International Journal of Otorhinolaryngology and Head and Neck Surgery
Gangadaran U et al. Int J Otorhinolaryngol Head Neck Surg. 2021 Mar;7(3):481-486
http://www.ijorl.com
pISSN 2454-5929 | eISSN 2454-5937

DOI: https://dx.doi.org/10.18203/issn.2454-5929.ijohns20210682

Original Research Article

Comparison of hearing outcome using ossiculoplasty with autologous incus versus titanium prosthesis

Udayachandrika Gangadaran*, Muthuchitra S., Mary Nirmala S., Ramya Devi K.

Department of Otorhinolaryngology, Government Kilpauk Medical College and Hospital, Chennai, Tamil Nadu, India

Received: 31 December 2020
Revised: 05 February 2021
Accepted: 12 February 2021

***Correspondence:**
Dr. Udayachandrika Gangadaran,
E-mail: vibhuvinays@gmail.com

ABSTRACT

Background: The aim of the study is to compare the efficacy of autologous incus versus allogenic titanium prosthesis in terms of anatomical results, hearing gain after surgery, operative course and complications.
Methods: This is a prospective interventional study of 20 patients out of which 10 underwent autologus incus and 10 underwent titanium prosthesis ossiculoplasties performed between April 2018 To April 2019 in Government Kilpauk medical college and hospital, Chennai after ethical clearance. The postoperative improvement of mean air-bone gap and air conduction over same frequencies between the two groups were studied. A improvement in pure tone average more than 10 dB was considered successful.
Results: In current study, 10 patients underwent ossiculoplasties using titanium ossicular replacement prosthesis and 10 patients underwent ossiculoplasties using autologous incus. 5 of the patients in each group underwent canal wall up and 5 underwent canal wall down procedure. The average ABG closure was 9.30 dB in incus group and 15.22 dB in titanium group.
Conclusions: Titanium ossicular prosthesis ossiculoplasties provide a significant hearing gain and are advantageous because of the easy insertion with pre-sculpted structure yet the cost is a concern. Better results were noted in canal wall up procedures more than canal wall down procedures.

Keywords: Ossiculoplasty, Titanium ossicular prosthesis, Conductive deafness, Hearing gain

INTRODUCTION

Hearing is one of most important senses required for human evolutionary survival. It bridges an individual both to his environment and to his society. Hearing impairment is estimated to be the most frequent sensory deficit of human population, affecting more than 250 million people in the world.[1] Middle ear causes of hearing impairment was one of the leading factor.[1]The prevalence of CSOM in India is classified under highest (>4%) by WHO. Globally the estimated CSOM incidence rate is 4.76 per thousand people for a total of 31 million cases.[2-4] The functional component of middle ear is formed by ossicular chain. The ossicle starts developing by 5 weeks of intra uterine life. Congenital ossicular abnormalities occours due to insult during the process of formation .there may be near normal developement or ossicular fusion or rudimentary mono block ossicular mass.[5] The congenital ossicular abnormalities include absence of manubrium of malleus, shortened long process of incus, failure of incus to connect with stapes, fusion of incudostapedial joint, incudomalleolar fixation, stapedial foot plate fixation. The malleus, incus and stapes are connected by synovial joints. The malleus and incus rotate in anteroposterior axis. At low frequency the movement is less where as at high frequency there is

slippage movement for better conduction. The stapes shows piston like movement. The middle ear ossicles transform the air pressure variation from tympanic membrane into mechanical movements that is conveyed to inner ear. The middle ear with the ossicles has developed in humans to match the impedance difference that occours as sound from low impedance air medium enters high impedance perilymph. The acquired causes of ossicular pathology include ossicular chain erosion is more common in cases of cholesteatoma. Most commonly preserved is malleus handle and most commonly eroded is incus long process. Traumatic ossicular disruption also occurs either due to barotrauma or due to temporal bone fracture. Reconstruction of the ossicular chain aims to surgically optimize the middle ear transformer mechanics so that sound energy is conducted from environment to the inner ear fluid efficiently with minimum loss. Autologous incus is used when incus is salvageable. The incus is inspected for residual disease and adequate height. After confirming for disease clearance incus is reshaped using derlacks ossicle holding forceps. Titanium prosthesis are the most biocompatible material available. Low ferromagnetism hence MRI compatible, light weighted and hence good capability for sound transmission, metallic acoustics being metal-osseointegration helps in integration with surrounding tissue, malleable and hence can be bent according to anatomical orientation, ppen head plate hence insertion can be made easy.

Objectives

Objective of the current study was to compare the efficacy of autologous incus versus allogenic titanium prosthesis in terms of anatomical results, hearing gain after surgery, operative course and complications.

