Barbell Technique: A Novel Approach for Bidirectional Bone Augmentation: Clinical and Tomographic Study

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Horizontal bone augmentation is a common surgical procedure used in implant therapy to achieve adequate bone volume to permit dental implant placement. However, most current techniques are focused on unidirectional bone reconstruction (grafting only on the buccal side). This study was carried out to validate a new device that will permit bidirectional bone augmentation. Ten patients of both sexes (7 women and 3 men), with ages ranging from 29 to 62 years, who needed a bidirectional horizontal bone augmentation in maxilla were separated in accordance with the horizontal alveolar change (HAC) classification published by Pelegrine et al (2018). The patients classified as HAC 3 (ie, containing remaining cancellous bone at the recipient bed) received the Barbell device with xenogeneic biomaterial and a collagen membrane, whereas HAC 4 patients (ie, with no remaining cancellous bone at the recipient bed) received the Barbell device with a mixture of autogenous bone chips and xenogeneic biomaterial covered by a collagen membrane. For each patient, two computerized tomography scans were performed (T0 at baseline and T1 at 6 months postoperative examinations). Mean bone thickness (T0) in the studied sites were 3.25 $\pm$ 0.35 in HAC 3 and 1.98 $\pm$ 0.5 in HAC 4 patients. The mean bone thickness achieved after 6 months was 7.70 $\pm$ 0.89 mm and 8.62 $\pm$ 0.89 in HAC 3 and 4, respectively. All grafted sites were able to receive dental implants in adequate prosthetic positions. Based on these results, the use of this novel device permits bidirectional horizontal bone augmentation.

Key Words: guided tissue regeneration, bone regeneration, bone grafts, alveolar bone atrophy, bidirectional bone augmentation

Introduction

Appositional bone reconstruction has always been a challenging issue in the field of implant dentistry. Horizontal bone augmentation can be performed with a number of techniques, and there is no consensus about what would be the most effective.[1] The prevalence of horizontal defects is high due to the tendency toward loss of bone thickness occurring after tooth extraction.[2–4] Along with the high demand for esthetics, there is a tremendous interest in the use of socket augmentation procedures.[5–7] Most surgical techniques used for horizontal bone augmentation focus on buccal bone gain; however, it is known that bone resorption occurs on the buccal and lingual (or palatal) sides of the alveolar ridge, due to the centripetal resorption of the alveolar bone crest.[8] Pelegrine et al (2010)[3] showed that 34.82% of the original thickness of the coronal aspect of an alveolar socket in the anterior maxilla was lost within 6 months of tooth extraction. This represented a total of 2.5 mm of bone loss, with a median of 1.75 mm and 0.62 mm of bone loss on the buccal and palatal sides, respectively. Although the majority of horizontal bone loss occurred on the buccal side, the palatal bone loss should not be neglected. The amount of bone loss tends to increase with time as well, owing to the lack of adequate stimuli to bone from tooth loss.[2]

Since the horizontal bone loss after tooth extraction is bidirectional, it would seem reasonable to reconstruct bidirectionally to restore the alveolar ridge to its original contours and skeletal relationship. In 2018, Pelegrine et al[9] developed a new classification for horizontal bone defects and suggested that in situations of severe bone loss with a lack of cancellous bone (ie, knife edge: HAC 4), a bidirectional bone reconstruction with autografts should be considered. The authors also suggested when there is significant horizontal loss, but with the presence of cancellous bone requiring bidirectional reconstruction, use of a bone substitute could be indicated. The current horizontal bone augmentation techniques involve mostly unidirectional bone reconstruction (ie, only on the buccal side) due to the difficulty involved in installing screws and pins on the lingual (or palatal) side. In most clinical studies specific guidelines for the use of autograft are not frequently related with the defect characteristics. The tent-pole, titanium–mesh, titanium-reinforced-membrane, and bone-block techniques commonly involve augmenting the bone only on the buccal/lateral aspect of the deficient ridge, followed by a second surgical step to install the implants. As a result, the implant position is often placed in a more buccal position.[10] The ridge-split technique also limits bone augmentation to the buccal side,

