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HUMAN RANDOMIZED CONTROLLED TRIAL

Long-term preservation of ridge dimension following tooth extraction and ridge preservation: A randomized controlled trial of healing at 4- and 12-month healing time points

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Abstract

Background: To date, the efficacy of ridge preservation in the maintenance of the residual alveolar ridge dimension beyond 6 months after treatment is unknown. The purpose of this study was to compare the differences in alveolar ridge dimensional change following ridge preservation between 4- and 12-month healing time points using cone-beam computed tomography (CBCT).

Methods: Fifty seven patients planned for tooth extraction and implant placement were enrolled. Following extraction, ridge preservation was performed. CBCT scans were taken within 72 hours following extraction with a customized resin stent containing a fixed radiographic marker. At either 4 months (short-term, ST group) or 12 months (long-term, LT group) after ridge preservation, patients had a second CBCT taken and an implant placed. Changes in ridge height and width were measured using the standardized radiographic marker.

Results: No significant differences were detected between the ST and LT groups in loss of buccal and lingual ridge height. Similarly, when adjusted for baseline ridge width, no significant differences were detected in ridge width loss at 3, 5, and 7 mm apical to the crest between the ST and LT groups.

Conclusions: The efficacy of ridge preservation in the maintenance of ridge width and height at the 12-month time point is similar to that of the 4-month time point. Clinicians may feel confident that a delay in implant placement for up to a year has no significant negative impact on the height and width of the healed ridge.

KEYWORDS
alveolar bone grafting, bone resorption, cone-beam computed tomography, dental implants, tooth extraction

1 | INTRODUCTION

The use of dental implants has significantly increased over the past decades, as they are a highly sought-after treatment by partially and fully edentulous patients.[1] Placing implants in a restoratively driven position is crucial to implant success. However, following tooth removal, significant changes in alveolar bone dimension may occur which complicate restoratively driven implant placement.[1–4] Following extraction of premolar and molar teeth, Schropp et al. found an average loss in ridge width of 6.1 mm, ≈50% of the total baseline ridge width, within a year after tooth extraction. Furthermore, they found that two-thirds of this loss occurred in the first 3 months following extraction.[2]

A strategy that has been proven effective in mitigating the loss in residual alveolar ridge width and height post-extraction is ridge preservation.[3,4] Dimensional changes to the alveolar ridge after tooth extraction with or without ridge preservation have been investigated using various means including serial cast measurements,[2] radiographic measurements using periapical radiographs,[2] or cone beam computed tomography (CBCT),[5–8] and direct clinical measurements of the alveolar ridge.[9,10] Studies comparing radiographic measurements taken on a CBCT to direct surgical measurements have found high correlation coefficients between techniques.[11,12] Additionally, the superimposition of CBCTs to measure ridge dimensional changes over time has been used in the literature.[5]

To date, minimal evidence exists regarding the impact of healing time on ridge preservation. In other words, does the effect of ridge preservation change over time? Two studies performed at the University of Texas Health Science Center at San Antonio (UTHSCSA) compared ridge dimensional change between a short-term and long-term group finding no significant difference in clinically measured ridge width and ridge height loss between treatment groups. However, the treatment groups in these studies were 2 months versus 4.5 months of healing, and only clinical measurements were made.[9,10] It is unknown how delay of a full year between ridge preservation and implant placement may impact the dimensional changes of the residual alveolar ridge.

The primary purpose of the current study was to use sequential CBCTs to compare the differences in alveolar ridge dimensional change following a 4-month healing time after ridge preservation versus a 12-month healing time. In addition, the effect of single- versus multi-rooted teeth and baseline ridge width on ridge dimensional change were investigated.

2 | MATERIALS AND METHODS

2.1 | Patient enrollment

This study was reviewed and approved by the UTHSCSA Institutional Review Board. The study was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2013. Written informed consent was obtained from each patient. Fifty-seven patients aged 25 to 81 years who required tooth extraction and desired replacement with a dental implant in the Graduate Periodontics clinic at UTHSCSA were enrolled in this randomized controlled clinical trial (Fig. 1). To be included in the study, patients had to have an incisor, canine, premolar, or first molar tooth that required extraction and replacement with a dental implant; adequate restorative space for a dental implant restoration; and be a non-smoker, past smoker, or current smoker who consumed ≤10 cigarettes per day. Exclusion criteria included second and third molar teeth, pregnant women, or women intending to become pregnant during the trial, any active infection other than periodontal disease, presence of a disease or medication regimen which may affect bone or soft tissue healing such as poorly controlled diabetes or history of bisphosphonate use, and active smokers who smoked >10 cigarettes per day.

