

An Analytical Study of the Factors Affecting Hearing Improvement after Ossiculoplasty – A Retrospective Study, Mathura, Uttar Pradesh

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ABSTRACT

BACKGROUND

Otologists always yearn to improve the hearing outcome of their patients with chronic suppurative otitis media. There are different options for ossiculoplasty to choose from, depending on the extent of disease, condition of ossicular chain and availability of implant material and there has always been a quest to make appropriate decision with a predictable outcome. In this study, we have tried to analyse various factors which can affect hearing outcome after Ossiculoplasty.

METHODS

A retrospective study was done to study the effect of implant material, condition of ossicular chain and disease in the mastoid on post-operative hearing improvement on 200 patients, who underwent tympanoplasty or tympano-mastoidectomy from January 2018 to January 2020, in Department of Otorhinolaryngology and Head and Neck Surgery, K.D. Medical College, Mathura. Decision of ossiculoplasty was made based on intra-operative findings. Autograft incus, Teflon TORP (total ossicular replacement prosthesis) and cartilage columella were used based on availability and feasibility.

RESULTS

Mean improvement in average air-bone gap of 200 patients was found to be 18.57 dB, with autograft incus, it was 19.99 dB, with Teflon TORP (total ossicular replacement prosthesis), 19.53 dB and with cartilage columella 16.73 dB ($P = 0.023$). Mean hearing improvement was 18.98 dB when handle of malleus was present and 15.59 dB when it was absent ($P = 0.023$). Mean hearing improvement was 19.42 dB when stapes superstructure was present and 16.92 dB when it was absent ($P = 0.016$). Even though the hearing outcome was better when mastoid was disease free (19.57 dB) compared to when it was diseased (18.30 dB), the difference was not statistically significant. ($P = 0.177$)

CONCLUSIONS

In our study, we found autograft incus to be the best material for ossiculoplasty and presence of handle of malleus and stapes superstructure improved post-operative hearing outcome significantly but involvement of mastoid by disease did not significantly affect the hearing outcome post-operatively.

KEYWORDS

Chronic Suppurative Otitis Media, Ossiculoplasty, Tympanoplasty, Ossicular Prosthesis, Autograft

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BACKGROUND

In a patient of chronic suppurative otitis media, surgery is the definitive modality of treatment and depending on the involvement of aditus, mastoid antrum and air cell system, we either do tympanoplasty if mastoid is disease free or tympanomastoidectomy if chronic suppurative otitis media is associated with diseased mastoid. Aditus, mastoid antrum and air cell system can be involved by cholesteatoma, granulation tissue or polypoidal/diseased mucosa or sometimes even pent-up secretion in mastoid antrum and air cell system may require mastoidectomy in addition to tympanoplasty. Only in cases of extensive disease involving difficult regions like sinus tympani or in cases of granulation tissue over exposed facial nerve, mastoidectomy alone is done as a stage I procedure and a second stage repair (tympanoplasty) is planned after mastoid becomes healthy that is usually after 3 - 4 months. More or less, making this decision, whether to do tympanoplasty or tympanomastoidectomy or a 2 staged procedure is straightforward. The surgeon faces a challenge in decision making when there is ossicular discontinuity associated with chronic suppurative otitis media. Every patient with ossicular discontinuity poses a different situation and surgeon has to take into account plethora of factors to make optimal decision and to give best possible hearing outcome to the patient.

Ossiculoplasty is evolving in a quest to improve patient's hearing ability to normality. We shall try to understand effects and interplay of some of the factors affecting hearing outcome after ossiculoplasty based on our current knowledge of literature. Different implant materials have been used and studied for their efficiency as a replacement to natural ossicular chain. Autologous incus, autologous cartilage and synthetic materials have been commonly used as implant material. Ossicle grafts made of cartilage often develop chondromalacia with loss of stiffness and a tendency to become resorbed over time. Hence, cartilage grafts are not optimal for ossicular reconstruction, although they are probably adequate as a buffer between a prosthesis and the tympanic membrane.¹

Autografts are tissues that are harvested from the same patient on which they are to be used, and can include ossicles, cortical bone and cartilage. Their primary advantage is excellent biocompatibility with low risk of extrusion.¹ When available, an autograft offers a low-cost solution compared to ossicular prostheses. Incus interposition is an example of a well described and popular technique in situations with an intact malleus handle and stapes superstructure.^{2,3} Cartilage tends to be less stable due to displacement or resorption and is less commonly used.^{4,5} Limitations to the use of autologous ossicles are that the incus is not uniformly present in diseased ears, while technical skill and time are required to sculpt the incus to the required shape. There is a risk of implanting residual disease if the ossicle has been enveloped in cholesteatoma, therefore careful assessment of its integrity is required. Some surgeons recommend autoclaving ossicles prior to reimplantation to reduce the risk of residual disease⁶ but this is not widely practiced.

