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Ossicular reconstruction of incudo-stapedial joint by glass ionomer—a study of 24 cases

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Abstract

Background: Chronic otitis media is one of the major health issues worldwide resulting in partial or complete loss of conductive hearing mechanism including the tympanic membrane and ossicular assembly. The aim of the study is to assess hearing improvement after reconstructing the incudo-stapedial joint with glass ionomer cement. Here, a prospective observational study was done in a tertiary care hospital. Patients of chronic mucosal otitis media were operated, and intraoperatively incudo-stapedial joint discontinuity was restored using glass ionomer cement. Post-operative follow-up was done at 1-month, 3-month, 6-month, and 1-year intervals, and hearing was evaluated by doing pure tone audiometry with air conduction at 0.5, 1, 2, 3, 4, 6, and 8 kHz and bone conduction at 0.5, 1, 2, 3, and 4 kHz. Tabulation was done by calculating the air-bone gap in each patient.

Results: In our study, the patients showed statistically significant improvement in air conduction thresholds and near closure of air-bone gap post-operatively. The mean AC threshold is 15 dB with 91.67% patients having closure of ABG < 20 dB at the end of the 3rd month. Hearing was also evaluated at 6-month and 1-year intervals, which showed good improvement in hearing levels.

Conclusions: Glass ionomer is a simple, physiological, and cost-effective method of tympano-ossicular reconstruction with certain significant post-operative hearing improvement.

Keywords: Hearing loss, Audiometry, Glass ionomer cement, Incudo-stapedial joint, Ossiculoplasty

Background

Chronic otitis media is one of the major health issues worldwide resulting in partial or complete loss of conductive hearing mechanism including the tympanic membrane and ossicular assembly. Patients often present in the advanced stages of the disease with symptoms of hearing loss that may range up to 60 dB [1]. Chronic otitis media may be with or without frank cholesteatoma with ossicular erosion. The long process of the incus is the most common site of ossicular erosion with or without an intact stapes suprastructure [2, 3]. The main aim of tympano-ossicular reconstruction is to maintain the

normal ossicular assembly between the tympanic membrane and stapes footplate [4]. The aim of this study is to assess hearing improvement after reconstructing the incudo-stapedial joint with glass ionomer cement. Glass ionomer cement comprises inorganic glass particles surrounded by an insoluble hydrogel matrix. It is biocompatible, biostable, moldable, cost-effective, and universally available [5–9]. It is used in dentistry and its usage in ossiculoplasty has been reported [10–12]. This study is necessary to assess the post-operative hearing improvement and how much reliable the procedure is.

Methods

This is a prospective observational study conducted on patients attending the otorhinolaryngology department of tertiary care hospital in Mumbai, West India, from February 2016 to February 2018.

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Inclusion criteria included patients aged between 15 and 55 years, attending ENT OPD, with conductive hearing loss. Microscopic examination showed a mucosal type of chronic otitis media. A high-resolution CT scan of the temporal bone showed a suspicious long process of incus necrosis without any evidence of any obvious cholesteatoma. Pure tone audiometry correlated with ossicular discontinuity with average AC threshold >40 to 50 dB hearing loss. Intraoperatively, the findings were confirmed. Patients having incudo-stapedial discontinuity with erosion less than 1/3rd of the long process of the incus were selected for this procedure (Fig. 1).

Exclusion criteria included patients having otosclerosis, cholesteatoma, tympanosclerosis, erosion of more than 1/3rd of the long process of the incus, middle ear effusion, and immunocompromised conditions.

Selected patients were admitted 1 day before surgery and detailed history, clinical examination, and microscopic examination were done. A pre-operative CT scan of the temporal bone and pure tone audiometry were evaluated and written informed consent taken.

