Teflon Implants Versus Titanium Implants in Stapes Surgery

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Abstract Otosclerosis is the most common cause of bilateral gradually progressive conductive hearing loss with normal tympanic membrane and Eustachian tube. Otosclerosis surgical treatment is one of the most gratifying operations in Otorhinolaryngology. It is not only the surgical techniques but also the prosthesis which are evolving in the attempt of providing best hearing results. Teflon piston is the most commonly employed prosthesis in stapes surgery. Titanium pistons are relatively the new development in the evolution of stapes prosthesis. The aim of this review article is to know and compare the surgical technicalities and postoperative outcomes including hearing improvement after the use of Teflon and titanium stapes piston. The adverse reactions occurred during follow-up were taken into consideration. The data in this article are supported by a Medline search. The use of both the prosthesis gave good results in cases of otosclerosis. The placement of titanium soft clip design was found easier than the earlier Wengen design of clip piston.

Keywords Otosclerosis · Stapedectomy · Stapedotomy · Teflon · Titanium prosthesis · Piston

Introduction

Stapes surgery is a successful and safe treatment modality with high success and low complication rates in the management of otosclerosis [1]. Minimum 20 dB air–bone gap

(ABG) is traditionally required before stapes surgery. The outcomes of stapes surgery are better in the hands of experienced otologic surgeon who are doing this surgery regularly [2].

The three distinct surgical procedures which have been employed in otosclerosis are stapedectomy [3], stapes mobilization and stapedotomy [4] with and without stapes prosthesis. The original technique of stapedectomy (total removal of stapes footplate) introduced by Shea [5] is more or less replaced by stapedotomy (small opening in stapes footplate). This surgical treatment was found to be far superior to the former mobilization operations, and thus, became the standard. The small opening stapedotomy [6] in posterior one-third of footplate may be made with an electric drill [4], laser (KTP, CO₂, erbium:YAG and argon) or hand held perforator. If anatomy permits footplate should be perforated before the division of stapedius tendon, disarticulation of incudostapedial joint and subsequently removal of stapes superstructure by fracturing the crura.

Many modifications have been developed using different sealing materials such as fat, fascia, gelatin foam, vein, blood and perichondrium. The thickness of the piston preferred by many is 0.6 mm and the diameter of footplate fenestration is kept at 0.8 mm [7, 8].

Prostheses vary in their design, material, weight, diameter and anchorage to incus long process. The prosthesis has been constructed with such material as steel, platinum, gold, Teflon, titanium and alloys [9–12]. Teflon piston is the most commonly employed prosthesis in stapes surgery [13]. The Teflon loop is first opened out on the shaft of a needle perforator and then positioned on the incus where it closes around the long process of incus. Titanium piston is relatively the new development in the evolution of stapes prosthesis [14].

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The crimping of stapes piston to the long process of incus is a critical step as overcrimping can lead to necrosis of the long process of the incus and loose piston can lead to poor hearing outcomes and higher incidence of displacement of piston. To address this problem of crimping different types of stapes prostheses with different techniques have been devised [15, 16]. The titanium soft clip stapes piston (Kurz, Germany), a new type of stapes piston is a modification of the earlier àWengen clip piston (Kurz, Germany) and is designed to avoid the crimping onto the incus in stapedotomy [16]. The newly designed nickel-titanium (Nitinol) piston band-shaped stapes prosthesis could minimize postoperative complications due to its new superelastic characteristic and design [11, 15]. The prosthesis selected is usually 4.5 mm [16] (0.25 mm longer than the distance from the medial surface of incus long process to the footplate).

The aim of this review article is to know and compare the surgical technicalities and postoperative outcomes. The adverse reactions occurred during follow-up were taken into consideration.

Material and Method

The data in this article are supported by a Medline search using the key words otosclerosis, stapedectomy, stapedotomy, Teflon piston and titanium piston. These were augmented by references from these articles. No limits were applied to year of study. Relevant articles not found in the Medline were sought by a hand search review of reference books. The data extracted included author, year of publication, evidence level of study, and recommendations made or disputed. The adverse reactions occurred during follow-up were taken into consideration.

Results

A relatively new composite metal stapedotomy piston which is biocompatible alloy of nickel and titanium known as nitinol, has the unique property of shape-memory that permits tight self-crimping when heat is applied to the wire [11]. Reineke et al. [15] performed stapedectomy and implantation of superelastic Nitinol piston stapes prosthesis in 22 patients. The average observed ABG in all frequencies was 12.8 dB postoperatively, whereas in the frequencies 0.5–4 kHz ABG was under 10 dB in 68.2 % of the patients, between 10 and 15 dB in 18.2 % and between 15 and 20 dB in 9.1 % of the patients. [15] Bast and Schrom [16] performed a Laser-Stapedotomy in 11 patients. Soft-Clip pistons with a shaft diameter of 0.4 mm and a length of 4.5 mm were used. Despite the new design of the

prostheses it wasn't possible to slip the prosthesis onto the incus in two cases, and in one case the needed size was not available [16].