The use of alloplastic materials for ossiculoplasty was first described in 1952 by Wullstein who used a 'palavit' (vinyl-acrylic resin) columella prosthesis to connect a mobile stapes footplate with the tympanic membrane. More recently, many other synthetic materials have been used for ossiculoplasty, including bioactive glasses (Bioglass TM, Ceravital™), aluminum oxide ceramic, TEFLON, hydroxylapatite, gold, titanium, hydroxylapatite-polyethylene.¹ These materials offer a good alternative when autologous ossicle is not available for reconstruction, but fear of extrusion, extensive fibrosis and foreign body reaction is a matter of concern while using synthetic implant material. Ossicular erosion and subsequent loss of integrity of ossicle is also found to affect the hearing outcome after ossiculoplasty. Lenticular process and long process of incus is most commonly eroded ossicle followed by stapes superstructure and handle of malleus in that order. Because we have to reconstruct or make some adjustment for the eroded ossicle to restore the ossicular continuity, extent of erosion does matter. The extent of erosion of ossicles dictates us whether usable autologous incus is available for reconstruction and what kind of assembly we are going to make in ossiculoplasty. Lesser erosion would usually demand least intervention and restoration of ossicular chain closure to normality resulting in better hearing outcome in patients theoretically. As incus is most commonly eroded ossicle, the presence of other two ossicles, malleus and stapes superstructure are desirable while doing ossiculoplasty.

Apart from the type of implant material used and the extent of erosion of ossicular chain, involvement of mastoid by disease process can also affect hearing outcome after ossiculoplasty by affecting health of middle ear mucosa. Interplay of so many factors and their various advantages and disadvantages pose a difficulty for surgeon in choosing the type of technique and material for ossiculoplasty and it is also difficult to explain to the patient regarding expected hearing benefit, he/she is going to receive from the surgery.

Objectives

To study the impact of implant material, condition of ossicular chain and disease in mastoid, on hearing improvement after ossiculoplasty.

METHODS

This is a retrospective analysis of 200 patients who underwent tympanoplasty or tympanomastoidectomy at K.D. Medical College, Mathura, from January 2018 to January 2020. Patients of chronic suppurative otitis media with or without cholesteatoma between 14 to 60 years of age and with ossicular chain defect were included in the study. Patients with complicated chronic suppurative otitis media, fixed or fractured/floating footplate and those with sensorineural hearing loss were excluded from the study.

A detailed history taking, clinical examination including otoscopy, examination under microscopy (if needed) and tuning fork test was done. Audiological assessment by pure

tone audiogram and radiological assessment (X-ray mastoid Schuller's view and CT temporal bone in selected cases) was done. Average air bone gap was taken as average of air bone gap at 500 Hz, 1000Hz and 2000Hz. All patients were operated under general anaesthesia and by post-aural approach. Condition of ossicular chain, middle ear and mastoid was assessed intra-operatively and surgery was modified accordingly.

Autograft incus was used wherever available, it was ensured that incus was free from granulation or squamous epithelium, the body of incus was drilled with 0.6 mm cutting burr to create a space for head of stapes and a groove for stapedius tendon and the short process of incus was placed below handle of malleus whenever handle of malleus was present.

If stapes superstructure was eroded and incus was available for reconstruction, incus was rotated so that the short process will sit on footplate of stapes and remnant of eroded long process was placed under handle of malleus. If this was not feasible because of anteriorly placed malleus or completely eroded long process, then malleus was relocated to place handle of malleus on the body of incus. If handle of malleus was also eroded, then temporalis fascia was directly placed on body of incus.

If incus was not available for ossiculoplasty but stapes superstructure was present, then a cartilage columella was placed over stapes head to increase the height of middle ear space and temporalis fascia was directly placed over the cartilage.

Teflon TORP was placed on stapes footplate when stapes superstructure was eroded, and incus was not available for reconstruction. TORP was supported by absorbable gel foam from all around to ensure stability and a piece of 0.2 - 0.3 mm conchal cartilage slice was placed between the TORP and temporalis fascia, further stability was ensured by placing chorda tympani (whenever intact) over the cartilage. Interposition of conchal cartilage and chorda tympani was done to avoid direct contact of TORP with temporalis fascia and to avoid subsequent extrusion of the prosthesis.