The data that support the findings of this study are available from the corresponding author upon reasonable request.

2.2 | Surgical protocol

A customized thermoplastic radiographic stent was fabricated for each enrolled patient before surgery including a radiographic marker[*] 20 mm in length, 10 mm in width, and 2 mm in thickness. To ensure stability, the stent was intimately adapted to the occlusal surfaces of at least 2 teeth anterior and posterior to the edentulous site. Minimally traumatic tooth extraction was performed using a mucoperiosteal flap reflected no greater than 3 mm past the alveolar crest. Sites with dehiscence or fenestration measuring 50% or greater of the total depth of the tooth socket were exited from the study and ridge augmentation was performed. A 70%/30% combination mineralized/demineralized freeze-dried bone allograft[†] was placed in the extraction socket until the graft material reached the crest of the ridge at its interproximal height. For the purpose of this study, the bone graft used was obtained from a single donor to minimize variability in the study method. A dense polytetrafluoroethylene (d-PTFE) membrane[‡] with a pore size <0.3 μm was trimmed to extend over the extraction socket and ≈ 3 mm beyond the facial and lingual bony crests. The flap and membrane were stabilized with 4-0 PTFE suture material.[§] Primary closure was intentionally not attempted, and the membrane was left exposed. Patients were prescribed 500 mg of amoxicillin to be taken three times a day for 1 week. Patients allergic to penicillin were prescribed azithromycin 250 mg tablets with the directions to take two tablets the first day, and then take one tablet per day on the second and third days. Additionally, all patients were prescribed 0.12% chlorhexidine gluconate mouth rinse and instructed to gently rinse twice daily for 14 days.

[*] US Patent 20060241406 A1, Dr. Noujeim, UTHSCSA, San Antonio, TX.
[†] enCore 70/30, Osteogenics Biomedical, Lubbock, TX.
[‡] TXT 200, Osteogenics Biomedical.
[§] Cytoplast, Osteogenics Biomedical.