METHODS

The study population comprises of patients who came to ENT outpatient department in Government Kilpauk medical college hospital and Government Royapettah hospital, Chennai after obtaining ethical committee approval from our institutional ethical committee. Study was a prospective interventional study conducted between April 2018 To April 2019 consisting of 20 patients. The sample size was calculated using open EPI software and the patients were selected by random sampling.

Inclusion criteria

The inclusion criteria comprises patients between 16 to 60 years, all cases with chronic otitis media with ossicular erosion and traumatic ossicular disruption.

Exclusion criteria

The exclusion criteria was patients with age below 16 years and above 60 years, patients with sensorineural and mixed hearing loss, patients with sinonasal pathology, patients with eustachian tube dysfunction, patients with disease of fixity of stapes foot plate, patient medically unfit for general anaesthesia or surgery.

Procedure

Patients were subjected to detailed history to identify type of disease, complication if present and assess outcome of surgery. Patients were made to undergo complete general examination and then ENT examination with tunning fork test. Patients were then subjected to pure tone audiogram which gave qualitative and quantitative assessment of hearing. Impedance audiometry was done for traumatic cases with suspected ossicular disruption in which an Ad curve was seen. Radiological investigation included X-ray both mastoids and high resolution computed tomography of temporal bone to assess the extent of middle ear pathology, ossicular status and inner ear anatomy. Patients are then subjected to complete blood investigations and fitness for general anesthesia was obtained. Procedure was explained in detail to patients and informed written consent was obtained beforeinvestigation.

Figure 1: Titanium ossicular prosthesis.

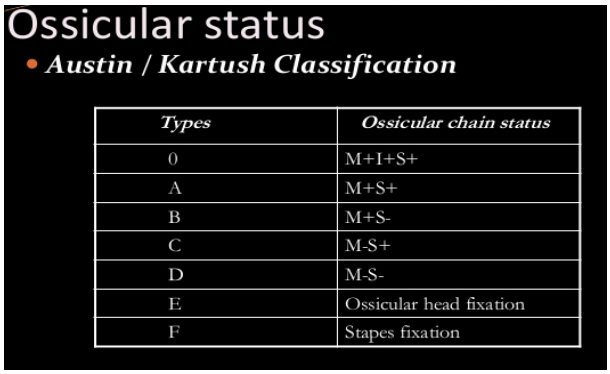

Figure 2: Austin-Kurtush classification of ossicular status.

All patients were operated under GA. Ossicular status was assessed by Austin-Kurtush classification (Figure 2). Extent of disease was analysed and procedure was proceeded after detrmining canal wall up or canal wall down techniques. If incus was salvageable, incus was

used. If non salvageable, titanium ossicular prosthesis was used. The type of titanium ossicular prosthesis depended upon presence or absence of suprastructure of stapes. If capitilum was intact partial ossicular replacement prosthesis was used and if capitulum was eroded, total ossicular replacement prosthesis was used. Patients of both groups were followed up every week for first four weeks and then followed up monthly for 3 months.

Post operative PTA was taken after 3 months. The mean pure tone average post op was calculated and compared in both groups and results derived. The results were obtained by statistical analysis using unpaired t test.

RESULTS

The findings and results observed were studied as comparison within various groups and between the procedures and statistical analysis was done using unpaired t test. The ossicular status plays an important role in determining the prosthesis selection in the patients. In titanium prosthesis group 66.7% had absent incus and 33.3 % showed partial erosion. This shows the advantage of titanium ossicular replacement prosthesis is that its ability to be used in situations where sufficient autologous material prosthesis can be used.

The mean pre op pure tone average in autologous incus was 52.30 dB and in titanium ossicular replacement prosthesis was 56.11dB.After post operative follow up the mean pure tone average in autologous incus was 42dB and in titanium ossicular replacement prosthesis was 39.22 dB. This gain in hearing was statistically significant. The average ABG closure was 9.30 dB in incus group and 15 .22 dB in titanium group.

Table 1: Comparison between age.

Groups						Total	
		Incus		Titanium prosthesis			
		N	%	N	%	N	%
Age in years	≤ 20	1	10	0	0	1	5.3
	21-30	1	10	2	22.2	3	15.8
	31-40	6	60	4	44.4	10	52.6
	>40	2	20	3	33.3	5	26.3
Total		10	100	9	100	19	100

Table 2: Comparison between procedures.

Groups						Total	
		Incus		Titanium prosthesis			
		N	%	N	%	N	%
Procedure	Down	6	60	4	44.4	10	52.6
	Up	4	40	5	55.6	9	47.4
Total		10	100	9	100	19	100

Table 3: Comparison of status of malleus.

