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### Assessment of Modified Polycaprolactone Membrane in Horizontal Ridge Augmentation of Atrophic Ridge

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#### **KEYWORDS**

Bone Resorption, GTR, Polycaprolactone, Ridge Augmentation, Atrophic Ridge.

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#### **ABSTRACT**

Aim : The aim of the study was to assess the modified polycaprolactone resorbable membrane in horizontal ridge augmentation of atrophic ridge. Subjects and Methods: Twenty Patients with alveolar bone resorption in the anterior maxilla that require alveolar ridge augmentation to allow rehabilitation with fixed implant-supported prosthesis were included in this study. Patients were divided randomly into two main groups; Group (A) to whom collagen resorbable membrane has been used. Group (B) to whom modified (PCL) resorbable membrane has been used. Results: In the present study, At 1 week, after 1 as well as 3 months; there was no statistically significant difference between Local infections, wound healing, and membrane exposures in the two groups. Immediately; there was no statistically significant difference between bone density measurements in the two groups. After 6 months, group (B)showed statistically significant higher mean bone density and ridge width than group(A) due to the flexibility present in the nature of the product used in group (B) that was not available in the product used in group (A). Conclusion: PCL has been introduced as candidate materials for bioactive GTR membrane due to its biocompatibility and simple fabrication procedure. PCL-membrane promote tissue formation.

#### INTRODUCTION

The placement of dental implants is a well-established treatment option to replace lost teeth, allowing the restoration of chewing, speech, aesthetics and functions .The long-term success of dental implants depends largely on the degree of osseointegration in a sufficient and healthy bone .Bone volume is often reduced due to prolonged time after tooth loss before implant placement, or due to periodontitis or previous traumatic extraction. <sup>(1-7)</sup>

The loss of horizontal bone volume entails great challenges for the placement of dental implants due to surgical difficulties and anatomical limitations .This lack of sufficient bone volume if not resolved eventually turns out to be detrimental to the final outcome of the treatment with respect to the success and survival.<sup>(2)</sup>

Bone augmentation techniques are done to achieve proper bone quality and quantity for implant placement which may be carried out using various materials and techniques. <sup>(1,5)</sup> The development of guided bone regeneration (GBR) as one of bone augmentation techniques has substantially influenced the possibilities for using implants. The use of bone augmentation procedures has extended the use of endosseous implants to jaw bone areas with insufficient bone volume. <sup>(1-8)</sup> Guided bone regeneration works on the principle of compartmentalization, allowing osteoblasts to populate the wound site before epithelial and connective tissue cells, thus regenerating bone. <sup>(9-12)</sup>

The primary role of the membranes in GBR is to be: soft tissue barrier and maintain the space. For this purpose, two categories of membranes (resorbable and non resorbable) may be used. The non resorbable membranes have the disadvantages of necessary second surgery to remove it and techniquesensitive approach. While resorbable membranes have the advantages of no need for second stage surgery to remove the membrane, decrease in patient morbidity, simplified surgical procedure and lower rate of exposure. The materials used for the fabrication of resorbable membranes are natural, such as collagen, or synthetic polymers, like aliphatic polyesters. The collagen membrane has the disadvantages of the uncontrolled duration of the barrier function, the lack of stiffness of the membrane to prevent its collapse (13)

Polycaprolactone (PCL) has been introduced as a candidate biomaterial for tissue regeneration. It has many properties that meet the criteria for the GTR membrane. For example, it exhibits biocompatibility properties and is not toxic. (14) It has been extensively researched as scaffolding material for the application of tissue engineering. <sup>(15, 16)</sup> In addition, it has been approved for clinical application, for example, suture materials, confirming biocompatibility and safety in clinical use. In addition, physical characteristics (for example, resistance and degradability) could be easily manipulated. In addition,

precise control of the membrane architecture could simply be manufactured. PCL is also less likely to induce an immune reaction. Together, it can involve the potential use of PCL as a GTR membrane based material. <sup>(15, 16)</sup> In the present study, the validity of using modified PCL as a resorbable membrane in increasing horizontal crest could be of great importance in the GBR technique.

