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Research Article

ALVEOLAR RIDGE PRESERVATION WITH D-PTFE MEMBRANE A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Purpose: Resorption of the alveolar bone is an unavoidable consequence of tooth extraction when appropriate alveolar ridge preservation (ARP) measures are not taken. The objective of this trial was to test the hypothesis that dimensional changes in the alveolar bone after tooth extraction would be reduced by using nonresorbable high density Polytetrafluoroethylene (d-PTFE)membrane to cover the alveolus (as ARP), in comparison to extraction with untreated alveoli.

Methods: In this randomized clinical trial, 40 single root teeth from the mandible of 35 patients (Male= 11 Female=24mean aged 55.3±8.9 years; age range, 35–68 years)were extracted. Twenty teeth were directly treated with d-PTFE membrane after extraction (in the ARP group). The other twenty teeth served as a control group. After extraction, no further treatment (i.e., no socket preservation measures) was performed in the control group. Changes in the height of alveolar process after three months of extraction and after six months were evaluated by means of cone-beam computed tomography CBCT.

Results: Both the ARP and control groups showed a reduction of bone height in the alveolar area after tooth extraction. However, significantly less bone height resorption was detected in the ARP group after three and six months compared to control group. The median bone height reduction after three months was 1.31±0.23mm in the ARP group and 2.89±0.49 mm in the control group (P=0.035). And the median bone height reduction after six months was1.98±0.35 mm in the ARP group and 3.93±0.51 mm in the control group (P = 0.046) .

Conclusions: The proposed hypothesis that inserting a d-PTFE over the fresh socket after extraction would lead to a difference in alveolar bone preservation which could be accepted for the clinically relevant height. In this area, covering the extraction socket with d-PTFE material led to significantly less alveolar bone resorption.

INTRODUCTION

After tooth extraction, The main changes take place in the resorption characteristics of the alveolar process after tooth extraction [1]. In particular, significant resorption of the buccal portion of the empty cavity of the alveolus can be detected [2]. The basis for bone regeneration is that the defect fills with blood. A stable blood clot is overgrown by epithelium, which seals the wound. Within the blood clot, fibrin forms a natural support structure and scaffold, which facilitates the formation of osteoid and its subsequent calcification [3]. Bone regeneration completes after approximately 120 days, and the periosteum fully stabilizes after approximately 180 days [4,5]. The regeneration processes start from the empty alveolus and result in mature and mineralized bone. These Processes occur over intervals that vary widely among individuals and are not predictable [6]. However, bone regeneration does not lead to complete replacement of the alveolar bone. A recent review showed that the above-described defect healing process results in a mean horizontal degeneration of the alveolar process of 3.8

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mm in the vestibular-oral direction and a mean vertical degeneration of 1.2 mm over the first 6 months after tooth extraction [7,8]. During this process, vestibular/buccal degeneration is significantly more pronounced, which could be due to a reduced blood supply to the thin vestibular bone [9]. It has been shown that the various ARP materials resulted in a reduction of the dimensional change in the hard and soft tissue of the extraction alveoli, but cannot entirely prevent resorption [8]. Adequate bone regeneration is significant for the functional and aesthetic prognosis of an implant [10].

In guided bone regeneration 4,methods can be used to increase the rate of bone formation and to augment bone volume: osteoinduction by the use of appropriate growth factors; osteoconduction, where a grafting material serves as a scaffold for new bone growth; distraction osteogenesis, by which a fracture is surgically induced and bone fragments are then slowly pulled apart; finally, guided tissue regeneration, which allows spaces maintained by barrier membranes to be filled with new bone [11].

Guided bone regeneration (GBR) techniques utilize barrier membranes to refrain gingival cells from penetrating into the defect to be regenerated. The concept of compartmentalization was introduced by Melcher [12] to explain periodontal wound healing, but it may not be applicable to socket healing. If it were, one would expect the socket to be filled with soft tissue in all instances. On the other side, even early observations in humans and animals demonstrated that the alveolar socket tends to heal by regeneration of bone up to the alveolar crest. As in periodontal wound healing [13–15], the stability of the blood clot previously described explains why the compartmentalization concept does not result in a socket filled by epithelium and how epithelial cells migrate over the granulation tissue to close the healing socket. Questions remain as to whether barrier membranes have an effect in maintaining alveolar ridge morphology. In 1997, Lekovic and coworkers adopted nonabsorbablee PTFE membranes for the preservation of the alveolar ridge following tooth extraction. No changes in clinical measures were noted in the test sites that remained protected for 6 months while significant volumetric changes were observed in control sites and in test sites experiencing membrane exposure [16]. Pinho and coworkers evaluated the use of a titanium membrane with or without autologous bone graft. They found no significant differences between groups and, therefore, concluded that space maintenance is more important than the use of grafting materials in the treatment of extraction sockets [17].

