Ossiculoplasty with Sculpted Incus; Hearing Results and Risk Factors

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INTRODUCTION

The main purpose of surgery in cases of chronic otitis media (COM) is to eradicate the infection and restore the middle ear hearing function (1). Both intact tympanic membrane and ossicular chain are essential for restoration of hearing in these cases. The most vulnerable ossicle to trauma and infectious processes is incus (2-4). Iurato reported that this situation is accompanied by an intact malleus and stapes superstructure in 60% of ossicular defects (Austin-Kartush group A)(5). Study on human cadaveric middle ear model has demonstrated that the mechanical performance of sound transmission when prosthesis used between tympanic membrane (TM) and stapes in contrast to TM directly contacts with stapes (6). Clinical studies showed that type III tympanoplasty, in which graft is placed over the stapes directly, resulted in 5-10 dB conductive hearing loss in comparison with type II tympanoplasty, in which a bridge is placed between drum and incus (7, 8). In 1957 Hall and Rytzner used the first sculpted autograft incus for reconstruction when the incuse was the only eroded ossicle. As several clear advantages of this method such as very low extrusion rate, high benefit/cost ratio and ready availability; it is now the most common ossicular reconstruction method in defects of incus (5).

The aim of this study was to survey the hearing results, success rate and risk factors of ossiculoplasty with sculpted incus.
PATIENTS and METHODS
A before-after clinical trial performed in a tertiary referral otolaryngology center (Amir Alam hospital, Tehran, Iran) between 2005 and 2007, which included patients by damaged incus because of COM, trauma or other causes who underwent primary or staged ossiculoplasty. Patients with fixed or eroded stapes were excluded. Secondary exclusion criteria were unsatisfactory follow-up period (< 3 months after surgery) and failure of surgery, not due to ossicular reconstruction failure. All surgeries were performed by a neurotologist under general anesthesia. Short and long processes of incus and the surface of ossicle joints with malleus were sculpted and a hole was made that stapes suprastructure was inserted. Autologous incus was preferentially used unless extensively involved or eroded by cholesteatoma. If the distance and angle between malleus handle and stapes suprastructure were favorable, incus interposed between them (incus interposition). However, if the angle was unfavorable or malleus handle was not intact, the sculpted incus placed between TM or graft and stapes suprastructure (incus transposition).

Of the 36 patients, 11 patients were excluded. Eight due to unsatisfactory follow up, 2 due to graft failure and 1 because of sever adhesive otitis media postoperatively despite cartilage tympanoplasty. Of the 25 remained patients, 4 underwent incus interposition and 21 underwent incus transposition ossiculoplasty. Of 10 patients with intact TM, 7 patients underwent staged ossiculoplasty, 2 had ISJ erosion and 1 had traumatic ISJ dislocation on middle ear exploration.

Demographic data as well as audiologic data including age, sex, type and sequence of surgical procedure, MERI, preoperative and postoperative (at least 3 months after operation) air-bone conduction threshold in 250, 500, 1000, 2000 and 4000 Hz, mean ABG at 0.5, 1, 2, 3 kHz and finally cause of failure were recorded in the information sheet designed based on study’s goals. Postoperative ABG < 20 dB was considered as favorable hearing result.

SPSS 14.0 for Windows was used for statistical analysis. Wilcoxon test was used to compare pre and postoperative bone, air conduction thresholds and mean ABG in various frequencies. Primary or staged ossiculoplasty results, MERI between patients with post-operative ABG <20 dB and those with post-operative ABG >20 dB, hearing results between cartilage and simple tympanoplasty groups were compared using Mann-Whitney test. Comparison between preoperative MERI and postoperative hearing