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Table 1

Demographic and clinical characteristics of patients

Patient Number	Gender	Age	Area	HAC
1	Female	52 years	Anterior	4
2	Female	52 years	Anterior	4
3	Female	55 years	Anterior	4
4	Female	57 years	Posterior	3
5	Female	57 years	Posterior	3
6	Male	56 years	Anterior	4
7	Male	56 years	Anterior	4
8	Female	53 years	Anterior	3
9	Male	38 years	Anterior	3
10	Male	35 years	Anterior	3

since only the buccal portion of the ridge is displaced and results in the same limitation when a dental implant is placed.[11]

Based on this issue, Pelegrine et al (2020)[12] proposed a new device (Barbell Technique) to promote horizontal bidirectional bone augmentation, maintaining the space for new bone formation and avoiding soft tissue compression on the lingual-palatal aspects of the ridge. The authors aimed to overcome the limitations of currently available surgical augmentation techniques and show the versatility and handling of the new device. After 6 months, an overall bone gain of 6.81 ± 1.33 mm was achieved. The authors clearly stated that this was a preliminary study that would be used for a sample size calculation, which was the basis for the present study.

The aim of this clinical and tomographic study was to evaluate bidirectional horizontal bone reconstruction with the Barbell Technique in HAC 3 and HAC 4 situations.

Materials and Methods

Study design and sample selection

This clinical and tomographic study was designed as a single-center, prospective study. The clinical procedures were undertaken in full accordance with the ethical principles of the World Medical Association Declaration of Helsinki (2013), and all the patients agreed to sign the written consent. The study was approved by the Research Ethics Committee of the Faculdade de Odontologia São Leopoldo Mandic (protocol registration 3.651.056, 2019).

Pregnant, diabetic, immunocompromised patients, smokers, and patients using any medication that could interfere with bone metabolism were excluded from the study. Healthy patients seeking oral rehabilitation with dental implants were recruited from October to December 2019. After applying these criteria, 10 patients of both sexes (7 women and 3 men), with ages ranging from 29 to 62 years, who needed a bidirectional horizontal bone augmentation in maxilla were included in this study (Table 1).

All patients were submitted to a cone beam computerized tomography (CBCT) using the i-Cat scanner (Imaging Sciences International, Hatfield, PA) set to operate at 120 kVp, 36 mA, with field of view of 13 cm and an exposure time of 40 seconds. Images obtained in DICOM format with 96 dpi resolution, 14-bit gray scale and 0.25 mm voxel size were used to verify the needs for bone augmentation and to categorize the bone defect in accordance with HAC classification[9] (Figure 1). Just HAC 3 and HAC 4 were selected in this study. HAC 4 score was pointed in situations of severe bone loss, with lack of remaining cancellous bone, and HAC 3 score in situations of moderate bone loss with some reminiscent cancellous bone.[9] The scans were taken at 2 stages: (T0) before surgery and (T1) 6 months after surgery, before surgical reopening.

Device

The device consists of 1 titanium Barbell screw, 1.5 mm in diameter, and 2 polyether ether ketone (PEEK) capsules. The length of the screw was selected according to the desired bone gain (8 or 10 mm in length), and the diameter of the capsule is fixed at 4.5 mm. The screws were installed after preparation of recipient bed with a 1.1-mm drill and the screw and caps were installed using a specific carrier especially designed to fit perfectly around the caps. The screw has an external hex tip on both ends and the caps have an internal circumference that allows the use of pressure to fit over the hex tip of the screw. Due to the characteristic of the final design of the device, this device/technique has been registered with the name "Barbell" (Figures 2 and 3).