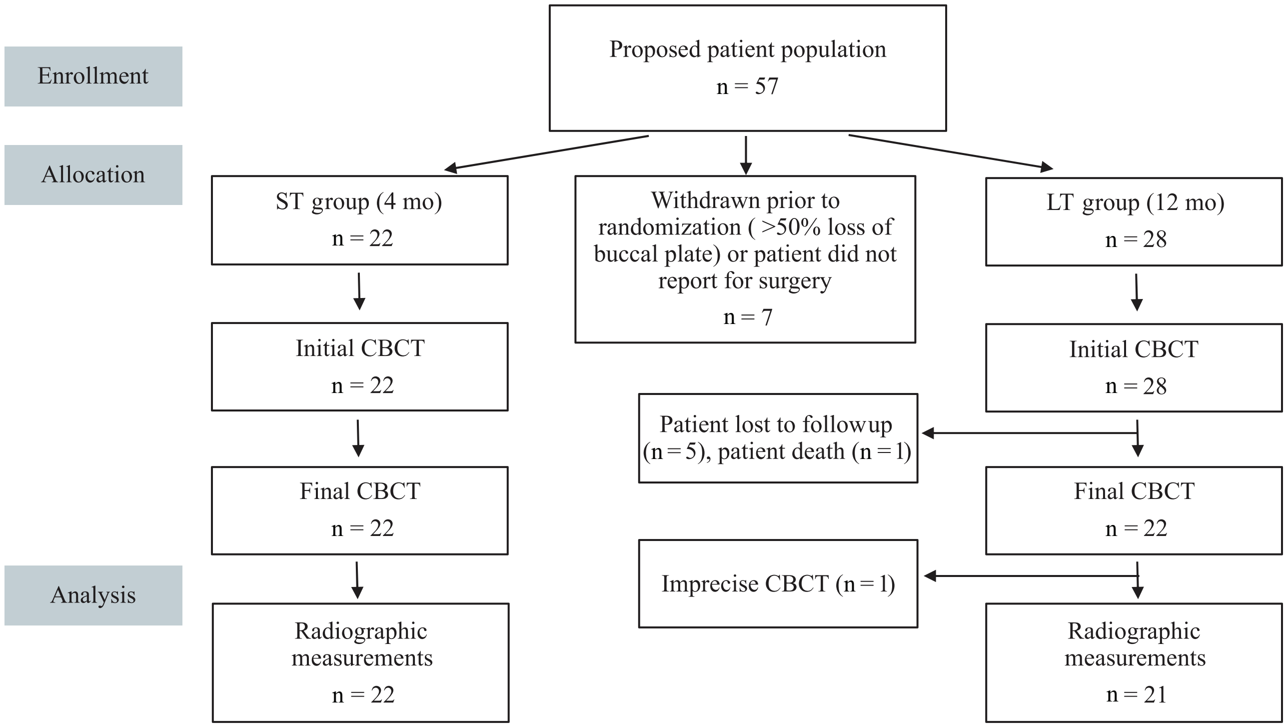

FIGURE 1 Study flowchart

Immediately after or within 72 hours of ridge preservation, a CBCT scan[‖] was taken with the radiographic stent in place. Following the CBCT scan, patients were randomized into the 4-month (short-term; ST) or 12-month (long-term; LT) group by choosing an envelope from a stack of unmarked envelopes in which a piece of paper was labeled "short" or "long". Patients enrolled in the ST and LT groups were planned to have the dental implant placed ≈4 and 12 months after ridge preservation, respectively, with the final CBCT taken about 2 weeks before implant placement. The final CBCT scan was taken with all patients wearing their original radiographic stent fabricated before tooth extraction. All CBCT scans were taken by the Oral and Maxillofacial Radiology Clinic at UTHSCSA. The scans were taken with a slice thickness of 0.24 mm and a field view size of 4 × 4 centimeters for 360° and exported using i software[¶] via digital imaging and communications in medicine (DICOM) files to a secure server.

2.3 | Radiographic measurement protocol

The CBCT scans were examined using viewing software[#] with a 0.1-mm slice interval in three planes (axial, sagittal, and coronal). A single investigator (HA), masked to treatment group, made all radiographic measurements in a dark room. Figure 2 shows the measurements performed on a baseline CBCT; measurements were made similarly on all baseline and final CBCTs. First, the radiographic marker was aligned in three planes on both the baseline and final scans (Fig. 2A). Then, both the sagittal and coronal planes on the baseline scan were rotated to be parallel with the long axis of the extraction socket (Fig. 2B). These angles were recorded and duplicated in the final scan. The midpoint of the socket was determined in the sagittal view and its location was recorded and duplicated on the final scan. At the socket midpoint in the coronal plane view, the vertical distances from the highest point on the buccal and lingual/palatal crest to the radiographic marker were recorded (Fig. 2C). Reference measurements were made from the horizontal edge of the marker to the point where the vertical distance measurements were taken to duplicate the vertical distance measurements at the same location on the final scan. These vertical distance measurements were also made on the final scan at the same location. The difference between the measurements was recorded as ridge height loss. The most coronal crest (buccal or lingual/palatal) on the baseline scan at the midpoint of the socket was recorded. Horizontal ridge width change was calculated by taking the difference in ridge width between the baseline and final scans at 3, 5, and 7 mm apical to the most coronal radiographic bone crest

‖ 3DX Accuitomo, J. Morita USA, Irvine, CA.
¶ i-Dixel, J. Morita USA.
\# Anatomage, San Jose, CA.