Barrier membranes seem to minimize alveolar bone resorption when compared to nonintact (released) periosteum regardless of the use of additional grafting material. Titanium membranes certainly would have a distinctly different mechanism of action when compared to resorbable membranes that on the other side reduce the potential of exposure and do not require a second surgical intervention for their removal.

In 1998, Lekovic *et al*. examined the effect of glycolide and lactide polymer membranes demonstrating reduced loss of alveolar height, more internal bone socket bone fill and less horizontal resorption than controls [18]. Luczyszyn *et al*. evaluated the effect of acellular dermal matrix with or without a resorbablehydroxylapatite graft. Both groups preserved ridge thickness, although, better results were achieved in the combined treatment group suggesting that bone grafts might benefit bone regeneration when using a resorbable membranes [19]. A recent study performed a detailed evaluation of the healing of extraction sockets covered with a resorbable collagen membrane. Through the use of histological evaluation, subtraction radiography, and of μ-CT analysis, this study demonstrated that adequate bone formation for implant placement occurs as early as 12 weeks following tooth extraction, with insignificant changes in alveolar ridge dimensions [20].
A procedure for reducing bone resorption by applying a nonresorbabled-PTFEmembranealone would therefore be of interest.

A systematic literature search regarding the use of nonresorbabled-PTFEmembrane alone for ARP using the search terms (clinical AND (trial OR study OR systematic review) AND (ARP OR “alveolar ridge preservation” OR “socket preservation” OR (tooth OR teeth AND (ridge preservation OR socket preservation) AND d-PTFE)) revealed no studies describing the clinical efficacy of ARP with a d-PTFE material alone compared with untreated post-extraction alveoli.

The objective of this trial was to investigate the clinical application of nonresorbable d-PTFE membrane alone for bone preservation and to compare the results to those observed in untreated post-extraction alveoli. The proposed hypothesis was that using nonresorbable d-PTFE membrane alone for ARP that might reduce the dimensional changes of the alveolar bone after tooth extraction to a significant extent in comparison with sites untreated after extraction.

MATERIALS AND METHODS

Trial design

The trial was performed as a monocentric, parallel-group randomized human clinical trial in accordance with the Declaration of Helsinki. It has been reported according to the CONSORT guidelines [21-22]. No modifications of the method were made after the trial began. Recruitment and enrollment of patients were performed from August 2016 to March 2018. The trial was designed in accordance with the following:

- The World Medical Association's Declaration of Helsinki
- Clinical Investigation of Medical Devices for Human Subjects-Good Clinical Practice (ISO 4155:2011)
- Guidelines of Good Clinical Practice (2001/20/EC).

The study protocol was approved by the Scientific Committee of Hama University (approval on 8th of June, 2016).

After receiving oral and written information about the study and before participating, all patients eligible for the study and willing to take a part provided written consent.

Participants

Thirty five patients took part in this study, each of them requiring the extraction of one or more mandible single root tooth (premolar 1 or 2). The indication for the extraction was the severe destruction because of caries or trauma. All patients visited the Oral and Maxillofacial Surgery department's clinic

in the Faculty of Dentistry, Hama University for a teeth extraction. Depending on theclinical examination, a tooth or more needed to be extracted. The patients were first verbally informed by the clinical examiner about the possibility of taking part in the trial. The written information for patients was handed out afterwards. Patients provided informed consent at the next appointment, if they wanted to take part in the study.
Participation in the trial was also subject to the following conditions:

- Age over 18 years, as the participants had to be legally competent.
- Non-smoker status or smoking fewer than 10 cigarettes/day.
- No administration of bisphosphonates.
- No pregnancy.
- No alcohol or drug abuse.
- No infectious disease, such as hepatitis or human immunodeficiency virus (HIV) and/or acquired immunodeficiency syndrome (AIDS).
- No uncontrolled severe diabetes mellitus. In patients with diabetes,

All patients were recruited at the OMFS (Oral and Maxillofacial Surgery) department's clinic. All interventions and follow-up assessments were performed at this clinic by the clinical investigator who was the only dentist who treated all participating patients.

