Evaluation of a Minimally Invasive Alveolar Ridge Reconstruction Approach in Postextraction Dehiscence Defects: A Case Series

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This study evaluated a panel of clinical, dimensional, volumetric, implant-related, histomorphometric, and patient-reported outcome measures (PROMs) following reconstruction of dehiscence defects in extraction sockets with a minimally invasive technique using particulate bone allograft and a nonresorbable dense polytetrafluoroethylene (dPTFE) membrane. Subjects (n = 17) presenting severe buccal dehiscence defects at the time of single-rooted tooth extraction participated in the study. The mean vertical dimension of the dehiscence defects at baseline was 5.76 ± 4.23 mm. Subjects were followed up at 1, 2, 5, and 20 weeks postoperatively. The dPTFE barrier was gently removed at 5 weeks. CBCT and intraoral scans were obtained at baseline and at 20 weeks. A bone core biopsy sample was harvested at 24 weeks (before implant placement). Linear radiographic measurements revealed a mean increase in buccal bone height from baseline to 20 weeks (5.66 ± 5.1 mm; P < .0001). A total alveolar bone volume gain of 9.12% was observed. Although approximately half of the sites required some degree of additional bone augmentation at the time of implant placement, all implants were placed in a favorable restorative position with adequate primary stability. Histomorphometric analyses revealed a mean mineralized tissue area of 31.04% ± 15.22%, and the proportions of remaining allograft material and nonmineralized tissue were 16.23% ± 10.63% and 52.71% ± 9.53%, respectively. All implants survived up to 12 months after placement. PROMs were consistent with minimal discomfort at different postoperative stages and a high level of overall satisfaction upon study completion. This study demonstrated that the reconstructive procedure employed was successful and predictable in treating large, postextraction alveolar ridge deformities to optimize tooth replacement therapy with implant-supported prostheses. Int J Periodontics Restorative Dent 2021;41:335–345. doi: 10.11607/prd.4785

Effective management of the extraction site is a core component of contemporary dental practice. Preclinical and clinical studies have demonstrated that tooth extraction triggers a physiologic process of structural remodeling, resulting in a variable degree of alveolar ridge volume loss, primarily due to bone resorption.1–3 The presence of severe ridge deficiencies may interfere with tooth replacement therapy. High-level evidence supports the efficacy of alveolar ridge preservation therapy in attenuating bone loss after tooth extraction in intact sockets.4

However, there is limited information available regarding the predictability of interceptive ridge reconstruction techniques for managing sites that present significant alveolar bone damage at the time of extraction. This is of great clinical relevance: As reported in a recent clinical study in which a total of 53 teeth were extracted in 30 patients, 28% of the sites presented some degree of buccal bone dehiscence, and 4% exhibited complete buccal plate loss in spite of applying minimally traumatic extraction measures.5

Only a handful of clinical studies and case reports have provided information regarding the outcomes of different clinical protocols for the management of extraction sites.

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presenting large bone dehiscences, regardless of whether immediate implant placement is performed or not. While most of these studies reported favorable horizontal and vertical bone gains, implant survival, and esthetic outcomes, with the exception of the only randomized clinical trial (RCT) conducted to date, none of them provided data on important parameters such as volumetric alveolar bone and ridge contour changes, histomorphometric outcomes, or patient-reported outcome measures (PROMs). Furthermore, information on the performance of nonresorbable barrier membranes in these clinical scenarios is scarce.

The aim of the present case series was to evaluate a novel, minimally invasive ridge reconstruction therapy (consisting of the application of a particulate allograft material and a nonresorbable dense polytetrafluoroethylene (dPTFE) membrane immediately after tooth extraction) in the function of clinical, dimensional, volumetric, implant-related, histomorphometric, and patient-reported outcomes.

Materials and Methods

Experimental Design and Center

This clinical study was designed as a prospective case series and was conducted in compliance with the Preferred Reporting of Case Series in Surgery (PROCESS) guidelines. The clinical component of the study was conducted in the Department of Periodontics at the University of Iowa College of Dentistry between March 2017 and May 2018. Details of the study timeline and events are shown in Fig 1.