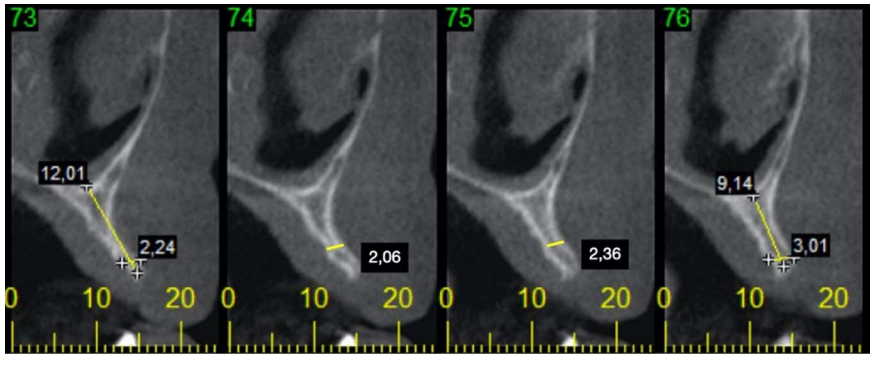

Figure 1. CT scan of a HAC 4 clinical situation (no cancellous bone) at baseline. Note the lack of bone thickness to allow implant placement. CT indicates computerized tomography; HAC, horizontal alveolar change.

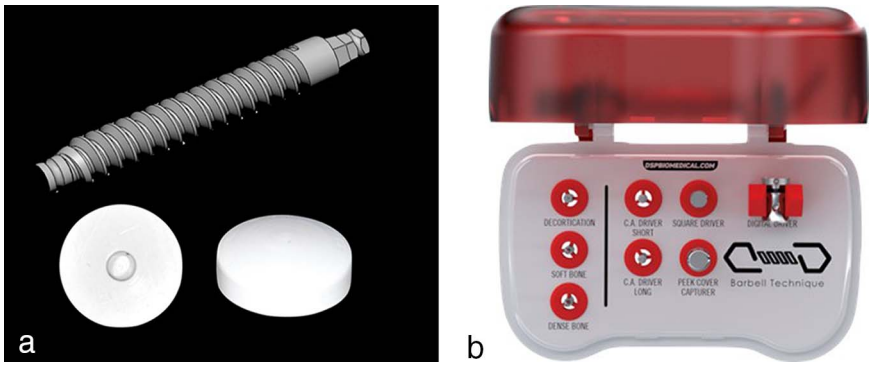

Figure 2. (a) Titanium Barbell screw and PEEK capsules. (b) Barbell Technique surgical kit. PEEK indicates polyether ether ketone.

Reconstructive augmentation surgery

All patients were instructed to take oral antibiotic prophylaxis with 2 g of amoxicillin (amoxicillin; Ranbaxy, Arsenal, Brazil) and 8 mg of dexamethasone (Hypofarma, Ribeirão das Neves, Brazil) 1 hour preoperatively. All surgical procedures were performed by the same experienced surgeon adopting a standardized surgical protocol.

To prepare the recipient area, local anesthesia was applied using 2% mepivacaine with 1:100 000 epinephrine (Mepiadre; DFL Indústria e Comércio S.A., Rio de Janeiro, RJ, Brazil), a horizontal crestal incision through the keratinized mucosa and two divergent vertical releasing incisions were made using a 15C scalpel blade and a mucoperiosteal flap was then reflected to expose the bone defect. After the debridement of the soft tissue remnants, cortical perforations of the buccal bone plate to create vascular channels were performed with the decortication drill and the specific perforation where the screw would be installed was performed with a 1.1-mm drill (Barbell Kit DSP Biomedical, Campo Largo, PR, Brazil), under constant irrigation to prevent overheating the recipient bed of bone. After the residual bone preparation, the dimension was checked using a periodontal probe and Barbell titanium screws were installed using a controlled maximum torque of 15 Ncm (Figure 4).

In accordance with a previously published bone defect classification for horizontal alveolar change (HAC),[9] 5 cases classified as HAC 3 received xenogeneic biomaterial alone (Geistlich Bio-Oss, Geistlich, Wolhusen, Switzerland) covered with a hydrophilic collagen membrane (Geistlich Bio-Gide, Geistlich), while the other 5 cases were classified as HAC 4 and the donor material consisted of a mixture of xenograft and autogenous bone harvested from ramus was used (Figure 5). To collect the autogenous bone, local anesthesia using the previously described technique was administered to the ramus of the mandible. An incision using a 15 surgical blade was made along the mucogingival line from the second premolar extending posteriorly to release a total flap to obtain access to the cortical bone. The particles of autogenous bone were collected using a bone scraper (MX-Grafter, Salvin Dental Specialties, Charlotte, North Carolina, USA) and mixed with the xenogeneic biomaterial (Bio-Oss) (Figure 4). A 4.0 Nylon (Ethicon, Johnson & Johnson, New Brunswick, New Jersey) interrupted suture was used to achieve primary wound closure.