Interventions

All patients were treated under local anesthesia (huons Lidocaine 2%:1:80,000, Sampyeong-dong, InnoValley Korea). Periotomes were used for atraumatic extraction and removal of the teeth after complete mobilization. The alveolus in the area of extraction was then carefully curettage and rinsed with sterile sodium chloride solution. Nofurther measures were taken in the control group. In the ARP group, a d-PTFE (Cytoplast™ Dense PTFE Membranes) were inserted in accordance with the manufacturer's instructions. This synthetic dPTFE, is manufactured to eliminate expansion of the nodes and fibrils, resulting in a micro-porous material that is impervious to bacteria while still allowing diffusion of gases and small molecules. Dense PTFE was designed to withstand exposure in the oral environment, which represents an improvement to earlier versions of ePTFE in many applications, especially socket preservation where deliberate membrane exposure offers several advantages. A full thickness mucoperiosteum envelope flap was elevated. The d-PTFE membrane is trimmed to extend 3-5mm beyond the socket walls and then tucked subperiosteally under the lingual flap, the buccal flap, and underneath the interdentalpapilla with a curette. The membrane should rest on bone 360°around the socket margins, if possible. Prior to suturing, it was ensured that there are no folds or wrinkles in the membrane and that it lies passively over the socket. To prevent bacterial leakage under the membrane, taking care to avoid puncturing the membrane, and not overlap two adjacent membranes. A cross mattress suture was applied to stabilize the position flap edges using silk braded 3\0 suture material. The membrane was left partially exposed during healing period. The wounds were visually inspected after 1 week. At that time, the suture was removed from the patients in the ARP group. The membrane is removed, non-surgically, in 21 - 28 days. Topical anesthetic is applied, and then the membrane is grasped with a tissue forcep and simply removed with a gentle tug.

After extraction, all patients received the following instructions for care for the next 24 hours:

- Avoid eating until the anesthetic effect subsides.
- Abstain completely from alcohol, coffee, and caffeinated drinks and cigarettes or other smoking products.
- Avoid rinsing the extraction wound to keep the blood clot in place.
- Avoid manual manipulation of the wound (e.g., pulling the lip, rigorous cleaning of the wound, etc.).

The patients were prescribed 600 mg of ibuprofen for pain reduction, to be self-administered as needed. No prophylactic antibiotics were prescribed. A provisional interim prosthesis was applied in exceptional cases only (e.g., for aesthetics when the front teeth were involved or for function where multiple teeth were lost) only for the patients who requested to receive implant therapy, the implants was fitted after 11 (±1) weeks. While for the patients who planned for fixed bridge it was fitted after 4 (±1).

Outcomes

The objective of this study was to determine the extent of resorption of the alveolar bone in the post-extraction alveolusarea. The bone height was inspected at the time of the extraction (T0) and after a healing time of 12 (±1) weeks (T1) and after a healing time of 24 (±1) weeks (T2).

A cone-beam computed tomography (CBCT) image (vatechsmart, Vatech Dental Systems, Korea) with a resolution of 0.1 voxels was produced at time T0,T1and T2. This image was used for making measurements of the alveolar height andwas the basis for the template-guided implantation if implant placement was planned, which was performed at 11 (±1) weeks after tooth extraction.

Quantitative measurements of the alveolar height were performed using (Ez-3D Plus 2009Vatech Dental Systems, Korea) software (Figure 1). The measurements was made on the Axial sections at the center of the alveoli.

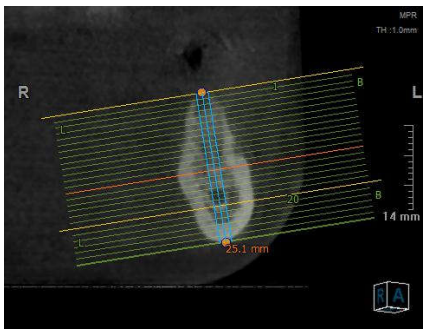

Figure 1 The measuring method on Axial sectionsof the alveoli using (Ez-3D Plus 2009 Vatech Dental Systems, Korea) software

Sample size

Due to a lack of clinical data, case numbers could not be estimated in advance. To achieve high clinical significance, 35 patients who required 40 single root tooth extraction (20 ARP and 20 control) from the mandible participated in the trial. The determination of the number of cases was based on similar

studies, which, however, investigated the feasibility of other materials for ARP [8,23]. From the biostatistical point of view, the trial was of an exploratory nature. Thus, all outcomes from the statistical tests must be interpreted as generating hypotheses and not as a proof of efficacy. We performed a post hoc power analysis to provide a basis for future comparative studies.