Under general anesthesia, tympanoplasty or mastoidectomy was done via a post-auricular approach. The tympanomeatal flap was elevated and the postero-superior bony overhang was removed to expose the ossicular chain. The middle ear was inspected for ossicular mobility and other diseases. A cortical mastoidectomy was done in certain indicated cases. Care was taken not to expose more than 2/3rd of the incus, which could later result in slow postero-superior retraction of the tympanic membrane. In patients where more than 2/3rd of the incus was exposed, a cartilage was kept in the postero-superior quadrant to prevent any retraction pocket in the future. Those patients who were diagnosed to have incudo-stapedial discontinuity intraoperatively with less than 1/3rd of the long process of incus necrosis were

included in the study (Fig. 1). The irregular/necrosed end of incus was freshened, nibbled, and cut with a House Dieter malleus nipper. This area was cleared of blood and good hemostasis achieved. Gelfoam was placed in the middle ear and below the incudo-stapedial joint to prevent any spillage of glass ionomer on stapes footplate, stapes suprastructure, and middle ear (Fig. 2).

Glass ionomer is made up of sterile powder and liquid. In our study, slow binding glass ionomer was used which gives some time to align the incudo-stapedial joint. Both were mixed on a sterile glass slide for 10s and used within 2 to 3 min. The mixture was placed between the incus and stapes by using a thin pick. A time period of 7 to 10 min is required for the fixation of the mixture on the joint. Warm air may be used near the ear for quick setting of the glass ionomer. The ossicular mobility was checked (Fig. 3). Protective gelfoam under the IS joint

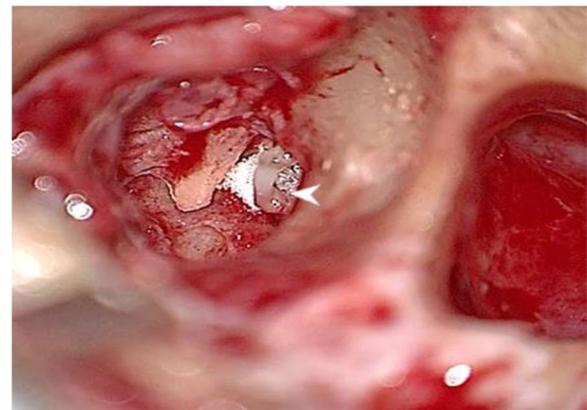


Fig. 2 Gelfoam placed below the incudo-stapedial joint to prevent spillage of the glass ionomer

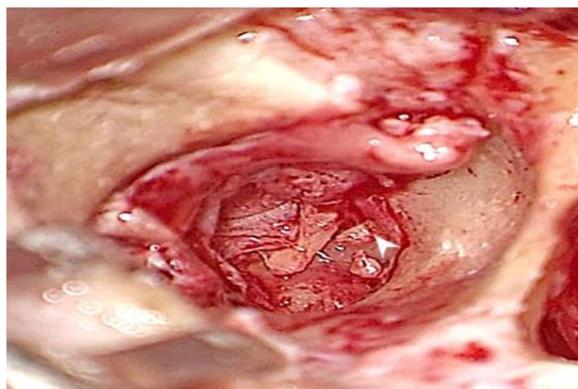


Fig. 1 Erosion of long process of the incus

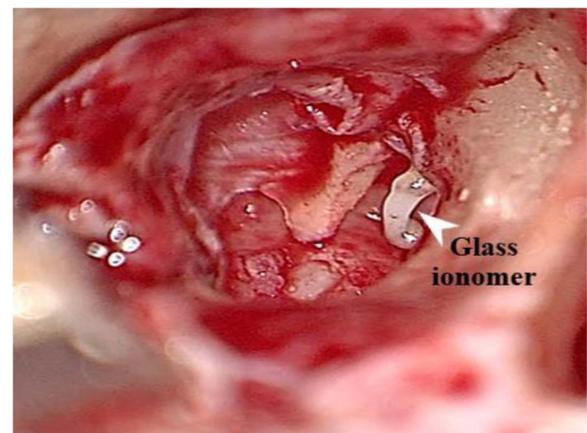


Fig. 3 Glass ionomer bridging the incus and stapes suprastructure

was removed. Gelfoam was placed in the middle ear. The graft was placed by the underlay technique (Fig. 4).

Post-operative follow-up was done at 1-month, 3-month, 6-month, and 1-year intervals, and hearing was evaluated by doing pure tone audiometry with air conduction (AC) at 0.5, 1, 2, 3, 4, 6, and 8kHz and bone conduction at 0.5, 1, 2, 3, and 4kHz. Pure tone average was calculated using 0.5, 1, 2, and 3kHz. Air-bone gap (ABG) was calculated and graft uptake and any other complications were noted.