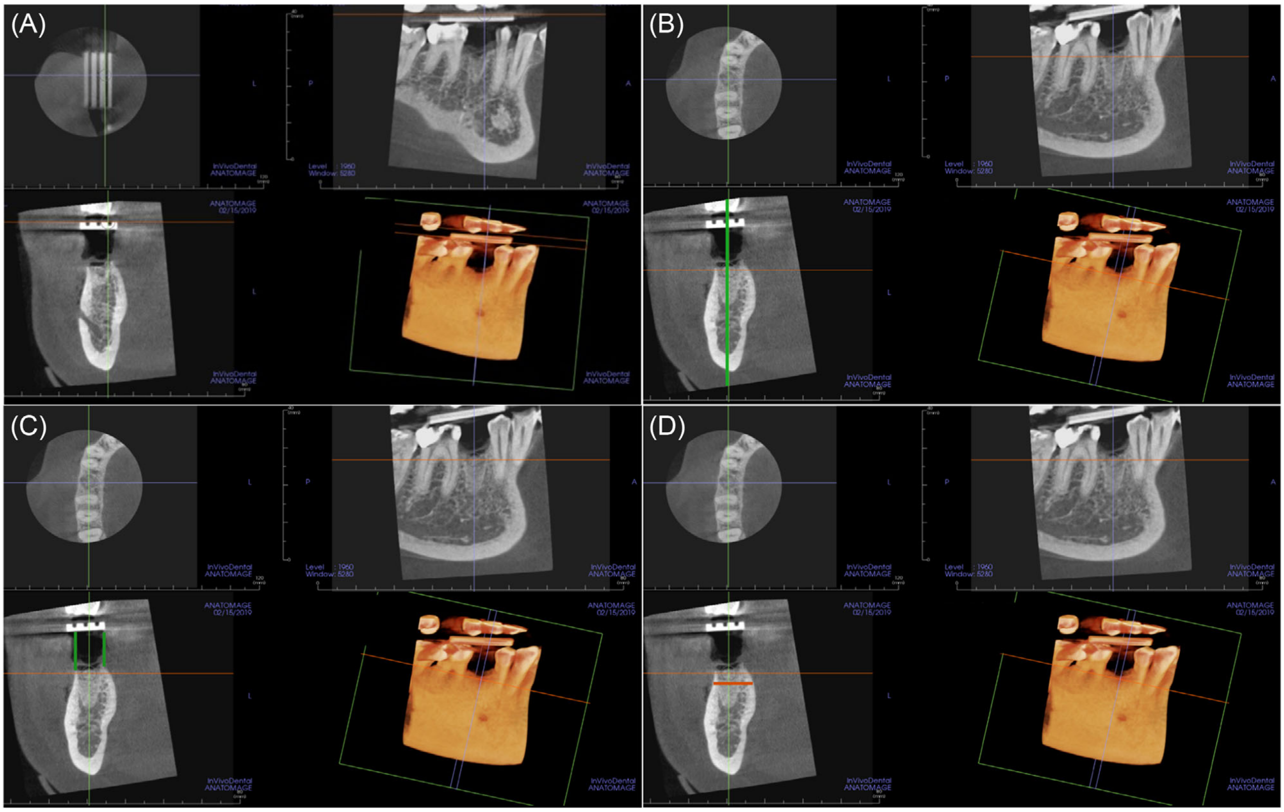

FIGURE 2 Radiographic measurements made on a baseline CBCT. Similar measurements were made for all baseline and final CBCTs. (**A**) Alignment of radiographic marker parallel to the axial, sagittal, and coronal plane slices. (**B**) Sagittal and coronal planes aligned parallel to the long axis of the extraction socket and socket midpoint determined. (**C**) Vertical height measurements made from fixed points on radiographic marker. (**D**) Horizontal width measurements made 3, 5, and 7 mm apical to crest

point (previously identified) in the coronal view at the midpoint of the radiographic socket. The most coronal crest point on the baseline scan was identified and vertical lines were drawn 3, 5, and 7 mm apical to this point on both the baseline and final scan. At these vertical points, the radiographic horizontal ridge width was measured, perpendicular to the vertical lines, from the most external surface of the crest ridges in the coronal view (Fig. 2D). These measurements were recorded on both the baseline and final scans. To determine the change in each parameter, the measurements made on the baseline CBCT scan were subtracted from the analogous measurements on the baseline scan to determine the change in each parameter. The percentage loss of ridge width was calculated by subtracting the baseline width from the final width, divided by the baseline width.