Randomization

The randomization was carried outby flip a coin to determine whether the tooth is going to be in ARP group or control group.

Blinding

Blinding of the socket treatment was not possible. However, the digital datasets acquired from the CBCT images taken at T0,T1 and T2were forwarded to the analyst (ID) in blinded and anonymized form. Deblindingwas performed only after completion of the analysis, documentation, and statistical analysis. The deblindingwas performed locally and by individuals who were not involved in the analysis.

Statistical methods

The maxima, medians, are reported for the metric target parameters.

The differences between the ARP and control groups were analyzed using the Wilcoxon rank-sum test. Due to the exploratory nature of the trial, all outcomes of statistical tests must be interpreted as generating hypotheses and not as proof. All statistical tests were performed at a significance level of α=0.05 (2-tailed) (Minitab®18). There was no adjustment for multiple testing. The power analysis and calculation of the sample size were carried out using the Proc Power feature of Minitab®18 For sample size calculation, a power of 80% and a 2-sided type 1 error of α=0.05 were assumed. For the post hoc power analysis, a 2-sided type 1 error of α=0.05 was assumed. All calculations were based on means and standard deviations.

RESULTS

All patients were treated according to the clinical protocol (Figure 6). Forty single root teeth from the mandible at 32 patients were extracted. Twenty tooth were assigned to the APR group as a result of randomization. Twenty tooth formed the control group and underwent extraction without further concomitant measures. The mean patient age was 55.3±8.9 years; age range, 35–68 years. There were no postoperative complications. All enrolled patients completed the trial. During the course of treatmentmembranes were left partially exposed after surgery. No signs of acute inflammation exudate or pain was detected. Plaque accumulation was observed on the exposed surfaces of the mrmbranes. After membrane retrival none epithelialized soft tissue was found in the area previously covered by the membranes. This tissue completely re-epithelialized clinically within 4 weeks after membrane removal. Nevertheless a slight but clearly distinguishable difference in color compared to the adjacent mucosa persisted. Clinically the whole keratinized gingiva was preserved.

The analysis revealed significantly less bone height resorption which was detected in the ARP group after three and six months. The median bone height reduction after three months was1.29±0.25 mm in the ARP group and 2.89±0.49 mm in the control group (P = 0.032). And the median bone height reduction after six months was1.78±0.32 mm in the ARP group and 3.93±0.51 mm in the control group (P = 0.041) .

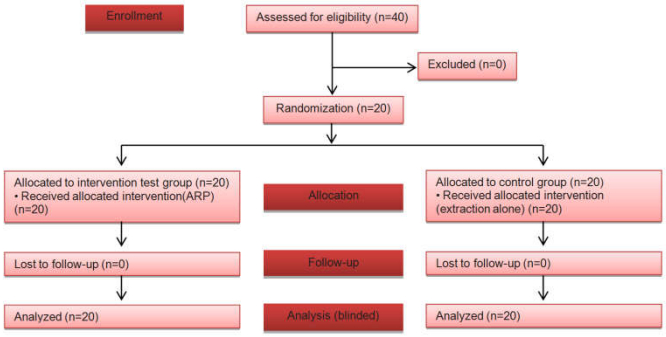

Figure 2 Follow diagram of this randomized trial comparing extraction alone to a ridge preserving procedure of alveolar bone after tooth extraction
APR: Alveolar ridge preservation.

No significant reduction in the bone height degeneration of the teeth was observed in the ARP group after three and six months (Table 1). However, the examination of the tooth regions highlighted a massive reduction of the bone height in the teeth in the control group after both three and six months, with a median value of2.89±0.49 and3.93±0.51 mmrespectively(ARP group: 1.29±0.25 mm and 1.78±0.32 mm) (Figure 3), (control: 1.35 mm, ARP: 1.10 mm).