Results

During the specified time period, 24 patients fulfilled the inclusion criteria. Majority of patients presented with a history of hearing loss (85%), ear discharge (70%), and ear pain (21%). On otoscopic examination, 23 (95.8%) patients had pars tensa perforation and 1 (4.2%) patient had pars flaccida perforation. Of the 23 pars tensa perforations, 21 had subtotal perforations and 2 had large size perforation. On CT scan of the temporal bone, all 24 patients (100%) had a suspicious long process of incus necrosis without evidence of any other bony erosion suggestive of cholesteatoma. On pure tone audiometry, the average AC threshold pre-operatively was 43.9dB. Student pair *t*-test was used to analyze the hearing improvement with a confidence interval set at 95% with *P*<0.05 being considered significant.

AC threshold changed from 43.9 to 23.13dB at the end of 1st month (*P*≤0.0001) and to 15dB at the end of 3rd month (*P*<0.0001), showing significant hearing improvement.

Similarly, ABG improved from 23 to 15.5 dB at the end of 1st month (*P*=0.0004) and to 10.5 dB at the end of 3rd month (*P*<0.0001) (Tables 1 and 2). Twenty-two (91.67%) patients had closure of ABG<20 dB, of which 13 (54.17%) were male patients and 9 (37.5%) were female patients.

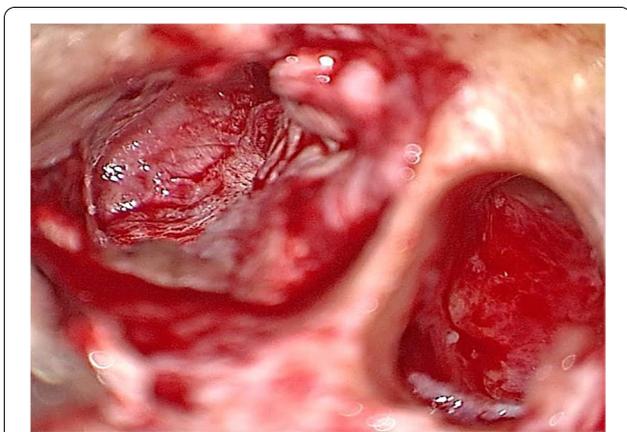


Fig. 4 Temporalis fascia graft placed by the underlay technique

Table 1 Post-operative air-bone gap at the end of 1st month

ABG value	Number of patients (%)
< 10 dB	7 (29.2%)
10–20 dB	14 (58.3%)
21–30 dB	2 (8.3%)
> 30 dB	1 (4.2%)

Hearing was also evaluated at 6-month and 1-year intervals, which showed no deterioration in hearing (Table 3).

Discussion

The advantage of glass ionomer cement on the incudo-stapedial joint is mainly maintaining the normal ossicular assembly. It is recommended in cases where there is less than 1/3rd of the long process of incus erosion. It is not recommended in cases where there is severely eroded ossicular assembly or frank cholesteatoma. Glass ionomer is biocompatible, biostable, inert, moldable, cost-effective, and universally available. Our results have shown a definitive good post-operative hearing improvement during the 1-year follow-up. Incudo-stapedial joint reconstruction by glass ionomer can be more advantageous over partial ossicular replacement prosthesis (PORP). It gives more physiological continuity between the incus and stapes at the same time maintaining the incudo-malleolar axis. This helps attain the natural process of sound amplification. Incudo-stapedial joint reconstruction by glass ionomer has no extrusion which is an added advantage over PORP or TORP (total ossicular replacement prosthesis) [5–8]. Our study did not exhibit any adverse reaction to glass ionomer. A piece of gelfoam is kept under the incudo-stapedial joint during the procedure to prevent any spillage of the glass ionomer in the middle ear, stapes footplate, or suprastructure. For perfect alignment of the bonding, we used the slow bonding glass ionomer which gives the surgeon time to align the reconstructed joint ends [7] and clear accidental spillage if any.

