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Original Article / *Özgün Araştırma*

Influence of a Biodegradable Synthetic Hydrogel Used as a Guided Bone Regeneration Membrane in Sinus Floor Augmentation

Sinüs Tabanı Ogmentasyonunda, Polietilen Glikol Hidrojel Membran Kullanımı ve Kollajen Membran ile Kıyaslanması

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Abstract

Objective: The purpose of this study is to compare the clinical, histological, and radiological aspects of the polyethylene glycol (PEG) hydrogel membrane and the standard collagen membrane in sinus floor augmentation procedures when the same bone filling material is used.

Methods: Fourteen patients (5 men and 9 women) were included in this prospective cohort study. Twenty sinus floor augmentation surgeries were randomly divided into two groups: the study group (n=10) and the control group (n=10). An anorganic bovine graft (Bio-Oss®, Geistlich Pharma AG, Switzerland) was used in all patients as the bone-filling material. As a protective membrane, a collagen membrane (Bio-Gide®, Geistlich Pharma AG, Switzerland) was used in the control group patients, as well as a PEG membrane (Membragel®, Institut Straumann AG, Switzerland) in the study group. After 6 months, the samples were collected during implant site preparation for histopathological evaluation.

Results: There were no statistically significant differences between the control and the study groups in the histological examination regarding the soft-to-hard tissue ratio. There was no statistically significant difference between the control and study groups in the resonance frequency analysis measurements at different times. No postoperative inflammation or exposure of the membrane was observed in any of the patients. The visual analogue scale scores measured at different times also showed no significant difference.

Conclusion: A PEG membrane can be used as an alternative to a collagen membrane as a barrier in sinus floor augmentation procedures.

Keywords: Sinus floor augmentation, bone substitutes, guided tissue regeneration, polyethylene glycol

Öz

Amaç: Sinüs tabanı ogmentasyonunda, benzer kemik doldurucu materyal kullanıldığında polietilen glikol (PEG) hidrojel membranın, standart kollajen membranla klinik, histolojik ve radyolojik olarak karşılaştırılmasıdır.

Yöntemler: Çalışmamızda 14 hastada, 20 sinüs tabanı ogmentasyonu operasyonu planlandı. 10 çalışma (n=10) ve 10 kontrol grubu (n=10) olmak üzere operasyonlar yapıldı. Operasyon sırasında tüm hastalara kemik doldurucu materyal olarak inorganik sığır grefti (Bio-Oss®, Geistlich Pharma AG, İsviçre), koruyucu membran olarak kontrol grubu hastalarına kollajen membran (Bio-Gide®, Geistlich Pharma Ag, İsviçre), çalışma grubu hastalarına ise PEG-membran (Membragel®, Institu Straumann AG, İsviçre) uygulandı. 1, 3 ve 7. günlerde hastalardan visual anolog skala skorları (VAS) alındı. Çalışma ve kontrol grubu hastalarından radyolojik değerlendirme için dental volümetrik tomografiler çekildi ve en az 6 ay sonra dental implantlar yerleştirildi. Dental implantlar yerleştirilirken implant yuvalarından alınan materyaller, histopatolojik olarak incelendi. İmplantların rezonans frekans analizleri (RFA) intraoperatif ve postoperatif 3 ay sonra olmak üzere iki defa yapıldı.

Bulgular: Histolojik inceleme sonuçlarına göre, çalışma ve kontrol grupları kıyaslandığında yumuşak doku/sert doku orantısı arasında ve farklı zamanlarda yapılan RFA ölçümleri arasında istatisksel olarak anlamlı bir fark bulunamadı. Çalışma ve kontrol grubundaki hiçbir hastada postoperatif enflamasyon saptanmadı ya da membran açığa çıkmadı. Farklı zamanlarda yapılan VAS skorları analizinde de anlamlı bir fark bulunamadı.

Sonuç: PEG-membranın, sinüs tabanı ogmentasyonunda kollajen membrana alternatif olarak tercih edilebilecek bir bariyer membran olduğu bulundu.

Anahtar Kelimeler: Sinüs tabanı ogmentasyonu, kemik greftleri, yönlendirilmiş doku rejenerasyonu, polietilen glikoller

INTRODUCTION

Maxillary sinus floor augmentation using the lateral window technique was first described by Tatum in the mid-1970s and was later described by Boyne and James in 1980 (1, 2) . In the current literature, there has been an increasing amount of studies published about this technique, and it is still the most frequently used method to enhance the alveolar bone height of the posterior maxilla prior to implant placement (3, 4).