Temporalis fascia grafting was done in every patient by underlay technique and middle ear was packed with absorbable gel foam to support the ossicular assembly and the temporalis fascia graft. External auditory canal was also packed with antibiotic soaked absorbable gel foam after placing the temporalis fascia graft and repositioning the tympanomeatal flap.

Mastoidectomy was performed if mastoid was found to be diseased, complete removal of disease was ensured before doing reconstruction. Attic was reconstructed with conchal cartilage if it was drilled to remove the disease. Similarly, posterior canal wall was also reconstructed with conchal cartilage, if canal wall down mastoidectomy was performed.

Mastoid bandage was applied in every patient after packing external auditory canal with absorbable gel foam and suturing the incision wound. In-patient monitoring and treatment with intravenous antibiotics and oral analgesics was given for 3 days. Mastoid bandage was removed on 3rd day and patients were discharged after 72 hours. Oral antibiotics and analgesics were given for next 4 days.

Patients were called for follow-up on post-op day 7, day 14, day 21 and day 90.

Ear was cleaned and remaining gel foam, if any, was removed on day 21 and otoscopy was done to note the status of the graft. Audiological assessment was done on day 90. Improvement in average air-bone gap was calculated by subtracting pre-operative average air-bone gap from the average air-bone gap at post-operative day 90.

Audiological assessment was done in every case even if graft was not taken up, to look for deterioration if any the results were included in overall calculation of average hearing improvement.

Statistical Analysis

Mean improvement in the average air-bone gap was calculated for all 200 patients. These 200 patients were subdivided into different groups based on factors which we wanted to study.

First, we studied the effect of implant material used and divided 200 patients into three groups based on whether incus, cartilage columella or Teflon total ossicular replacement prosthesis was used and mean improvement in average air-bone gap was calculated separately for each group.

Similarly, we divided 200 patients into those in whom handle of malleus was present and those in whom handle of malleus was absent and mean improvement in average air-bone gap was calculated for both groups separately.

We also divided 200 patients into those in whom stapes superstructure was present and those in whom stapes superstructure was absent and mean improvement in average air-bone gap was calculated for both group separately.

We also divided 200 patients into those in whom mastoid was diseased and those in whom mastoid was disease free and mean improvement in average air-bone gap was calculated for both groups separately.

The difference observed between means of different sub-group were checked for their level of significance by applying student-t test and analysis of variance (ANOVA) test to calculate P values as and when applicable.

RESULTS

In this study, we collected data of 200 patients who underwent tympanoplasty or tympanomastoidectomy, to look for effect of the factors affecting hearing outcome. Mean age of patients was 32 years, 55 % were male and 45 % were female. Autograft incus was used in 70 patients, cartilage columella was used in 80 patients and Teflon TORP was used in 50 patients. Malleus handle was resistant to erosion and was present in 176 patients and was absent in 24 patients. Stapes superstructure was present in 132 patients and absent in 68 patients. Mastoid was found to be disease free in 42 patients and in them mastoidectomy was not performed, while in 158 patients mastoidectomy was done to remove the disease. (table 1.) Mean improvement in average air-bone gap was 18.57 dB in 200 patients.

Sl. No.	No. of Cases
1. Material used	Autograft incus 70 Cartilage columella 80 Teflon TORP (total ossicular replacement prosthesis) 50
2. Malleus handle	Present 176 Absent 24
3. Stapes superstructure	Present 132 Absent 68
4. Condition of mastoid	No disease 42 Cholesteatoma/granulation 158

Table 1. Division of Subgroups

Effect of the Type of Material Used for Ossiculoplasty

Mean AB gap closure was highest for autologous incus (19.99 dB) followed by Teflon TORP (19.53 dB) and cartilage columella (16.73 dB) in that order, overall, this difference was found to be statistically significant ($P = 0.023$) (Table 2). The difference in hearing improvement of autograft incus and cartilage columella was also found statistically significant. ($P = 0.046$). But the difference in outcome while comparing autograft incus with Teflon TORP ($P = 0.94$) and cartilage columella with Teflon TORP ($P = 0.101$) was not found statistically significant.

