The Effects of Usage of Glass Ionomer Bone Cement for Hearing Ossiculer Chain Reconstruction on Hearing Results

🕲 Hasan Mervan Değer¹, 🕲 Gökhan Yalçıner², 🕲 Ahmet Kutluhan³

¹Department of Otorhinolaryngology, Kocaeli University Faculty of Medicine, Kocaeli, Türkiye ²Department of Otorhinolaryngology, University of Health Sciences, Ankara Bilkent City Hospital Faculty of Medicine, Türkiye ³Department of Otorhinolaryngology, Pamukkale University Faculty of Medicine, Denizli, Türkiye

ABSTRACT

Objective: The aim of this study is to evaluate the results of the applications of glass ionomer bone cementin (GIBC), which is used to ensure ossicular chain continuity in otologic surgery between incus-stapes and malleus-stapes.

Materials and Methods: In the study, the medical records of 28 patients who were operated on for chronic otitis media or conductive hearing loss with intact membranes in the Ear, Nose, and Throat Clinic of a training and research hospital between January 2006 and June 2009, GIBC was used for hearing reconstruction in the operation, and the necessary file information was obtained were evaluated retrospectively. Pure tone averages (PTA) and air bone gaps (ABG) were measured in the pre-operative and post-operative pure tone audiogram evaluations of the patients, and the results were compared statistically.

Results: While the pre-operative mean PTA of the patients was 51.3±12.8, this figure was found to be 26.6±13.7 in the post-operative audiological evaluation. Again, while the pre-operative ABG average was 36.9±9.2, this value was measured as 10.8±5.2 postoperatively. The difference between pre-operative and post-operative averages was statistically significant (p<0.001).

Conclusion: The use of GIBC to bridge the malleus and stapes in ossicular chain reconstruction, especially in cases where incudostapedial joint defects and incus are not suitable for use, is suitable for hearing results, ease of use, cost advantage, and biocompatibility.

Keywords: Chronic otitis media, glass ionomer bone cement, pure tone audiogram

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INTRODUCTION

Ossiculoplasty is the reconstruction of the middle ear ossicular chain, which has been impaired or damaged due to reasons such as trauma, surgical manipulation, or cholesteatoma, using certain devices to restore the original mechanics of the ossicular chain to transmit sound energy to the inner ear.^[1] The aim of ossiculoplasty, which is influenced by many factors such as abnormalities in the middle ear, the condition of the Eustachian tube, the surgeon's technical skills, and the type of ossicular reconstruction, is to improve hearing.^[2] Materials used in ossiculoplasty include autografts such as autologous ossicles, cartilage, and bone; homografts such as homologous bone; and synthetic materials such as plastipore, hydroxyapatite, and titanium.^[3] Prostheses such as partial ossicular reconstruction prostheses (PORP) and total ossicular reconstruction prostheses have also been introduced.^[4] Although numerous ossiculoplasty techniques are used to reconstruct the ossicular chain, the ideal ossiculoplasty material should be biocompatible, stable, easy to use, and safe.^[5] Glass ionomer bone cement (GIBC), originally developed as a restorative dental material, is now used in various fields due to its biocompatibility and lack of significant reported adverse



Address for Correspondence: Hasan Mervan Değer, Department of Otorhinolaryngology, Kocaeli University Faculty of Medicine, Kocaeli, Türkiye E-mail: degermervan@gmail.com ORCID ID: 0000-0002-7415-5465 Received date: 11.02.2022 Revised date: 09.09.2022 Accepted date: 23.02.2023 Online date: 15.10.2023



reactions.^[6] GIBC is stable, easy to use, and does not irritate adjacent tissues. When in contact with bone, the cement hardens and adheres firmly to the bone. Another advantage is that the hardened cement can be easily shaped to restore the original anatomy of the repaired structure.^[7] Chronic middle-ear inflammation can often lead to tympanic membrane perforation and disruption of the ossicular chain. In addition, middle ear granulations can restrict the movement of the ossicular chain.^[8] Conductive hearing loss occurs in patients with disrupted ossicular chain continuity.^[9] GIBC is widely used in these patients, especially to establish a connection between the incus and stapes or malleus and stapes, due to its low cost, ease of use, and bridge-building capabilities.^[10,11] The aim of this study is to evaluate the results of the applications of GIBC, used to ensure ossicular chain continuity in otologic surgery between incus-stapes (IS) and malleus-stapes (MS).