Ethical Approval and Registration

The experimental protocol was approved by the University of Iowa Institutional Review Board in January 2017 (HawkiRB #201612718). The study was also registered in the National Institutes of Health (NIH) database for clinical studies, under the clinicaltrials.gov identifier NCT02980211.

Eligibility Criteria and Recruitment

Adult subjects with tooth-bound single-rooted teeth (not including mandibular incisors) indicated for extraction who also presented with a large dehiscence defect affecting at least the coronal third of the buccal bone were eligible to participate in the study. The exclusion criteria were as follows: (1) any periodontal attachment loss > 1 mm affecting the interproximal sites of neighboring teeth; (2) current heavy tobacco use, defined as > 10 cigarettes per day; (3) uncontrolled diabetes mellitus, defined as HbA1c > 7.0; (4) severe hematologic disorders; (5) organ failure; (6) uncontrolled or severe metabolic bone diseases or disorders; (7) previous head and neck radiotherapy or chemotherapy within the past 12 months; (8) intake of medications known to largely influence bone metabolism; (9) pregnancy at the time of screening or trying to conceive; and (10) mental disabilities that may interfere with reading, understanding, and signing the informed consent and/or with following study-related instructions. In the screening visit, candidates were informed of the purpose, design, and timeline of the study, as well as expected benefits and possible risks associated with their participation. Potential subjects were required to read, understand, and sign the consent form.

Clinical Procedures

All clinical procedures were performed by the first author (M.A.). Before starting the baseline surgical intervention, a CBCT scan (i-CAT Next Generation, KaVo) was done. The field of view was approximately 6 cm at 0.3 mm voxel size, and the exposure factor settings were fixed at 120 kVp and 5 mAs for all scans. Additionally, a surface scan of the area of interest, including the adjacent teeth and the base of the vestibulum, was obtained using an intraoral scanner (True Definition, 3M ESPE). All surgical procedures were performed under local anesthesia. Buccal keratinized mucosa width and thickness were measured at 1 mm apical from the gingival margin using a UNC-15 periodontal probe (Hu_Friedy) and a no. 30 endo condenser (Kerr), respectively. The vertical extent of the defect was measured by determining the distance from the gingival margin to
the crestal bone on the midbuccal aspect using a UNC-15 probe, and subtracting the 2 mm that, on average, corresponds to the supracrestal soft tissue.

Tooth extraction was completed in a minimally traumatic, flapless, fashion (Fig 2). Subsequently, the existence of the suspected dehiscence defect was confirmed; absence of a defect resulted in subject exclusion. After carefully elevating one papilla (usually distal), a full-thickness soft tissue “pouch” was created using tunneling instruments around the bony defect. A nonresorbable dPTFE membrane (Cytoplast TXT-200, Osteogenics Biomedical), trimmed to a size and shape that allows complete extension over the defect, was tucked between the mucosa and the alveolar bone. A combination particulate bone allograft (a mixture of 70%
mineralized and 30% demineralized freeze-dried bone allograft; enCore, Osteogenics Biomedical) was used to fill the socket to the crestal level and to overcontour the surrounding buccal bone housing. The socket access was sealed with an extension of the dPTFE membrane to ensure compartmentalization of the underlying alveolar bone and grafting material. An external cross-mattress and a simple interrupted suture (Cytoplast 5/0 suture, Osteogenics Biomedical) were applied to stabilize the marginal mucosa and the elevated papilla, respectively (Fig 3). An intraoral periapical radiograph was taken to verify adequate distribution of the grafting material. Detailed postoperative instructions were given to the subjects, including care to avoid mechanical disturbance or excessive pressure of the surgical site and to avoid brushing the area for 1 week. Additionally, prescriptions were provided to each patient for an anti-inflammatory medication (600 mg ibuprofen every 6 to 8 hours for 48 hours, then as needed), a systemic antibiotic (500 mg amoxicillin every 8 hours for 7 days or, in case of penicillin allergy, 300 mg clindamycin every 6 hours for 7 days), and a mouth rinse (chlorhexidine [CHX] gluconate 0.12% to be used every 12 hours).