Table 1 Bone degeneration after tooth extraction in the ARP group and control group, including the maxima, medians,

Parameter	Time	Group	Cases No.	Median	Standard Deviation	Max	Min	P Value
Bone height changes	Three months post surgery	APR	20	1.31	0.23	1.9	1	0.035
		Control	20	1.78	0.32	3.8	1.9	
	Six months post surgery	APR	20	1.98	0.35	2.7	1.3	0.046
		Control	20	3.93	0.51	4.6	2.9	

The distances are reported in millimeters (mm). The total sample size was 40 patients (20 ARP and 20 control),.
ARP: alveolar ridge preservation.

1. Statistically significant differences at $P<0.05$, Wilcoxon rank-sum test.

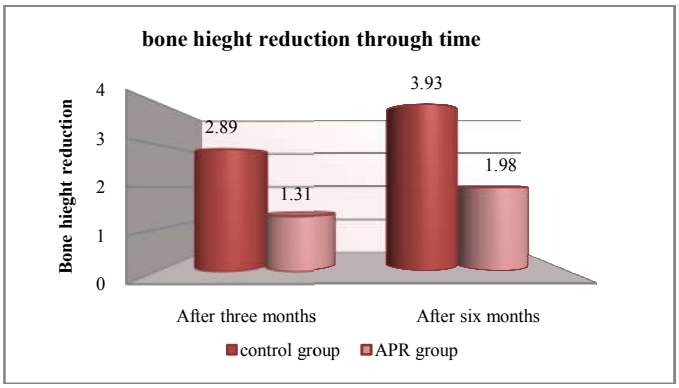

Figure 3 Significantly less bone degeneration was found along thealveolar ridge height in the ARP group (mm).

APR: Alveolar ridge preservation.

DISCUSSION

This trial was designed in such a way that post-extraction changes in the mandible alveolus were compared to a healing

process without external influences as a baseline. Moreover, a non-invasive procedure was implemented for data acquisition, which also permitted independent review and testing of the outcomes.

The outcomes in this trial revealed a significant difference in the alveolar bone reduction at three and six months post-surgery between alveoli treated with the use of d-PTFEmembrane and untreated alveoli. boneheight degeneration differed significantly between the control and ARP groups after three months (1.31±0.23 mm and 2.89±0.49 mmrespectively(P = 0.035). Andalso after six months (1.98±0.46 mm and 3.93±0.51 mmrespectively (P = 0.041).

Bone height reduction after tooth extraction appeared more pronounced on the CBCT images than in clinical measurements using periodontal probes or similar measurement devices. For example, the mean bone height degeneration in control patientswas measured as the difference between CBCT-based measurements before extraction and at 3 months post-extraction, has been reported as 5.36 mm for single-rooted teeth and 5.89 mm for multi-rooted teeth [24].

A further trial based on the analysis of CBCT images revealed comparable results: the mean reduction of boneheight 8 weeks after tooth extraction was 5.2 mm (range, 0.7–12.2) [2]. The magnitude of bone height loss was also confirmed in this trial. Conversely, a meta-analysis based primarily on clinical measurement outcomes reported buccal bone reductions of −1.1 to −3.5 mm in the test groups and −1.0 to −4.2 mm in the control groups [25].

The hypothesis that the application of the d-PTFEmembrane would lead to a reduction in bone degeneration after tooth extraction was therefore confirmed.

The power analysis calculated in this study showed that a sample size of 40 tooth at 35 patients, using the linear measurement method, would be needed to detect differences in clinically relevant bone height degeneration. The number of cases used in this study can therefore be regarded as sufficient.
Numerous clinical studies have used different clinical or radiological measurement methods in addition to diverse materials and surgical methods for ARP [5,8, 23]. Consequently, standardized measurement protocols in trial designs have been called for(?) [1]. The protocol used in this trial, which involved the measurement of alveolar changes after three and six months after surgery using CBCT, appears to be appropriate. A possible source of error with the use of CBCT data for bone modeling may be the detectability of incompletely mineralized bone. However, it was possible to demonstrate that marginal bone was visible in CBCT images with an accuracy of 0.6 mm, and that this measurement exhibited high reliability [26]. The ability to validate and reproduce the measurements must also be regarded as strengths of this method [10].

In the authors' opinion, methods involving digitalization and semi-automated software analysis offer significant benefits in terms of reproducibility, and they facilitate higher comparability than clinical measurement with probes. The method described in this study appears to offer lower rates of error and deviation due to measurement errors[27].

The choice of measurement time (T1 ,T2) and the condition of the healed alveolar bone have a significant effect on the assessment of the outcomes. It was expected that after 3months, bone healing would not be complete [3]. The 3 months time point was chosen in the present trial to detect the ability of early implantation after grafting the alveoli (6 months post extraction), which would allow patients to benefit from the potential advantages of this timing [10].