After the fixating the selected tenting screw through the residual bone ridge with a specific carrier (Barbell Kit DSP Biomedical, Campo Largo, PR, Brazil), the PEEK caps were attached to maintain the space for bone augmentation (Figure 6). The bone graft was then delivered to rebuild the contour of the bone following the requirements of the prosthetic plan. Based on the principle of guided bone regeneration (GBR), all grafts were covered using a hydrophilic collagen membrane (Geistlich Bio-Gide, Geistlich) to exclude cells from the epithelium and connective tissues (Figures 7 and 8). A periosteal releasing incision was made 4 mm beneath the apical position of the graft material between the 2 vertical releasing incisions to

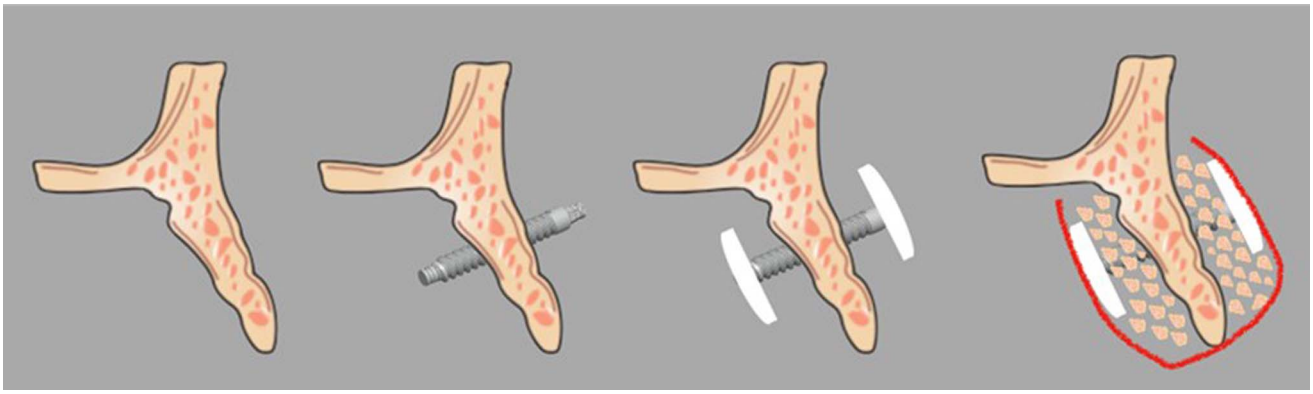

Figure 3. Barbell Technique: sequence of screw insertion, PEEK caps installation, and bone graft material.

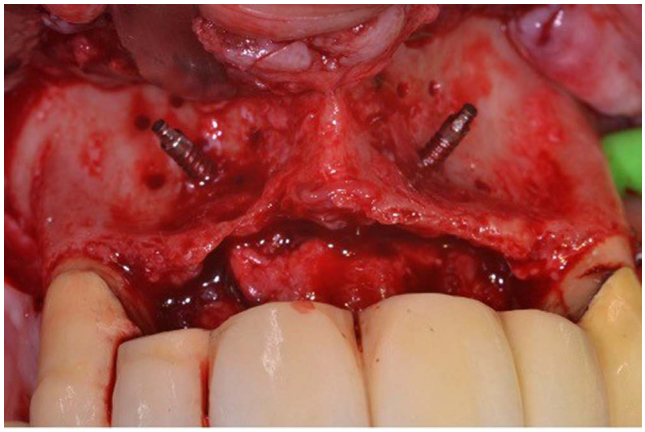

Figure 4. Recipient bed after cortical perforations and Barbell titanium screw fixation.

allow tension-free coronal advancement of the flap, wound closure, and suturing. The flaps were closed using 5-0 prolene (B-Braun, Melsungen, Germany) and interrupted mattress sutures.

