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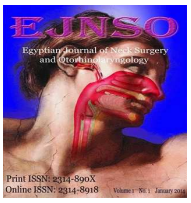

Glass Ionomer Bone Cement: Is it the Magic Solution for Ossicular Defects?

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ABSTRACT

Objective: This study aimed at evaluation of the hearing outcome of using glass ionomer bone cement GIC to manage different patterns of ossicular discontinuity. **Study design:** prospective clinical study. **Subjects and methods:** The study included 53 patients with conductive hearing loss caused by ossicular pathology rather than fixed stapes. Thirty three cases were primary surgery and 20 cases were planned 2nd stage. According to the ossicular situation during surgery the patients were classified into 6 groups. In the 1st group the 3 ossicles were articulated and mobile but the handle of malleus was amputated. GIC was used to elongate the handle by cementing a bone chip to it. In the 2nd group, the Long process of incus LPI was necrosed by the hook of the Shea piston, here,GIC was used to elongate the LPI and reconnect it with the piston. In the 3rd group, only the handle of malleus was present and a bone chip or the preserved incus was cemented with the GIC both medially to the foot-plate and laterally to the handle of malleus. In the 4th group The incudo-stapedial joint ISJ was necrosed and the GIC was used to establish the connection of the LPI to the stapes. In the 5th group, malleus to stapes assembly was established with a bone chip or incus remnant fixed in place with the GIC. In the last group GIC was used to elongate the stapes to become as lateral as the tympanic membrane. Hearing results at about one year were analyzed. **Results:** The Pure tone average PTA improvement was 12.2 dB. Forty eight patients showed a degree of PTA improvement, 4 cases showed no improvement and one case showed a 15 db deterioration. There was an average air -bone gap ABG improvement by 13 dB. The best improvement in the ABG was in the group with ISJ reconstruction and the least was in the group of malleus handle elongation. No complications were reported rather than that case of 15 dB hearing deterioration. The preparation, handling and cementing with the GIC is simple and easily mastered. **Conclusion:** GIC is a good tool available to the otologist. It can be used alone to re-establish the continuity of the ossicular chain in minor ossicular chain defects. It can also be used to stabilize other forms of re-bridging surgery.

Introduction

Although the earliest reported attempt at restoring connection between the tympanic membrane(TM) and oval window(OW) in the case of a missing ossicle was in 1901 (1), till now the ideal way to re-establish a sound and stable sound-conduction mechanism that withstands the test of time in the unique middle ear(ME) environment is still a dream to come. The reason for that is probably not the nature of the material used for reconstruction rather than the circumstances of the middle ear itself in terms of the status of the Eustachian tube function, mucosa of the middle ear and the remaining part of the ossicular chain.

There are 2 schools of opinion among otologists in regards to the best material for Ossicular chain reconstruction. The first group believes that the ME should not be violated by non biologic materials and only autografts or homografts should be used for such work. They believe that ME with chronic infection has marked intolerability to foreign materials and the inertness of most of the available materials is relative and the subsequent fibrosis –even if minimal- will result in scaring, displacement and probably extrusion of these materials (2). The second group uses the relatively new biocompatible materials and believes that they are less foreign than homografts and sometimes even autografts stored in a variety of chemical solutions for variable times under variable conditions before being used in the ME (3).

Plester (4) examined 500 surgically –removed ossicles from cases of chronic otitis media COM with cholesteatoma under the microscope and detected histologic evidence of residual debris of cholesteatoma in 75% of speciments. Peng and Hope (5) detected squamous epithelium and osteomyelitis in about one fourth of ossicles removed from patients with COM.

For this reason and because of concerns about disease transmission and some cultural and social barriers against obtaining homograft ossicles for use, the use of alloplasts in ossicular surgery is gaining more and more supporters in its side. Glass ionomer bone cement GIC was invented by Wilson and Kent in 1971 and first used in dentistry then it was introduced to orthopedics and ME in 1989 (6).

GIC is provided commercially in a separate liquid and powder containers. When mixed together, a whitish paste-like material results that hardens gradually over minutes. During these minutes it can be used to meet various needs for ossicular reconstruction. It adheres well with bone and metals (6). After 24 hours it has a comprehensive strength and elasticity comparable with cortical bone. The thermal energy released from the reaction is minimal and the porous nature of the cement allows osteoconduction and bone in-growth (7) .Gabor has noticed that when GIC came in contact with the CSF, a toxic amount of aluminum has released and resulted in encephalopathy (6).

In this study we are presenting our results with using GIC in different types of ossicular reconstruction.

Materials & Methodology:

The study was conducted in the department of ENT Assiut University Hospital from January 2011 till December2013. Fifty-three patients with conductive hearing loss (CHL) caused by ossicular pathology rather than stapes fixation were included in this study. Thirty one patients were females and 22 were males. The age of patients ranged from 11 to 46 years with a mean of 22.9 years. There were 33 cases of primary surgery and 20 cases of planned second stage after cholesteatoma surgery or revision surgery for CHL after successful stapes surgery. Pre-operative Pure tone average PTA thresholds and air –bone gap ABG at 500, 1000, 3000 Hertz were calculated and recorded. The causes of CHL were summarized in table (1).

