

Evaluation of using Bioglass® in obliteration of mastoid cavity

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ABSTRACT

Background: A mastoid cavity resulting from a canal wall down mastoidectomy can result in major morbidity for patients due to different open cavity problems. Mastoid obliteration with reconstruction of the bony external ear canal recreates the normal anatomy to avoid such morbidity. **Methods:** This retrospective observational study was conducted for 4 years (between 2008 - 2013) to determine if mastoid obliteration with bioactive glass (Bioglass®) following mastoidectomy overcomes the open cavity problems or not. Patients with cholesteatoma had subjected to mastoidectomy with primary or secondary mastoid obliteration, by using bioactive glass (Bioglass®), then our primary outcome measure. **Results:** Forty patients were interviewed. Forty of them were primary or secondary obliteration after canal wall down mastoidectomy of a primary cholesteatoma. The most frequent fate of obliteration or reconstruction of mastoid was Grade 1 (47.5%) then Grade 0 (30%). Postoperative hearing assessment showed that the average (mean) air conduction (0.5-4 KHz) was 31.1 dB and the average (mean) bone conduction (0.5-4 KHz) was 15.5 dB. The gain average in air conduction was 26 dB and in bone conduction it was 0.5 dB. Ear discharge was found in 36 patients (90%) preoperative and it was found only in 6 patients (15%) postoperative, in 4 patients (10%) cholesteatoma recidivism or recurrences was present. **Conclusion:** This study shows that the bioactive glass (Bioglass®) is one of the best materials used in mastoidectomy with obliteration of open mastoid cavity.

Key words: bioactive glass (Bioglass®), Cholesteatoma, Mastoidectomy, Obliteration

Introduction

The surgical treatment of cholesteatoma often requires canal wall down mastoidectomy (CWD) to ensure complete removal of disease (Ramsey *et al.*, 2004). But the complications associated with open cavity mastoid operations are identical to those possible in any procedure in which the mastoid bone is removed and structures in the middle ear are manipulated. These include: (1) Deafness or further hearing loss, (2) Facial paralysis, (3) Vestibular symptoms, (4) Cerebrospinal fluid leak, (5) Infection, (6) Recurrence, (6) aural drainage, (7) A "chocolate" or mucous retention & (8) Recurrent cholesteatoma (Kveton, 2002). Obliteration methods are performed to resolve these problems. The obliteration is more practical for anatomic and physiologic reason and can be performed by various techniques. Although these problems can be avoided using the canal wall up technique (CWUT), the incidence of cholesteatoma recurrence is higher with CWUT than with CWDT (Charachon *et al.*, 1988). In particular, when patients have a destructive scutum or poor Eustachian tube function, surgeons usually choose to perform the CWDT to prevent the occurrence of retraction pockets, despite the disadvantages of this technique (Lee *et al.*, 2005).

Yung and Karia (1997) recommend mastoid obliteration as a routine procedure in all mastoid surgery. Nevertheless, mastoid obliteration should not be undertaken lightly, because it carries a risk of enclosing cholesteatoma within the cavity. Computed tomography (CT) may or may not be effective in detecting these residual. Over all the clinical follow up in the valuable method in detection of recurrence.

Different synthetic materials can be used to obliterate and reconstruct the mastoid cavity; Dost and Jahnke, (2004) was the first one used the Biomaterials (Bioglass®) in reconstructive middle ear surgery.

Bioactive materials:

Four major categories of surface-active biomaterials have been developed; dense hydroxylapatite (HA) ceramics, bioactive glasses, bioactive glass-ceramics, and bioactive composites (Fiench and Wilson, 2008). The requirements of biomaterials used for middle ear reconstruction according to Jahnke *et al.* (1996) are biocompatibility, High surface energy, High resistance to degradation and infection, High mechanical stiffness, Low weight, No bone deposition, Function-appropriate design, Easy to tailor and position, No imaging artifact.

