

Original Article

A comparative study of surgical outcomes of ossiculoplasty using biomaterials and autologous implants

Rahul Kawatra, Puneet Maheshwari

Abstract

Objective: To determine amongst biomaterials (Teflon and Silicon) and autologous materials (autologous incus and cartilage), the one which give the best results of ossiculoplasty, in terms of increase in hearing sensitivity including cost effectiveness.

Methods: Study was conducted in Era's Lucknow Medical College & Hospital, Lucknow, India. Randomized prospective crossover study with eighteen months follow up. 80 patients of Chronic Suppurative Otitis Media (CSOM) were randomly assigned for ossiculoplasty using biomaterials (Teflon and silicon) and autologous materials (bone and cartilage). Surgical outcome was compared for all the four types of implant material used, in terms of increase in hearing sensitivity, extrusion rate, cost effectiveness. Pre-operatively all patients had a pure tone audiogram with a four frequency average (0.5/1/2/4 kHz) calculated for both air conduction and bone conduction. Post-operatively a pure tone audiogram using (0.5/1/2/4 kHz) was performed at 18 months follow-up.

Results: Mean hearing gain (change in A-B gap) was 20.80 ± 7.08 dB in autologous group and 19.93 ± 7.27 dB in biomaterials. Hearing Success Rate-It indicates, total no. of patients, whose postoperative AB Gap (calculated at 500Hz, 1, 2, 3 KHz) is equal to or less than 20 dB. In the present study the overall hearing success rate at follow up period of 4 months is 78.8%. For autologous implants it is 80% and for biomaterials it is 77.5%.

Conclusion: The study concluded that there is no significant difference in improvement in AB gap, extrusion rate of implant and overall success rate between biomaterials (Teflon, silicon) and autologous implants (autologous incus, cartilage). The only significant difference between the two groups was the cost effectiveness. Hence, it is concluded in our study that the biomaterials and autologous implants used in the study have equal overall efficacy. The autologous material requires no extra cost so it can be considered as a preferred choice of implant, in comparison to biomaterial in SAARC countries, where the majority is of poor patients.

Key words: *Chronic suppurative otitis media; Ossiculoplasty; Autologous implant; Biomaterial*

Era's Lucknow Medical College and Hospital.
RML Awadh University, Faizabad, India

Address of Correspondence: Dr. Rahul Kawatra
Era's Lucknow Medical College and Hospital.
RML Awadh University, Faizabad, India, email:
Dr. Rahul Kawatra <kawatrarahul_ent@
rediffmail.com>

Introduction

Chronic Suppurative Otitis Media (CSOM) is a very common disease in the developing countries especially in our country affecting mainly the younger population. Various factors like socioeconomic condition, over-crowding, lack of concern about hygiene, poverty,

illiteracy *etc.* contribute much towards the occurrence of this disease.

The audiological impairment is very distressing to the patients even if recurrent otorrhea ceases. To improve upon the hearing and to check the recurrence, tympanoplasty surgery came into existence.

Ossiculoplasty is defined as the reconstruction of the ossicular chain. The ideal prosthesis for ossicular reconstruction should be biocompatible, stable, safe, easily insertable, and capable of yielding optimal sound transmission.

There is not much literature of comparison among biomaterial implants both nationally as well as internationally.

In the present study, we compared biomaterials (Teflon and Silicon) and autologous materials (autologous incus and cartilage), the one which give the best results of ossiculoplasty, in terms of increase in hearing sensitivity.

Aims and Objectives:

General: To determine amongst biomaterials (Teflon and Silicon) and autologous materials (autologous incus and cartilage), the one which give the best results of ossiculoplasty, in terms of increase in hearing sensitivity.

Specific:

1. To study and compare amongst all patients the outcome of ossiculoplasty, using different implant materials.
2. To evaluate the efficacy of various implant materials used in ossiculoplasty including cost effectiveness.

Methods

Study design and Setting: This Randomized prospective crossover study was carried in

the Department of ENT, Era's Lucknow Medical College and Hospital, Lucknow in 80 patients of chronic suppurative otitis media (CSOM) with conductive hearing loss and ossicular chain discontinuity. This study was conducted after clearance from the ethical committee. Patients were properly informed regarding the nature of the disease process, the proposed surgical procedure including expected outcomes, potential complications, and alternative treatments. Written consent was signed by patient and attendant both.

Study period: The duration of the study was around 32 months including observational study for 18 months.

