

Research Article

Evaluation of the Effectiveness of Collagen Membrane in the Management of Oro-Antral Fistula/Communication - A Clinical Study

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Abstract

Background: The opening adjoining maxillary sinus with the oral cavity is termed as Oroantral Communication (OAC) which when left untreated leads to oroantral fistula or maxillary sinusitis. Surgical closure within 48 hours is recommended for OAC to circumvent complications like sinus infections. The current study is designed to evaluate collagen membranes for the treatment of OACs which was reported as a safe and easy procedure.

Method: The study was conducted with the patients who needed the management for Oroantral Fistula/Oroantral Communication (OAF/OAC) which developed following the posterior maxillary tooth removal. To cover OAF/OAC with a collagen membrane, Bio-Gide (GTR/GBR Collagen Membrane) was inserted in the socket. The particular membranes were then attached using sutures to the adjoining gingiva, and medication like Amoxicillin 500 mg, Metronidazole, nasal decongestant drops and steam inhalation were prescribed for one week to each patient. After day 7, sutures were removed. Patients were checked following the first, third, six weeks and third month. Data were statistically analyzed and an Independent T-test was performed.

Results: All the patients accepted Bio-Gide (GTR/GBR Collagen Membrane) perfectly, soft tissue was recovered completely without any problem. Soft tissue was completely epithelialized in the defective area for all the samples. No relapse was reported in any of the patients following a 3-month follow-up.

Conclusion: Bio-Gide (GTR/GBR Collagen Membrane) technique is simple and effective for treating OACs with a diameter of 5 mm or less and with negligible complication.

Keywords: Oro-Antral Communication; Oro-Antral Fistula; Collagen Membrane; Guided-Tissue Regeneration; Guided-Bone Regeneration

Introduction

It might appear fascinating how a pea-sized air space during birth within-side the maxilla (body) changes into a full-blown cavity surrounding the biggest portion in it. The event occurs during the pneumatization process as a functional and adaptive phenomenon. A clinical complication experienced by oral and maxillofacial surgeons with the growing evolution of oro-antral fistula is an Oro-antral communication. This episode of complication may differ from 0.31 to 3.8% following maxillary teeth removal [1].

An Oro-antral Fistula of >2 mm diameter has the chance of unconstrained healing, but in diameter of < 3 mm, voluntary healing is obstructing due to sinus inflammation or periodontal region inflammation [2]. There is likewise much less possibility of spontaneous healing while the OAF has been present for three to four weeks, or while its diameter is >5 mm [3]. Untreated oro-

antral opening leads to sinusitis. Many techniques and treatments are described for managing oro-antral communication or Oro-antral Fistula. Various local flap techniques namely soft palate flap, buccal flap, hard palatal flap with related modifications have been attempted earlier [4].

Above mentioned techniques have their pros and cons. Buccal flap technique might be attempted as the alveolar ridge is extremely low and when it's almost impossible to use the procedure of interseptal alveolectomy, however buccal flap brings down the vestibular sulcus depth, and hence vestibulopathy is required. A palatal flap of complete thickness allows the closing down a fistula opening alongside the mucous membrane of the hard palate. The palatal flap holds blood vessels that allow decent blood circulation, and with its thickness and width, it envelops the area of the fistula better and safer. A lead of this approach when compared to the buccal flap approach states no lowering of the vestibule and thus the flap is more resistant to injury and infection [5]. Drawback of this approach includes the denudation of palatal surface pain, likewise as a later aspect consisting of roughness and deepening of this region because of secondary epithelialization over 2-3 months. The tedious complication is the necrosis of the palatal flap [6].

Lately, third molar transplantation has been used as an approach in the closing of Oro-antral Communication. This suggested modality for management for OAC is favourable and specific, however has the drawback of known complications of 3rd molar extraction. Oro-antral Fistula can't be closed in this fashion. A transplanted tooth is recommended for root canal treatment [7]. Numerous materials can be put to use for restoring the oro-antral defect. Goldman in his study used gold foil to secure the firmness of the flap while closing the fistula and preventing viable recurrences [7]. Zide and Karas used hydroxyapatite blocks for shutting down the OAF to fill up the bone defect in the alveoli [8]. There are other varieties of graft materials to be used instead of bone, including tantalum, freeze-dried collagen and fascia lata, Dura mater [7,9,10]. Buccal Fat Pad (BFP)-pedicle BFP graft was used to close an OAC [11]. These are applied in patients having a fistula of 8-20 mm diameter. Over a span of 3 weeks, the fatty tissue transforms into granulation tissue and epithelium, which had been established by documented histopathologic findings. Bio-Gide, a manufactured collagen membrane that is porous and non- allergenic, and used to shield up the wound to achieve epithelialization. The porous area facing the bone allows the in-growth of osteoblastic cells. Any reaction or infection are not seen due to high purity of the material [9].