Groups						Total	
		Incus		Titanium prosthesis			
		N	%	N	%	N	%
Malleus	Absent	1	10	3	33.3	4	21.1
	Present	8	80	4	44.4	12	63.2
	Partial erosion	1	10	2	22.2	3	15.8
Total		10	100	9	100	19	100

Table 4: Comparison of status of incus.

Groups						Total	
		Incus		Titanium prosthesis			
		N	%	N	%	N	%
Incus	Absent	0	0	6	66.7	6	36.8
	Partial erosion	10	100	3	33.3	13	63.2
Total		10	100	9	100	19	100

The type of procedure also has an importance in the results of the study. In autologous incus group 40% cases underwent canal wall up mastoidectomy. In titanium ossiclar prosthesis group 55.6% cases underwent canal wall up mastoidectomy. Comparing hearing gain based on procedure in canal wall down the mean pre op pure tone average is 55.20 dB and post op was 41.20, where as in canal wall up mean pure tone average is 52.89 and post op was 40.11 dB. In current study no significant difference in outcome based on type of surgery was found, yet better results were obtained with canal wall up procedure.

Table 5: Comparison of status of stapes.

Groups						Total	
		Incus		Titanium prosthesis			
		N	%	N	%	N	%
Malleus	Absent	1	10	3	33.3	8	42.1
	Present	9	90	4	44.4	9	47.4
	Partial erosion	0	0	2	22.2	2	10.5
Total		10	100	9	100	19	100

DISCUSSION

The age group of our study is from 16-60 years. Current study group had 20 patients, among them 10 underwent autologous incus ossiculoplasty and 10 underwent titanium ossicular prosthesis. In titanium group 5 underwent TORP ossiculoplasty and 5 underwent PORP ossiculoplasty. There were 10 males and 10 females. In current study 5.3% of cases belonged to less than 20 years. 15.8% cases belonged to 21-31 years, 52.6%

cases belonged to 31-40 years of age, 26.3% cases belonged to above 40 years. Regarding the ossicular status, in all cases incus was involved. In incus interposition predominantly partial erosion on incus was observed. In titanium ossicular replacement prosthesis predominantly complete absence of incus was observed. This was the most susceptible ossicle in various literature, as in Varshney et al who have observed absent incus in 40% of cases, partial erosion in 45%, similar finding was observed in current study which showed 66.7% absent incus and 33.3% partial erosion.[4]

Presence of ossicles was one among the important determining factor, since the presence of incus and stapes superstructure determined the type of prosthesis. Presence of malleus was a favourable prognostic factor in our study and its presence reduced the interface of prosthesis with tympanic membrane or temporalis graft and reduced risk of extrusion. Presence of malleus helps in converging the sound and conveys effecticely into reconstructed ossicular chain and hence improving the success.

According to Varshney et al malleus was found to be absent in 10% of cases, eroded in 35% of cases and intact in 55% of cases; whereas stapes was found intact in 48.33% of cases and found eroded in 51.67%.[4] Current study showed 21% absent malleus, 63.2% intact malleus, 15.8% partially eroded malleus and 44.4% cases had intact stapes and 22.2% cases had partial erosion of stapes.

Table 6: Comparison of pre and post-operative hearing by unpaired t test.

Groups		N	Mean	SD	P value
Pre	Incus	10	52.30	10.20	0.0367
	Titanium prosthesis	9	56.11	7.29	
Post	Incus	10	42.00	8.54	0.0447
	Titanium prosthesis	9	39.22	4.03	

Table 7: Comparison of improvement in hearing by unpaired t test.

Groups		N	Mean	SD	P value
Hearing	Incus	10	9.30	11.24	0.0317
	Titanium prosthesis	9	15.22	13.77	

*t value; 1.032

Table 8: Comparison of percentage change in hearing.

Groups		N	Mean	SD
% change	Incus	10	16.80	24.35
	Titanium prosthesis	9	28.22	20.52

Table 9: Comparison of results between procedures.