Autogenous bone is widely considered the gold standard for grafting material. However, clinicians tried to find out some other solutions because of the donor site morbidity and increasing costs of autogenous bone grafting (5). Various bone substitutes, including allografts and xenografts, are often used to simplify the surgical procedure by reducing the need for bone harvesting ((6, 7).

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Studies have shown that using an anorganic bovine bone in sinus floor augmentation presented higher biocompatibility, low rates of resorption, and final replacement with vital host bone (8, 9).

Guided bone regeneration has been used for many years to treat minor alveolar bone defects (10, 11). In this method, barrier membranes are used to guide new bone formation and inhibit the soft tissue migration to the defect sites (12, 13).

Despite its long-term clinically successful outcomes, membrane usage has several disadvantages. Non-resorbable membranes that often require a second-stage surgery for removal have the risk of exposure and may cause severe cellular reactions (14, 15). Resorbable membranes, on the other hand, might be considered as a reliable alternative but have a more limited effect in protecting the marginal bone at its intended level (16). Several studies have shown that marginal bone is increased when a resorbable membrane is used with the osteoconductive support material that prevents barrier collapse (17, 18).

There is a various number of materials used, as a membrane might be produced from different synthetic or natural polymers. In most of the cases, resorbable collagen membranes are preferred (19). All membranes, currently in the market, are fabricated and standard in shape and form. On the other hand, most of the time, membranes do not stay in situ as placed. There is no technique to stabilize the membrane on the recipient site other than using fixation pins.

These restrictions on the use of collagen membranes have led to the need for different materials as membranes in GBR. Experimental studies have shown that a synthetic hydrogel made from polyethylene glycol (PEG) can be used for bone regeneration (20–22). A PEG hydrogel membrane has high biocompatibility and has been used in other medical disciplines as a spray-like adhesion barrier (23).

The limits of a PEG hydrogel material as a barrier membrane have been evaluated in many preclinical and clinical trials (20, 21, 23). The purpose of this study is to compare the clinical, histological, and radiological aspects of both the polyethylene glycol (PEG) hydrogel membranes and standard collagen membranes in sinus floor augmentation operations using the same bone filling material.

MATERIALS AND METHODS

Patient Selection

This study was carried out in the Oral and Maxillofacial Surgery Department, Bezmialem Foundation University, after the approval of the ethics committee with the number of B.30.2.BAV.0.05.05/252. Inclusion criteria were the following: having insufficient bone volume in the dental volumetric examination (DVT), asking for implant-supported prosthetic rehabilitation, and to voluntary undergo two-stage surgery. Medical or psychological conditions such as uncontrolled diabetes, head and neck radiotherapy, the use of bisphosphonate-derived drugs, sinus infection, poor oral hygiene, smoking, and alcohol or drug abuse were defined as exclusion criteria

All patients were informed about the treatment modality and the possible complications, and written informed consent was obtained. Clinical findings such as age, gender, oral hygiene, and existing sinus pathology were recorded. In the posterior maxilla, the residual crest height was measured in the DVT, before the operation at each implant region.

Surgical Procedure

All the patients underwent the same surgical technique, consisting of sinus floor augmentation via a lateral approach. The surgical procedures were performed under local anesthesia. The perioral region was flushed with a 10% povidone-iodine antiseptic solution and followed by rinsing the oral cavity for 1 minute with a 0.2% chlorhexidine gluconate solution. Local anesthesia was applied using a local anesthetic solution (Ultracaine®, Hoechst Marion Roussel) containing 40 mg articaine hydrochloride and 0.012 mg epinephrine hydrochloride/ml with a blockade of the posterior superior alveolar nerve and using the palatal infiltrative method.

The incision line began at the distal end of the canine, extended at the palatal side of the alveolar crest, finished at the tuber maxilla in the horizontal direction, and terminated with a vertical incision. The full-thickness mucoperiosteal flap, including the zygomatic arch in superior direction, was elevated.

The window size and position were determined according to anatomical variations. An osteotomy was performed in the anterior wall of the maxilla using a piezoelectric ultrasonic device (Piezosurgery®, Mectron Dental, Italy). The maxillary sinus was observed from the boundaries of the created window. The sinus membrane was gently elevated at the mesial, distal, and inferior borders with the appropriate tips of the piezoelectric ultrasonic device or with the appropriate hand tools. Perforations were controlled having the patient breathe through the nasal pathway to monitor the membrane mobility.