MATERIALS and METHODS

The patients in the study underwent surgery for chronic otitis media with the use of GIBC for hearing reconstruction in the Ear, Nose, and Throat Clinic of a Training and Research Hospital between January 2006 and June 2009. All of the patients underwent intact canal wall tympanoplasty and disrupted ossicular chain integrity. Patients with a post-operative disease-free middle ear cavity and intact tympanic membrane along with mastoid bone were included in the study, while patients with erosion and/or fixation of the stapes or malleus were excluded from the study. A total of 28 cases were included in the study, with a mean age of 31.3±16.2 years (range: 10-64 years), including 15 (53.6%) females and 13 (46.4%) males. The follow-up period ranged from 6 to 36 months. Pre-operative and post-operative 6-month puretone audiometry was performed for all patients, and puretone averages (PTA) and air-bone gaps (ABG) were obtained. Pure-tone thresholds were obtained at frequencies of 500 Hz, 1 kHz, 2 kHz, 3 kHz, and 4 kHz.

All patients underwent pre-operative and post-operative 6-month pure-tone audiometry, and pure-tone thresholds and ABG before and after the procedure were obtained. Pure-tone thresholds were obtained at frequencies of 500 Hz, 1, 2, 3, and 4 kHz. PTA and ABG were calculated by averaging the values at 500 Hz, 1, 2, and 3 kHz. A reduction of more than 20 dB in the ABG was considered a successful outcome in the post-operative audiometric evaluation.^[12]

The cases were divided into two groups: IS and MS GIBC bridging. Changes in PTA and ABG before and after the procedure were compared within and between the groups to investigate the effectiveness of GIBC in ossiculoplasty.

Surgical Technique

After accessing the middle ear through a retroauricular or endaural approach, the posterior superior wall of the external auditory canal was removed using a curette or a drill to expose the ossicular chain. In cases where the integrity of the incudostapedial chain was compromised, two different procedures were performed: (a) GIBC was placed between the incus and stapes when disarticulation and partial erosion in the long process of the incus were observed; (b) in cases where the incus was severely eroded and could not be used, the incus was removed, and GIBC was used to reconstruct the transmission chain between the malleus and stapes. KetacTM Cem Radiopague (3M Germany) was used as the GIBC material. The powder component contained 33 g of fluoroaluminosilicate particles, polycarboxylic acid, and pigments, and the liquid component contained 12 mL of tartaric acid and benzoic acid. The liquid and powder components were mixed in a sterile container to achieve a suitable consistency (paste-like). Then, the prepared ossicular region, which was previously cleaned and dried, was applied with the mixed GIBC using a thin, blunt-ended probe. To protect the middle ear mucosa from possible accidents due to the toxic effect of GIBC on soft tissues, absorbable gel foams were placed in the middle ear. After the bone cement hardened, the absorbable gel foam was removed. After waiting for 5 min for drying and stabilization, the stability and movement of the ossicles were checked, and the surgery was completed. The gap between the incus and stapes was slowly filled dropby-drop with GIBC and a pick. The gap between the malleus and stapes was filled gradually, starting from the malleus, preferably from the middle and inferior 1/3, until reaching the stapes head, thus creating a bridge of bone cement. In cases where this process took a long time, re-preparation and re-application of GIBC might be necessary.

In cases where grafting was performed, the selected graft material was supported from below with absorbable gel foam and placed as an underlay. For graft stabilization, a bundle was prepared from silk strips, which filled the external auditory canal from above, and the bundle was filled with antibiotic-soaked cotton.

RESULTS

A post-auricular approach was applied to 25 patients (89.3%), while 3 patients (10.7%) underwent an end-aural approach for chronic otitis surgery. In 14 out of 25 patients who had undergone surgery for chronic otitis media, mastoidectomy was performed, and the condition of the ossicular chain was evaluated after the cleaning of pathological tissues (Fig. 1).



GIBC was applied between the incus and stapes in 21 patients (75%). In 7 patients (25%) with severely worn-out and unusable incus, the incus was removed and a bridge was established between the malleus and stapes with GIBC. The pre-operative mean AC threshold was 51.3 ± 12.8 , while the post-operative mean AC threshold was 26.6 ± 13.7 (p<0.001). The pre-operative mean ABG was 36.9 ± 9.2 , while the post-operative mean ABG was 10.8 ± 5.2 (p<0.001) (Fig. 1 and Table 1).

In cases where bone cement was applied between the incus and stapes, the pre-operative mean ABG was 37.2 ± 8.8 , while this average was 36.0 ± 10.7 in cases where bone cement was applied between the malleus and stapes (p=0.959).

After the operation, the ABG in cases where IS bone cement was applied was found to be 10.4 ± 4.6 , while it was 11.9 ± 7.1 in cases where MS bone cement was applied (p=0.876). The postoperative audiological success rate (ABG being 20 dB or less) was 66.7% (14/21) in cases where IS bone cement was applied and 71.4% (5/7) in cases where MS bone cement was applied. There was no significant difference between the two groups in terms of audiological success (p=1.00) (Table 1).

