

Evaluation and Comparison of Hearing Outcome in Ossiculoplasty Using Different Graft Materials.

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ABSTRACT

Background: Chronic Otitis Media is a middle ear pathology which commonly leads to ossicular loss thus effecting conduction of sound. Ossiculoplasty refers to the operation performed on the middle ear to restore the hearing mechanism by ossicular chain reconstruction. There still exists a considerable difference of opinion in using either type of graft in terms of selection of graft material, graft remodeling intra-operatively, extrusion rates and postoperative hearing outcome. **Methods:** All cases with chronic suppurative otitis media were examined in detail. The patients were categorized into 03 groups randomly i.e 20 patients in each group. Patients in Group A underwent ossicular reconstruction using allograft (Teflon) and Group B underwent ossicular reconstruction using Autograft (Tragal cartilage) and Group C underwent ossicular reconstruction using autograft (Autologous bone). **Results:** The closure of air bone gap was maximum in bone group 12.60±9.65 than in cartilage group 10.46±10.62 and least in Teflon group 2.51±4.90. The pre-operative mean hearing loss was 52.05±5.74db in Teflon group. In cartilage group mean hearing loss was 50.98±6.82db, in bone group it was 48.65±6.63db. While the post-operative hearing loss after 6 months was 48.18±8.87 in Teflon group, 37.26±13.98 in cartilage group, 32.03±13.03 in bone group. There was statistically significant difference between pre and post-surgery PTA values and ABG in all the groups. **Conclusion:** Reconstruction with bone was found superior than cartilage and cartilage had better post-operative outcomes than teflon group with respect to post op hearing threshold, closure in air bone gap, hearing improvement.

Keywords: Chronic Otitis media, autograft, Ossiculoplasty, Teflon graft.

INTRODUCTION

The ossicles are the smallest bone in the body and are functionally most complicated. They are in the form of ossicular chain across the tympanic cavity from the tympanic membrane to the fenestrae vestibule.^[1] Loss of ossicles or discontinuity of the ossicular chain is the most common cause of conductive hearing loss in adults.^[2]

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Chronic Otitis Media (the commonest cause for ossicular discontinuity) is a middle ear pathology which commonly leads to ossicular loss thus effecting conduction of sound.^[3] Chronic Otitis Media (COM) in almost any form can result in the disruption of the integrity of the ossicular chain. The pathology can be restricted to the incudo-stapedial joint with loss of the lenticular process, sometimes with preservation of a soft-tissue connection;

usually, however, there is a complete loss of some portion of the distal incus.^[4]

The term Ossiculoplasty refers to the operation performed on the middle ear to restore the hearing mechanism by ossicular chain reconstruction. The goal is a stable and reliable connection between the tympanic membrane and the mobile stapes footplate, and to achieve the best long term hearing result.^[3] Many materials have been used for ossicular substitution or reconstruction, including both biologic and alloplastic materials. Biologic materials include autograft or homograft ossicles, cortical bone, teeth, and cartilage. Alloplastic materials used are gold, titanium prosthesis, hydroxyapatite, ceramics and synthetic plastipore. The most commonly used autograft material has been the incus body, which is often reshaped to fit between the manubrium of the malleus and the stapes capitulum. If the incus is unavailable, the malleus head may be used.^[5]

Hearing improvement varies depending upon several factors like the material used, the stage of the disease, degree of destruction, state of middle ear

mucosa, Eustachian tube function and the degree of pre-operative hearing loss.^[6]

A common cause of Ossiculoplasty failure is inadequate contact between the prosthesis and the graft, which may be caused by sliding or resorption of the cartilage. Additional causes of functional failure include improperly sized prosthesis, fracture of stapes crura, contraction and movement of the healing tympanic membrane. Each of these results in poor contact between the footplate and the graft.^[7]

There still exists a considerable difference of opinion in using either type of graft in terms of selection of graft material, graft remodeling intra-operatively, extrusion rates and postoperative hearing outcome. Thus, there is a need felt to comprehensively and holistically evaluate the outcome of Ossiculoplasty using Autograft versus Synthetic Graft.

