The Efficiency of Titanium Middle Ear Prosthesis in Ossicular Chain Reconstruction: Our Experience

Kshitij Dhaval Shah · Renuka A. Bradoo ·
Anagha A. Joshi · Deepti D. Sapkale

Received: 26 April 2011 / Accepted: 15 November 2011 / Published online: 3 December 2011
© Association of Otolaryngologists of India 2011

Abstract Middle ear ossicular reconstruction is a challenging task for any otologist. Over a period of time, surgeons have tried various types of materials as ossicular prosthesis with varying amount of success. In the last decade, numerous studies have been conducted that have proved that titanium prosthesis is biocompatible. We have conducted this study to investigate the efficiency of titanium middle ear prosthesis (Eon Meditech Pvt. Ltd.) in tympanoplasty. Nineteen patients who underwent tympanoplasty with titanium prosthesis placement from January to October 2010 were included in the study. Fifteen patients underwent reconstruction using titanium PORP while four patients required titanium TORP. The average follow up period was 11.1 months. The pre-operative and post-operative PTAs and the closure of the air-bone gap (ABG) at 0.5, 1, 2, 3 KHz (as per the AAO-HNS guidelines) were analyzed. As per the Indian speech and hearing association (ISHA) guidelines, the patients were classified into groups based on the amount of hearing loss. The improvement in the mean PTA (AC) was 16.21 dB in the PORP group while it was 20.47 dB in the TORP group (P value < 0.05). According to ISHA guidelines, 18 out of 19 (94.8%) patients had either a normal hearing or a mild hearing loss post-operatively. The overall success rate (post-operative ABG ≤ 20 dB) of this series is 68.4%. In this series, there has been no extrusion of the prosthesis. Titanium prosthesis is delicate,

easy and quick to handle. They are efficient and suitable implants for middle ear ossicular reconstruction. The use of cartilage between the prosthesis and the graft helps to prevent extrusion of the prosthesis.

Keywords Ossicular reconstruction · Titanium middle ear prosthesis · PORP · TORP

Introduction

The aims of tympanoplasty are to eradicate disease from the middle ear, to provide a dry ear and to improve hearing. While the first two objectives have been achieved consistently by most surgeons, hearing improvement often continues to be a challenge in quite a few cases. The middle ear ossicles are the key to a functional middle ear. More than half of chronic middle ear diseases are reported to have ossicular involvement [1].

There are a variety of materials to choose from when performing ossicular reconstruction, including autogenous tissues and alloplasts. A literature search revealed that of all available materials, hydroxyapatite (HA) was the most commonly used in the last decade [2]. However, long-term studies for HA alloplasts have reported an extrusion rate of 5–15% [3, 4]. Present evidence indicates that titanium has a greater ability to transmit sound than the heavier HA [5]. This material is biocompatible, delicate and easy to handle [6]. Its use in reconstruction of the ossicular chain during middle ear surgery has been increasing [7, 8]. The use of titanium ossicular prosthesis was first reported by Stupp et al. in 1999 [9], and later reports have shown success rates (ABG less than or equal to 20 dB) ranging between 57 and 77% [10–14]. We would like to report our results using titanium middle ear prosthesis.

K. D. Shah (✉)
Department of ENT, LTM Medical College and General Hospital, Flat No. 8, Monisha Co-operative Housing Society, 67, S.V. Road, Andheri (W), Mumbai 400 058, Maharashtra, India
e-mail: kdshah81@gmail.com

R. A. Bradoo · A. A. Joshi · D. D. Sapkale
Department of ENT, LTM Medical College and General Hospital, Mumbai 400 058, Maharashtra, India

Materials and Methods

A prospective study was performed at our institute from January 2010 to October 2010 to evaluate the efficiency of titanium middle ear prosthesis in ossicular chain reconstruction. All patients with chronic suppurative otitis media [CSOM] (mucosal variety) who had an ossicular chain discontinuity detected during surgery were included in the study. Patients with a squamous type of CSOM and those with sensorineural type of hearing loss were excluded from the study. All the patients underwent a tympanoplasty (canal wall-up procedure) with the use of titanium middle ear prosthesis. The data includes 19 patients (7 males, 12 females) ranging from 14 to 50 years of age. The overall follow-up period ranged from 6 to 15 months (mean–11.1 months). Pure tone audiogram of all patients was performed a day prior to surgery and then at regular intervals after surgery (1 month, 3 months, 6 months and 1 year).

