

Original Research Article

Study of hearing results of ossiculoplasty in patients with safe chronic suppurative otitis media

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ABSTRACT

Background: Ossicular discontinuity can occur as a result of erosion by chronic otitis media or due to trauma. Reconstruction of the ossicular chain aims to surgically optimize the middle ear transformer mechanism. The goal of this study was to devise a protocol to manage the ossicular discontinuity, provide good hearing to the patients and to demonstrate that use of ossicle for ossicular reconstruction is a safe, physiological, practical, successful and cost effective method.

Methods: The present study is retrospective study of 50 patients who underwent ossiculoplasty in our institute over the period of 2 years. Most patients presented to us with a history of chronic intermittent ear discharge and decreased hearing. Detailed clinical examination included general examination and local examination of ear, nose and throat. Examination of ear included otoscopy, tuning fork tests, and examination under microscope.

Results: The average pre-operative air-bone gap in patients with ossicular disruption was 34.95 dB and after ossiculoplasty was 12.93 dB. The mean air-bone closure after surgery was 27.88 dB. In most cases the post-operative air bone closure was within the range of 20 dB. The hearing results in ossiculoplasty are dependent on various factors but middle ear status in one of the most important factor in deciding the final outcome.

Conclusions: The ossiculoplasty using autograft has stood the test of time and the results are superior to that of prosthesis. They have less rate of complications, are economic and easily available. The expertise to sculpt the ossicle can be easily developed with practice.

Keywords: Ossiculoplasty, Air-bone gap, CSOM, Hearing loss

INTRODUCTION

Auditory sensation is one of the vital sensations to the man, like vision. Deafness upsets the tranquility of life. When such a great vital sensation is lost, life naturally loses its charm.

A disruption of the ossicular chain of the middle ear causes conductive hearing loss in patients, since it interferes with the conduction of sound to the oval window.

Ossicular discontinuity can occur as a result of erosion by chronic otitis media or due to trauma.¹ Various theories have been postulated to explain the pathophysiology leading to the erosion of ossicle. An eroded incudo-stapedial joint is seen in approximately 80% of patients with ossicular erosion. The incus may be absent alone or may be associated with loss of stapes superstructure and/or malleus. In developing countries, widespread prevalence of CSOM may be due to poor hygiene, nutrition and poor living conditions.^{2,3} Due to the

presence of cholesteatoma or granulations, ossicular destruction is much greater in cases of unsafe CSOM.⁴

Reconstruction of the ossicular chain aims to surgically optimize the middle ear transformer mechanism so that sound energy is conducted from environment to the inner ear fluid with only minimal loss.

In our study we analyzed various variables with regards to age, sex, middle ear mucosa and intraoperative ossicular status. The goal of this study was to devise a protocol to manage the ossicular discontinuity, provide good hearing to the patients and to demonstrate that use of ossicle for ossicular reconstruction is a safe, physiological, practical, successful and cost effective method

Objectives

- To determine hearing results in patient who have undergone ossiculoplasty using auto-graft ossicle and ossiculoplasty in relation to the status of middle ear mucosa intra-operatively.

METHODS

The present study is retrospective study of 50 patients who underwent ossiculoplasty in ARMCH and RC, Solapur from 2016 to 2018.

The pre-operative and post-operative audiometric findings were documented and analyzed to study the hearing improvement with the use of ossicle as a graft for ossiculoplasty.

Most patients presented to us with a history of chronic intermittent ear discharge and decreased hearing.

The history included details of ear discharge and hearing difficulty. Associated history of trauma, tinnitus, and giddiness if any was noted. Details of previous ear surgery, if any, was also noted.

Detailed clinical examination included general examination and local examination of ear, nose and throat. Examination of ear included otoscopy, tuning fork tests, and examination under microscope.

Inclusion criteria

Only patients with ossicular discontinuity found intra-operatively and patients with revision surgery were included.

Exclusion criteria

The patients with any evidence of cholesteatoma or unsafe chronic otitis media and patients with only safe CSOM without ossicular disruption were excluded from the study.

Investigations included hemogram, audiogram for all patients and X-ray PNS for selected patients. ECG and blood sugar for patients with h/o DM or age >40 yrs.