Subjects were recalled at 1, 2, 5, and 20 weeks to assess healing and level of discomfort. At 1 week, the sutures were removed. At 5 weeks, the dPTFE membrane was gently retrieved using cotton forceps without administration of local anesthesia. At 20 weeks, a second CBCT and intraoral scan were obtained for data analysis and to plan the implant placement procedure. At 24 weeks, subjects returned for the second surgical intervention, which involved harvesting a bone core biopsy sample and implant placement (Fig 4).

After full-thickness flap elevation, following a simple supracrestal
Fig 3 (a) Verification of custom-trimmed dPTFE membrane design prior to insertion. (b) Gentle insertion of the membrane after creating a buccal tunnel. (c) Occlusal view showing the membrane in position and the socket filled with the combination bone allograft material. (d) Surgical site upon completion of the procedure and postoperatively at (e) 1 week, (f) 2 weeks, and (g) 5 weeks, when the membrane was removed.

Fig 4 (a) Occlusal view of the site after 24 weeks of healing. (b) A bone core biopsy sample was obtained prior to implant placement. (c) Clinical view upon completion of the surgical procedure. (d) Buccal and (e) periapical radiographic views of the area at approximately 12 months after implant placement.
incision within keratinized mucosa, a trephine drill with an inner diameter of 2.5 mm (EasyRetrieve Kit, ACE Surgical Supply Co) was used to harvest the bone core, which was immediately submerged in a solution of 10% neutral buffered formalin. Two different implant systems were used (Astra Tech OsseoSpeed EV, Dentsply Sirona; SLActive Bone Level, Straumann), and selection of the implant system was left to the judgment of the restorative dentist. Implant site preparation and placement was completed according to the implant system manufacturer’s recommendations using a surgical guide. Simultaneous bone augmentation was completed if necessary. Upon radiographic verification of implant position, flaps were advanced using simple interrupted sutures to achieve primary closure. Subjects were finally recalled 2 weeks later to assess healing and plan the restorative phase.

Outcomes of Interest and Data Collection

Clinical assessments Clinical assessments included the following:

- Determination of buccolingual and mesiodistal barrier membrane exposure at 1, 2, and 5 weeks, measured in millimeters with a UNC-15 periodontal probe.
- Visual assessment of wound healing at 1, 2, 5, and 20 weeks postoperatively using a three-point wound healing index (WHI), as reported in a previous publication.15
- Incidence of complications during the study period.

Vertical bone change
To ensure data quality, two independent examiners (M.A. and E.C.Q.) made vertical linear measurements on the CBCT scans obtained at baseline and at 20 weeks using a software package (Invivo version 5.3, Anatomage) to determine the change in the position of the buccal bone crest. Measurements were obtained using a reproducible landmark (ie, a line connecting the cementoenamel junction of the adjacent teeth) for assessment consistency.

Alveolar bone and ridge contour volume change
The same independent examiners assessed the magnitude of volumetric reduction (in mm$^3$) of the alveolar ridge, both at the hard and soft tissue level, to express it as a percent change from baseline to 20 weeks.

For the bone assessments, the CBCT data sets (Digital Imaging and Communication in Medicine [DICOM] files) were imported into a software package (Materialise Simplant 17 Pro, Dentsply Sirona). A constant threshold was used to separate the soft and hard tissue elements, and manual segmentation using reproducible landmarks was performed to select a volume of interest (VOI) on both data sets. The VOI was confined to the following boundaries: a horizontal plane at the apex of the root tip or guiding landmark at the equivalent location when the tooth was not present (apical boundary), the buccal crest (coronal boundary), the buccal and palatal plates of the alveolar bone (buccolingual boundaries), and vertical planes placed at the interproximal height of contours of the adjacent crowns (mesiodistal boundaries). The volume of each VOI was computed automatically.

