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EVALUATION OF BIOXCLUDE AMNION CHORION MEMBRANE IN THE REPAIR OF ORO-ANTRAL COMMUNICATION (CLINICAL AND RADIOGRAPHICAL STUDY)

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ABSTRACT

INTRODUCTION: After posterior maxillary teeth extraction, oroantral communication is a reasonably common significant consequence. At the time of injury, if the opening is > 4-5 mm, surgical closure of the antral perforation is required. This study aimed to check the value of BioXclude amnion chorion membrane in repairing oroantral communication.

MATERIALS AND METHODS: Ten patients with oroantral communication that occurred after posterior maxillary teeth extraction were included in the study. Surgery was considered successful in case of negative nose blowing 1-month postoperatively. Post-operative pain was assessed. Evaluation of bone formation at the communication site by computed tomography was measured post operatively at 3 and 6 months.

RESULTS: After 3 and 6 months, all patients (100.0%) showed bone formation, and a significant increase in bone density was noted. After 6 months there was a significant closure of OAC.

CONCLUSION: Amnion chorion membrane is an excellent scaffold layer for covering iatrogenic oroantral communication defect. BioXclude has self-adhering properties once it becomes moist. This eliminates the need for suturing of the membrane.

KEYWORDS: BioXclude aminion chorion membrane, Oroantral communication, Maxillary sinus.

RUNNING TITLE: Evaluation of BioXclude membrane in oro-antral communication repair

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INTRODUCTION

The largest part of the upper jaw is taken up by the maxillary sinus, which is described as a large, pneumatic space (1). The sinus floor can be found in three fundamental positions: under, on, or above the level of the nasal cavity's floor. Due to the fact that the maxillary sinus floor may extend to the tops of the dental roots or even deeper between them, the relationship is critical when the maxillary sinus floor is lower than the nasal cavity floor. A thin bone lamella and its mucous membrane separate such roots from the sinus, or, in rare cases, merely the sinus mucous membrane (2). This relation makes the risk of maxillary sinus affection by any disease or surgical manipulation of maxillary teeth expected.

The most common complication associated with maxillary posterior teeth surgical procedure regarding the maxillary sinus is oroantral communication. The most frequent cause of OAC is maxillary posterior teeth extraction (80%) (3).

Oroantral communication has been treated with a variety of techniques over time, including tissue transfer, bone grafts flaps, and stem cells. Flaps use is linked to morbidity at the donor site. No surgical flap is preferable than another; each has its own set of benefits and drawbacks. Fascia lata, titanium and gold plates, dura mater, and freeze-dried collagen have all been employed as graft materials in place of bone (4).

Biomaterials appear to be an appropriate therapeutic option as they reduce the infection incidence and the contraction degree induced by scarring. However, no existing biomaterial has met the stringent requirements for biocompatibility and integration. the buccal fat pad flap can only cover small to medium defects and because of its thinness, it cannot provide any bulk. (5) These variables may interfere with the graft materials' adhesion and retention, leading to epithelialization

failure and scar tissue development. Impaired healing of large mucosal defects can be a source of annoyance to patients because oral functions are highly sensitive to contraction caused by scarring (6, 7). Complications connected with oroantral communications impede their treatment for all of the reasons stated above, in addition to total covering and the creation of scars.

Because of its low immunogenicity, the amnion is considered a potential tissue for allografts (8). It has anti-inflammatory, wound-healing, and scar-reduction effects as well. For decades, preserved amnions were employed in various therapeutic settings, including ophthalmology and wound treatment (9, 10). Recent research has discovered that stromal cells of the aminion chorion membrane, commonly known as aminion chorion mesenchymal stem cells (ACMSC), exhibit properties that close to those of bone marrow mesenchymal stem cells. ACMSC can differentiate into three distinct germ layers (11). The early 1990s provide a good starting point for tracking the recent history of amniotic membrane utilization in oral and maxillofacial surgery (12).

Fetal tissues are composed of amnion and chorion tissues (13). This chorion tissue, which defines the circumference of the sac that contains the fetus, is formed of several types of collagen, cell adhesion bioactive factors, and a multitude of growth factors that help granulation tissue formation by stimulating fibroblasts growth and revascularization (12).