Steps of surgery

The procedure was done under local anaesthesia with standard infiltration with 2% xylocaine and 1:200000 adrenaline in post aural region.

Postural incision was taken 0.5 cm behind postural groove and temporalis fascia was harvested. Posterior tympanotomy was done to expose tympanic membrane. Margins of perforation were freshened. Tympanomeatal flap was raised. Postero-superior bony overhang was curetted with house curette to expose incudo-stapedial joint. Ossicular discontinuity was confirmed and then remnants of incus were removed. Annulus was elevated all around and graft bed was prepared.

Incus sculpturing done with 2.3 mm diamond burr. 1 mm diamond burr was used to make fenestra for head of stapes.

Temporalis fascia graft was then placed by underlay technique and then resculptured incus was placed between the handle of malleus and stapes head. The tampanomeatal flap was then reposed back. Gelfoam soaked in ciprofloxacin ear drops was placed in external auditory canal. Wound was closed in layers.

Postaural sutures were removed on 7th day and graft was inspected at 3 weeks under microscope.

Audiometry was done 3 months post-operatively.

The types of ossiculoplasty done were based on the ossicular defects:

- If the long process of the incus was not in contact with the head of the stapes. The ossicle was used to connect the head of the stapes with the handle of the malleus.
- If the long process of the incus was not connected to the head of the stapes, and the crural arch of the stapes was missing producing a gap between the malleus and the oval window, then the ossicle was used to build a connective bridge from the footplate of the stapes to the handle of the malleus.

Ossiculoplasty

A small curved clamp holds the incus body so that no change of its position is necessary while drilling.

A 2.3 mm diamond burr is used to remove the long process of the incus and the posterior part of the incus body.

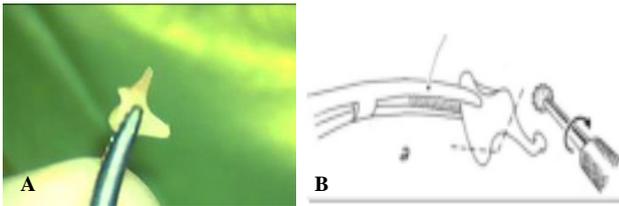


Figure 1: Incus for grafting.

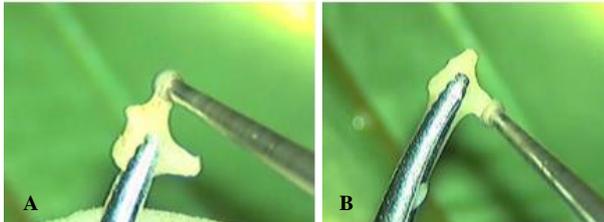


Figure 2: (A) Sculpting long process (B) sculpting short process.

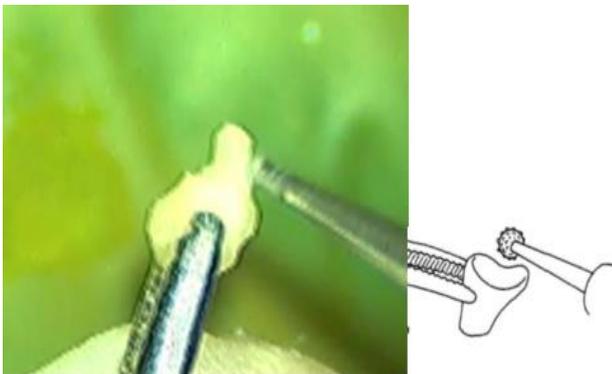


Figure 3: Sculpting groove for malleus handle.

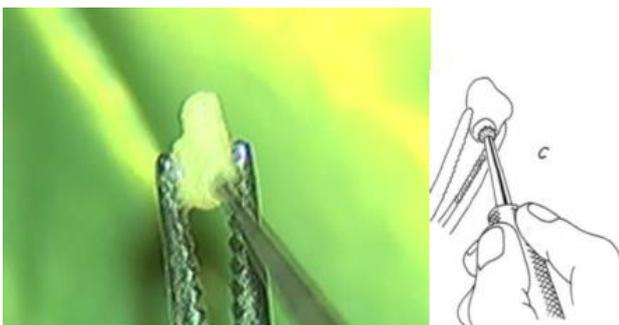


Figure 4: Sculpting stapes head notch.