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Risk value</th>
</tr>
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<tbody>
<tr>
<td>Otorrhea</td>
<td></td>
</tr>
<tr>
<td>I: Dry</td>
<td>0</td>
</tr>
<tr>
<td>II: Occasional wet</td>
<td>1</td>
</tr>
<tr>
<td>III: Persistently wet</td>
<td>2</td>
</tr>
<tr>
<td>IV: Wet, cleft palate</td>
<td>3</td>
</tr>
<tr>
<td>Perforation</td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td>0</td>
</tr>
<tr>
<td>Present</td>
<td>1</td>
</tr>
<tr>
<td>Cholesteatoma</td>
<td></td>
</tr>
<tr>
<td>O:M+I+S+</td>
<td>0</td>
</tr>
<tr>
<td>A:M+S+</td>
<td>1</td>
</tr>
<tr>
<td>B:M+S-</td>
<td>2</td>
</tr>
<tr>
<td>C:M- S+</td>
<td>3</td>
</tr>
<tr>
<td>D:M- S-</td>
<td>4</td>
</tr>
<tr>
<td>E:Ossicle head fixation</td>
<td>2</td>
</tr>
<tr>
<td>F:Stapes fixation</td>
<td>3</td>
</tr>
<tr>
<td>Middle ear: granulations or effusion</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>Previous surgery</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>0</td>
</tr>
<tr>
<td>Staged</td>
<td>1</td>
</tr>
<tr>
<td>Revision</td>
<td>2</td>
</tr>
</tbody>
</table>

Of 10 patients with intact TM, 7 patients underwent staged ossiculoplasty, 2 had ISJ erosion and 1 had traumatic ISJ dislocation on middle ear exploration.

Table 1. Middle ear risk index
results was tested with Kruskal-Walis test, and between pre and post-operative mean ABG was tested with correlation test and Pearson coefficient. P-value < 0.05 was considered.

**RESULTS**
Final data analysis performed on 25 patients included 12 females and 13 males. The mean age was 38.7 years (ranged from 20 to 55 years). Postoperative follow-up period ranged from 3 to 21 months, with a mean of 9.6 months (Table 2).

Mean postoperative bone conduction thresholds were improved statistically significant in 250 Hz and 2000 Hz (p-value= 0.002 and 0.037) (Figure 1). Mean postoperative air conduction thresholds had statistically significant decrease in all measured frequencies (p-value = 0.005 in 250 Hz and < 0.001 in 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz) (Figure 2). Pre and postoperative ABG closure was different significantly in all measured frequencies (p-value <0.05).

The best result achieved in 2000 Hz with 50% closure and ABG <10 dB (mean ABG closure is 13 dB), and the least closure in 4000 Hz with 28% reduction and postoperative ABG >20 dB (mean ABG closure is 8.8 dB) (Figure 3).

The mean preoperative air bone gap was 33.9 dB and the average postoperative ABG was 19.4 dB with statistically significant closure (p-value = 0.001). Seventy six percent of subjects had postoperative ABG less than 20 dB, although 88% achieved postoperative ABG less than 25 dB (Figure 4).
DISCUSSION

Incus is the most vulnerable ossicle both to trauma and infectious processes because of its anatomic position and the course of its blood supply (1). Mawson and Glasscock both reported damaged incus as the surgical finding in three fourth of ossicular reconstructions (3, 4). Therefore, replacement of the incus poses a significant challenge to the otologists. Various surgical techniques and materials have been used as treatment options:

1) Prosthesis that is replaced between capitulum and remainder of incus (11).

2) Interposition of commercially available partial ossicular replacement prostheses (PORP) made of ceramics, hydroxylapatite, or titanium between TM and capitulum (5, 12, 13).

3) Ossicular reconstruction using bone cement to form a bridge between the incus remnant and the stapes superstructure (14, 15).

4) Ossiculoplasty using autologous or homologous sculpted incus (5).

Iurato and Marioni achieved equally good hearing results in patients who underwent ossiculoplasty for Austin-Kartush group A impairments (incus eroded, malleus handle present, stapes superstructure present) with autograft (no difference was found between interposition of the incus or the head of the malleus), homograft, or alloplastic partial prostheses (5). Successful hearing restoration was achieved in the patients undergoing bone cement ossiculoplasty similar to results reported in the patients who underwent other incus-stapes rebridging procedures (15). Although numerous approaches to ossicular reconstruction have been proven to be successful, but no single technique has received universal acceptance. Because of several obvious advantages, ossiculoplasty with sculpted incus is the most common method used for Austin-Kartush group A patients. Considering the positions and distances between ossicles, incus has sufficient length for reconstructive purposes (16).

In the analysis of the cumulative data obtained from six studies from 1970 to 1998 on a total of 931 patients that underwent ossiculoplasty...
with auto or homograft sculpted incus, an ABG within 10 dB was obtained in 48% of the cases, and on a total of 779 ears, a postoperative ABG within 20 dB was obtained in 84% of the cases (5).