Bioxclude amnion chorion membrane (ACM) allograft is a human amnion chorion membrane allograft that has been prepared for human transplantation. BioXclude aminion chorion membranes promote epithelial development and inhibit epithelial apoptosis by facilitating epithelial cell migration, reinforcing basal epithelial cell adhesion (13, 14), and preventing epithelial apoptosis (15). Vascular endothelial growth factor, platelet-derived growth factor, transforming growth factor beta 2 (TGF-2), angiogenin, tissue inhibitor of metalloproteinase 1 (TIMP-1) and TIMP-2 are among the cytokines released by amniotic cells that are important for wound healing. The BioXclude aminion chorion membranes inhibit the proliferation of T lymphocytes in allografted limbal cells, indicating immunosuppressive properties that may increase graft success rates.

The amnion chorion enhances wound healing as well, all these properties make the amniotic membrane graft an attractive surgical option (17). The aim of the present study, was to check the value of BioXclude amnion chorion membrane in repairing oroantral communication.

MATERIALS AND METHODS

The research ethics committee, Faculty of Dentistry, Alexandria University, approved the study, and it was registered in ClinicalTrials.gov (ID: NCT04990011).

- **Study design:** This study was a case series.
- **Settings and location:** Ten Participants were recruited from the outpatient clinic, Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University, Egypt. The surgical procedures were performed at the minor oral surgery clinic of the same place.
- **Sample size calculation:** G*power version 3.1.9.2. was used for sample size calculation.

Eligibility

Inclusion criteria

Patients were included if they were free of any significant systemic disorders, were between the ages of 20 and 55 years old, had recent oroantral communication (O.A.C) (24 to 72 hours), with communication more than 5 mm and had good dental hygiene (18).

Exclusion criteria

Patients with an immune compromised state, previous sinus surgery or disease, intra-antral foreign bodies and the need for cold well-luc procedure, intra-sinus pathology, smoking, alcohol or drug abuse, and those not willing to participate were excluded from the study.

Informed consent

The patients gave their informed permission after all of the treatments were explained in full, including the advantages and negative effects. It was also mentioned that the patient has the right of withdrawal at any time.

Surgical phase

- Local anaesthesia was used for all patients.
- The oral cavity was prepared by 0.12% chlorhexidine mouth rinses solution (Hexitol: Chlorhexidine 125mg/100ml, concentration 0.125%: Arabic drug company, ADCO) for thirty seconds before operation. **Figure (1)**

Figure (1): Clinical photographs showing BioXclude, Amnion chorion Membrane (ACM) (20x30mm) allograft.

- The surgical field was swabbed with Betadine before operation
- Infiltration anesthesia (mepivacaine (Mepecaine hydrochloride 2 percent by Alexandria pharmaceutical company) HCL with epinephrine 1:100.000) was administered.
- Trapezoid mucoperiosteal buccal flap incision using scalp no. 15
- Refreshment of the bony edges using bone file.

- The OAC was closed by bioxclude Aminion chroin membrane (BioXclude™, amnion-chorion membrane, Snoasis Medical, snoasismedical.com, LLC.) which is applied over the extraction socket. The buccal flap's undersurface periosteum was cut horizontally at its base to facilitate progress. Then the flap was repositioned to support the ACM. **Figure (1 & 2)**
- Then the flap was sutured with horizontal mattress method using silk 3/0 suture material with tension free sutures. **Figure (3)**

Figure (2): OAC was closed by bioxclude Aminion chroin membrane which is applied over the extraction socket.

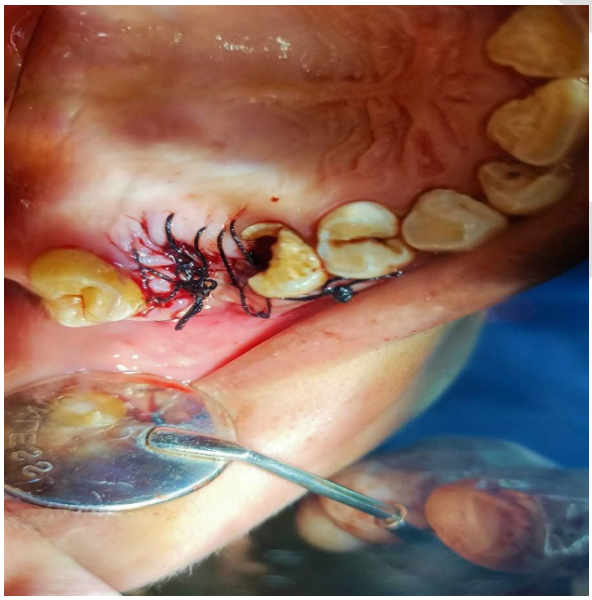

Figure (3): The flap was sutured using silk 3/0 suture material.