The articular surface of the incus is carved with a drill to accommodate the malleus handle.

Notch for the stapes head is drilled in the incus body using a 1.0 mm diamond burr.

The modified incus is picked up with the largest micro-suction tube and placed in contact with the malleus handle caudal to the preserved Chorda tympani.

It is placed last, between stapes head and handle of malleus after the temporalis graft has been placed and positioned.

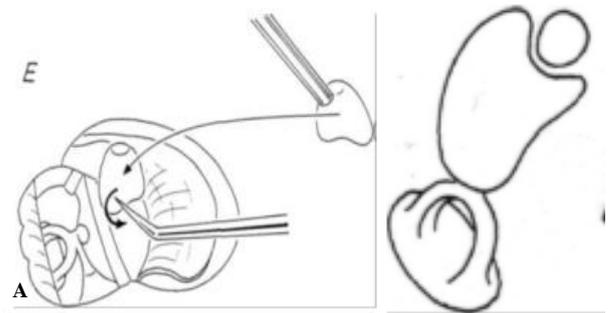


Figure 5: Repositioned graft.

The interposed incus should fit between the stapes head and proximal malleus handle so as to make sure that there is no stress transmitted to stapes.

In cases where Incus is completely necrosed malleus head is sculpted and placed over the capitulum.

Statistical analysis

Descriptive statistics such as mean, SD and percentage was used. Comparison between two groups were performed by using unpaired t test for parametric and Man-Whitney for non-parametric distribution. Comparison between pre and post perative by using paired t-test for parametric and Wilcoxon Signed ranks test for non-parametric distribution. A p-value less than 0.05 were considered as significant.

RESULTS

In our study of 50 subjects who presented with chronic suppurative otitis media, 29 (58%) patients were male and 21 (42%) were female (Table 1).

In our study, the number of patients in age group 0-20 yrs. were 8 (16%), between 21-40 yrs were 24 (48%) and 18 (36%) patients were above 40 yrs (Table 1).

Table 1: Demographic characteristics.

Characteristics	Frequency	Percentage (%)
Sex		
Male	29	58
Female	21	42
Age (in years)		
Up to 20	8	16
21 to 40	24	48
Above 40	18	36

In our study majority of patients were middle aged. We applied Wilcoxon signed ranks test to each age group individually and found that there was significant (p<0.001) average post-operative air bone closure in each age group (Table 2).

In our study 39 (78%) of patients underwent ossiculoplasty as primary surgery and 11 (22%) were revision cases who had been operated elsewhere and presented to us with conductive hearing loss or residual perforation. The mean post-operative ABG was within 20 dB in both study group. The primary group has slightly better result than revision group (Table 3).

In our study 35 (70%) patients had normal middle ear mucosa, 15 (30%) patients had adhesive tympanic membrane. We found that patients with normal middle ear mucosa had a significant improvement in the hearing after ossicular reconstruction compared to patients with adhesive middle ear mucosa. Average air-bone closure in patients with normal mucosa was 32.1 dB and that of adhesive mucosa was 18 dB (Table 4).

Table 2: Comparison of age groups between pre and postoperative ABG (dB).

Age (in years)	Pre op avg. ABG (dB)		Post op avg. ABG (dB)		Avg. ABG gain (dB)		Wilcoxon signed ranks test value	P value
	Mean	Std. dev	Mean	Std. dev	Mean	Std. dev		
Up to 20	34.53	12.52	12.97	7.59	21.56	9.68	-2.524	0.012
21 to 40	35.57	9.81	12.19	8.02	35.57	62.09	4.28	<0.0001
Above 40	34.31	10.07	13.89	8.27	20.43	9.09	3.720	<0.0001

Table 3: Distribution of study group as per type of surgery.