2.4 | Statistical analysis

For sample size estimation the authors assumed a mean crestal bone height change of -1.53 mm (SD: 0.88) based on estimates reported in a systematic review examining ridge dimensional changes after tooth extraction.[13] It was estimated that 18 patients in each treatment group would result in 90% power to detect such a difference based on a two-sample two-tailed *t*-test at $\alpha = 0.05$. Thus, 18 patients will result in sufficient power (>0.90) for changes in both ridge width and ridge height. Potential patient attrition was calculated separately for the ST versus LT groups, in anticipation that greater loss-to-follow-up would occur in the longer healing period group. In the ST group, at least 70% of enrolled patients were expected to complete the study, resulting in a calculated population of 26 patients in the ST group. Because patients in the LT group were believed to be at increased risk of patient dropouts, the authors estimated a potential for a 40% loss-to-follow-up, which resulted in an effective sample size of 31 patients in the LT group.

Summary statistics were calculated using mean ± SD. Intergroup differences at baseline were estimated using two-sample *t*-tests for continuous variables and Chi-square tests for categorical variables at a significance level alpha = 0.05. Significant differences between the changes from baseline to end point in the two treatment groups were assessed via two-sample *t*-tests. To increase

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TABLE 1 Demographic distribution, days between CBCT scans, and tooth type

	Mean patient age (years)	Days between CBCT scans	Sex		Tooth Type					
			Male	Female	Max incisor	Max canine	Max premolar	Max first molar	Mand premolar	Mand first molar
ST group	54.7 ± 14.7	113.4 ± 21.3	13	9	6	1	11	0	0	4
LT group	55.4 ± 14.2	353.3 ± 17.2	6	15	0	1	12	2	1	5
P value	0.88	<0.0001	0.04		Anterior versus posterior: *P* = 0.02 Maxilla versus mandible: *P* = 0.42					

rigor in the analysis, because ratio of single- versus multi-rooted teeth and baseline ridge width, differed between the two arms at baseline, these two critical covariables were adjusted for in sensitivity analyses using adjusted multiple linear regression models. Independent models were constructed with the outcome measure of interest as the dependent variable, the treatment arm as a factor predictor variable, and adjusting for either tooth type (single-rooted versus multi-rooted) or baseline ridge width, respectively. Intra-examiner reproducibility for radiographic measurements was assessed by estimating the deviations between two independent repeated measures made by the same examiner. The statistician was not involved in any way with the data collection or patient examination. All analyses were a priori determined at a team meeting when the statistician did not have any access to the collected data. All analyses were performed using statistical software.[**]

3 | RESULTS

3.1 | Clinical observations

In total, 57 patients were enrolled in this clinical trial between October 2018 and July 2020. Seven patients were excluded before randomization, one because the patient decided not to proceed with the study immediately before tooth extraction and six due to the presence of a dehiscence or fenestration >50% of the socket wall after extraction. In the LT group, six patients underwent tooth extraction but did not complete the study; five were lost to follow-up, and one died. One additional patient in the LT group completed the study but the final CT scan was not taken in the same manner as the baseline CBCT. Thus 43 patients completed the study, 21 in the LT group and 22 in the ST group between February 2019 and June 2021 (Fig. 1).

The amount of time between CBCT scans in the ST and LT groups differed significantly, as intended by the design of the study (Table 1). In the ST and LT groups, an average of 16.2 and 50.5 weeks passed between CBCTs. There were significantly more women in the LT group than the ST group (*P* = 0.04), with no significant difference in age between the groups. No significant difference was found in the number of maxillary versus mandibular teeth between the ST and LT groups. The ST group had significantly more anterior teeth than the LT group (*P* = 0.02). Tooth location (anterior versus posterior) was correlated to baseline ridge width, and baseline ridge width was significantly smaller in the ST group (*P* = 0.02) (Table 2), since the ST group had more anterior teeth.

3.2 | Radiographic observations

The mean baseline radiographic ridge widths were 9.99 mm ± 1.38 for the ST group and 11.52 mm ± 2.45 for the LT group (*P* = 0.02) (Table 2). Without adjustment for initial ridge width, a statistically significant difference in ridge width loss was detected at 3 mm apical to the original radiographic ridge crest height between the ST and LT groups (*P* = 0.01), which remained significant when adjusted for multi-rooted teeth (*P* = 0.03). When an adjusted analysis accounting for baseline ridge width was performed, no significant difference in ridge width change was noted between the treatment groups (*P* = 0.18) (Table 2). Similarly, before adjusting for initial ridge width a statistically significant difference in ridge width loss was detected at 5 mm apical to the original ridge crest height between the ST and LT groups and remained significant when adjusted for multi-rooted teeth (*P* = 0.02). However, after adjusting for baseline ridge width, there was no significant difference in ridge width change at the 5 mm measurement point (*P* = 0.15) (Table 2). At 7 mm apical to the crest, no significant difference in ridge width change between the two treatment groups was noted (*P* = 0.39). Percent ridge width change at all three measurement points was also calculated (Table 2), with no significant difference between groups. No significant differences were detected in the change of alveolar ridge height, measured at the buccal and lingual crest heights, between the ST and LT groups (Table 3). No significant difference in

[**] GraphPad, San Diego, CA.

