

Alveolar Ridge Preservation Using Anodized Titanium Foil Associated with Blood Clot Stabilization: A Randomized Controlled Tomographic Clinical Trial

Bianca Domingues de Andrade Rebello DDS, Msc^{1*}, Alexandrino Costa Gonçalves DDS, Msc¹, Tatiana Rodriguez Moreira DDS¹, Jonathan Meza-Mauricio DDS, Msc, PhD¹, Tamires S. Miranda DDS, Msc, PhD¹, Marcelo Faveri DDS, Msc, PhD¹

¹Department of Periodontology, Dental Research Division, Guarulhos University, Guarulhos, SP, Brazil.

*Corresponding Author: Bianca Domingues de Andrade Rebello, Centro de Pós-Graduação e Pesquisa-CEPPE - Universidade Guarulhos, Praça Tereza Cristina, 229. 07023-070 - Guarulhos, SP, Brazil.

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Abstract

Objective: The aim of this randomized clinical study was to compare changes in alveolar ridge dimensions six months after surgery using an alveolar ridge preservation (ARP) technique with anodized titanium foil (Tseal) and blood clot, compared to natural healing.

Materials and Methods: Twenty-four patients requiring extraction of a single hopeless tooth in maxilla were included in this randomized controlled clinical trial. Participants were randomly allocated to either the test group, in which extraction sockets were protected using anodized titanium foil associated with blood clot stabilization, or the control group, in which sockets healed spontaneously after tooth extraction. Cone-beam computed tomography (CBCT) scans were obtained at baseline and after 6 months. Horizontal ridge dimensions were measured at 1 mm, 3 mm, and 5 mm below the palatal crest.

Results: Both groups demonstrated reduction in horizontal ridge dimensions after 6 months. However, the test group showed significantly greater preservation of alveolar ridge width compared with the control group at the 1-mm and 3-mm levels below the palatal crest ($p < 0.05$). At the 5-mm level, dimensional changes were less pronounced and no significant intergroup differences were observed. Overall, the test group demonstrated greater maintenance of horizontal ridge dimensions throughout the healing period.

Conclusion: The use of anodized titanium foil associated with blood clot stabilization demonstrated beneficial effects on alveolar ridge preservation after tooth extraction, particularly in the coronal portion of the socket, when compared with spontaneous healing. This minimally invasive approach may represent a viable alternative for reducing post-extraction horizontal ridge resorption without the use of grafting materials.

Keywords: Alveolar Ridge Preservation; Tooth Extraction; Titanium Membrane; Blood Clot; Cone-Beam Computed Tomography.

Introduction

The preservation of the alveolar ridge after tooth extraction is crucial for preventing alveolar bone resorption, which can make future dental implant procedures more challenging (Tan et al., 2012). Various methods have been proposed to maintain ridge dimensions, such as the use of graft materials (Avila-Ortiz et al., 2014), barrier membranes (Lekovic et al., 1998), or a combination of both (Bartee, 2001). However, the effectiveness of these approaches remains a topic of debate within the scientific community.

A systematic review conducted by Tan et al. (2012) found that during natural alveolar healing, there is an average horizontal reduction of 3.8 mm in alveolar width and a vertical reduction of 1.24 mm in height within the first six months after tooth extraction. Approximately 40% of the alveolar height and 60% of the alveolar width are susceptible to bone resorption in the same period following tooth extraction (Johnson, 1969; Pietrokovski & Massler, 1967). It is also important to note that post-extraction changes affect soft tissues as well (Amler, 1969), as the mucosal contour adapts to the new shape of the underlying bone. Consequently, dimensional reductions in the height and width of the edentulous alveolar ridge, along with their effects on the gingival mucosa, can hinder or even prevent successful dental implant outcomes unless preventive or corrective regenerative techniques are applied (Araújo & Lindhe, 2009). To mitigate these changes, alveolar ridge preservation (ARP) techniques have become essential tools in daily practice.