Bioglass® is a commercially available family of bioactive glasses, composed of SiO₂, Na₂O, CaO and P₂O₅ in specific proportions. Bioactive glass ceramics such as (e.g. 45S5 or Bioglass®) which is composed of 45% silicone dioxide, 24.5% calcium oxide, 24.5% sodium dioxide and 6% phosphorous pentoxide (Neo *et al.*, 1993).

*Patient and Methods:**Patient epidemiology:*

Forty patients with either primary (first time open cavity) or secondary (opened cavity after radical and modified mastoidectomy in case of cholesteatoma) from 2008 till 2013 were identified as possible candidates.

Surgical technique:

Under local anesthesia in 36 patients (90%) and general anesthesia in 4 patients (10%), Postauricular incision, 5 mm behind the sulcus, was done in 38 (95%) cases and endaural approach was done in 2 cases. Open techniques were used in this study. A complete mastoidectomy was performed with removal of the posterior canal wall. The cholesteatoma sac, pathologic mucosa, incus, malleus head, and tensor fold were removed if needed. This was followed by reconstruction of tympanic membrane and obliteration of the mastoid. A revision mastoidectomy is completed as required to remove any diseased mastoid cells and to obtain clean. Obliterative measures should be used only if it is absolutely certain that all epithelium has been removed; otherwise the ossifying bone dust or ceramic might conceal residual cholesteatoma.

The mastoid was exposed via a postauricular incision, and a temporalis fascia graft was harvested. The postauricular flap, canal skin, and remaining TM were reflected anteriorly until the entire medial surface of the drum remnant was exposed. The bioglass was mixed with blood to fill the mastoid cavity as shown in Figure 1. The bioglass fills the mastoid cavity but the epitympanum was not obliterated as shown in Figure 2. The temporalis fascia graft was placed on the bioglass. Final packing with ointment-impregnated gauze was.

Outcome measure & Postoperative follow up:

The patients' dressing were removed after 2-3 days. Stitches were removed after 7 days and gauze packs were removed. The ear filled with antibiotic ointment. This was repeated weekly for 2 weeks then every 2-3 weeks 1.5-2 months till complete healing occurred. Then clinical follow up was done after 1, 2, 3, 6, 12 months and 2 years. The patient was instructed for recording ear discharge or obstruction.

Postoperative clinical assessment included:

- 1- The healing of tympanic membrane.
- 2- The size of the mastoid cavity. Scoring system to evaluate the results of obliteration in our patients and classified mastoid cavity in following four grades (from 0 to 5) as shown in Table 1.

Table 1: Grades of mastoid cavity obliteration:

Grade	means that
Grade 0	The cavity appears as a normal meatus or complete reconstruction (no cavity).
Grade 1	The meatus appears wider (the attic included the meatus).
Grade 2	The meatus appears wider (attic & antrum included the meatus).
Grade 3	The cavity appears small cavity; the facial ridge is slightly visible (upper mastoid is included in the cavity).
Grade 4	The cavity appears medium size cavity (middle mastoid).
Grade 5	The cavity appears as not obliterated (whole mastoid).

3- Cavity problems were determined in terms of presence of facial palsy, vestibular symptoms, discharge, infection or recurrences.

- 4- Subjective hearing improvement and Postoperative hearing assessment.

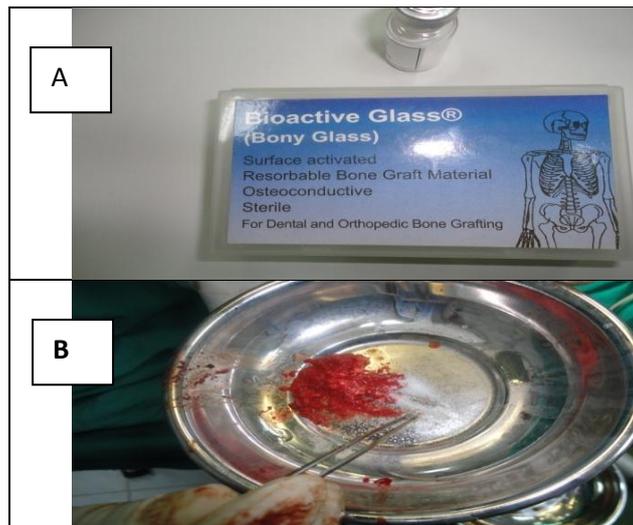


Fig. 1: A-Bioglass® maples. B-Bioglass® mixed with blood.