The space obtained after the elevation of the sinus mucosa was filled with a bovine bone graft (Bio-Oss®, Geistlich Pharma AG, Switzerland). The reconstructed site was covered with either a PEG hydrogel membrane (Membragel, Institut Straumann AG, Basel, Switzerland) in the test group, or with a collagen membrane (Bio-Gide®, Geistlich Pharma, Wolhusen, Switzerland) in the control group. The full-thickness flap was then closed to the primary incisions and sutured with 4/0 vicryl (Figure 1, 2). Patients were applied 1000 mg amoxicillin and clavulanic acid twice daily for 5 days (Augmentin®, Glaxo Smith Kline), 50 mg diclofenac (Cataflam®, Novartis), and chlorhexidine (Klorhex®, Drogsan) postoperatively. The sutures were removed after 1 week. All patients were followed up clinically for postoperative complications

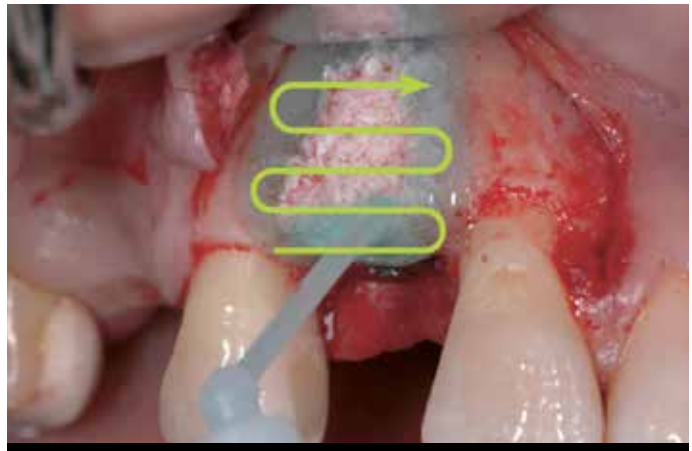

Figure 1. Application of the PEG membrane.

including infection, exposure. or maxillary sinusitis. The visual analog scale (VAS) scores were analyzed on Day 1, Day 3, and Day 7 postoperatively. After 6 months, a panoramic radiograph was obtained to assess graft stabilization and the consolidation of the residual bone with the graft.

Five months after surgery, all patients received at least two implants on the grafted side. During the implant surgery, block bone specimens were obtained using a 2.5 mm diameter trephine as an entry bur. The samples were fixed in a 4% formaldehyde solution and sent to the Trakya University Faculty of Medicine, Department of Pathology, for histological evaluation.

The biopsy specimens were retained in a 20% formic acid solution for 48 hours to remove the calcium present in the bone following a 24-hour 10% buffered formaldehyde fixation. After 30 minutes of exposure to flowing water, the specimen was cleaned from the acid and subjected to an overnight alcohol bath. Following the paraffin embedding, 5-µm sections obtained from the tissues were stained with a hematoxylin and eosin stain and evaluated under a light microscope (Olympus BX51).

The augmented area was evaluated histomorphologically by three aspects:

a) New bone formation (i.e., the ratio of new bone formation to the whole area)
b) Presence of graft particles (i.e., the ratio of t the graft particles to the whole area)
c) Soft tissue presence (i.e., the ratio of the soft tissue to the whole area)

A resonance frequency analysis (RFA) was performed twice—intraoperatively and 3 months postoperatively—using the Osstell™ Mentor (Integration Diagnostics, Sweden) instrument, and the obtained implant stability outcomes (ISQ) were recorded as the 1st control and the 2nd control values. The RFA measurements were performed for each implant in the buccal and palatal directions, and the arithmetic average of the two values was recorded as the ISQ value.

Statistical Analysis

Statistical analyses were performed using the SPSS 15.0 program. In addition to the descriptive statistical methods (mean, standard deviation), the following tests were used to evaluate the data: the Mann–Whitney U test was used to compare the two groups, the Wilcoxon test was used to assess repeated measurements, the chi-squared test to compare the qualitative data, and simple correlation and partial correlation analysis were used to determine the interrelationships of the variables. The results were evaluated as $p<0.05$.

RESULTS

Fourteen systemically healthy patients (9 men and 5 women) aged between 34 and 71 years were included in this study. The mean age was 51.4±9.2 years (range: 38 to 65 years). The time between the maxillary sinus floor augmentation (MSFA) procedure and the time of implantation ranged between 6 and 14 months. The mean residual crest height was measured at between 2.10 mm and 4.25 mm on the dental volumetric radiographs. The mean residual crest height in the control group was 3.53±0.68 mm, and the mean residual crest height in the study group was 3.31±0.58 mm (between 2.10 mm and 4.00 mm).