The primary goal of ARP is to maintain the ideal ridge shape and prevent significant collapse of the alveolar crest. This helps to preserve proper bone contour, facilitating the correct three-dimensional positioning of the implant and ensuring successful oral rehabilitation (Ashman, 2000). Avila-Ortiz et al. (2019) concluded that the most effective materials for reducing horizontal ridge loss were xenografts and allografts covered with membranes (Avila-Ortiz et al., 2019). Similar results were reported by Madi et al. (2023). In this context, Maeda et al. (2021) conducted a case study aimed at evaluating dimensional changes in the alveolar ridge using cone-beam computed tomography, following the use of an anodized titanium membrane (Tseal) in conjunction with bovine bone graft in post-extraction sockets, using an open-healing approach. The authors reported that the treatment protocol preserved 86.48% of the distance between the buccal and lingual walls in the maxilla and 93.57% in the mandible six months post-extraction.

One of the basic regenerative principles for bone defects is the stability of the blood clot (Araujo et al., 2005). However, the concept of protecting the post-extraction clot using only non-resorbable membranes has been minimally explored in the literature. Therefore, based on these premises, this randomized clinical study aimed to observe the three-dimensional changes in the dental socket after extraction, comparing alveolar preservation techniques using an anodized titanium membrane for clot protection with natural healing six months after treatment.

Materials and Methods

Study Design

The present study was a parallel, randomized, single-center controlled clinical trial. The study was conducted and reported according to CONSORT statement (<http://www.consort-statement.org/>). The study protocol was approved by Guarulhos University Board (approval 78655417.7.0000.5506). An informed consent was obtained from all eligible patients. The study was conducted in compliance with the principles outlined in the Declaration of Helsinki on experimentation involving human subjects, as revised in 2013.

Participants

Eligible patients were recruited from a pool of patients seeking ridge preservation treatment at the Dental Clinic of Guarulhos University (Guarulhos, SP, Brazil) between August 2018 and July 2020. Participants were selected based on the following inclusion and exclusion criteria:

Inclusion criteria

- Age >18 years and < 60 years;
- Indication for extraction of maxillary anterior (incisors, canines) and upper premolar teeth.
- No systemic diseases contraindicating surgery;
- Agreement with the procedures to be performed in the study;

Exclusion criteria

- History of debilitating chronic diseases, such as hepatitis, rheumatic fever, diabetes, immune or blood disorders, or other diseases contraindicating surgery;
- Autoimmune diseases with oral manifestations;
- Use of steroid anti-inflammatory drugs in the three months preceding the study;
- Smoking;
- Pregnant and/or lactating participants.

Sample Size

Horizontal dimensional change was chosen as the primary outcome variable and sample size was estimated based on a previous study (Maeda et al., 2020) and assuming a difference of 20 % could be considered clinically significant (with common SD = 10%) Power calculation was performed considering $\alpha=0.05$ and at $\beta=0.20$, equal to a power of 80%. Under this assumption, a minimum of 10 patients were deemed necessary in each group to reach a significance level. This number was increased to a total sample size of 12 patients in each group to compensate for possible dropouts during the follow-up period.

Randomization /Allocation concealment/ and blinding

Patient randomization was performed using a computer-generated randomization table prepared by an investigator with no clinical involvement in the trial (MF). Allocation concealment was obtained by using a sealed coded opaque envelope containing the treatment for the specific subject. The envelope with the patient's allocation was only opened immediately after tooth extraction.

Each individual was assigned to one of the following two groups:

Test group (n=12): Tooth extraction + Titanium membrane (Bionnovation Titanium Seal)

Control group (n=12): Simple tooth extraction

Tooth extraction and grafting procedure

Teeth were extracted in an atraumatic manner, using periostomes, thin luxators, and forceps in order to maintain the anatomy of the buccal and lingual bony plate. Then, the granulation tissue was thoroughly removed, and the integrity of the bony walls was evaluated. Then, patients were randomly assigned in one of the treatment groups. In the experimental group, the sockets were then covered with new non-resorbable anodized titanium foil (Bionnovation Titanium Seal). According to the manufacturer, Titanium seal (Tseal), a 0.04mm thick titanium foil without porosity is produced by an anodization process without any electric charges. The titanium membrane was adapted, placed so that it extended 5 mm over the buccal and lingual bone plate and the flap was then sutured with 5-0 nylon sutures (Ethicon, Johnson & Johnson, Sao Paulo, Brazil), leaving the Tseal (Figure 1) exposed to the oral cavity. On the other hand, in the control group only tooth extraction was performed.