Table (1): Causes of CHL

Diagnosis	Number of cases
C S OM	42
Tympanosclerosis	6
Revision stapes surgery	4
CHL after head trauma	1

Six groups of ossicular reconstructions were done, based upon 6 ossicular situations found at surgery.

- Group (1). (No. 3 cases). In this group only the handle of malleus was amputated while the malleus head, incus and stapes are present and mobile.
- Group (2). (No.4 cases). In this group the long process of incus was necrosed by Shea piston after initially successful stapedectomy.
- Group (3). (No.8 cases). In this group of planned 2nd stage, only the handle of malleus was present. The stapes was absent and the incus was either absent or removed together with the malleus head to clean the attic in the primary surgery.
- Group (4). (No.12). The incudo-stapedial joint area ISJ was discontinuous due to necrosis of the stapes head, Lenticular process and or distal part of LPI.
- Group (5). (No. 12). Here the stapes is intact, so is the handle of malleus, while the incus is absent.
- Group (6). (No. 14).In this group both malleus and incus were absent, and only mobile stapes was present. Six cases here were primary surgery for frozen attic and 8 cases were planned 2nd stage.

All operations were done under general anesthesia with hypotensive technique. We have used the post aural approach when grafting the TM or obtaining a piece of cortical bone was required and the per-meatal approach when there was an intact or previously grafted TM. The status of the ossicular chain is checked and the procedure of ossicular reconstruction is selected

Preparation of the GIC.

On a sterile glass slide one drop of the cement liquid (polycarboxylic acid) is added to a measuring spoon of the cement powder and mixed well until the mixture is homogenous and paste-like here it is ready to be used.

In group (1). After harvesting the TFG, a chip of mastoid cortex is obtained and drilled away to the suitable length and diameter to meet that of the malleus- handle remnant. The ME is packed with a dry cotton piece and the prepared bone chip is placed over it in such away to contact the malleus end to end and by a fine needle the GIC is used to cement the chip to the malleus. When the connection is hard (usually from 7 to 10 minutes) the cotton piece is removed and the TFG is laid over the malleus and the wound closed as usual.

In group (2). After freeing the adhesions around the prosthesis, a hook is used to gently bring the piston close to the necrosed end of the incus and a fine needle is used to elongate the LPI through the hook of the piston. The piston is held in place until the cement hardens and the connection is stable.

In group (3). In this group handle to foot-plate assembly was done. Part of the patient previously preserved incus in the ME or a chip of cortical bone is fashioned to bridge the gap between the handle of malleus and the mobile foot-plate. GIC is then used to establish a firm connection both medially and laterally to the foot-plate and handle respectively.

In group (4). All these cases were primary surgery for safe COM with one case of CHL after head trauma. Using a fine needle, the GIC is used to replace the eroded head of stapes, lenticular process and/ or distal part of the LPI.

In group (5). The GIC iwas used to build 2 or 3 floors of bone cement over the head of the stapes each after the previous one got hard. When the

appropriate length of the stapes wass achieved the malleus handle was rotated posteriorly and cemented to the lateral end of the elongated stapes with GIC.

In group (6). Like the previous group, the GIC was used to elongate the stapes laterally until it became in contact with the TM and tented it a little bit.

The patients were followed up as routine in ear surgery. The post-operative PTA threshold at 500, 1000, 3000 Hertz and the post operative ABG were obtained at an average of 12 months and compared with the pre-operative values for all patients .We considered a post operative ABG of 20dB or less our successful hearing results according to the guidelines of the American Academy of Otolaryngology Head and Neck Surgery Committee on Hearing and Equilibrium 1995. Any decline of more than 10 dB in bone conduction threshold is considered failure. The patients were observed also for complications such as facial weakness, vestibular symptoms, or extrusion of the GIC.

The data was analyzed using the SPSS version 19 statistical software package.

Results:

There was an average improvement in the ABG by 13.7dB. The average pre-operative ABG of 33 dB has improved to an average of 19.3 dB.

PTA changes

In our patients the overall PTA improvement was 12.2 dB. Forty eight patients showed a degree of PTA improvement. 4 cases showed no improvement and one cases showed decline in its PTA.

The best improvement was by 41 dB. It occurred in a case of elongation of the LPI to connect it with the stapes in 25-year old male. The case which deteriorated was one of the revision surgery for stapedectomy. It looks like the manipulations of the piston caused injury to the inner ear structures and ended by 15 dB decline in the PTA.

Apart from this case with hearing decline, no other complications were noticed during the one-year follow up of these patients.