Parameter	Pre-op ABG (dB)	Post-op ABG (dB)	Hearing improvement (dB)	Pre-op ABG (dB)	Post-op ABG (dB)	Hearing improvement (dB)
Count	39	39	39	11	11	11
Mean	33.62	11.28	29.85	39.66	18.75	20.91
Std. dev	9.30	6.82	49.15	12.06	9.10	9.99

Table 4: Comparison of ABG between middle ear normal and adhesive.

	ME normal			ME adhesive			Unpaired t-test	P value
	N	Mean	Std. dev	N	Mean	Std. dev		
Pre-op ABG	35	35.82	10.63	15	32.92	8.96	0.926	0.359
Post-op ABG	35	12.07	8.19	15	14.92	7.11	-1.168	0.248
Avg. ABG gain	35	32.1	51.8	15	18.0	3.1	1.048	0.300

Table 5: Comparison of only incus and incus and stapes involved between pre and post operative ABG.

	Pre-op ABG			Post-op ABG			Wilcoxon signed ranks test	P value
	Mean±SD	Median	IQR	Mean±SD	Median	IQR		
Only Incus (n=33)	33.59±9.98	33.75	16.25	11.59±7.56	10	11.25	5.02	<0.0001
Incus and stapes involved (n=13)	38.75±9.67	40.00	10.00	17.21±8.22	18.75	7.50	3.18	<0.0001

Table 6: Comparison of hearing improvement between incus and malleus.

	Incus			Malleus			Unpaired t-test	P value
	N	Mean	Std. dev	N	Mean	Std. dev		
Pre-op ABG	40	34.03	10.65	10	38.63	7.18	-1.288	0.204
Post-op ABG	40	11.38	7.81	10	19.13	4.90	-2.982	0.004
Hearing improvement	40	30.0	48.7	10	19.5	5.7	0.675	0.503

In our study of 50 patients, 33 (66%) patients had only necrosed incus or absent incus with intact malleus and stapes suprastructure, 13 (26%) patients had necrosis of incus and stapes suprastructure, 1 (2%) patient had all three ossicle involvements and 3 (6%) patients had malleus and incus involvement. We found that there was significant ($p < 0.001$) average air-bone closure in all patients. We applied Wilcoxon signed ranks test for paired samples in group with only incus necrosis and incus with stapes necrosis and found that the hearing gain and post-operative air-bone closure in both group was significant and comparable. Other groups were excluded since sample size was too small (Table 5).

In our study of 50 patients who underwent ossicular reconstruction in 40 patients we used autologous incus as ossiculoplast and in remaining 10 patients in whom incus was absent or necrosed to that extent that cannot be used as ossiculoplast we used head of the malleus as ossiculoplast. We found that the patients in whom incus was used as ossiculoplast had significant improvement in post-operative air-bone closure ($p < 0.01$) than patients with malleus head as ossiculoplast (Table 6).

DISCUSSION

The aim of middle ear reconstructive surgery is to restore the ossicular chain as near to normal as possible or to achieve continuity and transmission in an entirely different way after abandonment of natural system. In the last three decades, various ossiculoplasty methods using different graft materials have evolved and good results were achieved. Nevertheless ossicular reconstruction continues to be a process in evolution.

The challenge during ossiculoplasty has been how to achieve a stable, reliable connection between the tympanic membrane and mobile stapes footplate that will provide the best long term hearing results, without complications, in a chronically infected ear. Out of several materials that are available for middle ear reconstruction we have studied autograft incus and malleus.

There are several variables in middle ear surgery that affect the results.

A) Most significant variable is the function of Eustachian tube. It affects the long term survival of the various grafts in middle ear surgery.

B) The second variable is the status of the middle ear mucosa. The presence of active infection, polypoid changes, granulation tissue, or bare bone can affect the subsequent function of an implanted autograft.

C) The condition of the tympanic membrane is the third variable. Ossicular reconstruction when the tympanic membrane is intact gives better results than when there is a perforation in tympanic membrane.

D) The fourth variable is the status of the ossicular chain. The presence of stapes superstructure is a very important to improve hearing in ossicular reconstruction.

E) The underlying process itself (disease or trauma factor) that has caused a specific ossicular defect is a fifth variable. Congenital ossicular abnormalities, cholesteatoma cases and traumatic ossicular discontinuities are difficult to manage.