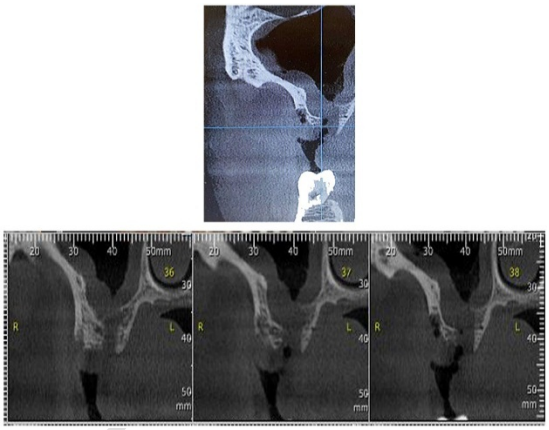

Figure (4): Preoperative computed tomography (C.B.C.T).

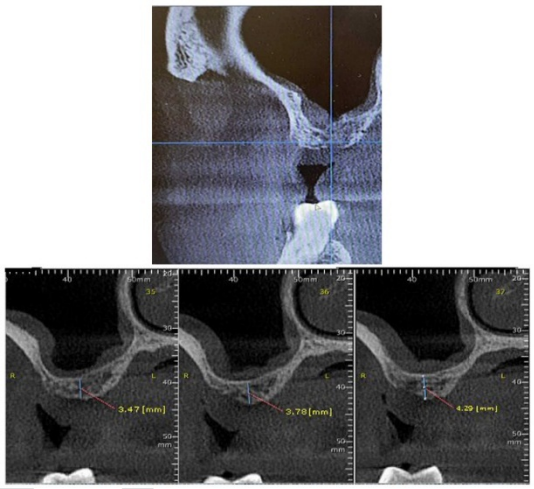

Figure (5): Six months post-operative computed tomography.

Post-surgical phase

- All patients were told to follow a soft diet for ten days and to keep the repaired region protected and avoid sucking, nose blowing, and sneezing.
- All patients were instructed to apply cold fomentation starting immediately postoperatively for one day.
- Oral hygiene instructions.
- Warm saline mouth wash from the next day.
- Postoperative medication:
  - Amoxicillin clavulanate (Augmentin: Amoxicillin 875 mg + Clavulanic acid 125 mg: GlaxoSmithKline, UK) 1 gm twice daily for 7 days.
  - Metronidazole: 500 mg/eight hours for 7 days (Flagyl: metronidazole 500mg: GlaxoSmithKline, UK).
  - Diclofenac potassium: 50mg every eight hours for 7 days (Cataflam: Diclofenac Potassium 50mg: Novartis-Switzerland).
  - All patients were instructed to rinse their mouth using chlorhexidine (Hexitol: Chlorhexidine 125mg/100ml, concentration

0.125%: Arabic drug company, ADCO) antiseptic mouth wash.
- Systemic decongestants: once daily for 7 days (Clearest: Cetrizine 5mg. + Pseudoephedrine 120mg: ChemiPharm).
- Local decongestants: twice daily for 7 days (Otrivin 1%: Xylometazoline Hdrochloride 1%: Novartis).

Clinical follow up

Along one month post-surgery, a thorough follow-up was done for assessing the primary and secondary outcomes.

Primary outcome: (success of surgery): Surgery was considered successful in case of negative nose blowing 1 month post operatively.

Secondary outcome: (pain): Post-operative pain was assessed 12 h post-surgery with visual analogue scale (VAS) of 100 units classified as mild pain (0-34), moderate pain (35 – 64), and severe pain (65 – 100).

2. Nose blowing test (19): The patient is asked to pinch their nostrils together and open their mouth and then blow gently through the nose. The clinician must observe if there is passage of air or bubbling of blood in the post extraction alveolus as the trapped air from closed nostrils is forced into the mouth through any oroantral communication.

Radiographic follow up: Evaluation of bone formation at the communication site by computed tomography was measured at 3 months and 6 months post operatively.

Statistical analysis: The data was examined using the IBM SPSS software version 20.0 (Armonk, NY: IBM Corporation). To describe qualitative data, we utilised the terms number and percent. To confirm that the distribution was normal, the Kolmogorov-Smirnov test was used. Quantitative data was described using the mean, standard deviation, median, range, and interquartile range (IQR). The obtained results significance was determined at a 5% level of significance. The following tests were used: McNemar's test, ANOVA with repeated measurements, Post Hoc test, Friedman test, and Cochran's test.