All patients received 875 mg of amoxicillin twice a day for 7 days and a nonsteroidal anti-inflammatory (100 mg) for 5 days after the surgical procedure for pain management. Postoperative instructions included a soft diet and use of 0.12% chlorhexidine mouthwash until the sutures were removed 15 days after the ridge augmentation procedure.

The patients underwent clinical and CBCT evaluations to assess the bone augmentation outcomes at 6 months after surgery. A second surgical procedure was performed to remove the Barbell device and install dental implants in a staged approach. To remove the Barbell devices, it was used the same

Figure 5. Mixture of autogenous bone and xenogeneic biomaterial used in HAC 4 clinical cases.

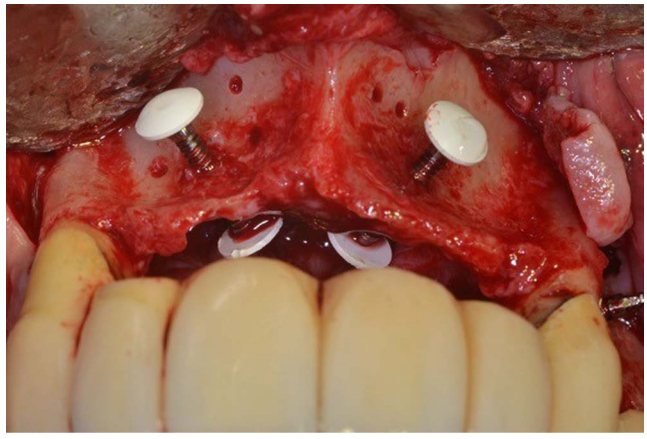

Figure 6. Barbell screw installed and PEEK capsules fixed in accordance with needs for bone gain.

tools for the installation procedure. A surgical guide based on the requirements of the prosthetic plan was used to place dental implants.

CBCT Measurements

CBCT scans were acquired using the i-CAT 3D Imaging system and i-CAT Vision Software. As stated before, the maxilla was scanned preoperatively (T0) and 6 months postoperatively (T1) (Figure 8). Accuracy was limited to the inherent voxel size (0.3 mm of the CBCT machine used for acquiring the scans). Measurements of the thickness were made at the central sagittal slices of the bony defects (baseline) and at the slices containing the device (screw and capsules) after 6 months postoperative examination (Figure 9). Two previously trained examiners blindly examined the images using the software Blue Sky Bio (Blue Sky Bio, LLC, Libertyville, IL, USA) with a 15-day interval between both analyses. Whenever disagreement occurred, the image was reevaluated, and a consensus was reached. All measurements were made 4 mm from the alveolar crest using the software ruler tool.

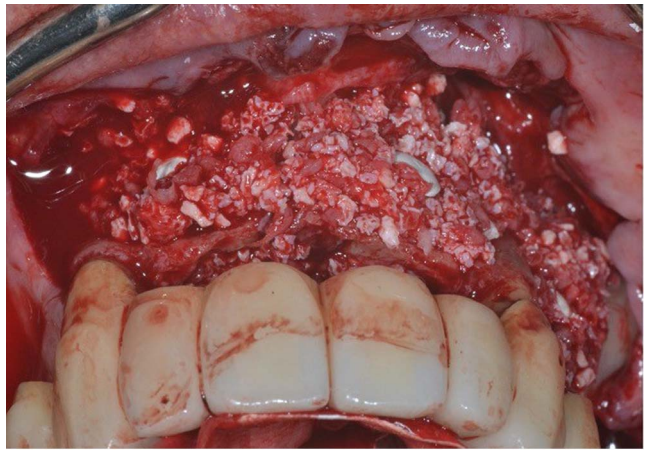

Figure 7. Bone graft (mixture of autogenous and xenogeneic biomaterial) covering the bone defect in buccal and palatal sides.