#### SUBJECTS AND METHODS

Twenty Patients with alveolar bone resorption in the anterior maxilla that require alveolar ridge augmentation to allow rehabilitation with fixed implantsupported prosthesis were included in this study. The patients were selected from those attending outpatient clinic of Oral and Maxillofacial Surgery Department, Faculty of Dental Medicine, Al-Azhar University. Patients were divided randomly into two main groups; ten patients in each; A (control) ten patients and B (test) ten patients. Group (A) to whom collagen resorbable membrane has been used. Group (B) to whom modified (PCL) resorbable membrane has been used. Inclusion criteria: 1. Patients suffering from loss of teeth with deficient alveolar ridge less than or equal to 4mm in buccolingual dimension. 2. Patients with good oral hygiene. 3. Patients with (20-35) years old. Exclusion criteria: 1. Patients with uncontrolled systemic disease which affect bone healing.\_2. Presence of any pathology in the site of operation. 3. Heavy smokers. 4. Treatment with lethal radiation to the head and neck area within the past 12 months.

#### Evaluation

**Clinical Evaluation:** 1) Absence of infection. 2) Absence of graft exposure. 3) Absence of pain or any subjective sensation. 4) Absence of membrane exposure.

**Radiographic Evaluation:** By using cone beam computed tomography (CBCT) software, the change in density of the graft was calculated in Hounsfield units (HU). Ridge width also evaluated.



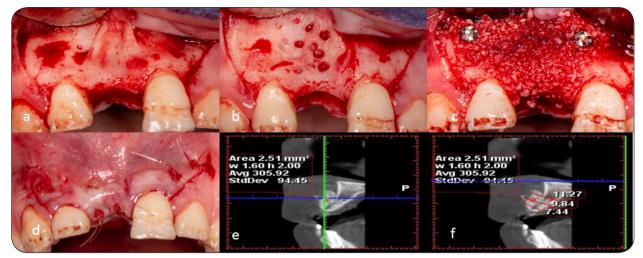


Fig. (1) a; flap design, b; bone decortication, c; graft and membrane in place, d; flap closure, e; width of ridge immediately after surgery group, f; bone density of ridge immediately after surgery group.

#### RESULTS

Table (1): showed the following

- Twenty patients ranged in age between 18-34 years. The mean age of group A was 25.70 ± 6.36 years while the mean age of Group B was 25.80 ± 4.73 years. There was no statistically significant difference between the two groups regarding to the mean of age.
- Group A had 7 males and 3 females, while
  Group B had 8 males and 2 females. There was no statistically significant difference between

gender distributions in the two groups.

- At 1 week, after 1 as well as 3 months; there was no statistically significant difference between Local infections in the two groups.
- At 1 week, after 1 as well as 3 months; there was no statistically significant difference between wound healing in the two groups.
- At 1 week, after 1 as well as 3 months; there was no statistically significant difference between membrane exposures in the two groups.

**Table (1):** Comparison between the two groups according to demographic data, Local infection, wound healing, and Membrane exposure

Groups	Group A (n=10)		Group B (n=10)		Test of sig.	р
	No.	%	No.	%		
Gender						
Male	7	70.0	8	80.0	χ2=	1.000
Female	3	30.0	2	20.0	0.267	
Age						
Mean ± SD.	25.70 ± 6.36		$25.80 \pm 4.73$		t=0.040	0.969
Local infection						
1 week						
Negative	8	80.0	9	90.0	0.392	1.000
Positive	2	20.0	1	10.0	0.392	

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Groups	Group A (n=10)		Group B (n=10)		Test of sig.		р
	No.	%	No.	%	5		
1 months							
Negative	10	100.0	10	100.0			_
Positive	0	0.0	0	0.0			
3 months							
Negative	10	100.0	10	100.0			_
Positive	0	0.0	0	0.0			
wound healing							
1 week							
Fair	2	20.0	1	10.	0.392		1.000
Good	8	80.0	9	90.			
1 months							
Fair	0	0.0	0	0.0			
Good	10	100.0	10	100	0.0	-	_
3 months							
Fair	0	0.0	0	0.0 - 100.0 -			_
Good	10	100.0	10				
Membrane exposure							
1 week							
Negative	10	100.0	10	100.0			_
Positive	0	0.0	0	0.0			
1 months							
Negative	10	100.0	10	100.0			_
Positive	0	0.0	0	0.0			
3 months							
Negative	10	100.0	10	100.0			_
Positive	0	0.0	0	0.0			

*c*<sup>2</sup>: *Chi square test* 

*p*: *p* value for comparison between the two groups

Table (2): show the following:

- Immediately; there was no statistically significant difference between bone density measurements in the two groups. After 6 months, Group B showed statistically significantly higher mean bone density than Group A.
- Preoperative and immediately post-operative; there was no statistically significant difference between ridge width measurements in the two groups. After 6 months, group (B) showed statistically significantly higher mean ridge width than group (A).