During the msfa operations, a sinus membrane perforation occurred only in one case, which was not large enough to cancel the surgery. The perforation was sealed with a collagen membrane (Bio-Gide®, Geistlich Pharma AG, Switzerland). A total of 41 implants were placed in the msfa areas of all patients. All patients completed the healing period of the sinus augmentation procedure without complications. No infections occurred in any of the patients, and all the implants were osseointegrated.

In the histological evaluation of tissue samples taken from the msfa regions, the connective tissue, fat tissue, graft, and bone tissue were observed and examined (Figures 3, 4, 5). There were no statistically significant differences in the comparisons of the connective tissue and bone tissue ratios in the control and study groups ($p> 0.05$) (Table 1).

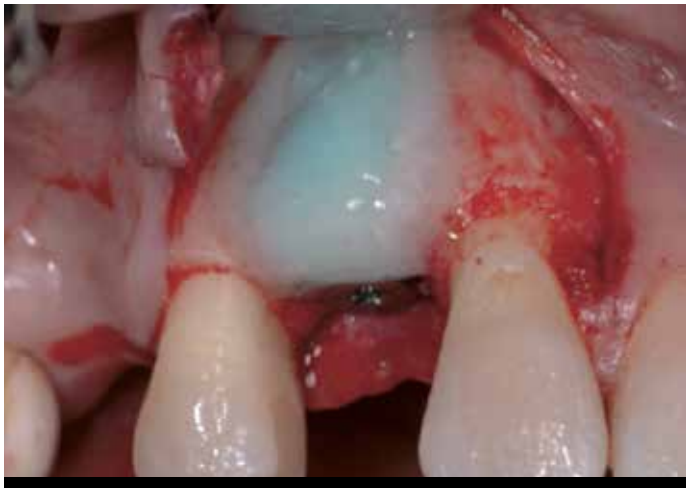

Figure 2. The newly applied PEG membrane.

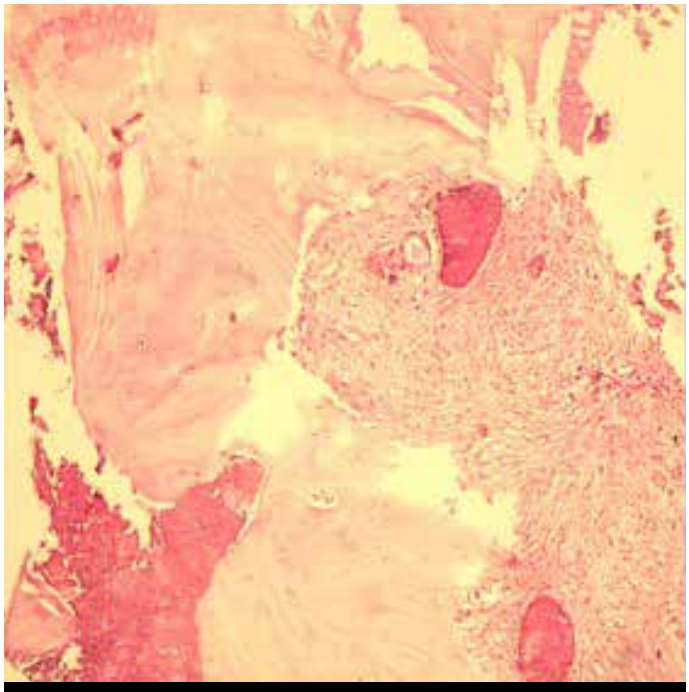

Figure 3. The histologic section shows lamellar bone tissue and connective tissue with bone tissue. From the presence of the osseointegrated osteoblast cells of the connective tissue, it appears the bone is still being produced. Test Group.