Postoperative care

After surgery, all patients received 100mg Nisulid (1 tablet every 12 hours for 3 days), and 0.12% chlorhexidine digluconate solution (Periogard, Sao Paulo, SP, Brazil) for mouth rinsing twice a day for 14 days. In addition, all patients were instructed to suspend tooth brushing in the area of the tooth extraction during this period. Fourteen days after surgery, the nylon sutures were removed and 21 days after surgery the titanium membrane was removed without local anesthesia.

Cone-beam computerized tomography analysis

Participants were referred to the tomography service on the second postoperative day and after six months (24 weeks) of healing. The width of the alveolar ridge was measured from buccal to palatal at three distinct points, from the highest point of the palatal crest, in three portions: L1 - at 1 mm; L2 - at 3 mm; and L3 - at 5 mm. Figure 1 illustrates the measurements performed in this study.

Both examinations were performed using a lip retractor (Januario et al., 2011), by the same radiology technician and on the same equipment. Image acquisition was performed using cone beam computed tomography (CBCT) (Prexion, San Mateo, CA, USA) with 37 seconds of exposure and a voxel size of 0.15. Axial, sagittal, parasagittal, and panoramic coronal cuts were obtained. Parasagittal cuts had a thickness of 1 mm and spacing of 1 mm (Fig. 1). The DICOM value - Digital Imaging and Communications in Medicine - was segmented by digital image software (Dental Slice, Bioparts, Brasília, Brazil). This evaluation aimed to measure and compare the preservation of architecture between the experimental groups.

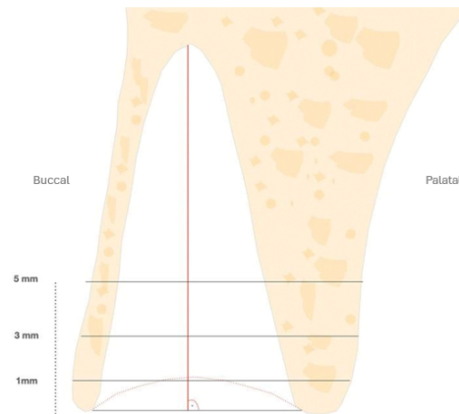


Figure 1. Schematic illustration of the tomographic analyses that were conducted. The width of the alveolar ridge was measured from the vestibular to the palatal at three different points, from the highest point of the palatal crest, at three portions: L1 – at 1 mm; L2 - at 3 mm; and L3 – at 5 mm.

Statistical Analysis

The data on the width and height of the alveolar ridges measured linearly at the three points of analysis were tabulated, and the percentage reduction of the alveolar horizontal volume was established. The linear values of alveolar thickness at the three points of analysis within each group were compared using Student's paired t-test, and significant differences between the groups at both experimental times were compared using Student's t-test. All tests were conducted using SAS 9.2 software (SAS Institute, Cary, NC, USA) at a significance level of 5%.

Results

Figure 2 presents the study flowchart. Twenty-four individuals were included in this study, and all individuals attended the 6-month follow-up appointment. Therefore, each group had 12 individuals, and the demographic data are presented in Table 1. Overall, no adverse effects were reported by individuals in the test and control groups. Of the 24 individuals evaluated, all reported total adherence to the therapeutic protocol employed. Figure 3 presents a clinical representation of the study groups addressed in this study.

Table 1 presents the demographic characteristics and distribution of teeth involved in the study. At the beginning of the study, there were no significant differences between the groups for any of the parameters evaluated ($p > 0.05$), including the distribution of teeth across the study groups.

The significant differences between the experimental groups were tested using the Student's t-test, and the difference in the distribution of dental elements involved was assessed using Fisher's exact test.