Aim and Objectives

Clinical estimation of the benefit of Bio-Gide (GTR/GBR Collagen Membrane) for treating Oroantral Fistula/ Communication is performed. The study has the following objectives:

- Vestibular Height
- Soft tissue healing
- Post-operative pain (VAS)
- Oroantral fistula closure using collagen membrane and quality of bone formation

Materials and Methodology

The present study was executed for the patients in the Department of Oral and Maxillofacial Surgery, ITS. Dental College and Hospital, Greater Noida who required treatment for the OAC, developed following the posterior maxillary tooth removal. Patients were enrolled randomly aged 18-50 years irrespective of gender, caste and creed. Patients Having significant sinus perforation, and systemically healthy subjects with no clinical or radiological evidence of acute or chronic sinusitis were chosen to be part of the study. However, patients distressed with uncontrolled known systemic disease, renal or hepatic disease, cardiac disease, blood dyscrasia, any previous or present gastric ulcers, hypersensitivities, allergies, idiosyncratic reactions to any study medications, sinus pathology, smokers and pregnant women or lactating mothers were excluded. Study began after obtaining approval from the institutional scientific and ethics committees (IEC/OS/17/01).

The technique was performed on patients in whom OAF/OAC had developed following the tooth removal. Informed consent was obtained after detailing the patients (n=10) about the intervention. The affected sinus was irrigated preoperatively through the fistula with physiological isotonic solution daily for the next 7 days to reduce infection. Subjects were asked to take Amoxicillin, Metronidazole, and nasal decongestant drops for 3 days, before the surgery along with steam inhalation.

Detailed clinical findings and radiological data of patients were collected in a standard case history proforma. The defect was assessed, diagnosed and confirmed by both radiographic and clinical assessment. The socket depth was measured using gutta-percha point and scale (Fig. 1,2). Preoperative vestibular depth was noted using Vernier Caliper. Clinical visibility on inspection was checked. Confirmation regarding OAC/OAF was obtained by performing the Water holding test. No preoperative preparation was performed for OAC.

Resorbable Bio-Gide guided tissue regeneration membrane (GTR Collagen Membrane) for surgically closing OAF was used. Pure collagen membrane Bio- Gide is extracted from pigs having a porous surface facing the bone, allowing the in-growth of osteoblastic cells and forming a dense surface against soft tissue. The collagen membrane is made up of type I and III collagen and will be resorbed in 24 weeks [12-14].

Surgical Procedure

The area was adequately anaesthetized with LA, extraction socket was irrigated and later curetted gently to take out any debris or granulation tissue present. Under local anaesthesia, partial removal of interdental bone and smoothing of the sharp bony projection was done. A circular incision with a 2-mm margin was made encircling the OAF after part preparation followed by complete removal of the epithelial tract and inflammatory tissue present in the opening, however, in samples having OAC this procedure was not performed. The GTR Collagen Membrane was properly fixed within the defected area attaining convexity against the sinus and a concavity toward the alveolar bone (Fig. 3). A figure of eight sutures was placed. No surgical splint or dressing was used (Fig. 4,5). Radiological assessment was done post operatively (Fig. 5). Routine standard post- operative instructions were given to the subjects. Pre-operative medicines were continued for one more week along with analgesics. Sutures were removed after 7 days. At the end of 1st, 3rd, 6th weeks and 3rd months evaluation of all the subjects on the basis of these parameters was done:

- Visual analogue scale (VAS) Vestibular depth
- Swelling present/absent Infection present/absent Healing period
- Radiological estimation of bone formation
- Graft accepted/rejected

Statistical analysis for the data was performed with SPSS version 15.0 statistical package (SPSS Inc., Chicago, Illinois). All the collected data were compared using the Independent T-test.



Figure 1: Pre-Operative IOPA (gutta percha point confirming OAC).