Thus, the aim of the study is to evaluate the outcome of Ossiculoplasty using different graft materials namely Autograft (Ossicle and cartilage) and synthetic grafts (Teflon).

MATERIALS AND METHOD

All cases with chronic suppurative otitis media (active/inactive mucosal disease) were examined in detail, which included detailed history, general physical examination, ENT examination, Otoscopy and Tuning Fork Test and patch test. This was followed by examination under microscope to study the pathology of the disease (presence of polypi, granulations, tympanosclerosis, ossicular damage). Pure Tone Audiometry and X-ray mastoids were done in all cases that were planned for surgery.

Inclusion criteria

- Patients with symptoms of Chronic Mucosal Otitis Media.
- Patients in the age group 06 – 65 years.

Exclusion criteria

- Patients with sensorineural hearing loss and mild CHL
- Patients with only hearing ear.
- Patients < 06 years and > 65 years.
- Patient with sino-nasal pathology.
- Patient not giving consent for surgery
- Patient unfit for surgery and general anesthesia.
- Chronic squamous Otitis media.

A thorough history according to attached performa was taken in each case followed by detailed clinical examinations and investigations. The patients were categorized randomly into 03 group's i.e 20 patients in each group. Patients in Group A underwent ossicular reconstruction using allograft (Teflon) and Group B underwent ossicular reconstruction using Autograft (Tragal cartilage) and Group C underwent ossicular reconstruction using autograft (Autologous bone). On admission Informed Written Consent was taken for all patients before surgery. All surgeries were done under general anesthesia by post auricular approach. Temporalis fascia as graft was harvested.

Meatotomy was done and tympanomeatal flap was elevated after freshening the margins of perforation. Condition of the middle ear mucosa as well as status of ossicular chain was noted. Any damaged Malleus, Incus or stapes were removed partly/wholly and reconstruction (Ossiculoplasty) was done using patient's own ossicles (after sculpturing) or tragal cartilage or Teflon allograft. Cartilage piece was kept additionally over the Teflon allograft to minimize its extrusion. Middle ear canal was packed with abgel and temporalis fascia graft was kept by underlay technique. Canal was packed with abgel and post auricular wound was closed in three layers. After surgery all cases were followed for a minimum period of 6 months and all cases were subjected to preoperative and postoperative average hearing threshold on pure tone audiogram and air- bone gap at 6 months gap after surgery was taken. All the data collected was compiled and statistically analysed to evaluate the efficacy of both the procedures using SPSS version 18 and medical 14 software.

RESULTS

A total of 60 cases with an age range were evaluated in our study. Patients between 6-20 yrs were 38.33%, 21-35 years were 48.33 %, between 36-50 were 8.33% and between 50-65 were 5%. The mean age was 26.30±9.88 in Teflon group, 22.75±9.20 in cartilage group while in bone group mean age was 28.05±10.50. Male: Female ratio was 1:1.4 in the present study. There was slight female preponderance. Unilateral involvement was 78.3%, out of which left ear was 61.7% and right ear was 38.33 % while involvement of both ears was seen in 21.66% cases. Left ear was operated in 55% cases and right ear was operated in 45% cases.

In our study all the patients had ear discharge and complaints of decreased hearing. Tinnitus was the next common symptom present in 29 (48%) cases followed by earache in 14 (23.3%) patients, aural fullness in 10 (16.6%), itching 9 (15%) and vertigo in 6 (10%) patients.