TABLE 2 Radiographic ridge width loss at measurement points 3, 5, and 7 mm apical to the crest

	Baseline ridge width at 3 mm	Amount ridge width loss (mm ± SD)			Percent ridge width loss (%)		
		3 mm	5 mm	7 mm	3 mm	5 mm	7 mm
ST group	9.99 ± 1.38	−2.15 ± 1.35	−1.28 ± 0.87	−1.05 ± 0.60	−21.98 ± 11.73	−14.86 ± 7.62	−10.77 ± 5.33
LT group	11.52 ± 2.45	−3.34 ± 1.70	−2.07 ± 1.25	−1.26 ± 0.89	−27.95 ± 13.40	−14.61 ± 9.00	−9.51 ± 6.13
P value*		0.18	0.15	0.39	0.29	0.55	0.41

No significant differences in loss of ridge width between groups after adjusting for baseline ridge width.
**P* values presented in this table arise from adjusted analyses of intergroup comparisons using linear regression models adjusting for baseline ridge width.

TABLE 3 Radiographic ridge height loss at buccal and lingual aspects of the alveolar crest expressed in mm

	Buccal height loss (mm ± SD)	Lingual height loss (mm ± SD)
ST group	−1.13 ± 0.87	−1.26 ± 1.03
LT group	−1.00 ± 0.94	−1.16 ± 0.91
P value*	0.63	0.76

**P* values presented in this table arise from two-sample *t*-tests.

ridge height loss was found in the linear regression model when adjusted for tooth type or baseline ridge width.

3.3 | Radiographic measurement reproducibility

Intra-examiner agreement of digital radiographic measurements was assessed by one of the authors who performed all measurements (HA), repeating all radiographic measurements on 10 of the 86 total scans (12%). In terms of assessment of bone width changes and buccal plate thickness measurements, 93% of these measurements differed by <0.5 mm, and 100% differed by <0.7 mm, indicating high intra-examiner reproducibility. In terms of changes in vertical height, 95% of the measurements differed by <0.5 mm with only one discrepant measurement noted, with the discrepancy being 0.56 mm between the initial and repeat measurement.

4 | DISCUSSION

After the extraction and ridge preservation of a tooth, patients may ask how long the results will “last”. That is, will bone loss occur if an implant is not placed within a short period of time after ridge preservation? Many variables may dictate when a patient is ready to undergo implant placement such as insurance benefits, establishment of a global restorative treatment plan, patient desires, or other life events. Therefore, while the clinician may prefer to place an implant a few months after ridge preservation, this may not be possible for the patient. To the authors’ knowledge, no evidence on the efficacy of ridge preservation beyond 6 months has been published. The primary purpose of this study was to determine if a significant difference was seen in alveolar ridge width and height loss between two different healing timepoints: 4 and 12 months post ridge preservation.

In this study, no significant difference in horizontal dimensional change was detected between 4 and 12 months of healing post-ridge preservation after adjusting for baseline ridge width. The mean ridge width change measured in millimeters was greater in the 12-month group than in the 4-month group, but this finding may be anticipated given the mean baseline ridge width in the LT group was ≈1.5 mm greater than that in the ST group. When the overall percent loss of ridge width between the two treatment groups is considered, the values are similar between ST and LT groups. The average ridge width loss found in this study, 2.15 mm in the ST group and 3.34 mm in the LT group, is consistent with Ten Heggeler et al. who found a reduction in alveolar ridge width post-ridge preservation ranging from 1.2 to 3.48 mm.[14]