In Iurato and Marioni study on 177 patients, who underwent ossiculoplasty with sculpted incus or malleus head between the stapes head and malleus handle (interposition) or come in contact with the tympanic membrane or tympanic graft (transposition), postoperative ABG within 10 dB, in 55% and postoperative ABG within 20 dB, in 85% of cases were achieved (5). In Siddiq et al. study on 24 patients who underwent incus interposition, 75% of cases had postoperative ABG less than 20 dB (17). In O’ Railly and colleague report on 137 patients who underwent ossiculoplasty using autologous or homologous sculpted incus interposition, mean preoperative ABG was 26.8 dB that decreased to 18.6 postoperatively, and 66.4% of cases achieved postoperative ABG less than 20 dB (18).

In the present series, the mean preoperative ABG was 33.9 dB, and the mean postoperative ABG was 19.4 dB. The best result was achieved in 2000 Hz with 50% closure with a mean postoperative ABG less than 10 dB and the least closure was in 4000 Hz with 8.8 dB closure with mean postoperative ABG still remained over 20 dB. As stated earlier, 76% of gaps were closed to within 20 dB. These results were comparable with previous studies. The influence of pathologic and technical variables in the functional outcome of ossiculoplasty is highlighted in several studies. Kartush et al. in 1994 summarized preceding systems and proposed the comprehensive MERI (table 1) (9). Although Kartush and Black (19) found the severity of underlying eustachian tube dysfunction has a significant influence on prognosis for hearing restoration, others such as Brackmann (12) and O’ Railly (17) and colleagues were not able to demonstrate statistical associations between the preoperative risk factors (MERI) with postoperative hearing results in ossiculoplasty.

In this series, we could not find a statistically significant difference between total MERI of group with postoperative ABG less than 20 dB and those with postoperative ABG above 20 dB (p-value = 0.79), MERI had no association with patient’s post-operative ABG, (p-value = 0.89). Although some authors believe that staged ossiculoplasty results in better hearing restoration and advocate it, but some researchers were not able to demonstrate statistically significant difference in hearing results between staged and primary ossiculoplasty (17). In the present study, which contains more patients, comparison of postoperative ABG and closure, were not significantly different among the groups (p-value = 0.22). Most previous studies had demonstrated that cartilage tympanoplasty had no significant effect on hearing outcomes. Gerber et al. (20) and Solmaz et al. (21) studied 11 and 30 patients respectively who underwent cartilage tympanoplasty and reported similar hearing results, SRT and closure of ABG with control group who underwent tympanoplasty with fascia. Recent studies such as Kirazli (22) and Kazikdas (23) reports did not indicate statistically different hearing outcomes in two groups with normal mucosa and ossicles who underwent tympanoplasty with or without cartilage (15 patients in each group), although success rate was significantly higher in patients with cartilage tympanoplasty in Kazikdas report (95.7% vs. 75%) (23).

Also, in our series, ABG closure has no difference between the two groups. In two patients, causes of failure were due to decreased mobility of stapes intraoperatively. In one patient dysfunction of eustachian tube that caused recurrence of retraction in anterior of TM and therefore, dislocation of cartilage and inadequate osculation surface with prosthesis. These patients had postoperative ABG above 20 dB but less than 25 dB. Among patients who had postoperative ABG >30 dB, two of them underwent incus interposition ossiculoplasty and probably unfavorable angle and distance between incus and malleus caused dislocation of prosthesis and failure of surgery. Therefore,
if angle or distance between incus and malleus is unfavorable or the surgeon has not enough skill or practice for incus interposition technique, sculpted incus is placed between TM and stapes suprastructure (incus transposition technique). Third patient of this group had lateralization of TM postoperatively that explained persistent conductive hearing loss.

**CONCLUSION**

Ossiculoplasty using sculpted autologous or homologous incus interposition or transposition provides acceptable hearing restoration if the patients are selected properly and the surgeon is skilled for appropriate procedure. In this reconstruction scenario, if the stapes is intact and mobile, hearing results appear to be independent of other middle ear risk factors and is recommended in first stage tympanoplasty.

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**CONFLICT of INTEREST**

The authors declare no conflict of interest.

**REFERENCES**