In addition, differences in surgical methods affect bone resorption outcomes. For example, even the choice to close the alveolus using primary wound closure or by covering the alveolus with a membrane has a significant effect on wound healing [28].

A further external factor is the type of defect, which further complicates comparability. Classifications into defined defect classes after tooth extraction (for example, according to the number and state of the alveolar walls or the defect size itself) would be useful [29]. The thickness of the alveolar walls could also have a major effect on healing and regeneration and/or the ARP procedures [4]. However, under clinical conditions, the ability to determine the extent of the defect before surgery is limited. In the same way, it is almost impossible to reproduce the assessment of the alveolus in the context of a clinical trial. A CBCT image taken before tooth extraction could supply this information, but such imaging is generally ruled out for ethical reasons and to minimize radiation exposure. In such cases, it would be suitable to use the relevant recommendations to improve trial quality for future research [30,31].

Currently, it must be assumed that ARP measures cannot entirely prevent the loss of bone tissue; however, it appears that appropriate measures can reduce it. Minimizing bone resorption requires further research, and there is a need for procedures that match patients' individual situations with materials that are appropriate to the indication. One of the main indications for ARP is the potential prevention of the need for additional interventions in the form of augmentations. In addition to preventing the risks and side effects of additional surgery, ARP might also lead to improvements in the cost-to-benefit ratio and patient comfort (reference).

present study demonstrates that the use of d-PTFEmembrane allowed for a significant regeneration of the volume of sockets following tooth extraction .Previous studies[18, 32, 33, 34] suggested that a significant amount of bone loss up to 40% of the alveolar height and 60% of alveolar with takes place after extraction if no steps are taken to preserve the existing bone record architecture the resulting facial soft tissue precision and precision of the interdental papilla May impair the aesthetic outcomes or render the placement of dental implants impossible.

A variety of Protocols of for the preservation of extraction sockets has been described previously such as the use of membranes grafting materials or combination of both although the use of grafting materials leads to a predictable positive outcomes the long time necessary for these materials to be replaced by Mature bone as a possible disadvantage[35, 33, 36].

ARP with GBR resulted in significantly less resorption in ridge height compared to unassisted socket healing, regardless of the type of membrane [37, 33]. Another option is the use of

expanded PTFE (e-PTFE) membranes. A drawback of this material is the high surface roughness which facilitates adhesion of bacteria. Thus a primary closure over the membrane needs to be achieved to avoid exposure to the oral environment and resulting bacterial colonization because of the resulting inflammation can impair the treatment outcomes [18, 38]. furthermore the removal of e-PTFE membrane often necessitates a second surgical procedure. It should be noted that in one study, three out of 10 cases, the exposed nonresorbable e-PTFE barrier had to be removed prematurely, highlighting the importance of sufficient soft tissue closure and timing of removal of the barrier[37]. The outcomes in these three cases were similar to the control sites. Where healing was uncompromised, a significant difference was found after 6 months in height changes in favour of the ARP group. Bioabsorbable membranes were made from different materials which can be used, however these require primary closure to avoid premature degeneration which is often not easily achievable when covering extraction sites. Here, there was a significant advantage of d-PTFEmembrane. The membrane is impenetrable for bacteria because of its surface characteristics.

Primary coverage over the membrane was not obtained in any case in this study. Irrespective of this fact positive treatment outcomes were observed in all cases and these outcomes corresponded largely to the ones observed in previous studies[18, 16, 32]. With the use of e-PTFE or bioabsorbable membranes as well as grafting materials. Because no primary coverage is necessary, there is no need for releasing incisions or additional freeing of the flap thereby facilitating the surgical procedure and enhancing the esthetic outcomes by not changing the mucogingival junction. Additionlly because of the comparatively smooth surface, d-PTFE membranes can usually be removed without an additional surgical procedure[39, 29].

In conclusion, the proposed hypothesis, according to which there would be a difference in bone reduction between alveoli treated with d-PTFEmaterial and untreated alveoli, can be accepted based on the outcomes of this trial. This hypothesis predicted improved bone preservation as a result of the application of the d-PTFEmembrane. Significantly less bone resorption was detected in the bone height of the ARP group. Therefore, the use of the d-PTFEmembranecan be recommended based on the available data.

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