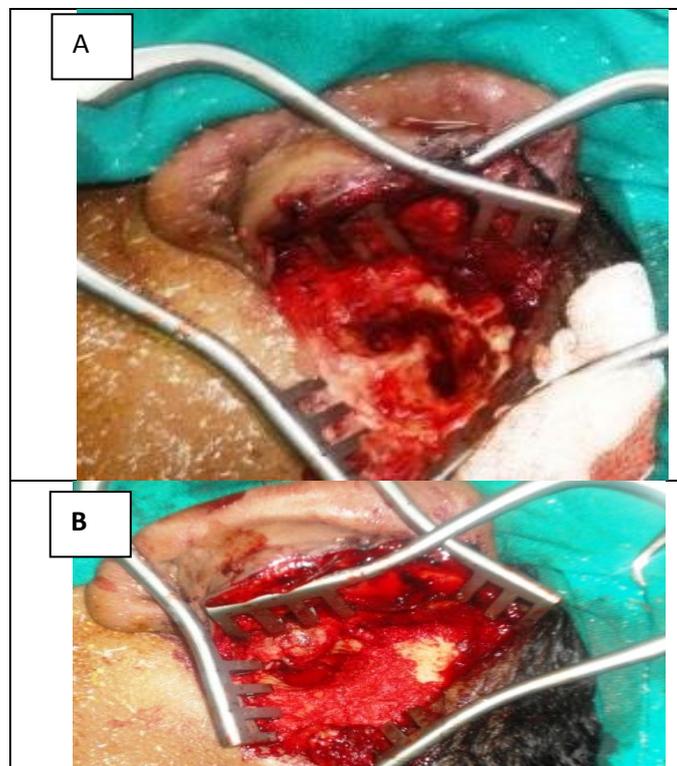


Fig. 2: (Lt. Ear) Intraoperative open mastoid cavity (Op M C) A- open mastoid cavity. B-Intraoperative mastoid reconstruction with Bioglass® mixed with blood.

5- This was done using pure tone audiometry 3 & 6 months then one year after operation. The method used to evaluate hearing in this study determination of the mean of hearing threshold of the patient's pre- & postoperative and postoperative hearing threshold gain. The mean was calculated in the following frequency, Air conduction average at 0.5 – 1 – 2 and 4 KHz and Bone conduction average at 0.5 – 1 – 2 and 4 KHz. Second look operation finding was also recorded

Results:

The patients were reviewed as the previous designed scheduled. The patients' ages ranged from 13 to 55 years old with a mean of 26.45 years old. Most of patients' ages were between 10-40 years. Five children up to 16 years old represented in this study while 35 were older than 16 years old. The study included 28 patients' living in rural area and 12 patients' lives in urban are as in table2,3 and 4.

Table 2: Patients' distribution according to age groups

Table 2:	Range			Mean	±	SD
Age (year)	13	-	55	26.45	±	12.416

Table 3: Patients' distribution according to sex.

Table 3:		Sex	
		No. patients	%
a)	Female	23	57.5
b)	Male	17	42.5
Total		40	100

Table 4: Patients' distribution according to residence.

Table 4:		Residence	
		No. patients	%
a)	Rural	28	70
b)	Urban	12	30
Total		40	100

The most frequent fate of obliteration or reconstruction of mastoid was Grade 1 (47.5%) then Grade 0 (30%) according to the previous classification as shown in table 4 and figures 3, 4 & 5.