The patients underwent a tympanoplasty by either a post-aural or endaural approach (as per the preference of the operating surgeon). The tympanic membrane was grafted using either temporalis fascia or tragal cartilage with perichondrium. Depending upon the intra-operative finding, either the Tita-prosthesis type Partial Vario Campana [for partial ossicular reconstruction (POR)] or the Tita-prosthesis type Total Vario Cask [for total ossicular reconstruction (TOR)] was used [Eon Meditech Pvt. Ltd., India] (Fig. 1). In all cases, cartilage was placed between the prosthesis and the tympanic membrane graft in order to minimize the risk of extrusion of prosthesis.

During surgery, when the stapes suprastructure was present, the titanium POR prosthesis (PORP) was used, while when only the stapes footplate was present, the titanium TOR prosthesis (TORP) was used. The round window reflex was elicited to ensure mobility of the remnant of the ossicular chain before deciding to use the

Fig. 1 Tita-prosthesis type Partial Vario Campana (PORP) and the Tita-prosthesis type Total Vario Cask (TORP) [Eon Meditech Pvt. Ltd.]

prosthesis. The hearing assembly created in either case was independent of the malleus and the incus. The position of the prosthesis was in the postero-superior quadrant of the tympanic membrane in alignment with the stapes so that all incident sound energy is transmitted to the stapes. Care was taken to ensure that the prosthesis was only in contact with the overlying cartilage and the underlying ossicle and that no part of the prosthesis was in contact with any other middle ear structure. The tensor tympani tendon was divided in patients in whom the handle of malleus was medialised in order to increase the middle ear space. After placement of the prosthesis, the round window reflex was elicited once again to confirm the adequacy of contact between the prosthesis and the ossicular chain remnant and to ensure the stability of the prosthesis.

Pure tone audiograms were performed 1 month, 3 months, 6 months and 1 year after surgery. The data was compiled and analyzed with regards to the pure tone average (PTA) of air conduction and the air-bone gap. Comparison of pre-operative and post-operative pure tone averages of air conduction (AC) and air-bone gaps (ABGs) was performed at frequencies recommended by AAO-HNS (0.5, 1, 2, 3 kHz) [15]. The most recent post-operative audiogram of the patient was considered for comparison to the pre-operative audiogram.

The following parameters were calculated:

- pre-operative PTA (AC): average of pre-operative AC threshold of 0.5, 1, 2, 3 kHz
- pre-operative ABG: PTA (pre-operative AC)—PTA (pre-operative bone conduction (BC))
- post-operative PTA (AC): average of post-operative AC threshold of 0.5, 1, 2, 3 kHz
- post-operative ABG: PTA (post-operative AC)—PTA (pre-operative BC)

The Indian speech and hearing association (ISHA) guidelines were used to assign the degree of hearing loss for each patient and they were grouped as follows:

- 0–25 dB: Normal hearing
- 26–40 dB: Mild hearing loss
- 41–55 dB: Moderate hearing loss
- 56–70 dB: Moderately severe hearing loss
- 71–90 dB: Severe hearing loss
- >90 dB: Profound hearing loss

Results

The salient features of the study group have been summarized in Table 1.

The average hearing loss of the patients and the post-operative hearing gain are shown in Table 2.