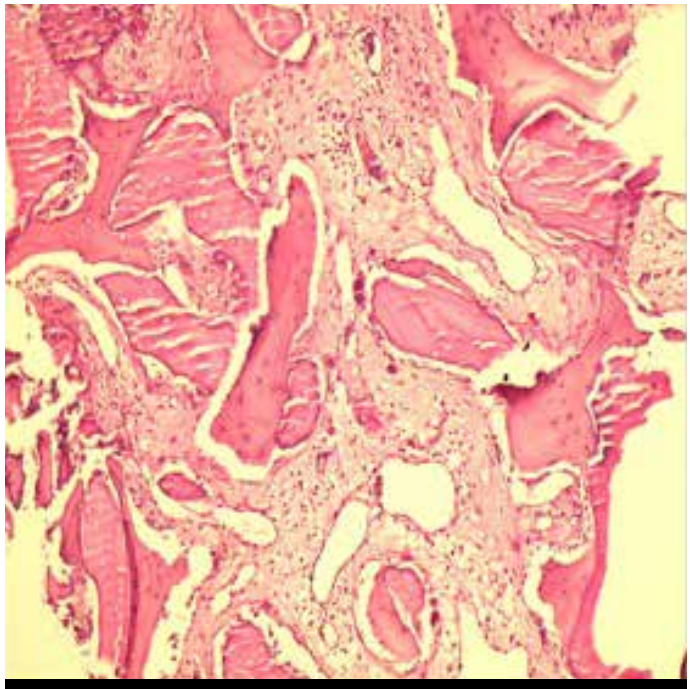

Figure 4. Together with connective tissue cells, there are some chronic inflammatory connective tissue cells. These are accompanied by connective tissue around bone trabeculae and some bone build-up. Test Group.

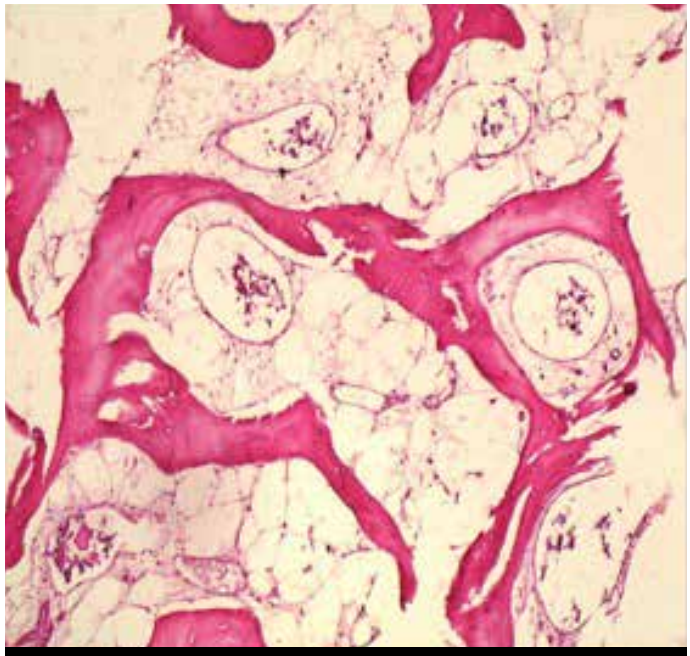

Figure 5. The histological section shows no connective tissue. Control Group.

There were no statistically significant differences between the control and study groups when the VAS scores were compared on Day 1, Day 3, and Day 7 (p>0.05) (Table 2).

There were no statistically significant differences between the first and second measures of the ISQ values of the control and study groups (p> 0.05) (Table 3).

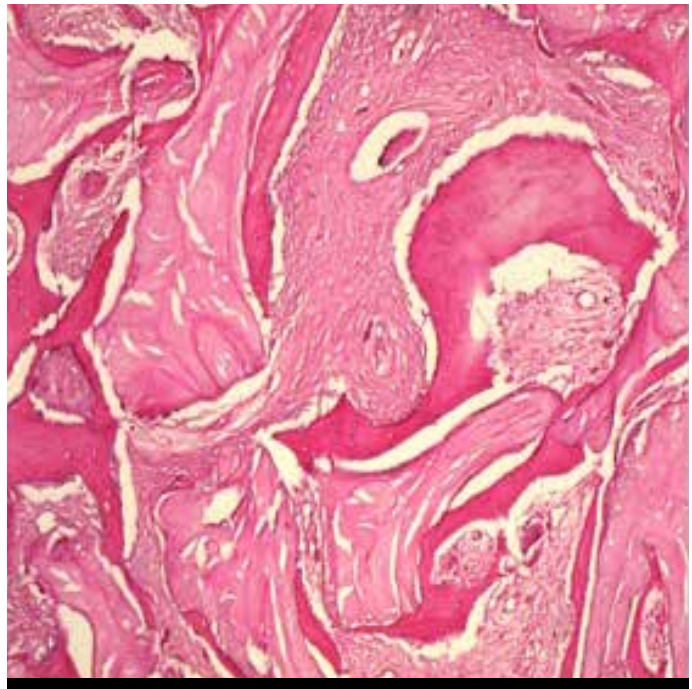

Figure 6. The grafted bone, along with the connective tissue cells developed around the bone marrow, has resorbed graft materials. There is no connective tissue at all in a field of 2 mm; there are connective tissue bruises all over the field, accompanied by a small number of inflammatory cells. Test Group.