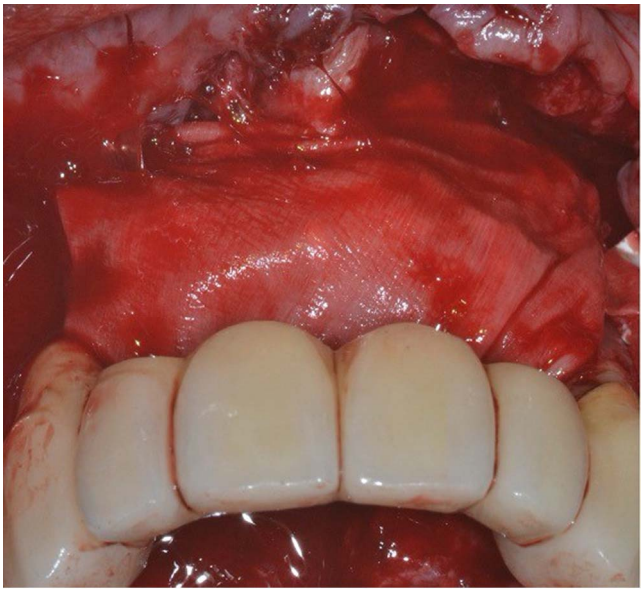

Figure 8. Hydrophilic collagen membrane covering the bone graft.

Statistical Analysis

Horizontal bone augmentation was the primary outcome variable. The sample size was determined by a sample size calculation using R software, based on the results of the pilot study entitled "Barbell Technique: A Novel Approach for Bidirectional bone augmentation: technical note,"[12] previously published in *Journal of Oral Implantology*. Descriptive statistics were calculated and expressed as mean ± standard deviation (SD). In addition, data normality was tested using the Shapiro-Wilk test. The statistical comparison between baseline and 6 months after bone augmentation was performed by the Student paired *t* test. The level of significance was set at 5% and the test power at 80%.

Results

The sample size calculation indicated 5 patients per condition (ie, 5 patients for HAC 3 and 5 patients for HAC 4). Nineteen implants were installed in 10 patients after 6 months. All implants had an insertion torque equal or higher than 35 Ncm and were placed in appropriate positions (Figures 10 and 11).

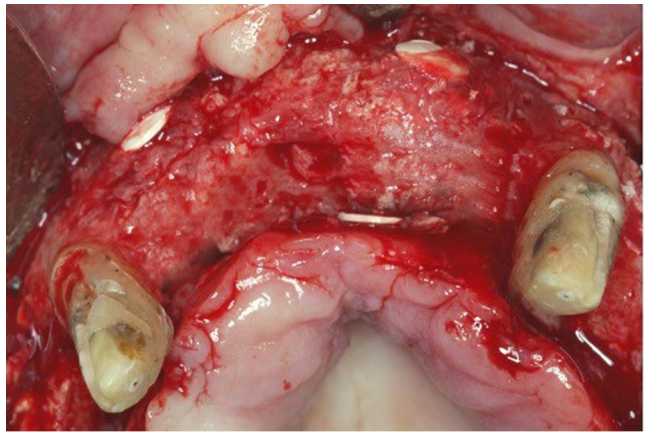

Figure 10. Clinical aspect of bone augmentation in a bidirectional manner after 6 months.

All Barbell devices were removed easily by using the carrier of the surgical kit and no exposure of the graft and/or barrier membrane was observed. The thickness measurements at baseline and 6 months postoperative examinations, and the amounts of horizontal bone gain for HAC 4 and HAC 3, are shown in Tables 2 and 3, respectively.