For the alveolar ridge contour change assessments, the stereolithographic (standard tessellation language [STL]) files obtained at baseline and at 20 weeks were superimposed for best-fit alignment using a specific software (Geomagic Control X, 3D Systems). To verify the alignment, a 3D color map comparison was used (Fig 5), which indicated the areas of adequate alignment (green), as well as areas of negative or positive discrepancies (blue/red). Aligned, raw STLs were exported to another software (Meshmixer, Autodesk). Virtual tooth crown removal was performed, and the superimposed STL files were trimmed to obtain a VOI defined by four planes: a coronal plane over the zenith of the mesial and distal papillae, an apical plane at the base of the shallowest vestibulum of the two scans, and two interproximal planes that contacted with the most proximal point of the adjacent teeth. The STL VOIs were exported back into Geomagic Control X to quantify the total volumetric difference between them.

Histomorphometric analysis
Bone core biopsy samples were de-mineralized in a hydrochloric acid solution and embedded in paraffin blocks. After longitudinal sec-
tions of 5 µm were obtained, the samples were mounted onto glass slides and dried overnight, then stained with hematoxylin and eosin (h&E) for image capture of the entire length of the specimens under a light microscope (Primo Star, ZEISS) by an independent examiner (G.A.O). The histomorphometric analysis was performed on a fixed length of 2 mm from the coronal end, so as to standardize the analysis across samples and to ensure that the tissue corresponded to a bone grafted area. Using an open-source software package (ImageJ, NIH),16 the total areas of mineralized tissue and remaining allograft were quantified based on appearance and expressed as a percentage of the total area. The remaining area in the sample was categorized as non-mineralized tissue (Fig 6).

Implant-related outcomes
The need for additional bone augmentation was determined when a minimum of 1-mm circumferential bone support was not present around the implant at the time of placement. Implant survival rate was assessed at 12 months after placement by evaluating the electronic health record of all subjects.

PROMs
Subjects were asked by a study team member (M.A.) to report their discomfort at 1, 2, 5, and 20 weeks postoperatively as well as their overall satisfaction upon study completion (at 14 weeks) using a 100-point visual analog scale. This was done prior to the clinical examination to minimize observer effect bias.

Statistical Analyses
Given the nature of this study, no formal sample size calculation was conducted. A minimum sample size of 15 subjects was based on feasibility according to the low rate of large dehiscence defects reported in the existing literature.5 Data was uploaded to a statistical analysis software (SAS version 9.4, IBM). Normality was verified using Shapiro-Wilk test. Measurements obtained by two examiners (M.A. and E.C.Q.) were averaged. Subsequently, mean and SD were calculated for all variables. One-sample t tests were completed to determine whether the changes in buccal bone height and the volumetric changes, both at the hard and soft tissue level, were significant (alpha was set to .05).

Results
Population
A total of 24 subjects were screened, of which 21 were enrolled in the study. Four of these subjects were excluded at the baseline surgery visit because a bone dehiscence meeting the eligibility criteria was not
confirmed, lending a total sample size of 17 subjects at baseline. All 17 subjects completed the study. This population included 13 men (76.5%) and 4 women (23.5%) between 30 and 71 years of age, with a mean age of 51.82 ± 13.61 years. All subjects were nonsmokers, except for one current light smoker (< 10 cigarettes/day).

**Baseline Data of Study Sites**

All teeth were extracted due to either vertical root fracture or endodontic failure. The tooth types treated in the study included 14 maxillary teeth (9 central incisors, 1 lateral incisor, 1 canine, 2 first premolars, and 2 maxillary premolars) and 2 mandibular second premolars. All sites demonstrated adequate width of buccal keratinized gingiva at baseline, with a range of 2 to 12 mm and a mean width of 5.03 ± 2.29 mm. Mean buccal soft tissue thickness was 1.38 ± 0.57 mm, ranging 1 to 3 mm. The mean vertical dimension of the dehiscence defects was 5.76 ± 4.23 mm.