Table 1. Distribution of all tissue samples in the control and study groups according to the histomorphometric evaluation criteria

Tissue Sample	Control Group n=10	Test Group n=10	MWU	p
Connective tissue	%51.61±42.87	%21.42±26.03	25.00	0.093
Bone tissue	%48.39±42.87	%78.58±26.03	25.00	0.093

MWU: Mann–Whitney U test

Table 2. Comparison of VAS scores in the control and study groups

VAS Score	Control Group n=10	Test Group n=10	MWU	p
VAS1	2.80±1.81	2.70±1.42	49.00	0.938
VAS3	4.00±2.79	4.70±2.91	43.50	0.618
VAS7	0.70±0.95	1.30±1.25	36.00	0.250

MWU: Mann–Whitney U test; VAS: Visual analog scale

In the control group, there was a statistically insignificant correlation between the residual crest height and the connective tissue ratio (r=–0.273, p>0.05). Also, in the control group, a positive but not statistically significant correlation was found between the residual crest height and the ratio of bone tissue (r=0.273, p>0.05). In the control group, there was no significant correlation between the residual crest height and the ratio of connective tissue and bone tissue (Table 4).

In the study group, there was a statistically insignificant negative correlation between the residual crest height and the con-

Table 3. ISQ values related to measurement times

ISQ	Control Group n=10	Test Group n=10	MWU	p
1st Control	69.60±7.66	69.12±11.01	46.00	0.762
2nd Control	78.28±3.37	80.57±2.69	23.50	0.076
In-Group, 1st and 2nd Control Differences				
Z	−2.670	−2.803		
p	0.008	0.005		

MWU: Mann–Whitney U test; ISQ: Implant stability quotient

Table 4. Relation to the histomorphometric evaluation criteria of the residual crest heights in the control and study groups

Control Group		Residual Bone Height	Connective Tissue Ratio	Bone Tissue Ratio
Residual bone height	r		−0.273	0.273
	p		0.445	0.445
Connective tissue ratio	r	−0.273		
	p	0.445		
Bone tissue ratio	r	0.273		
	p	0.445		
Test Group		**Residual Bone Height**	**Connective Tissue Ratio**	**Bone Tissue Ratio**
Residual bone height	r		−0.136	0.136
	p		0.728	0.728
Connective tissue ratio	r	−0.136		
	p	0.728		
Bone tissue ratio	r	0.136		
	p	0.728		

nective tissue ratio (r=−0.136, p> 0.05). Also, in the study group, a positive but not statistically significant correlation was found between the residual crest height and bone tissue ratio (r=0.136, p>0.05). In the study group, no significant relationship between the residual crest height and the bone and bone tissue ratios was found (Table 4).

In the control group, there was a statistically insignificant positive correlation (r=0.011, p>0.05) between the connective tissue ratio and the waiting period. Also, in the control group, a negative correlation (r=−0.011, p> 0.05) was found between the bone tissue and the waiting period. In the control group, there was no significant relationship between the connective and bone tissue growth and the waiting times (Table 5).

Table 5. Relation to the histomorphometric evaluation criteria of the waiting period in the control and study groups

Control Group		Connective Tissue Ratio	Bone Tissue Ratio	Waiting Time
Connective tissue	r			0.011
	p			0.976
Bone tissue	r			−0.011
	p			0.976
Waiting time	r	0.011	−0.011	
	p	0.976	0.976	
Test Group		**Connective Tissue Ratio**	**Bone Tissue Ratio**	**Waiting Time**
Connective tissue	r			0.218
	p			0.573
Bone tissue	r			−0.218
	p			0.573
Waiting time	r	0.218	−0.218	
	p	0.573	0.573	

In the study group, a positive but not statistically significant correlation (r=0.218, p>0.05) was determined between the connective tissue ratio and the waiting period. Also, in the study group, a negative correlation (r=−0.218, p> 0.05) was found between the bone tissue and the waiting period. There was no significant relationship between the rates of connective tissue and bone tissue growth and the waiting times in the study group (Table 5).