Discussion

Achieving appositional bone reconstruction using various bone grafting techniques has been a challenge considering the number of clinical studies performed to show predictable results. Four techniques for horizontal bone augmentations have been described: bone blocks, tent pole, split crest, and titanium mesh/titanium reinforced membranes.[13–18] However, all of the described techniques achieve horizontal bone augmentation only on the buccal side. This fact is the result of the difficulty of placing screws and/or pins on the palatal/lingual side and/or the difficulty of displacing the palatal/lingual portion of the ridge (for ridge split techniques). The ideal technique for horizontal bone reconstruction should allow a bidirectional bone augmentation (ie, to gain bone augmentation on the buccal and palatal/lingual sides), as bone remodeling and resorption occur on both sides of the alveolar ridge after exodontia.[3] In this regard, Barbell Technique was recently introduced by the publication of a technical note.[12] The results of this preliminary study

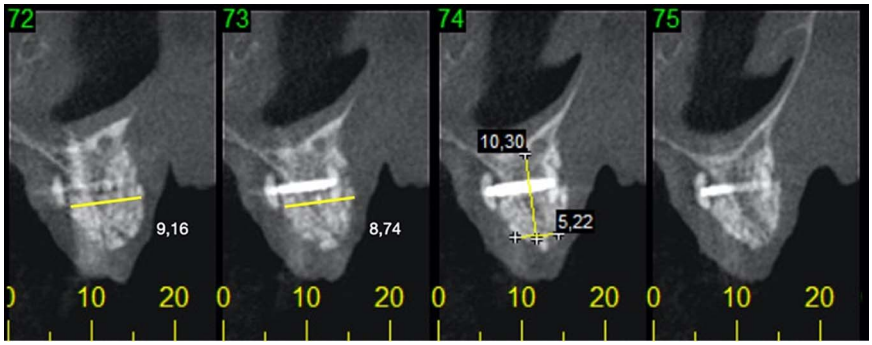

Figure 9. CT scan after 6 months showing the outcomes of bone augmentation with Blue Sky Bio software.

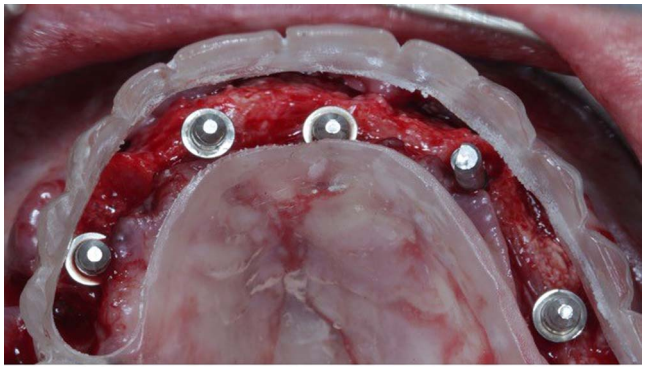

Figure 11. Indicator pins of the implant positions in accordance with the prosthetic guide.

were used to perform a sample size calculation, which was the basis to determine the *n* of the current study.

This study was undertaken to assess the effects of the Barbell Technique in clinical situations that ideally required bidirectional horizontal bone augmentation. All patients were categorized using HAC Classification.[9] According to these guidelines, horizontal defects that have complete absence of cancellous bone (ie, HAC 4) must be grafted with autografts while horizontal defects that contain some amount of cancellous bone (eg, HAC 3) may be grafted with bone substitutes alone. In the present study, all patients received Barbell devices, HAC 4 patients were grafted with a mix of autograft and xenograft (1:1), and HAC 3 patients were grafted with a xenograft alone. In all sites a resorbable collagen membrane was used to cover the graft, following the principles of GBR. No HAC 1 and 2 situations were enrolled in this study because these are minor defects that do not require bidirectional augmentation.

The following hypothesis was made by the inventors of the Barbell Technique device: a soft tissue tenting cap that can be placed on both sides (buccal and palatal) of the deficient ridge may maximize the bone regenerated tissue volume and permit a better 3-dimensional implant placement. It is important to note that the occlusive membranes used in this study were not fixated or secured, as Barbell devices theoretically prevent soft tissue compression over the bone grafts. Moreover, use of a PEEK capsule, well known as a biocompatible polymer, may

Table 2

Measurement results in preoperative CT (T0), 6 months postoperative CT (T1), and the total amount of horizontal bone gain (in mm) in HAC 4 patients*

Patient Number	Baseline	After 6 Months	Gain
1	1.68	9.18	7.50
2	1.35	9.02	7.67
3	1.90	8.78	6.88
4	2.54	8.71	6.17
5	2.41	7.42	5.01
Mean ± SD	1.98 ± 0.50 (A)	8.62 ± 0.70 (B)	6.65 ± 1.09

*Different letters in brackets indicate statistically significant difference between them—paired *t* test (statistical significance considered when $p < .05$).

