EVALUATION OF THE USE OF SONICWELD® RESORB X® FOIL MEMBRANES IN THE REPAIR OF OROANTRAL FISTULA

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ABSTRACT
Introduction: There is a variety of treatment modalities for oroantral defects relying on repair of soft tissue component only of the defect. However, guided bone regeneration (GBR) is needed to allow the simpler later restoration of the missing tooth.
Objectives: The aim of this study was to evaluate the efficacy of using Sonicweld® Resorb X® foil membranes as a type of GBR in oroantral defects.
Materials and methods: This study was conducted on fourteen patients suffering from oroantral defects of more than three weeks duration and having a width of at least five millimeters (mm). The patients were divided into two groups;
Group I (study group): Seven patients were treated with placement of Sonicweld® Resorb X® foil membranes along with buccal advancement flap.
Group II (control group): Seven patients were treated with only buccal advancement flaps.
Results: There was a significant difference in the wound healing and pain scores of the intermediate follow-up period between the two groups, with mainly group I having inferior scores than group II. But at the end of the follow-up period, there was no significant difference between the two groups.
Conclusion: Sonicweld® Resorb X® foil membranes were shown in this study to prolong the time of healing of the soft tissue flap in oroantral defects, with minimal ability of bone formation in the oroantral defect. Further studies are needed in this field, with greater sample size of study group, and the trial of the membrane with other types of soft tissue flaps. Using soft tissue adhesives in mandibular third molar surgery

Key words: sonicweld, oroantral, maxillary sinus, bone regeneration.

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INTRODUCTION
The major cause of odontogenic maxillary sinusitis is iatrogenic, one of which is the oroantral communications, accounting for 47.6% of iatrogenic causes (1). This is the pathological loss of hard and soft tissues between the oral cavity and maxillary sinus leading to a connection of both cavities. If this is left unmanaged, the pathway in between becomes epithelialized evolving into an oroantral fistula (OAF). This epithelium originates from granulation tissue filling the tract or from polyposis of the sinus membrane. Epithelialization starts after 48-72 hours of the defect formation and is completed after seven days (2-4).

Oroantral communication is essentially due to maxillary teeth removal. The posterior teeth are more of a cause than anterior teeth since their apices are nearer to the floor of the sinus. This floor ranges from complete absence to a height of 12 millimeters (mm). The upper second molar is the closest to the sinus, followed by the upper first molar, upper third molar, upper second premolar, upper first premolar, and canine respectively. Oroantral communication may also be due to a periapical infection or osteomyelitis destructing the floor of the sinus, incorrect extraction leading to forcing root into sinus or perforation of the floor; and removal of maxillary cysts or tumors. Extensive trauma to the face or improper surgical planning during dental implant insertion may also lead to formation of an OAC (1–5).

Clinically, presence of escape of fluids from mouth to nose, unilateral epistaxis, escape of air from nose to mouth and severe pain around area of affected sinus indicate presence of the OAC. OAF presents itself with subsidence of pain and presence of foul, unilateral nasal discharge along with postnasal drip (2).

Radiologically, OAC is best evident in intraoral periapical, orthopantomogram (OPG) and the computerized tomography (CT) scans. Signs of OAC may be sinus floor discontinuity, sinus opacity, focal alveolar atrophy and associated periodontal disease. Computed axial tomography can assess the size of the fistula, the characteristics of the bone and mucosa surrounding the perforation, and the nature of the sinus mucosal lesion (6).

When chronic oroantral fistula defects are wider than 5mm and persist for more than 3 weeks, a secondary surgical intervention is required. Defects less than 5mm in width and without epithelialization might heal spontaneously in the absence of infections (5). Treatment modalities to repair the oroantral fistula include local or free soft tissue flaps, with or without autogenous grafts or alloplastic implants. The common methods used to treat OAC are the buccal advancement flaps, palatal rotation and palatal transposition flaps, tongue flaps, and nasolabial flaps. There is also an increased use of the buccal fat pad (BFP) (7). The disadvantages of these are the high morbidity, discomfort for the patient, and no possibility to repeat the same technique after surgical failure (8).

Guided bone regeneration (GBR) has been proposed as a method of treatment of OAC. It aims to repair both the hard and soft tissues, which facilitates the later use of dental implant for restoration of the extracted teeth (3). A new material that has been used before for ridge augmentation is the resorbable membrane made of 100% amorphous poly D-lactide (50%) and L-lactide acid (50%) (PDLLA), a chemical substance made up of lactic acid molecular chains, which are in fact natural constituents of the human body. It is characterized by an unbeatably high body compatibility, combined with reliable degradation.
characteristics. The pins of this system are inserted into the bone by ultrasonic vibrations, which melts the pins and allow it to weld with the bone. The membrane is then also welded onto the pins creating the high mechanical strength and stability of this system. This material is totally biocompatible with a safe degradation process (9). It is hypothesized that this membrane can be used as a GBR (guided bone regeneration) technique in the treatment of OAF.