Table 5: Fate of obliteration and its G* *(G= grade)

Fate of obliteration	G0	G1	G2	G3	G4	G5
No. of pats.	12	19	8	0	1	0
Per- cent %	30%	47.5%	20%	0.0%	2.5%	0.0%

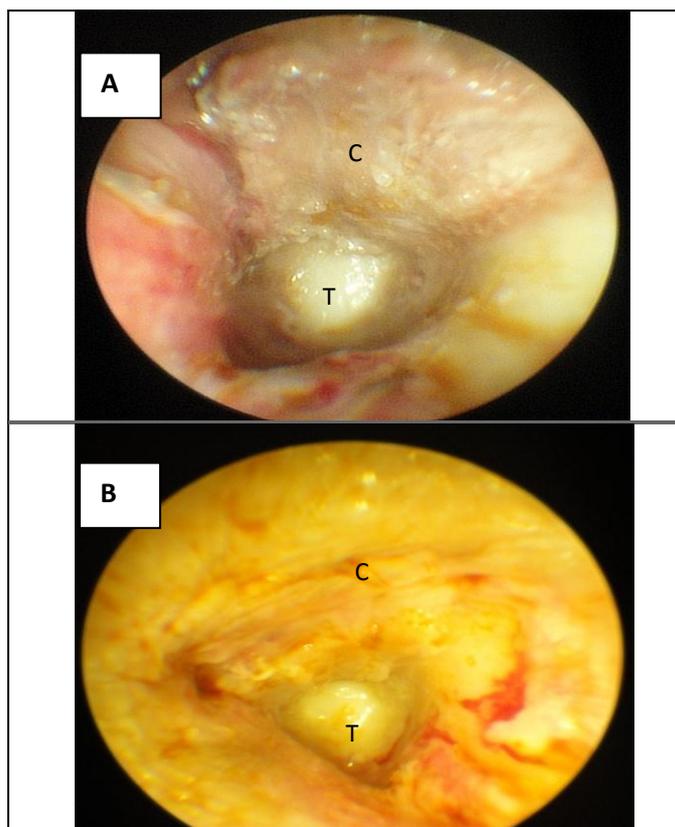


Fig. 3: (Lt. ear) fate of obliteration with Bioglass® A- Early postoperative mastoid reconstruction with Bioglass®. B- Late postoperative mastoid reconstruction with bioglass after 6 month (grade0).The (C) represent the cavity and (T) represent Tympanic membrane.

The result of postoperative assessment:

As reared to Hearing assessment, Preoperative hearing assessment showed that the average (mean) air conduction (0.5-4 KHz) was 57.1 dB and the average (mean) bone conduction (0.5-4 KHz) was 16.25 dB.

Postoperative hearing assessment showed that the average (mean) air conduction (0.5-4 KHz) was 31.1 dB and the average (mean) bone conduction (0.5-4 KHz) was 15.5 dB. The gain average in air conduction was 26 dB and in bone conduction it was 0.5 dB. Preoperative hearing assessment showed that the average (mean) air conduction (2 KHz) was 55.8 dB. Postoperative hearing assessment showed that the average (mean) air conduction (2 KHz) was 26.6 dB. The gain average in air conduction was 29.1 dB. Serviceable hearing (threshold 40 dB or less) was obtained after surgery in 40 of 40 patients (100%).

As reared to Facial palsy assessment, The facial nerve was exposed in 4 patients, the facial palsy occurs in 2 patients (5%) as partial, the first patient was (grade 1) and recovery occurs after 3month and other case was (grade 3), with pre operative facial palsy and the recovery occurs after 6 months, there is no patient developed facial palsy after operation without a previous exposed facial nerve and also there isn't any relation between the obliteration materials or techniques and facial nerve palsy.

As reared to Vestibular symptoms and labyrinthine fistula, Vertigo was found in 26 patients preoperative and it was found only in one patient (2.5 %) postoperative (in attacks for 6 months and then disappears). Labyrinthine fistula was found in 2 patients preoperative and it wasn't found postoperatively and no other vestibular symptoms occur postoperative.