Groups		N	Mean	SD	P value
Pre	Down	10	55.20	10.23	0.058
	UP	9	52.89	7.61	
Post	Down	10	41.20	9.0	0.036
	UP	9	40.11	6.41	

Type of procedure and its influence

The type of procedure offers a difference in results of the hearing outcome in the cases. In a study conducted by Meulamans et al 33% underwent canal wall down mastoidectomy, 72% underwent canal wall up mastoidectomy. Canal wall-down mastoidectomy was found to have no negative impact on functional results by Vassbotn et al and De Vos et al.[6-10] as mentioned by Meulamans et al In their study, the postoperative PTA ABG in the CWD group was significantly higher compared with that in the CWU group.[11-16] Also in previous study conducted by Iñiguez-Cuadra et al among 56 canal wall down patients 33 and among 37 canal wall up patients 24 had successful ABG closure of 0-20 dB.[17-19] In current study, totally 10 cases underwent canal wall down 6 in incus group and 4 in titanium group, one case lost follow up in titanium group. In four cases malleus was totally absent, here in 1 case, the total ossicular replacement prosthesis was used placing it between the temporalis fascia graft and mobile foot plate with cartilage cap in four cases malleus was completely present, where total ossicular replacement prosthesis was placed between malleus and foot plate of stapes in titanium group.In incus group 8 cases had malleus. In four cases malleus was partially eroded, in which all the 3 cases in titanium group, total ossicular replacement prosthesis was placed 44.4% had canal wall down mastoidectomy. 10 cases underwent canal wall up procedure 4 in incus group and 5 in titanium group, among them 2 cases had squamous disease with attic cholesteatoma, hence had undergone intact canal wall mastoidectomy here PORP was placed. 3 cases had mucosal disease and had undergone cortical mastoidectomy with preserved posterior canal wall, here PORP was placed with the ariel end over malleus or temporalis fascia graft with cartilage cap. In this group 55.6% cases underwent canal wall upmastoidectomy. Comparing hearing gain based on procedure in canal wall down the mean pre op pure tone average is 55.20 dB and post op was 41.20, where as in canal wall up mean pure tone average is 52.89 and post operative was 40.11 dB. In current study no significant difference in outcome based on type of surgery was found, yet better results were obtained with canal wall up procedure. In a study conducted by Brendon et al conducted with 156 subjects, no difference was observed in short term follow up noted between PORP and TORP whereas in long term follow up PORP showed mild deterioration of 4.9 dB was noted while that of TORP was only 2.5 dB deterioration was seen.[20] The similar better results were observed in PORP more than TORP in the study conducted by Schmerber et

al.[21] Yet in current study there was no difference in outcome between PORP and TORP in short term follow up.

Hearing gain characteristics

The study conducted by Bartel et al showed preoperative ABG of 31.74 dB (SD 10.51); post-operative ABG of 18.97 dB (SD 10.6); dB gain of 12.76 dB (SD 14.97); and ABG closure rate of 64.48%. PORP group: preoperative ABG of 28.02 dB (SD 10.47); postoperative ABG of 16.27 dB (SD 10.45); dB gain of 11.75 (SD 15.02); and ABG closure rate of 71.32%.[17] Orfao et al showed a postoperative decrease of 11.0 dB in air-bone gap and 12.4 dB in pure-tone average was observed in titanium ossiculoplasty compared with a reduction of 4.0 dB in air-bone gap and 5.1 dB in pure-tone average when autologous reconstruction was used.[18] In current study, the mean pre op pure tone average in autologous incus was 52.30 dB and in titanium ossicular replacement prosthesis was 56.11dB. After post operative follow up the mean pure tone average in autologous incus was 42dB and in titanium ossicular replacement prosthesis was 39.22 dB. This gain in hearing was statistically significant. The average ABG closure was 9.30 dB in incus group and 15.22dB in titanium group.

Limitations

The titanium prosthesis used in the study although being innovative had its own setbacks in terms of financial constraints in procurement and obtaining informed consent from the patients regarding the usage of a new foreign material. From the surgeons point of view, the time period given was found to be limited considering the practical difficulties in procuring and the usage of the given material. Total and partial ossicular replacement was considered depending upon the given conditions of the cases, extensive study is needed to analyse the differences in results between the two prostheses. Canal wall up and canal wall down procedures were determined according to the given pathology, further evaluation should be done to analyse the hearing outcome as well as the complications between the two procedures. Usage of prosthesis in the middle ear requires a longer followup of the complications which is seen as a major pitfall in this study.