This study evaluated the treatment of oroantral fistulous defects by the use of GBR (guided bone regeneration), through the placement of Sonic Weld® Resorb X® foil membranes, compared to the traditional sole use of buccal advancement flaps.

MATERIALS AND METHODS
This study was performed as a controlled randomized clinical trial and was done on fourteen patients suffering from oroantral defects selected from the Outpatient Clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University.

Inclusion criteria for the study were:
- Patients of both sexes having oroantral defects
- The OAF defect had to be of at least three weeks duration
- OAF defect diameter at least 5 mm
- Whether clear or infected sinus

Exclusion criteria for the study were:
- Acute sinusitis
- Systemic conditions contraindicating surgery
- Generalized bony disorders

The patients were divided into two groups;
- **Group I (study group):** Seven patients were treated with placement of SonicWeld® Resorb X® foil membranes along with buccal advancement flap.
- **Group II (control group):** Seven patients were treated with only buccal advancement flaps.

The ethical clearance was obtained by the ethical committee before starting the study, the selected patients were informed about the nature of the study and informed consents were obtained.

Materials:
- SonicWeld® Resorb X® foil sheet (KLS Martin, Tuttlingen, Germany)
  - It is a biodegradable non perforated foil sheet made of PDLLA, with dimensions of 25 mm width, 25 mm length, and 1 mm thickness. It was used to cover the oroantral defect to offer protection to the soft tissue flap and aid in GBR. It disintegrates by hydrolysis leaving no byproducts.
- SonicWeld® Rx® pins (KLS Martin, Tuttlingen, Germany)
  - This is a biodegradable pin made also of PDLLA, 5 mm in length and 1.6 mm in diameter. It is used to fix the foil sheet in place.
- SonicWeld® ultrasound generator and sonotrodes (KLS Martin, Tuttlingen, Germany).
  - The ultrasound generator creates microvibrations to be able to liquefy the material whether in insertion of the pins into the bone or welding the membrane with the pins. These microvibrations are transmitted to the material via sonotrodes mounted on the handle of the ultrasound generator. (Fig 1)
  - Xcelsior® water bath (KLS Martin, Tuttlingen, Germany)
    - Electrically-powered water bath to be able to heat the foil membrane to enable its adaptation to the defect site. (Fig 1)

Methods:
I—Preoperative assessment and examination:
Every patient was assessed and evaluated by proper history taking, thorough clinical and radiographical examination as follows:

A—History of the patient:
A detailed case history was recorded for each patient including personal data of the patient, date and time of incidence of the communication, time of last dental extraction, history and cause of tooth extraction, nature of extraction, and history of any edema or swelling in the area.

B—Clinical examination:
Both extraoral and intraoral examination were done through inspection and palpation. Extraoral examination included detection of swelling with presence or absence of facial deformity, nasal discharge from nostril of the ipsilateral side, tenderness over the cheek area and palpation of lymph nodes. Intraoral examination included size and site of the OAF, presence or absence of polyps, presence of purulent discharge from the fistula, postnasal discharge, presence of swelling or edema buccal or palatal, condition of neighboring teeth, previous surgical intervention. Valsalva maneuver (4) was done to confirm the communication. This was done by asking the patient to close both his mouth and nose and attempt to blow, and then immediately opening his mouth to see if any air bubbles appear in the site of presumed defect.

C—Radiographic examination:
A CBCT was done for every patient unless the patient was already admitted with a CT scan. From the x-ray, fluid level, sinus obliteration, mucosal thickening, size of bone defect
and any foreign body in the sinus were determined for each patient.

For both preoperative and postoperative readings to be comparable, the axes of the CBCT views were fixed according to certain points on the x-ray, such as apices or cementoenamel junctions of nearby teeth, according to each patient. The same points for each patient were to be used in the postoperative x-ray to obtain measurements in the same exact area of the defect. (Fig 2a)

**II-Pre-operative preparation:**
Each patient was prepared by irrigation of the sinus by saline and antibiotic metronidazole (Flagyl, Pfizer, USA) until disappearance of signs of infection. Oral hygiene care and blood analysis and any other required investigations were undertaken to be fit for the surgery. Informed consent was signed by the patient prior to the operation. (Fig. 2b)

**III-Operative Phase:**
The operations were done under general anesthesia, using intravenous induction with propofol (Diprivan®, AstraZeneca, USA) and then maintained with inhalational isoflurane.