Table 2 Post-operative air-bone gap at the end of 3rd month

ABG value	Number of patients (%)
< 10 dB	15 (62.5%)
10–20 dB	7 (29.16%)
21–30 dB	1 (4.17%)
> 30 dB	1 (4.17%)

Table 3 Age, air conduction threshold, and air-bone gap of all the cases included in this study

Serial number	Age	Pre-op AC threshold	1-month AC threshold	3-month AC threshold	ABG pre-op	ABG after 1 month	ABG after 3 months
1	35	45	23	14	22	9	9
2	33	43	22	15	23	8	8
3	15	44	21	16	24	9	7
4	22	40	20	17	23	10	8
5	26	46	24	15	25	20	10
6	35	47	23	15	26	25	11
7	34	45	23	14	23	32	31
8	27	43	26	14	22	28	21
9	44	38	27	14	21	14	9
10	54	48	26	13	22	14	7
11	52	45	25	18	21	15	8
12	42	45	24	16	21	17	10
13	45	46	23	16	23	8	7
14	40	44	23	15	23	16	8
15	30	43	22	15	25	8	7
16	37	37	21	14	26	18	10
17	55	46	21	15	23	9	7
18	36	47	22	14	21	19	11
19	35	46	22	16	23	19	13
20	32	38	21	14	21	18	9
21	30	45	26	16	23	17	15
22	27	46	23	14	25	9	8
23	34	47	26	16	23	19	9
24	37	40	21	14	23	11	9
Total	857	1054	555	360	552	372	252
Average	35.71	43.9	23.13	15	23	15.5	10.5
Confidence interval			95%	95%		95%	95%
P value			<0.0001	<0.0001		0.0004	<0.0001
Significance			Extremely significant	Extremely significant		Significant	Extremely significant

Abbreviations: AC air conduction threshold, ABG air-bone gap

This prospective observational study is conducted to see the efficiency of glass ionomer in incudo-stapedial joint restoration and the subsequent hearing improvement post-operatively.

Baglam et al. conducted a study on 136 patients of incudo-stapedial discontinuity reconstructed by glass ionomer of which 81.6% of patients attained post-operative ABG of <20 dB [9]. He also inferred that those having less than one-third of the long process of incus are ideal candidates for this technique of reconstruction and it did not interfere with graft uptake rate. In our study, we followed the same inclusion protocol.

In our study, the mean pure tone average pre-operative of the patients was 43.9 and the mean pure tone average post-operative at the end of 1st month and

3rd month was 23.13 dB and 15 dB respectively with P value <0.0001 which showed significant hearing improvement. The post-operative ABG in our study was <20 dB in 91.67% of patients of which 54.17% were male and 37.5% were female which correlates with the above study. These results were also similar to Brask et al. whose study on 44 patients showed post-operative ABG <20 dB in 83.3% of cases [10].

Babu and Seidman conducted a study on 80 patients with incudo-stapedial disarticulation using glass ionomer. The results showed improvement of ABG from a pre-operative average of 33 to 10 dB post-operatively [11]. In our results, there is an improvement of ABG from the pre-operative average of 23 to 10.5 dB post-operatively at the end of 3rd month (P<0.0001), showing excellent hearing improvement. We did not

experience any case of graft extrusion, foreign body reaction, infection, or any other complication.

Conclusions

Glass ionomer is a simple, easy, physiological, and cost-effective method of ossicular reconstruction. This technique helps to maintain the natural ossicular assembly with good post-operative hearing improvement. It saves considerable operative time and money and hence more trials should be conducted using this method.

Abbreviations

ENT: Ear, nose, throat; OPD: Outpatient department; CT: Computed tomography; AC: Air conduction; ABG: Air-bone gap; PORP: Partial ossicular replacement prosthesis; TORP: Total ossicular replacement prosthesis.

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Not applicable.

Authors' contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by MJ and BS. Both the authors contributed in writing the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

All data generated or analyzed during this study are included in this article.

Declarations

Ethics approval and consent to participate

This prospective observational study involving human participants was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The Bombay Hospital Ethics Committee approved this study with registration number ECR/296/Inst/MH/2013, 15/01/2021, Retrospectively registered. Informed written consent to participate in the study was provided by all participants or their parent or legal guardian in the case of children under 16.

Consent for publication

Written informed consent for the publication was provided by all participants or their parent or legal guardian in the case of children under 16.

Competing interests

The authors declare that they have no competing interests.

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