The pre-operative mean hearing loss was 52.05±5.74db in Teflon group. In cartilage group mean hearing loss was 50.98±6.82db, in bone group it was 48.65±6.63db. While the post-operative hearing loss after 6 months was 48.18±8.87 in Teflon group, 37.26±13.98 in cartilage group, 32.03±13.03 in bone group. There was statistically significant difference between pre and post-surgery PTA values in all the groups. [Table 1]

The pre-operative air bone gap was 31.85±3.65db in Teflon group. In cartilage group pre-operative mean air bone gap was 31.55±5.44db, in bone group it was 31.93±5.14db. While the post-operative air bone gap after 6 months was 27.71±5.27 in Teflon group, 17.17±7.27 in cartilage group, 15.27±7.02 in bone group. [Table 1] There was statistically significant difference between pre and post-surgery PTA values

in all the groups. Post op closure of air bone gap in ossicular reconstruction with teflon was <10 dB in 45 % cases and 11-20 dB in 10% cases. In cartilage group, post op closure of air bone gap was <10 dB in 5% cases, 11-20dB in 45% cases and 21-30dB in 5% cases. While in third group in reconstruction with bone, post op closure of air bone gap was <10dB in 10% cases , 11-20 dB in 45% cases, 21-30 dB in 20% cases.[Table 1]

The closure of air bone gap was maximum in bone group 12.60±9.65 than in cartilage group 10.46±10.62 and least in Teflon group 2.51±4.90. There was significant difference in air bone closure between all the groups.[Table 2]

The pre-operative mean hearing loss was 52.05±5.74db in Teflon group. In cartilage group mean hearing loss was 50.98±6.82db, in bone group it was 48.65±6.63db. While the post-operative hearing loss after 6 months was 48.18±8.87 in Teflon group, 37.26±13.98 in cartilage group, 32.03±13.03 in bone group.[Table 1] There was statistically significant difference between pre and post-surgery PTA values in all the groups.

Bone has maximum success rate 75%. Teflon had minimum success rate among the groups i.e 55%, while cartilage group had 60% success rate. There was statistically significant difference in success and failure rate in all the groups [Table 3].

Table 1: Pre and post PTA and ABG values in various groups.

| Group | | Pre | | Post | | p-value |
|-----------|-----|-------|------|-------|------|-------------|
| | | Mean | SD | Mean | SD | |
| Teflon | PTA | 51.55 | 6.51 | 46.49 | 8.54 | 0.005; Sig |
| | ABG | 31.85 | 3.65 | 27.71 | 5.27 | 0.004; Sig |
| Cartilage | PTA | 46.98 | 9.61 | 29.69 | 8.79 | <0.001; Sig |
| | ABG | 31.55 | 5.44 | 17.17 | 7.27 | <0.001; Sig |
| Bone | PTA | 46.90 | 8.82 | 26.33 | 5.90 | <0.001; Sig |
| | ABG | 31.93 | 5.14 | 15.27 | 7.02 | <0.001; Sig |

Table 2: Comparison of mean closure of ABG in various groups.

| Closure | Group | | | | | | p-value |
|---------|--------|------|-----------|-------|-------|------|------------|
| | Teflon | | Cartilage | | Bone | | |
| | Mean | SD | Mean | SD | Mean | SD | |
| ABG | 2.51 | 4.90 | 10.46 | 10.62 | 12.60 | 9.65 | 0.004; Sig |

Table 3: Comparison of success and failure rates between the groups

| | | Group | | | | | | p-value |
|-------------|---------|--------|-------|-----------|-----|------|-----|------------|
| | | Teflon | | Cartilage | | Bone | | |
| | | N | % | N | % | N | % | |
| Outcome PTA | Success | 11 | 55.0% | 12 | 60% | 15 | 75% | 0.393, sig |
| | Failure | 9 | 45.0% | 8 | 40% | 5 | 25% | |

Patients were regularly followed up weekly for four weeks and then after every month for 6 months. In ossicular reconstruction with Teflon 9 (45%) extrusion of graft was seen, 9(45%) had secondary perforation, 3(15%) had granulation and 2(10%) had discharge, no patient had stitch abscess while 1(5%) case complains of pain. In ossicular reconstruction with Bone, 3 (15%) patients had extrusion of graft, 2(10%) had secondary perforation, 1(5%) patient had stitch abscess while 1(5%) case complains of pain [Figure 1].

had secondary perforation, 2(10%) had secondary abscess, 1(5%) had discharge, no patient had stitch abscess while 1(5%) case complains of pain. In ossicular reconstruction with Bone, 3 (15%) patients had extrusion of graft, 2(10%) had secondary perforation, 1(5%) patient had stitch abscess while 1(5%) case complains of pain [Figure 1].