DISCUSSION

In chronic otitis media, the integrity of the ossicular chain is most commonly disrupted by erosion of the incudostapedial joint and/or the long process of the incus. Various methods have been described for the treatment of the IS transmission disorder, including PORP, incus repositioning, and the use of cortical bone. However, the use of these methods presents disadvantages due to difficulty in stabilization, high rejection rates, and cost. On the other hand, the use of GIBC is an easy, accessible, and inexpensive material.

In this study, a significant decrease (10.8±5.2) in average ABG was observed in patients after the operation. In the study conducted by Baglam et al.,^[5] which included 136 patients who underwent incudostapedial bone cement application, pre-operative PTA and ABG averages were found to be 52.8 dB and 31.1 dB, respectively, and after the operation, these values were obtained as 32.8 dB and 16.5 dB, respectively.

Ozer et al.^[13] reported an average ABG of 14.3 dB in a longterm follow-up (1 year after the operation) of 15 cases who received incudostapedial GIBC. In another study, GIBC repair was compared with incus repositioning in the repair of erosion of the long process of the incus, and the post-operative mean ABG was found to be significantly higher in patients who underwent incus repositioning (19.3 dB) compared to those who underwent GIBC repair (15.2 dB). ^[10] Elsheikh et al.^[14] reported that the post-operative ABG in the group of patients who received GIBC was significantly better than the control group who underwent PORP usage. When these values obtained from the studies are evaluated as both PTA and ABG gains, they are statistically significant. These results demonstrate that GIBC is an effective method in creating ossicular chain integrity in cases where IS integrity is compromised.

Although GIBC is a successful method, its use in cases of wide or complete erosion of the long process of the incus is controversial. In this study, GIBC was found to be equally successful in bridging both the IS and MS gaps. These results demonstrate that GIBC can be used to bridge wide gaps and in cases where the incus is not visible, be completely eroded or removed. In the study conducted by Elsheikh et

Table 1. IS and MS groups pre-operative and post-operative air bone gaps values			
	IS (n=21)	MS (n=7) (%)	р
Pre-operative ABG (dB)	37.2±8.8	36.0±10.7	0.959
Post-operative ABG (dB)	10.4±4.6	11.9±7.1	0.876
Success (ABG>20) (dB)	14 (66.7)	5 (71.4)	1.000
Success (Post-operative PTA<20) (dB)	15 (71.4)	4 (57.1)	0.646

IS: Incus-stapes; MS: Malleus-stapes; ABG: Air-bone gaps; PTA: Pure tone averages

al.^[14] with 62 patients, the defect in the incudostapedial joint was divided into two groups: below and above 2 mm. The pre-operative and post-operative ABGs of 34 ears with defects >2 mm and 48 ears with defects <2 mm were compared separately, and both groups were statistically successful. In addition, no significant difference was found in terms of ABG gain between these two groups, and it was concluded that the size of the incudostapedial defect was not important. In a study conducted by Bayazit et al.^[11] with 50 patients in 2005, incudostapedial joint was applied in 42 patients and bone cement was applied between MS in eight patients, and the results were compared. Significant hearing gains were achieved statistically in both groups, but no difference was found between the two groups in terms of success.

This study, which reveals the effect of GIBC on hearing outcomes, has an important contribution to the field since it supports the results of the studies in the existing literature. However, it also has limitations since the sample size is not large enough for generalization.

Based on the results of this study, GIBC is an effective and reliable method in cases where the IS ossicular chain integrity is compromised. In addition, MS GIBC bridging can be successful in closing ABG until IS bridging when it cannot be performed.

In addition, if the filling mixture is not prepared properly, the bridge may not reach the sufficient hardness level. If the filling does not reach sufficient hardness before the end of the surgery or if the bridge is damaged during the closure of the tympanomeatal flap or placement of the pouch, sufficient improvement in hearing may not be observed after the operation.^[11] In addition, excessive manipulation of the GIBC bridge during the operation can cause microfractures in the bone cement. However, there is no study supporting the formation of microfractures due to manipulation. In this context, future studies in this field will be important both in terms of literature and surgical technique.

CONCLUSION

According to the results of this study, GIBS can be used to reestablish the connection and ensure conduction in cases where the connection between incus-stapes and malleus-stapes is impaired in patients with conductive hearing loss. Bone cement is an easily accessible and inexpensive material that can be used in ossicular chain reconstruction. The results of this study show that it can provide effective treatment in the management of conductive hearing loss in the appropriate indication.

Disclosures

Informed Consent: Written informed consent was obtained from all patients.

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