A statistically insignificant correlation was found between the residual crest height and the connective tissue ratio (r=−0.120, p> 0.05). Similarly, a statistically insignificant correlation was found between the residual crest height and the connective tissue ratio (r=−0.220, p>0.05) when the type of membrane used (in the control and variable groups) was controlled (i.e., kept constant). The correlation coefficients calculated at both correlations are very close to each other and are not significant. The correlation coefficient and the lack of change in the level of significance indicate that the membrane type doesn't affect the relationship between the residual crest height and connective tissue growth (Table 6).

A statistically insignificant correlation was found between the residual crest height and the bone tissue ratio (r=0.120, p>0.05). Similarly, a statistically insignificant correlation was found between the residual crest height and the bone tissue ratio (r=0.220, p>0.05) when the type of membrane used (in the control and variable groups) was controlled (i.e., kept constant). The correlation coefficients calculated at both correlations are very close to each other and are not significant. The correlation coefficient and the lack of change in the level of significance indicate that the membrane type used does not affect the relationship between the residual crest height and the bone tissue (Table 6).

Table 6. Relation of the residual crest heights to the histomorphometric evaluation criteria

		Residual Bone Height	Connective Tissue Ratio	Bone Tissue Ratio
Residual bone height	r		−0.120	0.120
	p		0.626	0.626
	r (partial)		−0.220	0.220
	p		0.380	0.380
Connective tissue ratio	r	−0.120		
	p	0.626		
	r (partial)	−0.220		
	p	0.380		
Bone tissue ratio	r	0.120		
	p	0.626		
	r (partial)	0.220		
	p	0.380		

DISCUSSION

Recent advances in the field of implant dentistry have provided clinicians with various treatment options to facilitate the placement of dental implants in patients with vertical bone deficiencies in the posterior maxilla. Sinus augmentation has evolved into a predictable surgical procedure to increase the existing height with bone of sufficient quality, allowing for the successful placement of dental implants (24, 25).

The subantral bone height is usually used to determine whether implants can be inserted simultaneously with the elevation of the sinus floor, or whether a staged approach should be preferred. Simultaneous implant placement can only be performed if the implant's primary stability can be achieved. However, this decision may also be affected by other factors, such as bone density (26).

Variables such as the patient's age, the vascularization of the operation site, the volume of the graft site, the shape and surface characteristics of the implant, the residual bone height, the residual bone quality, the duration of the postoperative healing, the type of graft material used, and the membrane closure of the osteotomy site may affect the success of the implant site.

Radiographic imaging is necessary for determining the anatomical complexity and type of implant treatment required for the optimal treatment approach. DVT is especially necessary before treatment planning of the atrophic maxillary posterior region. DVT provides a detailed diagnostic view of the upper jaw that cannot be achieved with only panoramic radiography (27). The disadvantages of exposure to radiation can be ignored (27, 28). Preoperative tomographic scanning is recommended for evaluating the anatomy of the maxillary sinus (29). DVT, preoperative panoramic radiographs, and postoperative panoramic radiographs were taken from all the patients for preoperative evaluation, to assess treatment course and the measurement of the areas where implants are to be placed. The OsiriX 64-bit DICOM Viewer program was used to measure the residual crest height.

The literature reports that the residual crest height is a factor affecting implant success (30). In our study, cases with close residual bone height were treated using the same surgical protocol (31).

Based on a statistical analysis, the lack of change in the correlation coefficient and significance level indicates that the relationship between the residual crest height of the membrane used and the ISQ 1 control values do not affect the correlation. Although there is no significant change in the correlation coefficient, the change in the level of significance indicates that the membrane type used influences the relationship between the residual crest height and the ISQ 2 control value. Considering this, there's only a weak significance between the residual crest height and the ISQ 2 control value.

A precise understanding of the healing process and a precise determination of the density and stability of the newly formed bone is only possible using histological and histomorphometric analyses (32, 33). Examining the biopsies taken from the augmentation region with histological and histomorphometric techniques determines suitability by allowing observation of the integration and resorption of the used material (34). The use of the trephine burs to perform biopsy is safe, and the morbidity is low. The amount of bone taken with the trephine burs is sufficient for histological and histomorphometric studies (35). In this study, biopsy specimens were taken from the prepared sockets of the implant beds with a 2.5 mm diameter trephine bur.

