug group. Results derived from the horizontal hard tissue linear analysis over 6 months showed similar amounts of linear buccal-lingual alveolar bone resorption from baseline at 1, 3, and 5 mm below the alveolar crest. There was a significant difference in linear bone loss between groups at 5 mm below the bone crest ($P = .029$). The collagen plug group showed a mean linear bone loss of 0.92 mm against 1.64 mm for the collagen matrix group.

Data from soft tissue volumetric analysis demonstrated less facial soft tissue loss in favor of the collagen matrix group (Figs 7 and 8). At the 1-month follow-up,
the collagen plug group demonstrated a mean soft tissue loss of 50.8 mm$^3$, while the collagen matrix group showed a mean 32.0 mm$^3$ in volumetric soft tissue loss. At the 3-month assessment, the facial soft tissue volumetric analysis demonstrated that the collagen matrix group lost a mean 64.8 mm$^3$ compared with 86.6 mm$^3$ lost by the collagen plug group sites. At the 6-month time point, the collagen matrix group lost a mean 68.8 mm$^3$ compared with 87.6 mm$^3$ in the collagen plug sites. Compared with the collagen plug group, the collagen matrix group exhibited an overall significantly less soft tissue volumetric loss pattern over the 6-month healing period ($P = .009$).

Data from hard tissue volumetric analysis are demonstrated in Figs 9 and 10. Results revealed similar findings for both groups in terms of bone volume remodeling. The collagen plug group showed a mean volumetric hard tissue loss of 66.4 mm$^3$. The collagen matrix group showed a mean volumetric hard tissue loss of 72.6 mm$^3$. The difference between collagen matrix and collagen plug groups was not statistically significant ($P = .668$).

**DISCUSSION**

This randomized clinical trial demonstrated that the use of a xenogeneic collagen matrix seal over a bone graft material resulted in an increase of approximately 22% soft tissue volume at the facial site of extraction sites compared with a collagen sponge plug over the same bone graft material. It has been widely demonstrated that socket augmentation techniques limit bone dimensional changes after tooth extraction, especially in esthetic zones.$^8,^{23,24}$ However, to the authors’ knowledge, this is the first study to report the soft tissue 3D volumetric remodeling associated with socket augmentation. The esthetic zone is considered an area of high risk for ridge alteration consequent to tooth extraction.$^{25}$ The maintenance of adequate soft tissue volume during socket augmentation procedures is crucial for the esthetics, diminishing the possibility of future additional soft tissue grafts.

In the present study, linear measurement analysis demonstrated that sites treated with xenogeneic collagen matrix had reduced soft tissue remodeling at 1 mm (1.97 mm collagen matrix; 2.07 mm collagen plug), 3 mm (1.58 mm collagen matrix; 1.8 mm collagen plug), and 5 mm (1.05 mm collagen matrix; 1.36 mm collagen plug) below the gingival margin compared with the collagen plug at the 6-month follow-up visit. The results of the present study are supported by other similar studies assessing the reduction of soft tissue loss using a xenogeneic collagen matrix. A recent study by Natto and investigators compared the clinical and radiographic soft and hard tissue dimensional changes during socket augmentation using freeze-dried bone allograft (FDBA) with a collagen plug or a xenogeneic collagen matrix. Clinical soft tissue measurements were performed using radiographic stents. The linear measurements showed that both treatment modalities were effective in preserving the alveolar ridge. A slight
increase in buccal gingival thickness at the coronal part was observed in both groups (0.9 mm collagen matrix and 0.5 mm collagen plug). In a similar study using models that were scanned and analyzed with digital software, the linear soft tissue analysis showed that sites treated with a xenogeneic collagen matrix and free gingival graft had a reduced amount of soft tissue loss, $1.2 \pm 0.5 \text{ mm}$ and $1.2 \pm 0.7 \text{ mm}$, respectively, compared to sites treated with beta-tricalcium phosphate ($\beta$-TCP) not covered and nongrafted sites, $1.7 \pm 0.7 \text{ mm}$ and $1.8 \pm 0.8 \text{ mm}$, respectively.

The present radiographic analysis demonstrated that the use of either collagen plug or xenogeneic collagen matrix over an extraction socket grafted with deproteinized bovine bone produces similar results in all volumetric measures and in most linear measures. This finding is in agreement with previous studies, which have determined that there is no statistical difference in treatment outcomes based on material used for socket augmentation at the time of tooth extraction. For example, Darby and collaborators evaluated 37 human studies utilizing a variety of techniques and materials for postextraction socket augmentation. It was determined that while socket augmentation procedures are indeed effective in minimizing horizontal and vertical ridge resorption, there is no evidence to support the efficacy of one technique or material as being superior to another. Another review and meta-analysis by Avila-Ortiz et al indicated that socket augmentation was effective in preserving vertical and horizontal dimensions compared with spontaneous healing, and that while a membrane and/or graft material did influence socket augmentation positively, the type of membrane or the type of grafting material (allograft vs xenograft) was not a determinant factor. Thus, as expected, the present study also did not show significant differences in the majority of radiographic bone measurements between the use of collagen plug compared with xenogeneic collagen matrix. The similarity in alveolar measurements could also be explained by the use of the same deproteinized bovine bone in the socket of both groups, with perhaps the material within the socket itself having a more dominant effect on the preservation of bone resorption than the barrier material that was used as soft tissue protection over the graft.

