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Original Research Article

Analysis of hearing improvement by various ossiculoplasty materials (autologous versus prostheses) in chronic otitis media patients

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ABSTRACT

Background: The main purpose of surgery in cases of chronic otitis media is to eradicate the infection and restore the middle ear hearing function. Both intact tympanic membrane and ossicular chain are essential for the restoration of hearing in these cases. The world of material science has provided otologists with array of biomaterials for middle ear reconstruction. The use of ossicular graft material in ossicular chain reconstruction has significantly improved hearing results after surgeries for chronic otitis media.
Methods: The study involved a total of 50 patients presenting with dry tympanic membrane perforation with ossicular disruption and air-bone gap (ABG) of >25 from July 2014 to December 2019. The patients were randomly allotted into two groups and they underwent tympanomastoidectomy with ossiculoplasty, in one group homologous incus was used as ossiculoplasty material and in the second group Teflon TORP/PORP was used as ossiculoplasty material.
Results: The present study concluded that there was no inter-group difference in post-operative hearing outcome however the two groups individually noted significant post-operative improvement in hearing.
Conclusions: In present study postoperative hearing improvement was similar in both groups. Although numerous approaches to ossicular reconstruction have been proven to be successful, no single technique has received universal acceptance.

Keywords: Total ossicular replacement prosthesis, Partial ossicular replacement prosthesis, Ossiculoplasty, Otitis media, Tympanomastoidectomy

INTRODUCTION

Otitis media is an infection of the middle ear that can result in perforation of the tympanic membrane.[1] The main purpose of surgery in cases of chronic otitis media (COM) is to eradicate the infection and restore the middle ear hearing function. Both intact tympanic membrane and ossicular chain are essential for the restoration of hearing in these cases. The most vulnerable ossicle to trauma and infectious process is incus.[2] The term ossiculoplasty the means repair of the ossicular chain and it is done to restore the hearing mechanism.

The middle ear is often referred to as an impedance matching system, allowing sound waves that pass through low-impedance medium of air to stimulate the high impedance fluids of the inner ear. For such impedance-matching to occur, the pressure that acts at the tympanic membrane must be substantially increased at the inner ear. Both biologic (autograft and homograft) and

alloplastic materials have been used to maintain the middle ear sound-conducting mechanism.[3]

Conventional teaching suggests that this pressure gain is achieved via two mechanisms

The tympanic membrane area ratio: Since the area of the tympanic membrane is approximately 20 times greater in area than the oval window, a similar pressure magnification is theoretically possible. However experimental studies have shown that all regions of the tympanic membrane do not always vibrate in phase (in the same direction), hence reducing the pressure magnification at the oval window;

The ossicular lever ratio: It has long been assumed that the ossicles rotate about an axis. Due to rotation about such as axis it is believed that the ossicles pride a mechanical leverage. Dahmann calculated this axis to run from the anterior ligament of the malleus the posterior ligament of the incus. Dahmann defined the effective lever ratio of the ossicles as the ratio of the displacement amplitude of the umbo to the displacement amplitude of the stapes, calculated to have a value of 1.3:1.

The world of material science has provide otologist with a wide array of biomaterials for middle ear reconstruction. Through many different materials were used in an attempt to improve the results of middle ear reconstruction and in particular ossiculoplasty. Ultimately, it became apparent that the main problem in terms of biofunctionality rested with an incomplete understanding of the biomechanics of the middle ear itself and how any given prosthesis performed. The knowledge of middle ear mechanics had remained relatively static or constant over many years until the advent of techniques such as Laser-Doppler vibrometry, analog models and finite element analysis.

Developments in micro CT and MRI scanning have enabled highly accurate models of biological systems to be developed. The advantage of such computational models is that they can be regularly are basis, as further information becomes available in the field. To fully appreciate the biomechanics of ossiculoplasty, one must first have a basic understanding of middle ear mechanics. The success of ossiculoplasty depends on various factors, such as the status of the ossicles and middle ear mucosa, surgical technique, and Eustachian tube function.[4]

Since the past 50 year have much developments in ossicular chain recontruction.[5] The first reconstructive options were homografts but later fell out of favor due to risk of possible transmission of infection and increased resorption.[6] The use of ossicular graft material in ossicular chain reconstruction has significantly improved hearing results after tympanoplasty and tympanomastoid surgery for chronic otitis media. Hearing results are not influenced by the performance of mastoidectomies.[7-9]

Today, ENT surgeons have a wide range of tools from which to choose, but may find it difficult to know which middle ear implant works best.

Aim

The aim was to assess the degree of hearing improvement by various ossiculoplasty materials.

Objectives

The objectives were to evaluate the degree of hearing improvement by using autograft as ossiculoplasty material in COM; and to evaluate the degree of hearing improvement by using Teflon TORP/PORP as ossiculoplasty material in COM patients.

METHODS

A prospective study involving a total of 50 patients presenting with dry tympanic membrane perforation with ossicular disrupt air bone gap (ABG) of >25 the existing ENT outpatient department of Era's Lucknow Medical College from July 2014 to December 2019 were included in the study. The patients were randomly allotted into two groups with 25 patients in each group who underwent tympanomastoidectomy with ossiculoplasty. Of the 25 patients in group I, 21 patients were included in the study as 2 patients follow-up and 2 patients had graft rejection. Similarly in group II of the 25 patients who were operated 19 patients were included in the study as 2 patients were follow-up, 3 patients had infected grafts and 1 patient had implant. Follow-up of the study participants was the done on 7th, 15th, 30th days and 3rd and 4th months. PTA was done at 1st, 3rd and 4th months. Surgery was considered to be post-operative ABG follow-up.