As reared to Infection or discharge and Cholesteatoma Recidivism or recurrences assessment, Ear discharge was found in 36 patients (90%) preoperative and it was found only in 6 patients (15%) postoperative, in 4 patients(10%) cholesteatoma recidivism or recurrences was present , one case(2.5%) inflammatory reaction from biomaterial was found with aural polyp and she underwent repeated packing and ended by residual small perforation and (we have done secondary look and it was free, a second case (2.5%) inflammatory reaction from biomaterial was found in the form of repeated discharge (we have done secondary look and it was free) and reconstruction by fascial between the skin and bioactive material was done.

Second look operation was done for 6 patients (15%) and cholesteatoma recidivism was found only in 4 patients (10%). The decision of second look operation was done after patients complained of persistent discharge or CT suspicion of cholesteatoma recurrence. One of them had cholesterol granuloma and other 3 patients had cholesteatoma in the oval window and at the under surface of the tympanic membrane. Also the decision of second look operation was made in 2 patient had ear pain and soft tissue and we find it was inflammatory reaction from bioactive material.

The patients underwent a second look surgery and no cholesteatoma recidivism was found and the cause was the bioglass wasn't cover by a facial graft, so this leads to an inflammatory reaction with under lined skin.

Discussion:

Bioglass is a commercially available family of bioactive glasses, composed of SiO₂, Na₂O, CaO and P₂O₅ in specific proportions. High ratio of calcium to phosphorus promotes formation of apatite crystals; calcium and silica ions can act as crystallization nuclei, while phosphorus ions don't. Generally, there are four classes of bio-glasses: 35-60 mol.% SiO₂, 10-50 mol.% CaO, 5-40 mol.% Na₂O: bioactive, bonds to bone, some formulations bond to soft tissues , <35 mol.% SiO₂: non-bioactive, nearly inert, gets encapsulated with fibrous tissue, >50 mol.% SiO₂, <10 mol.% CaO, <35 mol.% Na₂O: bioactive, resorption within 10–30 days, >65 mol.% SiO₂: technologically impractical.

Bioactive glass ceramics such as (e.g. 45S5 or Bioglass[®]) bind to soft tissues and bone, and (e.g. 5S4.3 or Ceravital[®]) bind only to bone, are designed to engender surfacereactions that lead to osseointegration (Neo *et al.*, 1993).

Roland and Leach(2004) reported that most biologic tissues have a tendency to atrophy over time, and some otologists recommend overfilling the cavity to compensate for the expected loss of the volume of the obliterating tissues over time. Also Yung stated (1996) that because the final shape and size of the obliterated mastoid cavity cannot be predicted, using biologic tissues for obliteration can be a drawback. Experience has shown that with long-term follow up, free muscle, and fascia flaps undergo atrophy, retraction, and fibrosis (Moffat *et al.*, 1994), this total different from the synthetic materials which have very little chances over time (Dost and Jahnke, 2004).

In this study Bioglass[®] as bioactive material was used and it was found that degree of fate for obliteration with Bioglass[®] was very good and it is very easy to apply. However there were two patients who had discharge due to inflammatory reaction.