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	Group A (n=10)		Group B (n=10)		t	р
	Mean	±SD	Mean	±SD		
Bone density						
Immediately	577.1	45.41	618.0	43.01	2.068	0.053
6 months	740.2	27.26	817.0	34.17	5.557*	<0.001*
Bone width						
preoperative	3.40	0.40	3.34	0.66	0.226	0.824
Immediately	9.88	0.68	10.10	0.91	0.625	0.540
6 months	7.27	0.82	8.95	0.85	4.548*	<0.001*

Table (2): Comparison between the two studied groups according to Bone density and ridge width

t: Student t-test

*p*: *p* value for comparison between the two groups

\*: Statistically significant at  $p \le 0.05$ 

#### DISCUSSION

In the present study, At 1 Week, after 1 as well as 3 months; there was no statistically significant difference between Local infections, wound healing, and membrane exposures in the two groups. Immediately; there was no statistically significant difference between bone density measurements in the two groups. On the other hand after 6 months, PCL group showed statistically significant higher mean bone density than Collagen group. After 6 months, PCL group showed statistically significant higher mean ridge width gain than Collagen group. For explanation of the results of the present study for difference in bone density and the ridge width; the fixation of the modified pcl membrane added more compaction to the graft particles due to the flexible nature of the product while the collagen membrane added no significant value in this point. The use of a mesh in bone regeneration is of great importance, and the membrane, in fact, acts as a physical barrier that prevents the migration of epithelial cells and fibroblasts into the defect. This allows the osteoprogenitor cells to reach the site and recreate new bone. There are very few studies in the literature that relate the pore size on fibrous tissue ingrowth into porous

barrier membranes and the consequent regeneration obtained. Salvatore et al. <sup>(17)</sup> examined the soft tissue response to polyurethane sponges in six pore sizes highlighting how reducing the pore size accelerates the growth of collagen and vascular tissue.

Chvapil et al. (18) suggested that pores in excess of 100  $\mu$ m are required for the rapid penetration of highly vascular connective tissue, and small pores tend to become filled with more avascular tissue. A similar result was obtained by Taylor and Smith<sup>(19)</sup> who tested 2 types of porous methyl methacrylate implants, and they found that small pore size was inadequate for penetration of capillaries. Gutta et al. (20) analyzed three different pore sized meshes, and compared with controls without the mesh, they showed how macroporous membranes facilitated greater bone regeneration compared with microporous and resorbable membranes. Furthermore, macroporous mesh also prevented significant soft tissue ingrowth compared with other types of meshes. In another study, Ari et al. (21) assessed two important properties of biomaterial: the pore size and hydrophobicity. As we said, the size of the pores can induce the formation of new blood vessels and improves the adhesion of progenitor cells to the re-

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generation material. Similarly, the degree of hydrophobicity of the material conditions cell adhesion and the speed of regenerative processes.

The introduction of non resorbable membranes has drastically changed the surgical techniques, increasing the regenerative capacity and improving the results of surgery. (22) The use of polycaprolactone mesh allows us to provide a shape and to maintain space between the membrane and the defect. Moreover, the presence of the pores permits to maintain a blood support both to the mucosa and to the bone during the regeneration phase, the presence of pores, in fact, facilitates metabolic processes and tissue nutrition. PCL is a practicable option for many applications in tissue engineering approaches. PCL has been approved by the Food and Drug Administration (FDA) for several medical applications, for example, suture materials and subdermal contraceptive implants. It has been applied as a beneficial biomaterial for drug delivery devices. The drug-releasing property is able to be controlled. Thus, the biological activity could be lengthened. For example, PCL was employed as wound-dressing materials, which released chemical antiseptic agent. (23-25)