Sample size: 80 patients from outpatient department of ENT, Era's Lucknow Medical College, Lucknow. (20 patients for each implant material).

Procedure: All cases of chronic otitis media with conductive hearing loss, with suspected ossicular chain discontinuity, (after diagnosing by Pure tone audiometry and otomicroscopy), were taken up for surgery. In all cases of ossicular discontinuity, ossiculoplasty was done by randomly selected autologous materials (autologous incus, cartilage) and biomaterial (Teflon, silicon) (Table I).



Figure.-1: *Cartilage Slicer(Used for reshaping cartilage and silicon)*

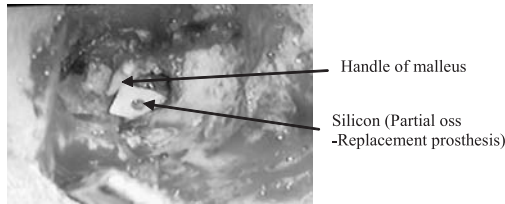


Figure.-2 Silicon Partial ossicular replacement prosthesis X 6

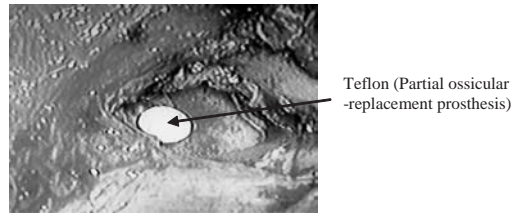


Figure.-3 Teflon Partial ossicular replacement prosthesis. X 10

All cases were performed using a post aurial approach and standard technique of ossiculoplasty by a single surgeon. After the surgery, every patient was followed for next 18 months.

Pre-operatively all patients had a pure tone audiogram calculated for both air conduction and bone conduction. Post-operatively, pure tone audiograms were performed at 1st, 2nd, 4th, 6th, 12th and finally at 18th months follow-up.

Hearing results were assessed by comparing pre-operative and post-operative pure tone averages as well as closure of the air-bone

gap. Extrusion rates and complications were also assessed till 18 months of follow up.

Inclusion criteria:

1. Cases of chronic otitis media Inactive mucosal disease with pure conductive hearingloss.
2. Both males and females in the age group of 10-55 years were included in the study.

Exclusion criteria:

1. Patient with sensorineural hearing loss.
2. Chronic suppurative otitis media squamosal disease with or without complications.
3. Patients below 10 years and above 55 years were excluded from the study.
4. Discharging ear, previous history of ear surgery, otitis externa.
5. Comorbid systemic diseases like hypertension, diabetes, or any chronic infection were excluded from study.

Result

A) Mean hearing gain (closure in A-B gap)– It was calculated for all the 4 implants individually as Table II

1. Autologous incus implant- 19.25±7.29 dB.
2. Cartilage implant- 22.35±6.69 dB.
3. Silicon implant- 19.50±7.98 dB
4. Teflon implant-20.35±6.67 dB.

Table I
Groupwise Distribution of Subjects

S. No.	Group	Description	No. of patients	Percentage
1.	I	Autologous	40	50
	la	Autologous incus used for implantation	20	25
	lb	Cartilage used for implantation	20	25
2.	II	Biomaterials	40	50
	lia	Silicon implant(Fig.2)	20	25
	lib	Teflon implant(Fig.3)	20	25

For random selection Computerized Randomized Controlled Table was used in study. In cases where silicon and Teflon were used, after placing the implant, a thin strip of conchal cartilage is freshened with the use of cartilage slicer (From Kalelker Surgicals, model no. 27.Q01.3S) (Figure: 1) of varying thickness ranging from 0.1 to 0.3 mm and is placed over the implant to lower the extrusion rate.

B) Hearing Success Rate: It indicates, total no. of patients, whose postoperative AB Gap calculated by an audiogram at 18 months of follow-up, is equal to or less than 20 dB.

In the present study the overall hearing success rate at follow up period of 4 months is 78.8%. (For Bone and cartilage implant it is same as 80%. For silicon it is 80% and for teflon it is 75 %.)

C) Extrusion Rate: The implant was extruded in 3 (7.5%) of autologous group and 4 (10%) of biomaterial group patients (Table III).

On comparing individually, the implant was extruded in 2 (10%) of bone group and 1 (5%) of cartilage group patients. The prosthesis was extruded in 2 (10%) of both the subgroups, (teflon and silicon).