Figure 2: Pre-operative measurement of vestibular height.

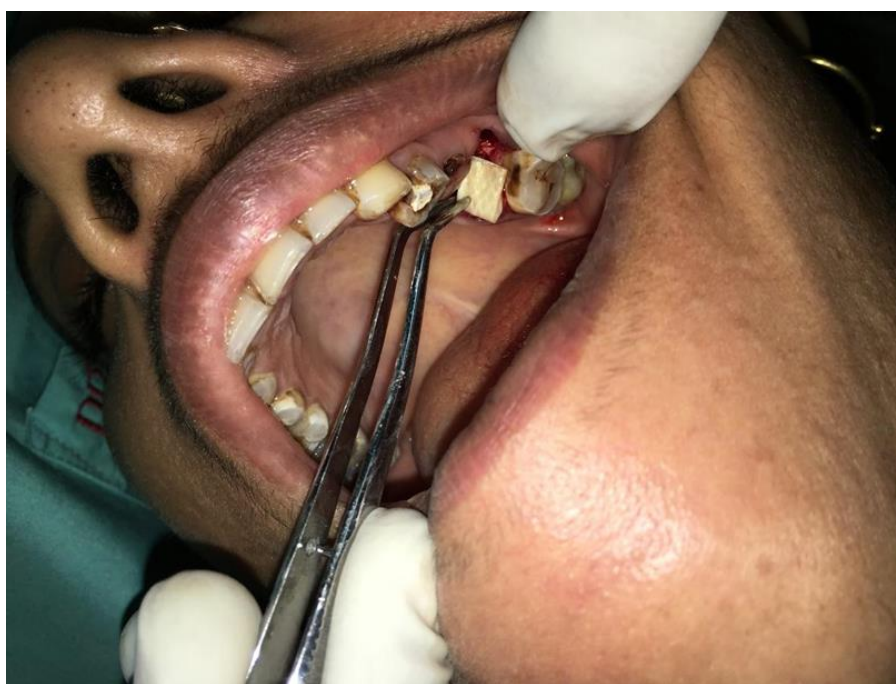


Figure 3: Placement of GBR collagen membrane.



Figure 4: Immediate post-operative measurement of vestibular height.



Figure 5: Post-operative IOPA (4 months), arrow showing bone formation.

Results

The study evaluated the efficacy of GTR Collagen Membrane for treating oro- antral fistula/ communication. Of the 10 patients (5 male/5 female) who presented at I.T.S. Dental college and hospital from 2015 to 2017 with Oroantral defects (i.e., OAC or OAF), OAC was determined in 4 patients (1 male/3 female), 6 patients (4 male/2 female) had OAF.

The Age distribution of total sample size. Age group 18-30 years, 31 to 40 years and 40 to 50 years with percentages 30%, 50% and 20% were part of the study with a mean age of 26.66 ± 1.154 , 35.0 ± 2.121 and 42.5 ± 2.121 years respectively (Table 1).

Age Group (years)	No. of Cases	Percentage	Mean Age	Standard Deviation
18 - 30	3	30%	26.66	1.154
31 - 40	5	50%	35	2.121
40 - 50	2	20%	42.5	2.121

Table 1: Age wise distribution of subjects (n=10).

Gender distribution of total sample size. 5 males and 5 females were part of the study with an average age of 35.4 ± 5.68 and 32.6 ± 6.84 years respectively. The result was not statistically significant between gender distribution ($P < 0.005$) (Table 2).

Gender	No. of Cases	Percentage	Mean Age	Standard Deviation	Pa
Male	5	50%	35.4	5.68	<0.005
Female	5	50%	32.6	6.84	

Table 2: Gender wise distribution of subjects.

The distribution of subjects - based on diagnosis 40% found with Oro-antral communication and 60% with Oro-antral fistula had taken part in the study (Table 3).

Diagnosis	No. of Cases	Percentage
Oro-antral Communication	4	40%
Oro-antral Fistula	6	60%

Table 3: Distribution of subjects based on diagnosis.

Pre and postoperatively the mean vestibular height was 9.44 ± 1.130 mm and 8.9 ± 1.197 mm respectively. However, the difference was not statistically significant in vestibular height ($P < 0.005$). Total 5 (50%) subjects with a size of OAF up to 5 mm² were there. In the size 6-10 mm² category, there were 4 (40%) subjects. Only one subject was in the >10 mm² size category. The mean size was 6.1 ± 2.76 mm² (Table 4).