Table (2): The overall pre-operative versus post-operative ABG groups

ABG groups	Pre-operative		Post-operative	
	No	%	No	%
0-20 dB	2	<4%	34	64%
21-30 dB	7	13%	15	28%
>30 dB	44	83%	4	8%

Table (3): The average pre-operative versus post-operative ABG for each group of reconstruction.

Type of reconstruction	Group (1)	Group (2)	Group (3)	Group (4)	Group (5)	Group (6)
No	3	4	8	12	12	14
Average pre-op ABG	23 dB	33.7 dB	34.2 dB	35.8 dB	35.8 dB	32.7 dB
Average post-op ABG	13.3 dB	21.2 dB	20.6 dB	18.6 dB	21.6 dB	21.1 dB
Average ABG improvement	9.7 dB *P-value <0.001*	12.5 dB *P-value <0.001*	13.6 *P-value <0.001*	17.2 dB *P-value <0.001*	14.2 dB *P-value <0.001*	11.6 dB *P-value <0.001*

Table (4): The details of the PTA changes.

PTA changes	**No**	**%**
Improved by 0-10dB	14 cases	26.4 %
Improved by 11-20 dB	24 cases	45.3 %
Improved by 21-30 dB	7 cases	13.2 %
Improved by> 30 dB	3 cases	5.7 %
Not improved	4 cases	7.5 %
Declined	One case	1.9 %

Discussion:

In the last 10 or 15 years, there is a remarkable worldwide interest among otologists about various types of bone cement, their clinical applicability to solve different otologic problems and the hearing outcome with various ossicular situations in which the cement is utilized.

In this study we have evaluated the results of using glass ionomer bone cement to solve different situations of ossicular defects starting from minor reconstructions as elongation of the malleus handle and repair of the ISJ area till the major ones in which one or more of the ossicles are absent. We also included 4 cases of revision stapedectomy in which the piston has necrosed the LPI with recurrence of the CHL. Considering a post-operative ABG of 20dB or less our main parameter of success, it was achievable in about 2/3 of cases. More than 90 % of cases had post-operative ABG less than 30 dB. Compared with the pre-operative ABG values where more than 80% of patients had ABG more than 30dB this is a significant improvement.

There was PTA improvement in more than 90% of our cases. About 2/3 of the cases showed PTA improvement by more than 10 dB. 1/4 cases showed improvement by less than 10 dB. The average ABG improvement ranged from 10 dB to 17 dB. The least average ABG improvement was in the handle elongation group. This is probably because the pre-operative ABG in this group was already the least. The best average ABG improvement was in the ISJ repair group, this is quite logic because the GIC here has returned the anatomy of the ossicular chain very much close to their normality.

Correction of the missing incus came next in the success results, followed by correction of the missing both incus and stapes, and lastly came correction of the missing incus and

malleus handle. We can conclude here the importance of keeping the handle of malleus in cholesteatoma surgery if possible because it serves as a lateral support for future ossiculoplasty. Revision stapes surgery is a special type of reconstruction, and it carries a higher risk of complications than both primary stapes surgery as well as other forms of ossicular surgery.

We had one case of deterioration of these 4 revision stapes surgery while the other 3 cases went well. Although 4 cases is a too little number to judge conclusive results from, the importance of experiencing the most gentle manipulations in these cases should not be overemphasized. Baylancicek etal (8) have found no significant difference when compared the results of bone cement with that of PORP in cases of necrosed ILP. The postoperative ABG was around 10 in both groups.

Considering the price of the PORP in the equation, the cheap bone cement wins the race in poor countries. In their recent and relatively larger sized study Edizer DT etal (9) found no significant difference in the results between cementing the malleus to the stapes and incus interposition. They recommend the first reconstruction because it is easier and more suitable when the incus is missing or its cleanliness of epithelium is questionable. Our results in this sector of patients were comparable to their results. Similar results of malleus to stapes assembly with GIC were reported by Bayazit YA etal (10).

In our last group, the GIC came in contact with the TM and we have noticed no reaction or extrusion of the GIC during the follow up period something in favor of the inertness of the GIC. The GIC should be dealt with as a cement material, should any drop of it dipped in the oval window or round widow area or touched the bony wall around the ossicles , it should be aspirated immediately before hardening to avoid fixation of the ossicles.

The GIC has proved very helpful not only to stabilize other traditional ways of ossiculoplasty as incus interposition and malleus footplate assembly and make them more stable during the healing process, its use as a substitute for part of ossicles in minor ossicular defects is possible. It showed to us no reaction and did no harm to the inner ear or facial nerve during our follow up period as far as it is kept away from the neural tissue.

Conclusion:

GIC is a very useful tool in the hand of the otologist during ossiculoplasty. It can be used to stabilize various forms of ossicular repositioning surgery, can replace some small ossicular losses. It is tolerated well in the unique ME environment . Other advantages of the GIC is its easy use, cheap price.

Recommendations

Longer follow up of these patients is mandatory to detect any delayed reaction. Also the behavior of the GIC in the presence of ME infection should be carefully monitored.

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