**Clinical Outcomes**

A mean increase in membrane exposure of 0.3 ± 0.28 mm in the buccolingual dimension and of 1.0 ± 1.40 mm mesiodistally was noted from baseline to 5 weeks. The mean WHI values decreased over the postoperative follow-up period, as shown in Table 1. No significant adverse events or complications were recorded throughout the study, with the exception of one patient who decided to remove the membrane himself between 2 and 5 weeks because it was “bothersome.”

**Vertical bone change**

The midbuccal crestal bone height increased from baseline to 20 weeks to a mean of 5.66 ± 5.1 mm (P < 0.0001), indicating that the ridge defects were effectively repaired.
Bone volume change
Two DICOM data sets could not be analyzed due to extensive scattering. Mean alveolar bone volume was 727.07 ± 267.28 mm³ at baseline and 800.33 ± 344.55 mm³ at 20 weeks, for a total gain of 9.12% (P = .075).

Alveolar ridge volume change
Mean alveolar ridge volume was 858.50 ± 332.17 mm³ at baseline and 765.52 ± 328.47 mm³ at 20 weeks, for a total volumetric reduction of the soft tissue contour of 10.83% (P = .002).

Histomorphometric analysis
Five bone core biopsy samples were not analyzable due to excessive deterioration of the sample upon harvesting or retrieval from the trephine. Histomorphometric analyses of 12 samples revealed a mean area of mineralized tissue of 31.04% ± 15.22%, while the proportions of residual allograft particles and nonmineralized tissue were 16.23% ± 10.63% and 52.71% ± 9.53%, respectively.

Implant-related outcomes
Though 8 of the 17 treated sites required additional bone augmentation at the time of implant placement (~47%), all implants could be placed in a favorable restorative position with adequate primary stability. All implants integrated successfully, achieving a survival rate of 100% 1 year after implant placement.

PROMs
Average discomfort scores remained low and decreased over the healing period following the baseline intervention, as shown in Table 1. Patients were generally very satisfied with their participation in the study. An average patient-reported satisfaction level of 95.1 out of 100 was recorded upon study completion.

Discussion
This case series study assessed the performance of a novel minimally invasive ridge reconstruction technique for the management of extraction sites presenting large bone dehiscences. Although the technique hereby described has been recently published by one of the authors in a book, the present article is the first report of a proper clinical study testing the performance of this specific approach. Overall, the surgical technique rendered favorable results for all parameters analyzed. Histomorphometric findings were comparable with those reported in a previous study on alveolar ridge preservation using the same grafting material. No serious complications or adverse events were observed.

There are only a few publications on the management of extraction sites exhibiting large dehiscences published to date, and most of them reported a limited set of outcomes. In a previous RCT in which the sites allocated in the test group were treated with a collagenated bovine bone xenograft covered with a collagen membrane, the mean midbuccal vertical bone gain after 12 months of healing was 2.50 ± 2.12 mm. This contrasts the present findings, which showed roughly twice as much gain (5.66 ± 5.1 mm). The bone volume changes observed in the present study also compare favorably to those reported in that RCT (gain of 9.12% vs loss of 9.14%, respectively). Although it may be argued that the minimally invasive approach and the use of a nonresorbable barrier could justify the superior outcomes, it must be acknowledged that other factors, such as methodologic differences and inherent characteristics of the surgical sites, may have also played a role.