Inclusion criteria

Patients of COM with ossicular disruption and ABG of >25 was included in the study.

Exclusion criteria

Patients with sensory neural hearing loss; congenital ear deformity; systemic diseases like diabetes, tuberculosis, HIV; revision surgery; fixed stapes footplate were excluded.

The patients were randomly allotted into two groups: group I: autograft (Incus remnant) as ossiculoplasty material; group II: Teflon TORP (total ossicular replacement prosthesis)/PORP (partial ossicular replacement prosthesis) as ossiculoplasty material.

Sampling technique

Sampling was done by computer generated randomization.

Statistical method and tool

The data was analyzed using Statistical Package for Social Sciences Version 21.0. Data has been analyzed using Chi-square test, Independent sample t test and paired t test respectively. A p value less than 0.05 was considered to be statistically significant.

RESULTS

Comparison of basic parameters and demographic data

The inter-group demographic details were not found to be statistically significant (Table 1).

Hearing outcome

On comparison of AB gap at baseline and different follow up intervals between two groups, there was no significant difference between the two groups (Table 2).

The % change in AB gap from baseline in group I was found to be statistically significant in all three visits (Table 3).

The percentage change in AB gap from baseline in group II was found to be statistically significant in all three visits (Table 4).

Interpretation

The percentage post-operative ABG closure in three visits was also significantly better in group I as compared to group II.

An average post-operative ABG closure of less than 25 dB (hearing gain) representing a successful outcome was achieved in 21 patients (42 per cent) in group I and 19 (38 per cent) in the group II at the end of 4 months.

In both the groups, at each follow-up interval mean change in AB gap was significant statistically as compared to baseline value.

At final visit, there was a % reduction of 44.88% in group I and 47.22% in group II.

Table 1: Comparison of demographic profile of cases in two groups.

S. No.	Variables	Group I (n=25)	Group II (n=25)	Statistical significance
1.	Mean age±SD	24.66±11.16	24.63±12.27	t=0.967; p=0.329 (independent samples t test)
2.	Gender N (%)			
	Male	10 (47.61)	9 (47.36%)	χ^2=0; p=1 (Chi-square test)
	Female	11 (52.39)	10 (56%)	
3.	Side N (%)			
	Left	10 (47.61)	11 (57.89)	χ^2=2.01; p=0.156 (Chi-square test)
	Right	11 (52.39)	8 (36)	

Table 2: Comparison of AB gap baseline and different follow up intervals between two groups.

S. No.	Variables	Group I (n=21)	Group II (n=19)	Statistical significance
1.	Baseline*	32.4±7.44	35.26±9.05	t=0.967; p=0.329 (independent samples t test)
2.	First visit	24.05±5.17	25.26±6.61	t=0.573; p=0.570
3.	Second visit	19.76±4.10	19.47±4.69	t=0.854; p=0.398
4	Third visit	17.86±3.38	18.61±4.13	t=0.535; p=0.596

*Baseline value of only those cases that completed follow-up.

Table 3: Patterns of within-group change in AB gap in group I.

S. No.	Variables	Group I (n=21)	% change from baseline	Statistical significance
1.	Baseline*	32.4±7.44		
2.	First visit	24.05±5.17	25.77	t=7.17; p<0.001
3.	Second visit	19.76±4.10	39.01	t=11.79; p<0.001
4	Third visit	17.86±3.38	44.88	t=11.72; p<0.001

*Baseline value of only those cases that completed follow-up.

Table 4: Patterns of within group change in AB gap in group II.

S. No.	Variables	Group I (n=19)	% change from baseline	Statistical significance
1.	Baseline*	35.26±9.05		
2.	First visit	25.26±6.61	28.36	t=9.89; p<0.001
3.	Second visit	19.47±4.69	44.78	t=10.93; p<0.001
4	Third visit	18.61±4.13	47.22	t=12.19; p<0.001

*****Baseline value of only those cases that completed follow-up**.**

DISCUSSION

The commonest type of ossicular chain erosion encountered in CSOM is necrosis of long process of incus. With the evolution of newer surgical techniques and advances in the instrument armamentarium available to the ENT surgeons, the hearing outcome of ossiculoplasty has shown a noticeable improvement over recent year. The present study was conducted in north Indian population visiting ENT OPD of Era's Lucknow Medical College and Hospital, Era University, Uttar Pradesh.

Comparison of basic demographic data showed that both groups had similar age, sex and other parameters. Lamba et al conducted a study in which 50 patients were operated and the mean age was 35.26±13.028 years with male to female ratio 1:1.[11] 74% were from rural background and 26% were urban.

Our study reported good stability of hearing results with both autografts and prosthesis which was in accordance with previous studies conducted by Austin 1972, Fisch 1994 and Penington 1983 who in their extended period of study reported good stability of hearing results with autografts.[10-12]

Our study reported an average post-operative ABG closure of less than 25 dB was achieved in 42% in group using autologous versus 38% in the group using prosthesis as ossiculoplasty material which was in accordance with study conducted by Al-Qudah 2006 who concluded that AB gap closure within 20dBHL was achieved in 77% of patients postoperatively with auto graft incus.[13]

There was loss to follow up, graft rejections and prosthesis extrusion which were the limitations of the study.

CONCLUSION

In the present study, post-operative improvement (as determined by ABG closure) was similar in both the groups. Although numerous approaches to ossicular reconstruction have been proved to be successful, both these techniques are beneficial in the restoration of hearing status.

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

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