D) Comparison of Cost of Implant: The cost of Silicon implant was around 40 INR (manually reshaped from commercially available silicon block), while the mean cost of Teflon implant was 600 INR.

The cost of implant in teflon subgroup was 15 times higher as compared to that in Silicon.

In Autologous Group, no cost was incurred on implant while in biomaterial Group; a mean cost of Rs 320±284.54 was incurred (Table IV)

Table II
Post-Operative Closure in Air-Bone (A-B) Gap

SN	Change in	Group I (n=40) Autologous		Group II (n=40) Biomaterials	
		No.	%	No.	%
1.	< 10 dB	3	7.5	4	10
2.	11-20 dB	11	27.5	13	32.5
3.	21-30 dB	25	62.5	22	55
4.	>30 dB	1	2.5	1	2.5
Mean Change in Gap±SD		20.80±7.08		19.93±7.27	

Table III
Acceptability of Implant

SN	Status	Group I (n=40) Autologous		Group II (n=40) Biomaterials	
		No.	%	No.	%
1.	Accepted	37	92.5	36	90
2.	Extruded	3	7.5	4	10

Table IV
Comparison of Cost of Implant

SN	Variable	Group I (n=40) Autologous		Group II (n=40) Biomaterials	
		Mean	SD	Mean	SD
1.	Cost in Rs	0	0	320	284.54

Statistically, there was no significant difference between two groups in terms of hearing gain, hearing success rate and extrusion rate, but the difference of cost between two groups was significant.

Discussion

Chronic suppurative otitis media often ends up in the breach in conductive chain of the middle ear leading to conductive deafness. The breach in conductive chain calls for rehabilitation of patient through prosthesis. Ossiculoplasty is the surgical treatment. It has been over 50 years since the use of implants has been started in the ossiculoplasty¹. Although, autologous and biomaterial implants, both are in practice, yet it is always of interest to find out innovative use of materials other than those being conventionally used. In present study, silicon implants are being used. Silicon implants have been successfully used in rhinoplasty^{2,3}. The prospects of silicon implants in jaw surgery and innovative areas has been proposed as long back as 1963⁴. Although autologous implants such as Bone and Cartilage are used extensively for ossiculoplasty, the use of biomaterials such as Teflon is also in practice since long. However, use of silicon implants in ossiculoplasty is rarely reported despite their enormous prospects⁵. The present study is an attempt to evaluate the feasibility and comparative efficacy of biomaterials in general and silicon implants in particular.

A host of biomaterials have been used including vinyl-acryl, polyethylene⁶, PTFE/

Teflon⁷, Stainless steel⁸, Proplast, Plastipore⁹, Aluminium oxide ceramic, Ceravital¹⁰, Hydroxyapatite^{11,12}, Bioglass¹³, Carbon¹⁴ and have shown to be comparable results in terms of change in- hearing status. The acceptability and extrusion rates in these materials were ranged from as low as 1.3% to 30%^{15, 16}. In the present study, the overall extrusion rate is 8.7% and both autografts and biomaterials behave equally well in ossiculoplasty^{17,18}. Biomaterials need to be reserved for cases in which these two are in short supply.

In the present study, the results obtained for silicon prosthesis were comparable to, not only the other biomaterial *i.e.* Teflon but they were also comparable to autologous implants. The success rate for silicon prosthesis group was 80% which was equivalent to biomaterials in too whereas as compared to Teflon group it was still better by 5%.

Conclusion

In our study, there is no statistically significant difference as far as improvement in AB gap, extrusion rate of implants and overall success rate between biomaterials (teflon, silicon) and autologous materials (bone, cartilage) are concerned. The only significant difference between the two groups was the cost effectiveness. The autologous material requires no extra cost so it can be considered as a preferred choice of implant, in comparison to biomaterial in our setup, where the majority is of poor patients. The role of biomaterial is only recommended for use, in places where the autologous implant could

not be harvested for some reason (revision surgery).

In the present study, a cost effective biomaterial, *Silicon* has been used which is not a new implant material but yet not tried in the middle ear. It showed promising results in terms of acceptability, hearing improvement, patient satisfaction and the results were comparable to other autologous materials. It is a very promising material which can be reshaped exactly like a cartilage with almost equally good results.