Table 1 Salient features of the study group

Parameters	PORP	TORP	Total
No. of cases	15	4	19
Age (years)	Range: 14–50 years		
Sex (%)	Males: 7 (36.8); Females: 12 (63.2)		

Table 2 Comparison of pre and post-operative mean PTA (AC)

	Mean PTA (AC) ($\bar{X} \pm SD$)		
	PORP (<i>n</i> = 15)	TORP (<i>n</i> = 4)	Total (<i>n</i> = 19)
Pre-operative (dB)	44.50 $\pm$ 12.94	51.88 $\pm$ 9.38	46.05 $\pm$ 12.43
Post-operative (dB)	28.29 $\pm$ 5.46	31.41 $\pm$ 6.82	28.95 $\pm$ 5.71
Hearing gain (dB)	16.21 $\pm$ 14.41	20.47 $\pm$ 9.15	17.11 $\pm$ 13.36

The pre and post operative mean PTA (AC) was analyzed using the Student *t* test. There is a significant improvement (*P* value < 0.05) in the post-operative PTA as compared to the pre-operative values. When the hearing gain between the PORP and TORP group was compared, the difference was not found to be significant.

As per AAO-HNS guidelines, successful outcome is defined as closure of post-operative AB gap by ≤ 20 dB. We have divided our patients into three groups on the basis of the AB gap (≤ 20 dB, 21–25 dB, >25 dB). The pre-operative and post-operative AB gap of the patients is summarized in Table 3.

The pre and post-operative ABG was analyzed using the Chi square test. Post-operatively 13 out of 19 (68.4%) patients had a closure of the ABG ≤ 20 dB. This was a significant reduction (*P* value < 0.05) as compared to the pre-operative values.

The patients were classified based on the amount of hearing loss as per the ISHA guidelines (Table 4). On analyzing the results using χ^2 test, a significant change (*P* value < 0.05) was found between the pre-operative and post-operative data.

Discussion

Over the years, numerous materials have been used for ossicular reconstruction, but none of them has shown to give consistent results. Titanium has been proven as the most light weight and biocompatible material amongst all the allogenic materials used for ossicular reconstruction [16, 17]. Various studies have reported the success rate of titanium prosthesis between 57 and 77% with an extrusion rate up to 5%.

Previous studies published in literature [18, 19] have used the Spiggle-Theis titanium prosthesis (Micromedics

Table 3 Comparison of pre and post-operative mean ABG

	Pre-op. ABG ≤ 20 dB (<i>n</i> = 3)	Pre-op. ABG 21–25 dB (<i>n</i> = 3)	Pre-op. ABG >25 dB (<i>n</i> = 13)	Total (%)
Post-op. ABG ≤ 20 dB	2	1	10	13 (68.4)
Post-op. ABG 21–25 dB	1	2	1	4 (21.1)
Post-op. ABG >25 dB	0	0	2	2 (10.5)

Table 4 Comparison of pre and post-operative hearing loss (according to ISHA guidelines)

	Pre-operative (%)	Post-operative (%)
Normal	–	6 (31.6)
Mild	7 (36.8)	12 (63.2)
Moderate	7 (36.8)	1 (5.2)
Mod-severe	5 (26.4)	–
Severe	–	–
Profound	–	–

Inc., Eagan, MN), the Tuebingen Type VARIO prostheses (Kurz GmbH) or the Micron All Titanium Monolithic prosthesis (Gyrus ENT LLC) for ossicular reconstruction. We have evaluated the efficiency of a new brand of titanium prosthesis manufactured by Eon Meditech Pvt. Ltd. (India) for ossicular chain reconstruction. Our early experience with this prosthesis has revealed encouraging results.

In this study, we have included only those patients who underwent a tympanoplasty and not a canal wall down mastoidectomy. Although a few previous studies [14] did find a difference in the hearing outcome between using a PORP and a TORP, we did not find a significant difference in our series. As a larger database of these patients develops, we may be able to determine whether the difference in the hearing outcome between using a PORP and a TORP is significant or not. Overall we were able to achieve closure of the ABG < 25 dB in almost 90% (17 out of 19) of our patients.

In order to objectively assess our results, we have used guidelines (Indian Speech and Hearing Association) to quantify the hearing loss of our patients. We had seven patients who had a central perforation and a mild hearing loss pre-operatively (26–40 dB). However, during surgery, 6 of those patients had a necrosed long process of incus and a normal and mobile stapes, while 1 patient had a necrosis of the long process of incus as well as the stapes supra-structure and only had a mobile stapes footplate. Hence, ossicular chain reconstruction was performed in these patients. Post-operatively, almost 95% (18 out of 19) patients have normal hearing to a mild hearing loss, while

one patient has a moderate hearing loss. This patient had undergone a tympanoplasty with TORP placement and has had a hearing gain of 20 dB.