Figure 4 presents the measurements in millimeters from the tomographic images at three distinct analysis points, starting from the highest point of the palatal crest, 1 mm, 3 mm, and 5 mm, at the beginning of the study (2 days after tooth extraction) and 6 months after the surgical procedure. No statistical differences were observed between the groups at the beginning of the study at any analysis point, demonstrating that the groups were homogeneous concerning the horizontal dimension of the alveolus. Both study groups showed a significant reduction in horizontal ridge dimension at the analysis points of 1 mm and 3 mm below the palatal bony crest at 6 months post-surgery.

However, at the 5 mm measurement, only the control group, which received only the blood clot, showed a reduction in horizontal ridge dimension, while the test group maintained similar values between the experimental time points, with no statistical differences between the analysis periods. When the groups were compared at 6 months post-surgery, higher measurements of the horizontal dimension of the alveolus were observed for individuals in the Test group compared to the Control group, at all analysis levels.

Figure 5 presents the percentage of horizontal ridge dimension maintenance at three distinct analysis points, starting from the highest point of the palatal crest, 1 mm, 3 mm, and 5 mm, at 6 months post-surgery. It can be observed that the control group showed an average maintenance percentage of approximately 60% of the alveolar horizontal ridge dimension, while the test group showed approximately 70%. Significant differences were observed between the groups at the analysis points 1 and 3 mm below the palatal bone crest, with the Test group showing higher mean percentages of alveolar horizontal ridge dimension maintenance compared to the Control group. No significant differences were detected between the groups in the 5 mm measurement below the bone crest.