CONCLUSION

Ossiculoplasty gives rewarding hearing gain in COM patients. Incus was the most common ossicle eroded and its disruption was most common cause of conductive hearing loss in COM patients. Autologous incus provides an average hearing gain of 9.30 dB and titanium ossicular replacement prosthesis hearing gain of 15.22 dB. Even though autologous incus was easily available, reconstruction was difficult and was time consuming. In titanium ossicular replacement prosthesis, insertion was easy with its presculpted structure, had the advantage of usage in situation where sufficient autologous incus was not available yet the cost of titanium is a concern. In current study we did not find any difference in audiological results between TORP and PORP. Both autologous incus and titanium ossicular replacement prosthesis gave good results. There were no complications and long term results are awaited. Hence we recommend autologous incus interposition if sufficient autologous material was available and to do titanium ossiculoplasty in cases of extensive ossicular erosion. The study provides complete understanding of the hearing mechanism of ossicles, the reconstruction techniques, the surgical procedures required and thereby gives an abundant scope for further refinement in techniques used.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. World health organization, deafness and hearing impairment. Available at: https://www.who.int/news-room/fact-sheets/detail/deafness-and-hearing-loss. Accessed on 20 October 2020.
2. Varshney S. Deafness in India. Indian J Otol. 2016; 22:73
3. Child and adolescent health and development; prevention of blindness and deafness. Chronic suppurative otitis media: burden of illness and management options. Available at: https://apps.who.int/iris/handle/10665/42941. Accessed on 20 October 2020.
4. Varshney S. Ossicular chain status in chronic suppurative otitis media in adults. Indian J otolaryngology Head Neck Surgery. 2010;62(4): 421-6.
5. Julianna A, Minor L, Poe D. Glasscock and Shambough, surgeries of the ear. 6th ed. Europe: Mc-Graw Hill publication; 2010:3-48.
6. Proctor B. The development of the middle ear spaces and their surgical significance. J Laryngol Otol. 1964;78:631-48.
7. Mawson S, Wright T. Diseases of the ear. 6th ed. USA: CRC Press: 1997;13-9.
8. Merchant SN, Rosowski JJ. Auditory physiology. In: Glasscock ME, Gulya AJ, eds. Surgery of the ear, 5th ed. New Delhi: Reed Elsevier India Pvt. Ltd; 2003:70.
9. Slattery WH. Pathology and clinical course of inflammatory diseases of the middle ear. In: Glasscock ME, Gulya AJ, eds. Glasscock-Shambaugh surgery of the ear. 6th ed. Europe: Mc-Graw Hill publication; 2010:386-91.
10. Deka RC. Newer concepts of pathogenesis of middle ear cholesteatoma. Indian J Otol. 1998;4(2): 55-7.

11. Austin DF. Ossicular reconstruction. Arch Otolaryngol. 1971;94(6):525-35.
12. Browning GG. Chronic Otitis Media. Gleeson M, eds. Scott-Brown's otolaryngology, head neck surgery, 7th ed. London: Hodder Arnold, 2008; 237c:3395-445.
13. Sade J, Berco E, Buyanover D, Brown M. Ossicular damage in chronic middle ear inflammation. Acta Otolaryngo. 1981;l92:273-83.
14. Naragund AI, Mudhol RS, Harugop AS, Patil PH. Ossiculoplasty with autologous incus versus titanium prosthesis: A comparison of anatomical and functional results. Indian J Otol. 2011;17:75-9.
15. Martin AD, Harner SG. Ossicular reconstruction with titanium prosthesis. Laryngoscope. 2004;114: 614-8
16. Meulemans J, Wuyts FL, Forton GEJ. Middle ear reconstruction using the titanium kurz variac partial ossicular replacement prosthesis: functional results. JAMA Otolaryngol Head Neck Surg. 2013;139(10): 1017-25.
17. Bartel R, Cruellas F, Hamdan M, Gonzalez-Compta X, Cisa E, Domenech I, et al. Hearing results after type III tympanoplasty: incus transposition versus PORP. A systematic review. Acta Otolaryngol. 2018;138(7):617-620
18. Orfao T, Julio S, Ramos JF. Audiometric outcome comparison between titanium prosthesis and molded autologous material. Otolaryngol Head Neck Surg. 2014;151:315-20.
19. Iñiguez-Cuadra R, Alobid I, Borés-Domenech A, Menéndez-Colino LM, Caballero-Borrego M, Bernal-Sprekelsen M. Type III tympanoplasty with titanium total ossicular replacement prosthesis: Anatomic and functional results. Otol Neurotol. 2010;31:409-14.
20. O'Connell BP, Rizk HG, Hutchinson T, Nguyen SA, Lambert PR. Long-term Outcomes of titanium ossiculoplasty in chronic otitis media. Otolaryngol Head Neck Surg. 2016;154(6):1084-92.
21. Schmerber S, Troussier J, Dumas G, Lavieille JP, Nguyen DQ. Hearing results with the titanium ossicular replacement prostheses. Eur Arch Otorhinolaryngol. 2006;263(4):347-54.

Cite this article as: Gangadaran U, Muthuchitra S, Mary NS, Ramya DK. Comparison of hearing outcome using ossiculoplasty with autologous incus versus titanium prosthesis. Int J Otorhinolaryngol Head Neck Surg 2021;7:481-6.