The results of ossiculoplasty are frequently reported in terms of closure of the air-bone gap. This parameter is a reliable indicator of the degree of technical success, and is useful in comparing different materials and types of reconstructions. However, assessment of the operated ear alone does not evaluate the effect of surgery on binaural hearing ability.

Fate of the transplanted ossicle

Autogenous malleus, incus and cortical bone grafts, and homograft ossicles behave similarly and maintain their morphology size, shape, and contour for long periods. They neither incite formation of new bone nor undergo resorption. They show varying amounts of replacement of nonviable bone by new bone through a slow process of creeping substitution that is dependent on revascularization and not on duration of implantation. These histologic observations support the continued use of bone grafts for ossicular reconstruction. Sculpturing of such grafts should be done with adequate irrigation to avoid thermal injury and subsequent bone necrosis.⁵

Homograft concerns

These natural materials gave good results. However, several problems were cited with their use⁶. Mainly,

Even with the advent of commercial tissue banks, the transmission threat of HIV, Creutzfeldt-Jacob disease, and other infectious agents became a concern.

Others have noted that homograft materials may become adherent to various middle ear structures, such as the stapes, and more difficult to remove during revision surgery compared with allograft.

Due to above concerns we have been using autograft incus and malleus in our institute.

Basic characteristics

In our study, there was a slightly male predominance, consistent with the sex distribution in the general population and considering the majority of working population being male, they will be more affected by decreased hearing.

The mean age group in our study was 36.44 years, it was consistent with other studies. The patients within age

group above 60 years were 2 but both had very good middle ear mucosa intra-operatively the post-operative air-bone closure was within 20 dB.

We conclude that the surgery will benefit patients in all age groups and age should not be a criterion to deny ossiculoplasty to any patient. Even in the elderly age group, where there is an imminent sensory neural component to hearing loss, yet we were able to give a good hearing by reducing the air bone gap.

The mean post-operative air-bone closure in each age group was within 20 dB, which we consider successful ossiculoplasty. The mean post-operative ABG in age group of >20 years was 12.19 dB, the group benefitted the most. We conclude that the earlier the patient of mucosal otitis media was treated, the better the results. As with time and recurrent infections the middle ear mucosa worsens and the results are not as good.

Hearing improvement

Farrion and Nichols studied patients who underwent Type III ossiculoplasty with autologous bone graft and the patients had improved hearing at 15 dB air bone gap or better 6 months after surgery.⁷ Likewise, Nikolaou et al. reported a postoperative air bone gap of less than 20 dB in 74% of patients who underwent incus interposition.⁸

Study again by Zheng et al, Switzerland showed that the residual air-bone gap was <20 dB in 86.1% of cases 2 months after surgery, in 77.0% 1 year later, and then remained stable over time, even in patients seen 5 to 15 years after the operation.⁹

In this study most cases were done under local anaesthesia with transcanal approach and columella placed between handle of malleus and stapes.

We conclude that the results of ossicle transposition are not only good but are stable over time in terms of hearing results.

In a comparative study by Ceccato et al, they found that the rate of extrusion was small in incus transposition group (1%) vs. titanium (4%).¹⁰ Average preoperative air bone gap of patients who received the Titanium prosthesis was 21.2 dB and 42.8 dB for the incus group. The average postoperative air bone gap was 16.9 dB titanium group and 25.5 dB Incus group ($p < 0.05$). The gain was 18.7 dB in the Incus group and 4.3 dB in titanium group ($p < 0.05$). They also concluded that the audiometric results obtained among patients with an incus transposition are better than those obtained with PORP Titanium prosthesis.

Recent study done by Naragund showed average postoperative ABG closure of less than 20 dB in 7 cases (58%) with autologous incus and 4 cases (33.3%) with titanium prosthesis.¹¹ There was a statistically significant

improvement in preoperative ABG of 43.3 dB \pm 8.34 SD to mean postoperative ABG of 24.5 dB \pm 9.16 SD ($p = 0.046$) in autologous incus group. Postoperative complications with autologous incus group were 25% as compared with titanium prosthesis in which the complication rate was 41.6%. Closure of ABG to less than 20 dB was regarded as successful hearing outcome. They found that hearing improvement and graft take-up rate were significantly better in ossiculoplasty with autoincus. The complication rate was also very less in this group.