References

1. Slater PW, Rizer FM, Schuring AG, Lippy WH. Practical use of total and partial ossicular replacement prostheses in ossiculo-plasty. *Laryngoscope*, 1997; 107: 1193-8. 104. <http://www.ncbi.nlm.nih.gov/pubmed/9292602>
2. Ahn J, Honrado C, Hom C. Combined Silicone and Cartilage Implants: Augmentation Rhinoplasty in Asian Patients. *Arch Facial Plast Surg* 2004; 6(2):120-123. <http://www.ncbi.nlm.nih.gov/pubmed/15023800>
3. Lam SM, Kim Y-K. Augmentation rhinoplasty of the Asian nose with the "bird" silicone implant. *Ann Plast Surg* 2003; 51: 249-256. 110. <http://www.ncbi.nlm.nih.gov/pubmed/12966235>
4. Brown JB, Fryer MP, Kollias P, Ohlweiler DA, Templeton JB. Silicone and Teflon Prostheses, Including Full Jaw Substitution: Laboratory and Clinical Studies of Ethern. *Annals of Surgery*. 1963; 157(6): 932-943. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1466453/>
5. Gerlinger MD *et al.* Effect of KTP laser on implants used in middle-ear surgery. *The Journal of Laryngology & Otology* 2002;116(7): 502-506. 39. <http://www.ncbi.nlm.nih.gov/pubmed/12238668>
6. Shea JJ. Vein graft closure of eardrum perforations. *J Otolaryngol*, 1960; 74: 358. <http://www.ncbi.nlm.nih.gov/pubmed/13854782>
7. Austin DF, Shea JT. A new system of tympanoplasty using vein grafts : *Laryngoscope* 1961; 71 : 596-611. <http://www.ncbi.nlm.nih.gov/pubmed/13685204>
8. Palva T, Palva A, Karja J. Ossicular reconstruction in chronic ear surgery. *Arch Otolaryngol* 1973; 98(5): 340-8. <http://www.ncbi.nlm.nih.gov/pubmed/4745309>
9. Shea JJ, Homsy CA. The use of proplast in otologic surgery. *Laryngoscope* 1974; 84:1835. <http://www.ncbi.nlm.nih.gov/pubmed>
10. Reck R. Bioactive glass ceramic: a new material in tympanoplasty .*Laryngoscope* 1983; 93(2):196-9 <http://www.ncbi.nlm.nih.gov/pubmed/4003541>
11. Goldenberg R, Emmet JR. Current use of implants in middle ear surgery. *Otol Neurotol* 2001; 22: 145-52 <http://www.ncbi.nlm.nih.gov/pubmed/11300260>
12. Grote J. Tympanoplasly with calcium phosphate. *Arch Otol* 1984; 110: 197-9. <http://www.ncbi.nlm.nih.gov/pubmed/6322733>
13. Merwin GE. Bioglass middle ear prosthesis: preliminary report. *Ann Otol Rhinol Laryngol* 1986; 95: 78-82 <http://www.ncbi.nlm.nih.gov/pubmed/6322733>

14. Podoshin L, Fradis M, Gertner R. Carbon-carbon middle ear prosthesis. A preliminary clinical human trial report. *Otolaryngol Head Neck Surg* 1988 Sep; 99(3): 278-81. <http://www.ncbi.nlm.nih.gov/pubmed/6322733>
15. Vincent R, Maroeska R, Mistry N, Oates J, et al. Ossiculoplasty in Intact Stapes and Malleus Patients: A Comparison of PORPs Versus TORPs With Malleus Relocation and Silastic Banding Technique. *Otology and Neurotology* 2011; 32(4): 615-625. <http://www.ncbi.nlm.nih.gov/pubmed/6322733>
16. Yung MW. Literature review of alloplastic materials in ossiculoplasty. *The Journal of Laryngology & Otology* 2003; 117(6): 431-436. <http://www.ncbi.nlm.nih.gov/pubmed/12825564>
17. Belal A Jr, Sanna M, Gamelotti R. Pathology as it relates to ear surgery. V. Ossiculoplasty. *Journal of Laryngology & Otology* 1984; 98(3): 229-40. <http://www.ncbi.nlm.nih.gov/pubmed/6366099>
18. Marcus N, Zahnert T, Lasurashvili N, Bornitz M, Lavcheva Z, Offergeld C. Partial Ossicular Reconstruction: Comparison of Three Different Prostheses in Clinical and Experimental Studies. *Otology & Neurotology* 2009; 30(3):332-338.