Similarly, no significant difference in buccal or lingual radiographic height change was seen between the two treatment groups. The average buccal and lingual radiographic vertical height loss in this study was 1.13 and 1.26 mm, respectively, in the ST group and 1.00 and 1.16 mm, respectively, in the LT group. This average vertical height loss is somewhat >0.4 to 0.7 mm average vertical loss reported in the systematic review by Ten Heggeler et al.[14] Nonetheless, our estimates of vertical loss agree with prior studies using pre- and post-measurements on CBCTs and periapical radiographs.[15] Despite the difference between the present study estimates on vertical bone height loss as compared with the systematic review-derived consensus estimate being clinically small (i.e., <1 mm), it is worth noting the differences in the measurement methodology as a limitation of ridge preservation studies. Because ridge resorption is a volumetric phenomenon that cannot be fully captured with 2D linear measurements, the optimal way of assessing its effects would be via volumetric longitudinal analysis. However, such measurements are not readily translational to clinical situations, because of the disproportionate burden of ridge resorption on the buccal plate versus the lingual plate.[6] Because the buccal plate dimensions are critical for esthetics and tissue stability, many studies,[6–8] including the current study, calculate vertical height loss from changes occurring at fixed reference points in measurement stents located directly above the edge of the buccal and lingual bony crests on the baseline scan. (Fig. 2C). When reviewing results of these measurements to those of periapical radiographs, it is important to consider that as resorption in ridge width occurs during healing, the vertical line drawn at this same location from the reference point to the buccal and lingual bony crests on the 4 and 12-months CBCTs may have intersected the bony crest at a more apical location than on the baseline scan. The possibility exists that in certain cases, the vertical loss reported may not always entirely reflect a loss of vertical height, but may also include a component of horizontal ridge width loss. The amount of vertical ridge width loss in the current study is similar to findings by Walker et al. whose radiographic measurement protocol was identical to that used in this study.[6] After ridge preservation in molars, Walker et al. found a vertical height loss of 1.12 and 1.16 mm at the mid-buccal and mid-lingual aspects of the ridge, respectively.[6]

A possible limitation of this study is that waiting a full year after extraction for implant placement may be complicated by factors not assessed in the present study including drifting of adjacent teeth, supra-eruption of the opposing teeth, and a longer period of unnecessary partial edentulism for the patient. An additional limitation was that each treatment group included anterior teeth, premolars, and first molars, and ridge dimensional change after ridge preservation may be affected by tooth location. Nonetheless, the authors wanted to include as many tooth types as possible since dental implants are commonly placed from first molar to first molar. The randomization schedule led to a slight imbalance in types of teeth between groups with the ST group having six more anterior teeth as compared with the LT group, which was reflected in the lesser baseline ridge width noted in the ST group. However, there was no selection bias since a randomization schedule was in place and any potential confounding effect of the imbalance in baseline ridge width was rigorously assessed according to CONSORT guidelines with the use of an adjusted sensitivity analysis. Specifically, adjusting for baseline ridge width was an important component of the analysis, as it accounts for variation in ridge width at different tooth locations and minimizes confounding by baseline clinical conditions. The high intra-examiner reproducibility, measurement methodology, and a single donor used as the allograft material source are strengths of this study. In this study, patients were randomized to two groups (ST and LT) based on the timing of final implant placement, with the final CBCT taken shortly before surgery. Future studies could enroll a single group of patients with CBCTs taken for each patient at baseline, 4 months, and 12 months to examine within patient changes at the short- and long-term healing points. Future research could also use superimposition of post-extraction and final healing CBCTs for each patient and perform automated measurements using artificial intelligence algorithms; this may provide more consistent measurement of ridge width and height changes.

5 | CONCLUSIONS

There was no significant difference between the alveolar ridge width and ridge height change between the 4-month and 12-month healing groups after ridge preservation. The results of this study give both patients and clinicians more freedom in decision-making regarding implant placement timing. In conclusion, clinicians may feel confident that a delay in implant placement for up to a year has no significant negative impact on the height and width of the healed ridge post ridge preservation.

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AUTHOR CONTRIBUTIONS

Drs. Allen, Zellner, and Mealey each contributed to conception, design, data acquisition and interpretation, and drafting and revising the manuscript. Dr. Kotsakis contributed to data analysis and interpretation and to drafting and revising the manuscript. All authors have given their final approval of the version to be published.

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