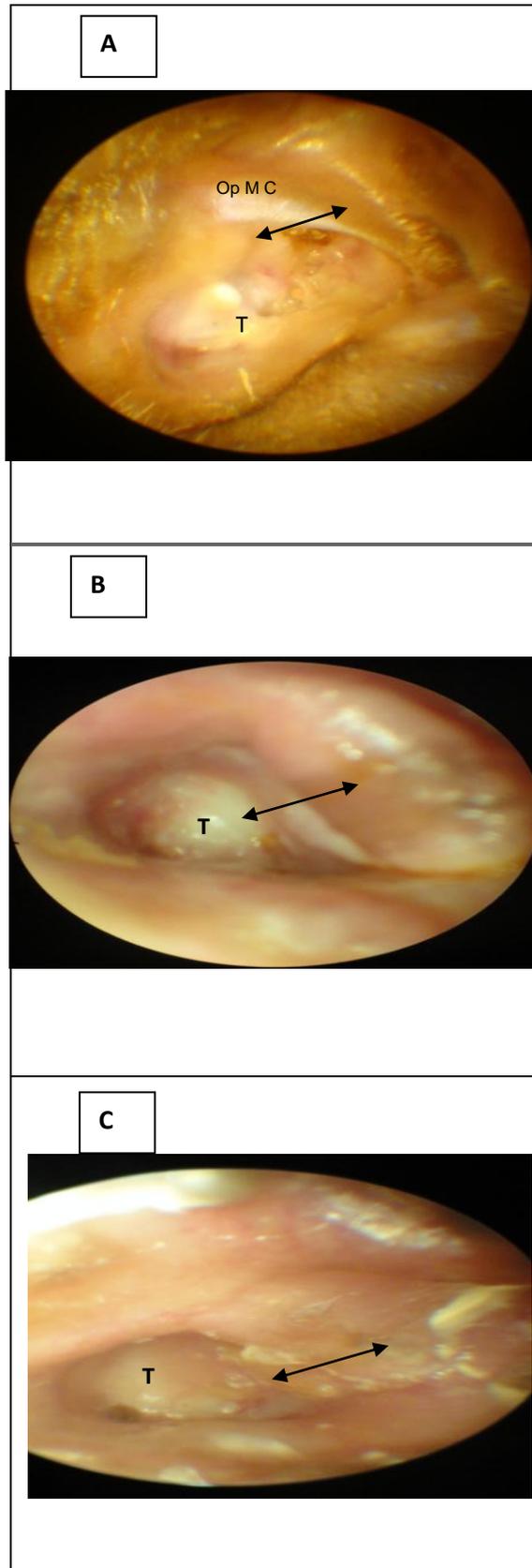


Fig. 4: (Rt. ear) A- Preoperative open mastoid cavity (Op M C) and remnant of tympanic membrane, **B-** Early postoperative mastoid reconstruction with bioglass and fascia, **C-**Late postoperative mastoid reconstruction with Bioglass[®] after 2 year (grade 0), the arrow represent the cavity(↔), and (T) represent Tympanic membrane .