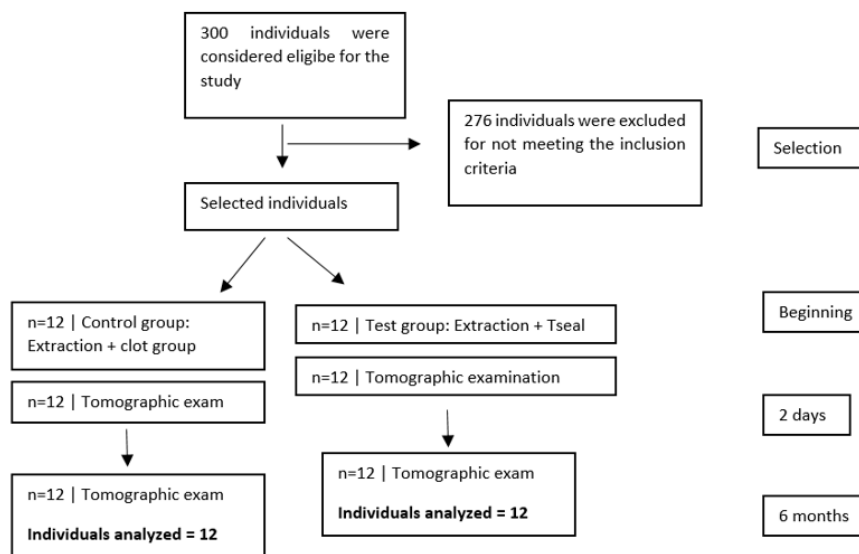


Figure 2. Study Flowchart

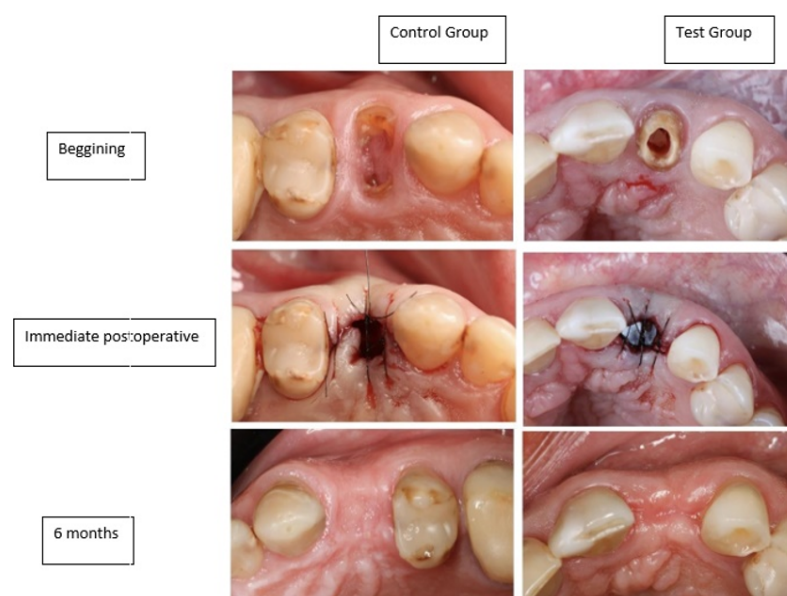


Figure 3. Figure showing the clinical aspects of both groups at the beginning of the study and at 6 months post-surgery.

Table 1. Demographic characteristics and distribution of dental elements involved in the study.

Variables	Control Group n=12	Test Group n=12	P value
Age	45.0±6.0	48.0±4.0	0.1777
Gender (M/F)	7/5	6/6	p>0.05
Central incisors	3	2	
Lateral incisors	2	3	
Canine	3	2	>0.05*
¹ o pre molar	2	3	
² o pre molar	2	2	

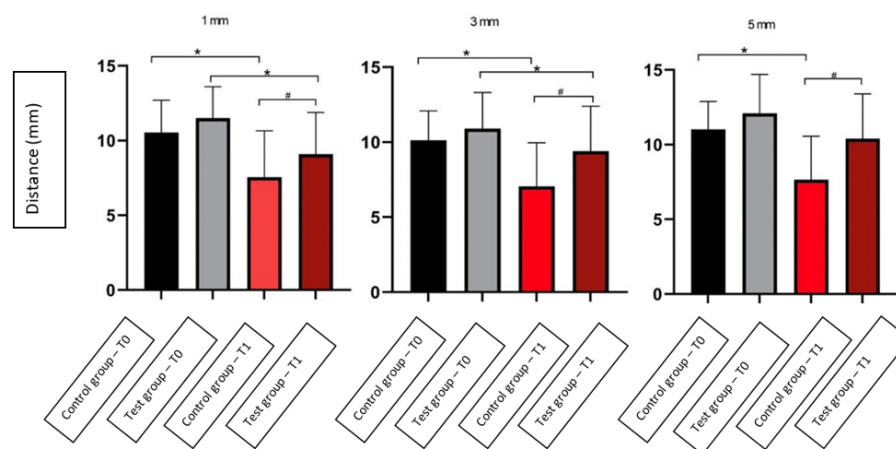


Figure 4. Mean (mm) values of horizontal measurements from tomographic images at three distinct analysis points, starting from the highest point of the palatal crest, 1 mm, 3 mm, and 5 mm, at the beginning of the study (2 days after tooth extraction) and 6 months after the surgical procedure. Significant differences between the beginning (T0) and 6 months (T1) post-therapy were tested using the paired t-Student test (*, $p < 0.05$). Statistical differences between the groups at the experimental time points were tested using the t-Student test (#, $p < 0.05$).

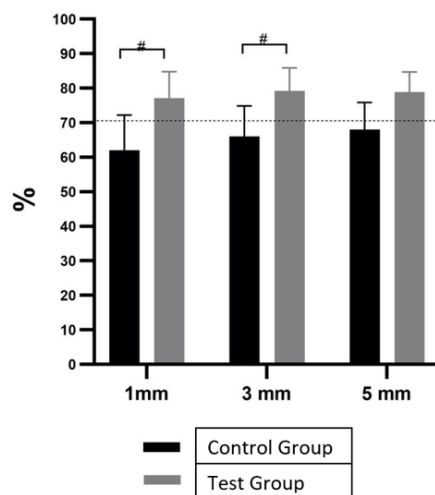


Figure 5. Percentage of maintenance of horizontal measurement at three distinct analysis points, from the highest point of the palatal crest, 1 mm, 3 mm, and 5 mm, at 6 months post-surgery.