The operation steps included:
- Decoring of the OAF with a Bard Parker blade number 11 and reflection of the buccal trapezoidal mucoperiosteal flap extending from mesial to the ipsilateral canine to a width of one tooth distal to the defect. (Fig 3a)
- Caldwell-Luc approach to the maxillary sinus using a surgical bur to create a window in the canine fossa about 1.5 cm wide and then proper debridement and curettage of the sinus, with removal of the affected Schneiderian membrane.
  - In study group, placement of the SonicWeld® Resorb X® foil membrane by:
    - Drilling of the pin sites around the fistula, using a low speed handpiece with a drill of 1.6 mm diameter, followed by placement of the Resorb® pin in the drilled site by ultrasound vibrations using the sonotrode applicator (Fig 3b).
  - Modification of the foil membrane by placing it in a 70°C (XCelsior® water bath (KLS Martin, Tuttingen, Germany) for 30 seconds to soften it for easier modification.
  - Adaptation of the foil membrane on the defect so that it obliterates all the defects and welding of the membrane with the already placed pins using the flat-ended sonotrode (Fig 3c, 3d).
IV- Postoperative phase and instructions

The patients were asked to apply cold fomentations for 24 hours, and to avoid any mouthwash, hot food or drinks, negative or positive pressure on the wound for 24 hours. Sutures were removed after 2 weeks to prevent food accumulation and chance of infection.

Postoperative medication was prescribed as follows:

- Broad spectrum amoxicillin and clavulanic acid as antibiotic (Augmentin, GlaxoSmithKline, Hungary) 1 gram, twice daily.
- Metronidazole (500 mg, three times daily) for anaerobic bacteria (Flagyl, Pfizer, USA)
- Antiedematous chymotrypsin and trypsin to resolve any edema (Alphintern, Amoun Pharmaceuticals, Egypt) three times daily.
- Nasal decongestant, oxymetazoline hydrochloride 0.05% (Afrin, Bayer Group Wuppertal-Barmen, Germany) three times daily.
- Diclofenac sodium for analgesia and anti-inflammatory (Cataflam, Novartis, Egypt) 50 mg, twice daily.
- Chlorhexidine mouth wash starting 24 hours after the operation.

IV- Follow-up evaluation

Evaluation of the two groups was performed by:

a. Clinical evaluation

Clinical evaluation was done at 1 week, 1 month, and 3 months postoperatively to observe postoperative pain (visual analogue scale (10)), edema, presence of any bleeding and/or infection, and the healing of the mucoperiosteal flap (11).

b. Radiographic examination

CBCT was carried out 3 months postoperative to evaluate fluid level of the sinus and the condition and amount of bone formation in the oroantral defect. The size of bone defect was measured at that time, and was used to calculate the percentage change from the preoperative size. Three measurements were taken; (1) apical border of defect (at the floor of the maxillary sinus), (2) midpoint of the defect, (3) coronal border of defect (at the crest of the ridge).

V-Statistical analysis of the data (12)

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0 (13). Qualitative data were described using number and percent. Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. While, McNemar-Bowker was used to analyze the significance between the different stages. The distributions of quantitative variables were tested for normality using Kolmogorov-Smirnov test, Shapiro-Wilk test and D’Agstino test. If it reveals normal data distribution, parametric tests was applied. If the data were abnormally distributed, non-parametric tests were used. For normally distributed data, comparison between two independent populations were done using independent t-test. For abnormally distributed data, comparison between two independent populations were done using Mann Whitney test.
To compare between the different periods Wilcoxon signed ranks test was applied. Significance of the obtained results was judged at the 5% level.

**RESULTS**

The study was performed on twenty patients; seven males and seven females; with a ratio of 1:1. They were treated in the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University. Patients’ age ranged from 22 to 54 years old with a mean of $34.0 \pm 10.03$ in study group and $36.29 \pm 11.80$ in control group.

**Preoperative Findings**

The patients gave a history of the duration of the oroantral communication ranging from 3 weeks to 60 months. The cause of the oroantral fistula was mainly due to extraction of the upper first molar, with only four cases due to extraction of upper second premolar, and one due to upper second molar. CBCT also showed presence of a remaining root in three cases in the study group and two cases in the control group.

**Clinical Results**

Clinical evaluation was done at 1 week, 1 month, and 3 months postoperatively to observe postoperative pain, healing, infection, bleeding and edema. In relation to pain, there was a significant decrease of pain as the postoperative period increases, with the maximum pain intensity immediately postoperative. This was the same in both groups. The pain intensity in the four weeks period was significantly lower in the control group than in the study group. There was neither significant postoperative bleeding nor edema in both groups. (Fig. 4)

According to the healing of the soft tissue flap, closure of the wound was recorded in the second week postoperative, along with the fourth and twelfth week. This was done according to a score from 1 to 4, “1” being completely healed and “4” having significant dehiscence. A significant difference is observed between the two groups in the second and fourth weeks’ postoperative period. The score for the control group was significantly lower in both periods. There was no significant difference after 12 weeks postoperative. (Fig. 5)

In the study group, two patients lost the membrane in full prior to the end of the follow-up period. The wound actually didn’t heal in these patients and they required further treatments later on. One patient also reported the loss of small pieces of the membrane throughout the healing period.