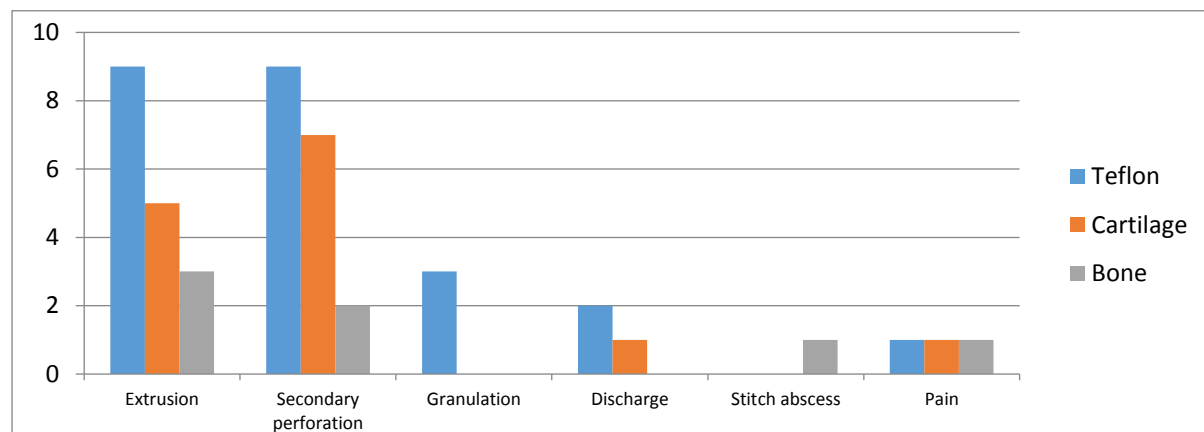


Figure 1: Comparison of complications after ossiculoplasty in various groups.

DISCUSSION

Loss of ossicular chain is the most common cause of conductive hearing loss in adults which can be managed. With this aim, in the present study, ossicular reconstruction using either cartilage, bone or teflon were evaluated. A total of 60 cases with an age range of 16-50 years were evaluated in our study. The mean age was 28.05 ± 10.50 in group 1, 22.75 ± 9.20 in group 2, and 26.30 ± 9.88 in group 3. Patients between 6-20 years of age were 23(38.33%), 21-35 years were 29 (48.33%), 36-50 years were 5(8.33%) and above 50 years were 3(5%).

Presentation of patients with chronic suppurative otitis media was in third decade (late) because earlier they took treatment but problem did not resolve with medical treatment.

Male: Female ratio was 1:1.4. Sheahan P (2001)⁸ did a study over a 15 month period, in 58 patients presenting with a new case of chronic otitis media. Females outnumbered males where 55.9% patients were females with Male: female ratio of 1:1.2. The higher incidence in females could be because they are the most neglected part of our society and hardly get early and proper medical treatments during episodes of recurrent upper respiratory tract infection or chronic otitis media leading to chronic Otitis media requiring surgical intervention. In our study involvement of both ears was seen in 21.66% cases. Unilateral involvement was 78.33%, out of which left ear was 61.7% and right ear was 38.2% involved.

These findings coincided with Khanna (2006)⁹ and Kamal (2004)¹⁰ studies where maximum number of cases had left ear involvement. In an Irish study on 58 patients, bilateral involvement was seen in 35% patients while most of the cases had unilateral presentation (65%).^[11] In a study, of the 510 patients, studied left ear was involved 50.2% while right ear was involved in 49.8% patients.^[12]

In our study all the patients gave history of ear discharge and decreased hearing. Tinnitus was the next common symptom present in 29(48.3%) patients followed by earache in 14(23.3%), aural fullness in 10(16.6%), itching 9(15%) and vertigo in 6(10%) patients. Most of the patient had ear discharge for 4-14 years. Moderate, mucopurulent, non-foul smelling, non-blood stained discharge was more common in all the groups.