Discussion

Alveolar ridge preservation procedures have been widely investigated as a strategy to minimize post-extraction dimensional changes and facilitate future implant placement. The present randomized controlled clinical trial demonstrated that the use of anodized titanium foil associated exclusively with blood clot stabilization resulted in greater preservation of horizontal ridge dimensions when compared with spontaneous healing after tooth extraction.

Physiological remodeling of the alveolar ridge following tooth extraction is a well-documented phenomenon. Previous studies have demonstrated that significant dimensional alterations occur predominantly during the first months of healing, especially in the horizontal dimension. Tan et al. reported that spontaneous socket healing may result in considerable alveolar ridge reduction, potentially compromising ideal implant positioning and esthetic outcomes. These findings are consistent with the results of the present study, in which the control group demonstrated substantial reduction in horizontal ridge width after 6 months of healing.

Different alveolar ridge preservation protocols have been proposed over the years, including the use of grafting materials, barrier membranes, or combinations of both. Although these techniques have demonstrated favorable clinical outcomes, they may increase treatment cost, surgical complexity, and patient morbidity. In contrast, the present study evaluated a minimally invasive approach based primarily on clot stabilization and maintenance of regenerative space, without the use of biomaterials to fill the extraction socket.

One of the main biological principles associated with bone healing is clot stability. Protection of the blood clot against epithelial migration, bacterial contamination, and soft tissue collapse may favor the organization of the coagulum and subsequent bone formation within the socket. In the present investigation, the anodized titanium foil likely acted as a protective barrier capable of maintaining space and stabilizing the clot during the critical early phases of healing, contributing to the improved dimensional outcomes observed in the test group.

Interestingly, the most pronounced differences between groups were observed in the coronal portion of the alveolar ridge, particularly at the 1-mm and 3-mm levels below the palatal crest. These findings are clinically relevant because the coronal aspect of the socket is the region most affected by post-extraction remodeling and plays a fundamental role in esthetic implant rehabilitation.

Another relevant aspect of the present technique is the open-healing approach. Since primary closure was not required and the titanium foil remained intentionally exposed to the oral cavity, flap advancement and releasing incisions were avoided. This may contribute to preservation of the mucogingival architecture, reduction of surgical morbidity, and simplification of the surgical procedure. In addition, previous *in vitro* findings demonstrated that anodized titanium surfaces may present favorable antimicrobial properties, including reduced levels of pathogenic bacterial colonization, which may further support the clinical use of this material in exposed healing protocols.

The dimensional outcomes observed in the present study were lower than those reported in some studies using grafting biomaterials associated with collagen membranes. Cardaropoli et al., for example, demonstrated limited horizontal dimensional reduction using bovine bone mineral associated with collagen membrane coverage. Similarly, Jung et al. reported favorable ridge preservation outcomes using grafting materials in combination with barrier membranes. However, unlike these protocols, the present study achieved significant ridge preservation without the use of grafting biomaterials, suggesting that clot stabilization itself may play an important role in socket healing.

Some limitations of the present study should be considered. The relatively limited sample size and the absence of histological analysis restrict the interpretation of the biological events associated with healing. Furthermore, only horizontal dimensional changes were evaluated. Therefore, additional randomized clinical trials with larger samples, longer follow-up periods, and histological assessment are necessary to better understand the regenerative potential of this approach and to compare this technique with established alveolar ridge preservation protocols using grafting materials.

Within these limitations, the present findings suggest that anodized titanium foil associated with blood clot stabilization may represent a viable and minimally invasive alternative for alveolar ridge preservation following tooth extraction.

Conclusion

Within the limitations of the present study, the use of anodized titanium foil associated with blood clot stabilization demonstrated beneficial effects on alveolar ridge preservation following tooth extraction, particularly in the coronal portion of the socket. This minimally invasive approach may represent a viable alternative for reducing post-extraction horizontal ridge resorption without the use of grafting materials.

Conflict of Interest

The authors declare no conflict of interest.

Acknowledgements

None

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