PCL has been introduced as root canal-filling materials. It was noted that PCL-filled root canal gave a predictable seal in an aqueous environment. PCL is also employed as materials for bone tissue-engineering scaffolds that could be used for bone augmentation. Furthermore, PCL composites are recognized for its significant uses in tissueengineering scaffolds in order to regenerate bone, ligament, cartilage, skin, nerve and vascular tissues. (26-29) PCL-based biomaterials have demonstrated the osteoconductive properties as they support various cell proliferations and differentiations, including bone marrow-derived mesenchymal stem cells, dental pulp stem cells, and adipose- derived mesenchymal stem cells in PCL scaffold which was confirmed. Further, PCL implantation in murine calvarial defect model does not significantly increase the total IgG levels as compared with sham surgery

group, demonstrating the immune compatibility of PCL-based materials.<sup>(30)</sup>

Many studies investigated on the effectiveness of PCL membrane in GTR reveals an improvement of bone formation in the presence of noticeable bone cell attachment and proliferation <sup>(31, 32)</sup>. Beside GTR membrane, PCL has been developed as bonedefect-filling materials aiming to promote bone regeneration in periodontal defects. The scaffolds aim to support periodontal ligament and alveolar bone cell migration and repopulation in the affected site, facilitating the regeneration process. In contrast, in a study conducted by Maiorana et al., (33) the exposure of the mesh led to an early resorption of the site between 15% and 25%, which however allowed placing the implant fixtures., the rate of exposure of the mesh varies from 5.3% to 52% depending on the studies, despite that the exposure does not affect the implant results.<sup>(34, 35)</sup> PCL membrane facilitates osteoblast-like cell proliferation and differentiation. <sup>(36)</sup> Moreover, PCL induce alkaline phosphatase activity and enhance mineralization. (37)

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## تقييم غشاء بولى كابرولاكتون المعدل القابل للتحلل في انماء الحافة النسخية الضامرة افقيا

#### سعد على احمد درويش \*، منصور محمد حسين ، بهاء الدين عبد ربه توفيق

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#### الملخص :

**الهدف** : دراسة فقدان حجم العظم السنخي الأفقي يؤدي إلى خديات كبيرة لوضع غرسات الأسنان لذا أجريت هذه الدراسة بهدف تقييم غشاء بولى كابرولاكتون المعدل القابل للتحلل فى ان*م*اء الحافة السنخية الضامرة أفقيا .

**المواد والاساليب:** تم تقسيم المرضى عشوائيا إلى مجموعتين رئيسيتين: الجموعة (التحكم) . تم استخدام غشاء الكولاجين. الجموعة ب (اختبار) . تم استخدام غشاء بولى كابرولاكتون المعدل القابل للتحلل. قبل الجراحة وضع جميع المرضى على مظلة المضادات الحيوية. تم الإجراء باستخدام التخدير الموضعي. تم رفع الغشاء الخاطي بالسمك الكامل. تم تحضير العظم المتلقي مع ثقوب إزالة التقشر باستخدام ببر مستدير صغير. وضعت العظام ذاتية المنشأ أو بدائل العظام في الخلل ووضع الغشاء وتم تثبيتها في مكانها بواسطة البراغي. تم إغلاق رفرف الغشاء الخاطي.

**النتائج :** في هذه الدراسة . في 1 أسبوع . بعد 1 وكذلك 3 أشهر : لم يكن هناك فرق ذي دلالة إحصائية بين الالتهابات الموضعية . والتئام الجروح . والتعرض الغشائي في الجموعتين فورا: لم يكن هناك فروق ذات دلالة إحصائية بين قياسات كثافة العظام في الجموعتين. بعد 6 أشهر . أظهرت مجموعة بولى كابرولاكتون المعدل القابل للتحلل إحصائيا كثافة متوسط العظم والقياس العرضي للتلال السنخية أعلى بكثير من مجموعة الكولاجين نظرا لمرونة شبكة البولي كابرولاكتون المعدل والتي لاتوجد في غشاء الكولاجين .

**الخلاصة**: شبكة بولى كابرولاكتون المعدل القابل للتحلل تقدم حلاً ممتازًا في تطبيقات الأسنان على أنواع الأغشية الأخرى. يمكن اعتبار النتائج الإيجابية الحالية مشجعة , لكن يجب تأكيدها من خلال إجراء المزيد من الدراسات طويلة الأجل على عينة أكبر من المرضى.

**الكلمات المفتاحية:** تأكل العظم، غشاء الكولاجين , غشاء بولى كابرولاكتون , ترقيع عظام الفك. ضمور عظام الفك