It has been extensively reported that the amount of ridge resorption that occurs after tooth extraction is heavily influenced by the initial thickness of the buccal wall, with a thicker initial thickness generally leading to a smaller amount of resorption that occurs. In a separate study, the authors reported that the average ridge reduction in premolar sites was 18%, while in anterior sites, ridge reduction was significantly higher at 34%. The present study did not find any significant correlation between initial buccal wall thickness and volumetric bone and soft tissue remodeling. In addition, the data for premolar and anterior teeth were evaluated separately, and volumetric differences between the test and control groups were still not statistically significant. This can be explained by the low study sample size and that teeth with an initial thin buccal wall (< 0.5 mm) were not considered for the study due to the higher potential of buccal wall fracture/fenestration during the extraction. In regard to the age range of the participants of the study (31 to 69 years), there was no significant correlation for age. A recent study in 547 patients evaluated the influence of age, sex, smoking status, and BMI on bone healing. Results reported that only smoking status significantly correlated with bone healing duration.

In recent years, the advancement in 3D imaging technology has increased its use in maxillofacial surgery, dental implantology, and various other medical disciplines. The 3D model superimposition can facilitate treatment planning and predict and evaluate treatment outcomes. For the analysis of soft tissue independent of bone quantification, the present study used an intraoral optical scanner to obtain 3D reconstructed images. In a validation study using the same IOS used in the present study, Imburgia and collaborators showed a trueness value ranging from 50.2 μm to 67.2 μm and a precision value ranging from 24.5 μm to 31.5 μm, which does not significantly interfere with the results from the present study. To evaluate the soft tissue dimensional variation, the present study utilized reverse engineering software in order to superimpose 3D models from different time points and subsequently calculate linear and volumetric changes. In a recent study, Gkantidis et al evaluated 3D superimposition techniques on various skeletal structures using surface models and concluded that it is possible to provide accurate, precise, and reproducible results. A precision analysis study using CAD files determined that surface reconstruction on Geomagic Qualify software provides a reliable analysis with a maximum deviation of 0.06 mm, standard deviation of 0.003 mm, and an average error of 0.002 mm. A validation study evaluating the reliability of 3D digital models obtained with a surface laser scanner and analyzed using the Geomagic software demonstrated that linear measurements on digital models are accurately reproducible. In the present study, using 3D models reconstructed from IOS and CBCT, the average error was 0.04 mm and 0.07 mm, respectively.

Soft tissue volume, color, and texture are key elements in achieving optimal esthetics in implant dentistry. Thicker soft tissue not only appears to be important in implant esthetics, but also plays a pivotal role in maintaining more favorable peri-implant health. The present study demonstrated that the
mean buccal soft tissue loss for the collagen matrix group was 68.6 mm³ compared with 87.6 mm³ found in the collagen plug group (P = .009) over a 6-month period. The use of volumetric unit (mm³) to measure soft and hard tissue changes has been published 37–39 but the clinical significance of the unit measured requires a different interpretation in relation to linear measurements reported in millimeters. The volume data in this study were mainly related to changes in soft tissue thickness located at the coronal portion of the extraction site. However, the clinical benefit is still questionable since the study did not analyze data related to peri-implant health and esthetics.

CONCLUSIONS

This study used a novel method for evaluating soft and hard tissue changes using 3D superimposed images. The images were analyzed using noncontact reverse-engineering software that provides the potential to precisely measure tissue changes not only by numbers, but also by generating 3D images, giving an additional perspective for clinical research analysis. The results of this study demonstrated that the use of a xenogeneic collagen matrix reduced the buccal soft tissue loss after tooth extraction. However, additional studies are necessary to evaluate the clinical significance of soft tissue augmentation after tooth extraction.

ACKNOWLEDGMENTS

This study was funded by Geistlich Pharma. Thiago Morelli was funded by NIH/NIDCR K23-DE025093. ShaoPing Zhang was funded by NIH/NIDCR K99-DE207086. Julie Marchesan was funded by NIH/NIDCR KO1-DE027087. The authors appreciate the assistance of Mrs Caroline Butler in segmenting the radiographic dataset and Dr John K. Spitznagel for his assistance in editing the manuscript. The authors reported no conflicts of interest related to this study.

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