A mean soft tissue contour loss of 11.81% was observed in the present study. Although this finding may be counterintuitive, it can be

<table>
<thead>
<tr>
<th>Time after extraction</th>
<th>WHI</th>
<th>Discomfort</th>
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<tbody>
<tr>
<td>1 wk</td>
<td>1.53 ± 0.51</td>
<td>19.06 ± 21.85</td>
</tr>
<tr>
<td>2 wk</td>
<td>1.19 ± 0.54</td>
<td>6.39 ± 12.91</td>
</tr>
<tr>
<td>5 wk</td>
<td>1.12 ± 0.33</td>
<td>7.82 ± 16.37</td>
</tr>
<tr>
<td>20 wk</td>
<td>1 ± 0</td>
<td>2.94 ± 10.17</td>
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WHI = wound healing index.
WHI was scored on a scale of 1 (minimum) to 3 (maximum). Patient discomfort was scored on a scale of 1 (minimum) to 100 (maximum). Values are shown as mean ± SD.
explained by two factors. First, part this change can be attributed to the physiologic atrophy of papillae on the scans performed at 20 weeks. Second, many of the sites required sharp dissection at baseline to remove inflammatory granulomatous tissue, after the intraoral scan was obtained. This “false positive” volumetric data, which was due to a larger ridge volume (based on pathosis rather than health), likely influenced the analysis.

Successful implant placement with adequate primary stability was feasible in all sites, avoiding the need for bone augmentation and delayed implant placement. However, roughly half of the sites required simultaneous bone augmentation at the time of implant placement, which is higher than the values reported in previously published studies on alveolar ridge preservation.19-21 This discrepancy can be explained by the different characteristics of the extraction sites included in those studies, which did not present a buccal bone dehiscence, nor the criteria applied to determine the need for bone augmentation.

The use of a nonresorbable dPTFE membrane likely played an integral role in the successful bone regeneration outcomes. Although a previous study including a mix of intact and partially damaged sockets concluded that the use of dPTFE membranes vs absorbable collagen membranes rendered similar outcomes,13 the use of a nonresorbable membrane becomes significantly more impactful in the management of sites presenting large dehiscences, as extended compartmentalization is critical in these situations. One of the distinctive features of this technique is the deliberate partial exposure of the membrane to the oral cavity, which was intended to avoid the need for primary closure, and minimize surgical trauma and unfavorable displacement of the mucogingival junction. Although this may be perceived as a risky decision that conflicts with some of the essential principles of guided bone regeneration (GBR),22 particularly when nonresorbable barriers are used, this technical detail is substantiated. The primary goal of GBR is to compartmentalize tissues (ie, bone and overlying mucosa) with different healing dynamics, thus the use of a barrier element. A secondary principle of GBR is primary soft tissue closure to protect the bone grafting material and membrane from bacterial colonization and a possible subsequent infection. Different from expanded PTFE membranes that have pores ranging from 5 to 20 µm, dPTFE barriers are virtually fully occlusive, as they have micropores (< 0.3 µm) that do not allow for direct bacterial penetration (the size of most bacteria ranges from 0.4 to 3 µm).23 This is a major benefit of dense PTFE that allows for extended intentional barrier exposure, provided that adequate postoperative care is followed (eg, gentle swabbing with CHX twice a day). Another important aspect that must be discussed is the rationale for membrane removal at approximately 5 weeks. According to a detailed histologic study of human socket healing, the proliferative phase, which is characterized by woven and lamellar bone formation, is typically reached between 4 and 6 weeks,24 and the barrier effect is no longer essential afterwards. It is important to highlight that a key clinical aspect to maximizing the success of this technique is little or no interproximal attachment loss present on the adjacent teeth.

The present study is not exempt from limitations. Additional outcomes of interest could have been collected, including, but not limited to, assessment of implant stability using resonance frequency analysis. A limitation to the volumetric measurements was that there were minor positional variations in the subjects’ orientation at the time the two scans were taken. Albeit minor, these differences may have affected the precision of digital measurements. Finally, future clinical trials on this topic should aim to evaluate the efficacy of different therapeutic modalities, including larger sample sizes and evaluating a full set of relevant long-term outcomes.

Conclusions

The minimally invasive alveolar ridge reconstruction technique presently evaluated was both effective and predictable in rebuilding large alveolar bone deformities at the time of tooth extraction, providing adequate ridge volume for future implant placement while being patient-friendly, having low postoperative pain scores, and achieving very high patient satisfaction.
Acknowledgments

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