Size (mm ²)	No.	Percentage
Upto 5	5	50%
10-Jun	4	40%
>10	1	10%
Mean $\pm$ SD	6.1 ± 2.766	

Table 4: Size of oroantral defect.

In the current study, the mean scores for pain were 7.50 ± 0.86 , 5.40 ± 0.96 , 3.90 ± 1.10 at 1st, 3rd and 7th day respectively in the given time duration. At 2-week, 2 (20%) samples had the infection. Infection developed in 1 (10%) patient at 3 and 4 weeks. However, evidence of infection was not detected following weeks 8 and 12 in any of the samples. Radiographically bone formation was evident by 8- week time interval in 9 (90%) subjects and highly statistically significant ($P < 0.001$) Bone formation was noted. In the 16th week, bone formation increased compared to week 8 (Table 5).

Time interval	Patients showing bone formation No.	Percentage	P
16 weeks	9	90%	<0.001

Table 5: Radiographic evidence of bone formation at different time intervals.

Independent t-test

GTR membrane was used as a graft, in 1 (10%) sample. Initially, GTR membrane graft was rejected initially in the first week, later no further graft rejection was found (Table 5). By the end of 2 and 3 weeks, satisfactory healing was shown by 9 (90%) and 8 (80%) samples respectively. However, the result after 4 and 8 weeks, showed satisfactory healing in 9 (90%) patients, and was constant by the end of week 12. (Table 6).

Time Interval	Satisfactory Objective Healing No.	Percentage
2 weeks	9	90%
3 weeks	8	80%
4 weeks	9	90%
8 weeks	9	90%
12 weeks	9	90%

Table 6: Objective of healing at different time intervals.

Discussion

Oro-antral fistula of < 2 mm diameter might heal voluntarily. While, for an Oro-antral fistula of diameter > 3 mm, healing is obstructed as a result of possible sinus inflammation or the periodontal region [2]. There are fewer chances of unconstrained healing when the OAF has been present for 3-4 weeks, or when its diameter is > 5 mm [3]. In both genders, the occurrence of OAF is almost identical, this finding is similar to Von Women, et al., Abramoff MM, et al., and Punwutikorn, et al., [1,15,16]. But there is a greater risk of OAF in females, possibly because of their larger sinuses compared to males [17]. The current study is similar to the clinical evaluation by Martin-Granizo that indicates OAF routinely occurs after the 3rd decade of livelihood and the finding was similar to findings of previous studies by Lin, et al., and Punwutikorn, et al., [1,17,18]. The mean size of the OAF defect was $6.1 \pm 2.766 \text{ mm}^2$, with statistically no significant difference. Nevertheless, strong confirmation of bone formation at 8- and 16-week intervals was noted, which was similar to the work of Ogunsalu, et al., and Hariram, et al., [19,20]. No notable postoperative infection was observed except in one patient. In the *in-vivo* conditions, the GTR collagen membrane is resorbable and shows good biocompatibility. GTR collagen membrane, used as a graft in this study is detailed as a bone replacement substance. This graft is stable in volume, biodegradable, and osteoconductive. GTR collagen membrane is non-toxic and does not produce any immunological or thermal interactions with the bone. The pre and postoperative mean vestibular height was $9.44 \pm 1.130 \text{ mm}$ and $8.9 \pm 1.197 \text{ mm}$ respectively, which was not altered and was suggestive of no further requirement of a secondary surgical procedure such as vestibulopathy. The findings for the postoperative healing had unvaried results for either of the groups and was similar to the results noted by Hanazawa, et al., and Ogunsalu, et al., [2,19].

Conclusion

This is crucial to compare an already well-accepted treatment method (soft tissue techniques) with a novel technique (GTR/GBR Collagen membrane) for clinical execution and patient acceptance. This study uses GBR collagen membrane as a grafting technique which gives a more favourable closure of OAC and provides an apt base for the regeneration of the lost bony structure at the floor of the maxillary sinus where a dental implant can also be placed. Furthermore, this graft aids to keep the vestibular height unaltered which is not possible when a closure is done using the buccal pad of fat or any other soft tissue technique. Hence, suggestive of no requirement for the second surgical procedure (i.e, vestibulopathy).

Conflict of Interest

The authors have no conflict of interest to declare.

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