RESULTS

The studied cases according to gender (n = 10). Regarding gender, male was 6 (60.0 %) and female was 4 (40.0 %). Preoperatively, the mean size of OAC was 5.29 ± 0.92 (mm). After 3 months, it was 2.45 ± 0.67 (mm). After 6 months, it was 0.0 ± 0.0, with a statistically significant difference (P <0.001*). After 6 months, there was a significant closure of OAC. Mean bone density was -29.01 ± 145.6 preoperatively. After 3 months, it was 161.2 ± 147.9. After 6 months, it was 289.4 ± 92.86, with a statistically significant difference (P <0.001*). After 3 and 6 months, bone density significantly increased. **Table (1)**

Table (1): Comparison between the three studied periods according to size of OAC and bone density (n = 10)

	Preoperative	Postoperative		F	P
		3 months	6 months		
Size of OAC (mm)	5.29 ± 0.92	2.45 ± 0.67	0.0 ± 0.0	161.618*	<0.001*
Sig. bet. periods.	p_1<0.001*,p_2<0.001*,p_3<0.001*				
Average of bone density	-29.01 ± 145.6	161.2 ± 147.9	289.4 ± 92.86	20.00	<0.001*
Sig. bet. periods.	p_1=0.025*,p_2<0.001*,p_3=0.025*				

SD: **Standard deviation** IQR: **Inter quartile range**

Fr: **Friedman test**, Sig. bet. periods was done using **Post Hoc Test** (**Dunn's)**

p: p value for comparing between the studied periods

p_1: p value for comparing between **Preoperative** and **3 months**

p_2: p value for comparing between **Preoperative** and **6 months**

p_3: p value for comparing between **3 months** and **6 months**

*: Statistically significant at $p \leq 0.05$

Preoperatively, all patients showed the presence of OAC with the nose blowing test. One month after membrane application, all patients showed no OAC with the nose blowing test, with a statistically significant difference (P = 0.002*). **Table (2)**

Mean VAS 12hr after surgery was 12.0 ± 13.98, 90.0 % of patients had Mild pain, 10.0 % had Moderate pain. **Table (3)**

Table (2): Comparison between preoperative and 1 month according to nose blowing test (n = 10)

Nose blowing test	Preoperative		1 month		χ^2	McNp
	No.	%	No.	%		
Negative	0	0.0	10	100.0	20.0*	0.002*
Positive	10	100.0	0	0.0		

χ^2: **Chi square test**

McN: McNemar test

p: p value for comparing between **Preoperative** and **1 month**

*: Statistically significant at $p \leq 0.05$

Table (3): Distribution of the studied cases according to postoperative pain 12hr after surgery (n = 10)

VAS	No.	%
Mild pain (0 – 34)	9	90.0
Moderate pain (35 – 64)	1	10.0
Severe pain (65 – 100)	0	0.0
Min. – Max.	0.0 – 40.0	
Mean ± SD.	12.0 ± 13.98	
Median (IQR)	10.0 (0.0 – 20.0)	

IQR: **Inter quartile range**
SD: **Standard deviation**

DISCUSSION

The oroantral communication (OAC) is the connection between the maxillary sinus and the oral cavity. If left untreated, it might lead to oroantral fistula or maxillary sinusitis (20). Oroantral communication normally occurs when the maxillary molar teeth are removed. To minimise problems such as sinus infections, it was suggested that the OAC be surgically closed within 48 hours (21).

Without OACs treatment, maxillary sinusitis occurs in 50% and 90% of the patients within 48 hours and two weeks, respectively (22). Spontaneous closure may occur if the defect is < 5 mm in diameter (23). However, the determination of the size of OAC is difficult in the clinical practice. Therefore, OAC spontaneous closure is unlikely. To avoid chronic sinusitis and fistula, it is recommended that closure should be done within 24 to 48 hours (23).

Untreated OACs may cause fusion of the Schneiderian membrane with the oral epithelium, which can lead to the formation of an oroantral fistula. Patients report during surgical follow-ups that liquids run into their nose when eating and that they have nasal congestion. Surgical therapy for oroantral communication is accomplished by sliding the mucoperiosteal flap (22). Mucoperiosteal flaps slid from the buccal region, on the other hand, have certain drawbacks. Swelling and discomfort are common side effects of surgery (24). The buccal sulcus depth is reduced with time, and the adaptation of the dental prosthesis is compromised (25). Due to surgical intervention's drawbacks, numerous alternatives have been proposed.