**Radiographic Results**

When considering the size of the oroantral bone defect, there was a slight amount of bone formation at all levels of measurement. The greatest change in the study group was at the apical measurement, where the defect decreased by a mean of $45.06 \pm 16.36$ % change, while at the coronal measurement it was a mean of $4.38 \pm 1.93$ % change.

There was a significant difference between the two groups, only at the apical measurements, with the study group forming more bone than the control group. (Table 1, Figure 6)
our study the extraction of the upper second premolar was more occurring than the upper second molar.

Occurrence of infection in this study was encountered more in the study group with 57.1% of the cases showing up with infected wounds at the first week postoperative. This could be accredited as one of the reasons for a slower rate of healing in the study group.

It was observed in this study that wound margins after the surgery experienced greater degree of inflammation in the study group cases. This was accompanied by healing occurring at a slower rate, with greater number of patients having wound dehiscence and higher wound healing scores. These findings were clinically significant at the second and fourth postoperative week. Conversely, healing had no significant difference between the groups at the end of the 12 months follow-up, when most of the cases had healed wound margins.

Results observed in the healing of control group cases was similar to those found by Guven (19), in which none of the cases experienced complications and were properly healed. Hernando (15) also stated that those cases that recurred postoperatively actually spontaneously closed within one and four months after. This was comparable to what happened in this study, where healing to wound dehiscence also occurred without further intervention. Only two of the study group cases needed resuturing to allow the closure of the wound margins again.

Wound dehiscence occurring in group I can be perhaps caused by the swelling that occurs in the foil membrane prior to the start of the degradation process, where it can actually increase to three times its original size (17). This might create tension on the buccal flap leading to improper healing. This excessive tension on flap margins was mentioned to be one of the most important reasons for failure of treatment of oroantral fistulas (21).

An important remark is that two out of the seven patients of group I reported the actual loss of the membrane as it is. These patients’ wounds were not healed at the end of the follow-up period of 12 weeks. A third patient said that the membrane was lost bit by bit as small pieces of it also fell into the oral cavity. This denotes that actually the membrane did not disintegrate fully into carbon dioxide and water as presumed.

The pain intensity whether using the SonicWeld® ResorbX® or not using it was the same at the end of the follow-up period, where both groups suffered no pain at that time. Yet, the pain intensity diminished quicker in the control group, having a more significant difference in the four weeks follow-up time. This could be due to the dehiscence of the wound still found at that time, with or without the fact of higher incidence of infection occurring postoperatively in the study group.

Rakhmatia (25) outlined certain criteria that ought to be attained in materials used for GBR. The membrane studied was only able to maintain space for bone formation and integrate with the host tissue by having suitable structural integrity. Although, this integrity was quickly lost postoperatively.
Tissue biocompatibility was not achieved since it is theorized that the degradation process of the membrane led to an increased inflammation in the wound and hindrance of their healing. It is repeatedly reported that macrophages play an important role in the degradation process (26). Certain researches have stated that these macrophages exist in many different phenotypes and that actually some of these types may produce increased inflammation and/or fibrosis thus leading to nonhealing or poorly healing wounds (27). Nonetheless, this is not proven for the understudied membrane and further investigations are required in this issue.

Another aspect of tissue biocompatibility is the observation that very little bone formed postoperatively in the defective site. A theoretical explanation to this might be according to the statement made by Shanti (28) that “PDLLA is hydrolyzed in vivo to carbon dioxide and water, leading to concerns regarding the formation of acidic byproducts that might have a negative effect on bone formation”. This might be supported by the finding that the significant difference between the two groups was at the apical measurement, the site farthest away from the membrane.

CONCLUSIONS
According to the results of the present study, it is concluded that SonicWeld® ResorbX® foil membrane causes some kind of hindrance of the healing of buccal mucoperiosteal flaps used for treatment of oroantral communications. The hypothesis of using this membrane for GBR of oroantral bone defects did not prove to be correct in this study.

RECOMMENDATIONS
It is recommended that:
1. Repeating the study with a greater sample size
2. Further studies to be carried out on the degradation products of the foil membrane and its effect on healing and health of the surrounding tissues
3. The study the use of this membrane with other types of soft tissue flaps for oroantral defects

CONFLICT OF INTEREST
The authors declare that they have no conflicts of interest.

REFERENCES