Table 3

Measurement results in preoperative CT (T0), 6 months postoperative CT (T1), and the total amount of horizontal bone gain (in mm) in HAC 3 patients*

Patient Number	Baseline	After 6 Months	Gain
1	3.20	6.46	3.26
2	3.40	8.62	5.22
3	2.93	7.18	4.25
4	3.77	8.41	4.64
5	2.95	7.82	4.87
Mean ± SD	3.25 ± 0.35 (A)	7.70 ± 0.89 (B)	4.45 ± 0.75

*Different letters in brackets indicate statistically significant difference between them—paired *t* test (statistical significance considered when $p < .05$).

enhance the pattern of tissue healing, as fibroblasts and osteoblasts show great affinity to PEEK.[19,20] To test this hypothesis, based on sample size calculation, 10 patients requiring horizontal bone augmentation were selected. The patient pool was evenly divided, with 5 patients having HAC 4 and the other 5 patients having HAC 3 defects.

The results of the present study confirmed the hypothesis that bone augmentation of HAC 4 and HAC 3 patients (6.65 ± 1.09 mm and 4.45 ± 0.75 mm, respectively) would be significant ($P < .05$). The bone volume gained with the Barbell technique was greater than the bone volume gained with the use of bone blocks and standard GBR techniques (4.18 ± 0.56 and 3.61 ± 0.27 mm, respectively) as reported in a systematic literature review published by Elnayef et al (2018).[21] A more recent systematic review with meta-analysis for lateral bone augmentation showed even lower results (2.90 ± 0.83 mm) for horizontal gain with bone blocks.[22] In a recent retrospective study, César Neto et al (2020)[23] compared the horizontal gain between tent pole technique and guided bone regeneration alone (without the use of screws). The authors observed a significant improvement when the titanium screws (i.e. tent pole technique) were used. It was speculated by the authors that "the use of tenting screws gave mechanical support for the membrane and thus may lead to increased stability of the graft particles underneath", validating the Barbell Technique concept. However, achieving more than 1mm improvement by using the screws (1.22 ± 0.86 mm), with the main horizontal augmentation gain (3.98 ± 2.53 mm at 3mm below the bone crest), obtained by César Neto et al (2020),[23] were lower than those obtained by the present study. It is reasonable to state that this difference can be related, principally, to the difficulty of achieving palatal/lingual bone augmentation with bone blocks, standard GBR, or GBR/tent pole techniques. Nonetheless, a direct comparison between studies is difficult to make as the study designs, selection criteria, and follow-up protocols are often different. It is well known that: (1) patients' age and recipient site may influence graft resorption; (2) use of a xenograft can reduce graft resorption; (3) initially smaller bone dimensions favor larger bone width gain.[22] The last statement was affirmed and highlighted in the present study, showing that more advanced bone loss (HAC 4), once treated, obtained

the highest volume of bone gain. However, in the present study, the use of autografts mixed with the xenografts in HAC 4 patients may also have contributed in this regard.

The novel Barbell Technique was designed for bidirectional horizontal bone augmentation, but this technique may also be used for unidirectional horizontal, such as vertical bone augmentation by placing only one PEEK cap instead of two and, in some clinical situations, using shorter screws. However, future studies are necessary to scientifically verify the outcomes of Barbell Technique for unidirectional augmentation, as this study has some limitations, such as the lack of a long-term follow-up and the fact that it was focused just on maxilla defects.

Conclusions

The use of the novel Barbell Technique device allows for bidirectional horizontal bone augmentation in maxilla.

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Note

The authors would like to declare conflict of interest as Luis Guilherme Scavone de Macedo and André Antonio Pelegrine are the inventors and the designers of the device and also the technique.

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