Sl. No.	No. of Cases	Average AB Gap Closure in dB	P - Value
1. Material used	Autograft incus 70 cartilage columella 80 Teflon TORP 50	19.99 16.73 19.53	0.023

Table 2. Effect of Implant Material on Hearing Outcome

Effect of the Condition of Ossicular Chain

Mean AB gap closure was more in presence of handle of malleus (18.98 dB) compared to when handle of malleus was absent (15.59 dB) and this difference was also found statistically significant ($P = 0.023$) (Table I). Presence of healthy stapes superstructure was found to significantly affect the hearing outcome post-operatively. Average AB gap closure was 19.42 dB in presence of stapes superstructure and 16.92 dB in absence of stapes superstructure. ($P = 0.016$) (Table 3)

Sl. No.	No of Cases	Average AB Gap Closure	P - Value
1. Malleus handle	Present 176 Absent 24	18.98 15.59	0.023
2. Stapes superstructure	Present 132 Absent 68	19.42 16.92	0.016

Table 3. Effect of the Condition of Ossicular Chain

Effect of Disease in Mastoid

Condition of mastoid at the time of surgery did not affect hearing outcome significantly. Average AB gap closure was 19.57 dB when mastoid was disease free and 18.30 dB when mastoid was found diseased ($P = 0.177$). (Table 4)

		No. of Cases	Average AB Gap Closure	P - Value
Condition of mastoid	Disease free	42	19.57	0.177
	Diseased	158	18.30	
Table 4. Effect Disease in Mastoid				

Table 4. Effect Disease in Mastoid

DISCUSSION

An ideal material for ossiculoplasty should be biocompatible, durable, easily available, cheap and above all, capable of efficient sound transmission. Being an autograft, incus is biocompatible, durable, easily available and doesn't cost at all. Shaping an incus demands little training and experience and there is probability of inadvertently placing granulation tissue or squamous epithelium. Therefore, it is important to make sure that incus is disease free before using it for reconstruction. In our study, we also found that autograft incus gave best post-operative hearing improvement followed by Teflon TORP and cartilage columella in that order. Therefore, we recommend use of incus for ossiculoplasty whenever sufficient length of incus is available for reconstruction. In absence of incus, total ossicular replacement prosthesis is better alternative.

While Jha et al. concluded that cartilage, bone and gold were better and cost-effective alternatives to Plastipore and titanium as an ossiculoplasty material.⁷ Jackson et al. got significantly better outcome with Teflon TORP than PORP.⁸ Matthew Yung found that type of prosthesis use did not significantly affect the outcome.⁹ In our study, we found presence of handle of malleus significantly affected post-operative hearing improvement and presence of stapes superstructure also significantly affected post-operative hearing improvement. Various studies done on this factor have different conclusions.

Mishiro et al. in their review concluded that presence of the stapes superstructure, presence of the malleus handle, normal mucosa, normal stapes mobility, and use of local anaesthesia were significantly favourable predictive factors.¹⁰ Yung et al. found handle of malleus to be only significant factor for hearing outcome of ossiculoplasty in long term.⁹ Dornhoffer et al. found handle of malleus to be statistically significant factor affecting the average post-operative air-bone gap, whereas stapes superstructure was not found to be a significant factor in their study.¹¹ While Brackmann et al. and Goldenberg concluded the handle of malleus to be statistically insignificant in contributing the outcome of ossiculoplasty.^{12,13}

We found that diseased mastoid did not significantly affect hearing outcome after surgery. Even though diseased mastoid seems to have a say in the ultimate hearing outcome but in our study, we did not find so, probably because tympanoplasty was performed along with mastoidectomy only after ensuring disease free condition of mastoid and middle ear otherwise a second stage repair was planned.

Albu et al. observed that granulating otitis media and cholesteatoma significantly worsen the outcome of ossiculoplasty.¹⁴ Brackmann et al. found no significance of cholesteatoma in hearing outcome.¹² Whenever there is associated ossicular chain defect along with tympanic membrane defect, the operating surgeon has many choices of materials and techniques which can be used. Ossiculoplasty techniques have evolved by trial and error method. Hearing improvement after ossiculoplasty is affected by many factors, apart from the decision of choosing most effective technique and implant material,

surgeon's expertise, case selection and post-operative care and precautions have equally important role to play, this makes it practically difficult to study the effect of a single factor at a time. Even after ensuring uniformity in surgeon's expertise, type of anaesthesia, approach to middle ear and post-operative care, we really cannot ensure the uniformity of precaution taken by patient. Episodes of upper respiratory tract infection, trauma to ear, sneezing, nose blowing, straining, constipation, heavy work done by patients can affect result of the surgery.

CONCLUSIONS

In our study, we found autograft incus to be the best material for ossiculoplasty and presence of handle of malleus and stapes superstructure improved post-operative hearing outcome significantly but involvement of mastoid by disease did not significantly affect the hearing outcome post-operatively. We hope to evolve our knowledge of ossiculoplasty with many similar studies in future at different centers, multicentric studies and finally meta-analysis of more and more such studies.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.

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