Oroantral fistulas have been treated with a variety of techniques over time, including tissue transfer, bone grafts, flaps, and stem cells. Flaps use is related to donor site morbidity. Amnion chorion membrane is a dehydrated human allograft made out of laminated human amnion-chorion membranes, according to bioxclude. The only minimally modified dehydrated human deepithelialized amnion-chorion membrane available for use as a barrier, conduit, connection, or cushion in a number of dental, endodontic, oral maxillofacial, and periodontal regeneration treatments. Biological components found in amnion-chorion tissue help in healing, increase angiogenesis, decrease inflammation, and speed flap reattachment. It also has antibacterial qualities by nature, and the tissue is non-immunogenic (26-29). The purpose of this study is to see how effective an amnion chorion membrane graft is in repairing oroantral connection after posterior maxillary tooth extraction.

The use of an amnion chrion membrane graft in the restoration of oroantral communication after posterior maxillary tooth extraction showed promise in this study as a simple and successful strategy for repairing oroantral communication after posterior maxillary tooth extraction.

The Nose Blowing Test revealed the presence of communication in all ten patients (100.0%) prior to surgery. 1 month after membrane application and closure, All 10 patients, (100.0 %) showed the absence of any oroantral communication with the Nose blowing test. after 6 months, the defect was completely closed.

In terms of bone production, preoperatively, 10 (100.0%) of the patients had no bone at the OAC site. Bone development was identified in all patients at the location of the OAC defect after 3 and 6 months. There was a considerable increase in bone density at 3 and 6 months.

Dehydrated human amnion/chorion membrane (dHACM) use to heal ruptured sinus membranes was investigated by Chang et al. (30) In the dHACM group, freshly created bone filled the augmented region with residual biomaterials, however, the repaired sinus membrane had inflammatory cells and non-ciliated flat epithelium. The dHACM group had a larger proportion of newly created bone area than the negative control group, suggesting that the dHACM might be a viable treatment for healing sinus membrane perforations occuring during sinus floor augmentation.

Lakshmi et al. (31) repaired an iatrogenic oroantral communication that formed during the extraction of the patient's right upper second molar using amniotic membrane, which is consistent with our findings. The study revealed that amniotic membrane was a promising graft material for treating a lesion caused by iatrogenic oroantral communication following tooth extraction.

Sharma et al., (32) suggested that AM can be a favorable graft material for vestibuloplasty, promoting healing and preventing relapse. Sham and Sultana (33) described the role of AM in biological wound healing in a buccal mucosal defect in an operative case of leukoplakia. At the structural level, AM contains two different cell types: human amnion epithelial cells and human amnion mesenchymal stem cells which have a strong osteoinductive potential (34, 35).

Amnion chorion membrane consists of a thin inner amnion layer and a thick outer chorion layer.

Amnion tissue is composed of a single layer of epithelium cells, a basement membrane, a thick compact layer, and a fibroblast layer. Amnion contains collagen types III, IV, and V. Chorion tissue consists of a reticular layer, a basement membrane containing a layer of dense connective tissue and a trophoblast layer. The reticular and basement membrane layers contain collagen Types I, III, IV, V, and VI. These tissues contain over 55 ECM proteins, interleukins, cytokines, and TIMPs. In-vitro, in-vivo, and clinical research demonstrated Rapid wound closure when left exposed, Cellular occlusive with rapid sealing of protected space. It also allows for rapid establishment of blood supply, recruitment of mesenchymal stem cells, suppresses inflammation, and promotes excellent early healing (36, 37).

Within the allograft, Koob et al. (38) found soluble angiogenic growth factors that promoted human microvascular endothelial cells proliferation and migration, as well as the creation and release of all 30 angiogenic growth factors examined. Angiogenic growth factors, neovascularization, and subsequent allograft resorption enables fast blood supply development when employing BioXclude (36).

BioXclude amniotic tissue transplant includes both the amnion and chorion tissue layers. It was the first and only amniotic tissue transplant to include both of them, and it remains to date. Compared to the amnion layer, the chorion layer is substantially thicker and contains almost 80% more cytokines and structural non-collagenous proteins. As a result, compared to amnion alone allografts, amnion chorion allografts (BioXclude) are more durable and include more biological components (39).

Extracellular matrix scaffolds containing cytokines, growth factors, and matrix proteins may be provided by amnion-chorion membranes to help flap edge approximation. They may act as a catalyst for rapid epithelialization and granulation tissue development, which can aid in rapidly closing the wound gap (40).

CONCLUSION

Amnion-Chorion Membrane showed to be an effective scaffold layer for masking an iatrogenic oroantral communication deficit. When BioXclude is wet, it has self-adhering capabilities. This removes the necessity for membrane suturing. BioXclude essentially closes itself to the region as it hydrates.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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