Comparing our results with the literature, we conclude that the results with ossicle are superior to that of prosthesis. This is because transposition of incus is well tolerated as it is more physiological and biocompatible, thereby giving better hearing results and reducing graft extrusion rate. We conclude that use of prosthesis does not have any advantage over ossicle except for the marketing and financial advantage to the manufacturer. Sculpting an ossicle does require expertise and skill of the surgeon.

If there is an option available to use the ossicle, it should be given preference since it is physiological, biocompatible and stable and of course cost effective.

Middle ear mucosa vs. hearing improvement

A study in Japan by Mishiro et al, in 720 patients, done in multiple models showed that mucosal status and the presence of the stapes superstructure and the malleus handle were significant predictors in of results in ossiculoplasty, which is similar to most of the previous reports.⁷

We conclude that middle ear mucosa status is an important factor in deciding the final outcome of hearing improvement in patients undergoing tympanoplasty with ossiculoplasty. If the middle ear mucosa is normal, healthy and middle ear is well ventilated with good Eustachian tube function, then the chances of post-operative graft uptake are excellent.

Adhesive mucosa can affect the outcome of ossiculoplasty because,

- The chances of re-adhesion are high
- The handle of malleus is medialised, this affects the articulation of the ossicular chain, and therefore the chances of ossicle getting displaced are high.
- The adhesive drum itself does not vibrate well with sound waves, therefore the air-bone closure can never be perfect.

We remove the granulation tissue from the middle ear cleft and apply medicated gelfoam which contain antibiotic and steroid, which improves the results of ossiculoplasty by decreasing adhesion formation.

Ossicular involvement and Air – bone gap

In a similar review conducted by Farrow and Nichols, 59% of 80 patients who underwent type III ossiculoplasty with autologous bone graft had improved hearing at 15 dB air bone gap or better 6 months after surgery. The average preoperative air bone gap was 30.2 dB, and the average postoperative air bone gap was 19.7 dB.¹²

Likewise, Nikolaou et al reported a postoperative air bone gap of less than 20 dB in 74% of patients who underwent incus interposition.⁸

Dornhoffer and Gardner identified absence of malleus, fibrotic middle ear mucosa, and otorrhea as univariate risk factors for outcome of ossiculoplasties.¹³

Whereas, in a multivariate analysis by Yung, the results predicted that those with present malleus were 6.36 times more likely to be successful.¹⁴

Comparing our study with other groups and literature, there is significant improvement in all groups.

- We also observed that in more than half (66%) of the patient, incus was either necrosed or lost, this is in conjunction with the theory that it is the most common ossicle to be involved. The cause of it is now hypothesized to be due to its structure and location than its tenuous blood supply¹⁵. If the reconstruction is done in a manner where its location is stable, then the chances of it getting resorbed can be minimized. We believe that the ossicle should not be snugly fitted under the tympanomeatal graft but should be loose enough to mobilize when the tympanic membrane vibrates.
- We conclude that the post-operative air bone is significantly better if only incus is involved compared to incus and stapes. The reason could be though the lever mechanism for conduction of sound is lost during ossicular reconstruction, the conduction of sound is still adequately good if only incus is involved. When both the incus and stapes suprastructure are lost, the ossicular conduction is maintained but not as physiological as with type 1.

CONCLUSION

The ossiculoplasty using autograft has stood the test of time and the results are superior to that of prosthesis. They have less rate of complications, are economic and easily available. The expertise to sculpt the ossicle can be easily developed with practice. The hearing results in ossiculoplasty are dependent on various factors but middle ear status in one of the most important factor in deciding the final outcome.

The best results were obtained in patients, where the middle ear mucosa was healthy intra- operatively; proving that the good middle ear status is the key for good ossiculoplasty.

The results were also good in patients who had only isolated incus necrosis. When more than one ossicle is involved the results as not so good.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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