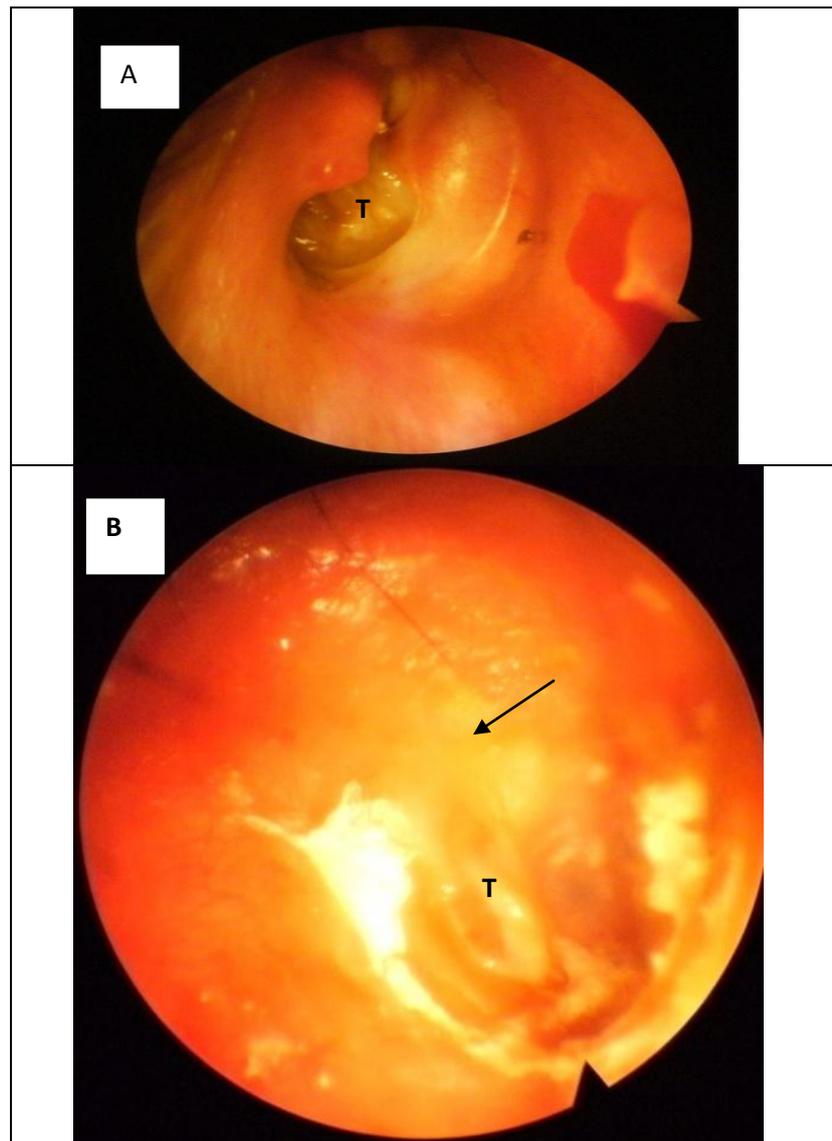


Fig. 5: (Rt. ear) A- Preoperative attic cholesteatoma remnant of tympanic membrane, **B-** Late postoperative mastoid reconstruction with Bioglass[®] after 2 year (grade0), the arrow (↔) pointing the obliterated cavity.

Ridenour *et al.* (2008) reported that after using the bioactive martial in mastoid cavity obliteration, three patients required revision surgery to remove bioactive ceramic martial form 99 patients. Two patients (one primary and one second look with obliteration) presented with granulations in the mastoid cavity, surrounding the cement. The third patient had extensive skull base osteitis and fistulae

Nyrop and Bonding (1997) compared the long-term results of three different surgical techniques (modified radical mastoidectomy, Canal wall up mastoidectomy and atticotomy and atticoantrotomy). They reported a recurrence rate of 70 % for cholesteatoma in cases treated with canal wall up surgery, as compared to 15 % in patients undergoing canal wall down mastoidectomy with obliteration. But the results of Karmarkar *et al.* (1995) who reported in a retrospective analysis the recurrent/residual rate was present in 12.4% of CWD cases and 42% of CWU cases in total 433 primary cholesteatoma cases over a 7 year period. In this study the recurrence or residual cholesteatoma was found in 4 cases (10%) by repeated follow up in the cases which presented by recurrent discharge and after a secondary look.

Whittemore *et al.* (1998) performed a cadaveric temporal bone study on the acoustic effects of changes in the volume of the middle ear air space resulting from CWU and CWD procedures and found that as long as the middle ear space is aerated and has a volume of more than 0.7ml there should be less than 10dB difference between CWU and CWD hearing outcomes.

Toner and Smyth (1990) mentioned that the comparison of patients who had CWU, CWD with reconstruction and CWD surgery with follow up of between 8 and 12 years. They found that the hearing benefit at one year (pure tone average (PTA) air conduction (AC) threshold) was greater in the CWU group.

In this study the use of Bioglass® in reconstruction it gives us postoperative gain average in air conduction was 29.1 dB. Serviceable hearing (threshold 40 dB or less) was obtained after surgery in 40 of 40 patients (100%).

Other complications, such as CSF otorrhea, have been reported. The overall in this study, the complication of open cavity was observed in obliteration of the mastoid but less than the CWU techniques. As reported by Magnan(2009), who stat that over 500 cases from 1976 to 2006 was after reconstruction of the canal wall in the same sitting after CWD technique with different material, preoperative mastoid cavities: cholesteatoma sac 75%, discharge 95%, postoperative safe ear: 87% long term, revision under local anesthesia for exposed canal 8%, 5% otorrhea recurrence cholesteatoma 2%, recurrence discharge 4%. He also find that reconstruction of the canal wall prevent tympanic retraction pockets to occur.

Conclusion:

This study shows that the bioactive glass (Bioglass®) is one of the best materials used in mastoidectomy with obliteration of open mastoid cavity.

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