In our series, we have not encountered any extrusion of the prosthesis. This is due to the fact that cartilage has been interposed between the prosthesis and the graft material. We have also not encountered any complication such as sensorineural hearing loss in our patients. Overall, we have achieved a success rate of 68.4% which is comparable to the other series that are published in international literature.

Key Message

In conclusion, we would like to state that the titanium prosthesis (Eon Meditech Pvt. Ltd., India) is biocompatible, delicate and easy to handle. They have proven to be suitable implants for ossicular chain reconstruction and are efficient in transferring sound energy from the tympanic membrane to the oval window. Our early experience with this prosthesis has shown encouraging results.

References

1. Chole RA (1999) Ossiculoplasty with banked cartilage. *Otolaryngol Clin North Am* 27:717–726
2. Goldenberg RA, Emmet JR (2001) Current use of implants in middle ear surgery. *Otol Neurotol* 22:145–152
3. Shinohara T, Gyo K, Saiki T (2000) Ossiculoplasty using hydroxyapatite prosthesis: long-term results. *Clin Otolaryngol* 25:287–292
4. Goldenberg RA, Driver M (2000) Long-term results with hydroxyapatite middle ear implants. *Otolaryngol Head Neck Surg* 112:635–642
5. Meister H, Walger M, Mickenhagen A, von Wedel H, Stennert E (1999) Standardized measurements of the sound transmission of middle ear implants using a mechanical middle ear model. *Eur Arch Otorhinolaryngol* 256:122–127
6. Stupp CH, Stupp HF, Grun D (1996) Replacement of ear ossicles with titanium prostheses. *Laryngorhinootologie* 75:335–337
7. Geyer G (1999) Materials for reconstruction of the middle ear. *HNO* 47:77–91
8. Begall K, Zimmermann H (2000) Reconstruction of the ossicular chain with titanium implants: results of a multicenter study. *Laryngorhinootologie* 79:139–145
9. Stupp CH, Dalchow C, Grun D, Stupp HF, Wustrow J (1999) Three years of experience of titanium implants in the middle ear. *Laryngorhinootologie* 178:299–303
10. Wang X, Song J, Wang H (1999) Results of tympanoplasty with titanium implants. *Otolaryngol Head Neck Surg* 121:606–609
11. Krueger WW, Feghali JG, Shelton C, Green JD, Beatty CW, Wilson DF et al (2002) Preliminary ossiculoplasty results using the Kurz titanium prostheses. *Otol Neurotol* 23:836–839
12. Ho SY, Battista RA, Wiet RJ (2003) Early results with titanium ossicular implants. *Otol Neurotol* 24:149–152
13. Martin AD, Hardner SG (2004) Ossicular reconstruction with titanium prosthesis. *Laryngoscope* 114:61–64
14. Vassbotn FS, Moller P, Silvola J (2007) Short-term results using Kurz titanium ossicular implants. *Eur Arch Otorhinolaryngol* 264:21–25
15. Committee on Hearing Equilibrium (1995) Guidelines for the evaluation of results of treatment of a conductive hearing loss. *Otolaryngol Head Neck Surg* 113:186–187
16. Maassen MM, Lowenheim H, Pfister M, Herberhold S, Jorge JR, Baumann I et al (2005) Surgical-handling properties of the titanium prosthesis in ossiculoplasty. *Ear Nose Throat J* 84(3):142–144 147–149
17. Schwager K (1998) Titanium as a biomaterial for ossicular replacement: results after implantation in the middle ear of the rabbit. *Eur Arch Otorhinolaryngol* 255:396–401
18. Neff BA, Rizer FM, Schuring AG, Lippy WH (2003) Tympano-ossiculoplasty utilizing the spiggle and thesis titanium total ossicular replacement prosthesis. *Laryngoscope* 113:1525–1529
19. Hales NW, Shakir FA, Saunders JE (2007) Titanium middle ear prostheses in staged ossiculoplasty: does mass really matter? *Am J Otolaryngol* 28:164–167