Studies by Gulati and Sheahan showed that otorrhoea and hearing loss were the most common complaints at presentation thus support the above findings.^[8,13]

Incus was the commonest ossicle to be eroded (80%) followed by stapes superstructure (30%). Malleus (25%) was the most resistant. 80% of incudi were eroded in patients who underwent ossicular reconstruction using PORP as compared to 30% stapes and 25% mallei. In another group of patients

in whom ossicular reconstruction was performed using autograft or homograft ossicles, 90% of the incus, 30% of the stapes and 15% of the malleus were eroded. While in group where cartilage was used as graft for ossicular reconstruction 75% of incus were eroded, 25% malleus and 35% stapes were eroded. Long process of incus was commonly eroded (54.8%) followed by erosion of both long and short process (10.4%). Long process, short process as well as body of incus was eroded in 34.2% cases. Handle of malleus was eroded in 71% cases while handle as well as head was eroded in 26.3% cases. Long process of incus is the most common ossicle to undergo necrosis and this can be attributed to its poor blood supply. Incus necrosis was found in about 60-80 % according to literature.^[12]

In our study pre op air bone gap in both the groups of ossicular reconstruction using either PORP, autograft cartilage, autograft ossicles was >20 db. Graft was placed between malleus and head of stapes (malleus stapes assembly), malleus and footplate and stapes head and newly constructed tympanic membrane.

Post op follow up of patients was done upto 6 months. Hearing results at 6 months follow up had been fairly good. Closure of air bone gap in ossicular reconstruction with Teflon was ≤ 10 db in 45% patients and within 11- 20 dB in 10% patients. In other group of patients who underwent ossicular reconstruction using autograft cartilage, post op air bone gap closure was within ≤ 10 db in 5% cases while closure within 11-20db was 45% and 21-30 db in 5% cases. While in group of patients who underwent ossicular reconstruction using autograft bone, post op air bone gap closure was within ≤ 10 db in 10% cases while closure within 11-20db was 45% and 21-30db was 20%. Jha et al. in 2007-2009 performed a study of ossiculoplasty outcome after 2 and 5 months of operation in relation to ABG and suggested success rate among cartilage was 57%, in case of incus it was 59% and for plastic PORP and total ossicular replacement prosthesis (TORP) it was (40%).^[14] Another study to assess the use of autologous cartilage in middle ear reconstruction after surgical eradication of disease. 48 patients underwent single stage reconstruction after canal wall down mastoidectomy. Overall 46.6% patients achieved a post op air bone gap of less than 10 db.^[15] In our study during follow up period least extrusion of graft was present in bone but in teflon group grafts got extruded and extrusions were found in cartilage the group.^[5,9] Many of the other studies also showed similar results. Mahanty et al shows extrusion rate of different prosthesis, PORP (25%), cartilage (20%) extrusion. Incus has the lowest (5.26%) extrusion rate Ossiculoplasty with cartilage, incus and PORP after modified radical mastoidectomy. He also concluded that among the ossiculoplasty materials, autologous incus gives best postoperative hearing gain and lowest extrusion

rate.^[16] The rate of extrusion depends on several factors, the most important of which is the status of the middle ear and eustachian tube and the implant material. Other causes are infection, displacement of graft, inability to maintain firm contact between graft and ossicular remnant or loss of stiffness of graft. Aeration of a mucosal-lined tympanic cavity is essential for a functioning middle ear. Extrusions of even the best designed prostheses occur because of abnormal middle ear pathology such as atelectasis, middle ear fibrosis, recurrent cholesteatoma, tympanic membrane perforation, and otitis media.

CONCLUSION

Reconstruction with bone was found superior than cartilage and cartilage had better post-operative outcomes than teflon group with respect to post op hearing threshold, closure in air bone gap, hearing improvement.

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