It is recommended that the biopsies should be the same length and diameter as the implant. Although it is possible that biopsies taken at the same diameter as the implant may reduce the primary stability, in some cases, the residual sinus floor may prevent obtaining adequate graft material (36). For these reasons, the appropriate amount of biopsy material necessary for a full histomorphometric analysis could not be obtained. However, based on earlier published literature, the number of biopsies obtained for the study and control groups was considered appropriate for comparison (37–39)

In many clinical practice cases, the use of collagen membranes for guided bone regeneration has become a standard procedure (19, 40, 41). These membranes are mostly fabricated. As a result, the membrane must be adhered to the defect in an appropriate way. The presence of a synthetic and resorbable membrane that is intra-operatively prepared and can be easily applied to the defect would help the procedure of guided tissue regeneration.

Experimental studies have shown that hydrogels produced from PEG can be used for bone regeneration (41, 42). PEG is highly biocompatible. It is presently approved for several pharmaceutical applications and medical devices (e.g., as a sprayable adhesion barrier) (23, 43). Several preclinical studies examining PEG's use as a barrier membrane in directed tissue regeneration have been performed with animal models (20, 22). In their 2009 clinical trial, Jung et al. reported that PEG could be used as an alternative to collagen membrane in the bone defects around dental implants (21).

In our study, a PEG hydrogel membrane (Membragel®, Institut Straumann AG, Switzerland) was used as a protective barrier in the test group, and a collagen membrane (Bio-Gide®, Geistlich Pharma AG, Switzerland)

was used in the control group. In our study, there were no statistically significant differences between the control and study groups in the histological and histomorphometric examinations of the biopsies comparing the ratio of connective tissue ($p>0.05$). Additionally, there were no significant differences in the bone tissue ratio ($p> 0.05$). According to these results, there were no differences in the comparison of the ratio of bone and connective tissue in the histological evaluator light of the two different membranes used in the study and control groups. None of the membranes used in any of the cases were exposed.

The stabilization of the implant might be classified as primary and secondary. Primary implant stabilization is achieved immediately after the implant placement. Preventing the micromovement of the implant stimulates the growth of fibrous tissue and has a positive effect on osseointegration (44). Primary implant stabilization depends on the surgical technique used, the geometry of the implant (length, diameter, and type), and the amount and density of the local bone (45). In this study, parameters such as the surgical technique used, the implant geometry and surface characteristics, and the amount of local bone were kept constant. Initial ISQ values of the implants applied in the control group were measured as 69.60±7.66. Initial ISQ values of the implants placed in the study group were measured as 69.12±11.01 on average. These results indicated that all implants had adequate primer stabilization values (45, 46).

A complex healing mechanism, involving revascularization and combination, occurs in the graft-implant space. The RFA technique precisely assesses the changes in implant stabilization (46–48). Thus, it is possible to evaluate the stabilization of the implants placed in the graft. In this study, no significant differences were found between the first and second ISQ measures of the study and control groups.

It is difficult to make patients to define their pain, as every individual experiences pain differently. VAS is used to translate some values that are not digitally measured (49, 50). In our study, VAS scores were taken from patients on Days 1, 3, and 7 and recorded. There were no statistically significant differences between the study and control groups, and it was concluded that the membrane used did not adversely affect the postoperative comfort of the patient.

CONCLUSION

Guided tissue regeneration is a procedure that is often used for the treatment of limited-sized alveolar defects in the jawbone, and it is based on the principle of preventing migration into soft tissue grafting. There are numerous studies that reported the usage of collagen membranes with successful outcomes. These membranes are of a standard shape and size, and they sometimes require fixation during their application.

Compared to collagen membranes, PEG hydrogel membranes are easy to use, as they have a short application time, and fixation is not required. In the histological examinations, no statistically significant differences were found in the soft tissue and the hard tissue ratio between the PEG hydrogel membrane and the collagen membrane. There are also no significant differences in the RFA measurements performed at different times during the study.

None of the patients in the study and control groups had post-operative inflammation or problems with clearance of the membrane. A significant difference in the analysis of VAS scores performed at different times showed that the postoperative comfort of the patients was not affected by the membrane used.

This study has determined that, in maxillary sinus floor augmentation procedures, PEG hydrogel membranes may be used as an alternative material to collagen membranes.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Bezmialem Foundation University Clinical Research Ethics Committee.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author contributions: Concept – Y.Ö., F.B.; Design - Y.Ö., F.B.; Supervision - Y.Ö.; Y.Ö., F.B.; Materials - Y.Ö., F.B., G.G.; Data Collection and/or Processing - Y.Ö., F.B., G.G.; Analysis and/or Interpretation - Y.Ö., F.B., G.G.; Literature Search - Y.Ö., F.B., G.G.; Writing - Y.Ö., F.B., G.G.; Critical Reviews - Y.Ö.

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