To substantiate the favorable initial observations with the SMART piston, Harris and Gong [11], compared results with those obtained using conventional stainless steel or platinum ribbon prostheses. When analyzed according to the American Academy of Otolaryngology-Head and Neck Surgery reporting criteria using an estimate of 3 kHz as a mean of the 2- and 4-kHz values, the postoperative mean ABG was 5.42 ± 5.4 dBHL for Group 1 SMART and 5.98 ± 5.47 dBHL for Group 2 conventional prostheses. Postoperative speech discrimination scores were 96 ± 8.64 and 97 ± 5.9 %, respectively. These differences were not shown to be statistically different [11].

Rajan et al. [14] presented their mid-term results of their multicenter study using the Nitinol self-crimping stapes piston. In this prospective, multicenter cohort study ninety patients with otosclerosis underwent laser-stapedotomy with the Nitinol stapes piston and were matched to reference patients from their titanium piston database. The mean postoperative ABG and the interindividual variations of the postoperative ABG continue to be significantly smaller in the Nitinol group; the extent of ABGC was significantly larger in the Nitinol piston group. The postoperative mid-term stability of ABGC was similar in both groups. No adverse reactions occurred during follow-up [14].

Tange and Grolman [6] evaluated the hearing results of stapedotomies with two different titanium stapes prostheses: A crimping and a non-crimping prosthesis. The hearing results of both titanium stapes prostheses were comparable. There was no difference in the final hearing results between the two pistons studied [6].

Casale et al. [2] evaluated hearing results after implantation of a fluoroplastic-platinum piston (FP) and of a titanium piston (T) with a shaft diameter of respectively 0.6 and 0.4 mm, in cases of stapedotomy performed by the same expert author. Post-operative air-bone gap (ABG) comparison between the two groups showed a better ABG for lower frequencies in the FP group and for higher frequencies in the T group, but the difference was not significant. No post-operative complications, including sensorineural hearing loss, were found. Bone conduction improvement was better in the FP group than in the T one and this difference was statistically significant at 1000 and 2000 Hz [2].

Brar et al. [13] compared hearing outcome using a Nitinol versus Teflon piston in stapes surgery and to ascertain the feasibility of using the Nitinol piston. Forty patients were selected and randomly allocated into two groups of 20 each. There was no significant difference

between the two groups in the postoperative air–bone gap and air–bone gap closure at 1, 2, 3, and 6 months [13].

Topdağ et al. [1] retrospectively analyzed 115 ears of 100 patients who were operated for otosclerosis. The postoperative air–bone gap less than 20 dB was accepted as a success criterion. Functional success rates according to types of piston for 0.6 mm wire Teflon piston ($n = 71$), fluoroplastic Teflon piston ($n = 30$), K piston ($n = 12$) and Easy piston ($n = 2$) groups were, 88.7, 93.3, 100, and 100 % respectively. Six patients (5.2 %) underwent revision surgery [1]. Cavaliere et al. [7] assessed whether the diameter of the prostheses used for stapedotomy (platinum piston/polytetrafluoroethylene, i.e. Teflon) has any effect on stapedotomy outcome. The analysis showed that the results obtained with 0.4-mm prosthesis or 0.6-mm prosthesis was almost identical [7].

Brar et al. [13] tried to ascertain whether titanium material and a clip attachment to the incus offered a hearing result advantage over the traditional Teflon piston in stapes surgery. Mean pure-tone average air–bone gap for the Teflon 0.6-mm piston (5.1 dB) was significantly smaller than for the titanium 0.6-mm piston (8.1 dB) and the Teflon 0.5-mm piston (7.5 dB). Success rate did not differ [12].

Durko et al. [9] reported a retrospective analysis of the post-op hearing results in 350 stapes surgery using different types of materials for stapes prosthesis after 12 months follow up. All patients were divided into 4 groups: group 1 ($N = 54$)–Portmann's method interposition, group 2 ($N = 160$)–stapes replaced with the Shea-type prosthesis, group 3 ($N = 60$)–platinum wire prosthesis (Zini-type), group 4 ($N = 76$)–Teflon-piston operation (Fisch-type). The percentage of patients with the mean air–bone gap value of 15 dB or less (500, 1000, 2000 Hz) has the following values in each group: group 1–75 %, group 2–81.3 %, group 3–83 %, group 4–85 %. 12 months post-op hearing results compared between the 4 studied groups showed statistically not significant differences [9].

Discussion

Reviewing outcomes data of stapes surgery is not that easy and straightforward as there are multiple variables, such as expertise of surgeon, size of fenestration and prosthesis and the technique employed, status of stapedius tendon, type of pathology, and the design and material of stapes prosthesis.

The various techniques of stapedotomy have been compared in many studies. No differences in results were seen in a prospective study between the use of a microdrill and hand-held perforator [4]. The review study conducted at the House Ear Institute did not find any difference between the outcomes whether the stapedotomy was

performed by microdrill or laser. The same findings were seen in a review of the use of picks, drills and laser in Marquet's study [17]. There are studies which compare the results with various piston diameters. A majority of studies show benefit for larger diameter piston for frequencies up to 2 kHz. In the study of Teig and Lindeman [8], 0.6 mm piston produced mean hearing outcomes 4–10 dB better than a 0.4 mm piston, whilst 0.8 mm was better than 0.6 mm piston by 5–7 dB. [8] Better results of FP for lower frequencies in the study of Casale et al. [2] suggest that an increase in diameter of the prosthesis results in a greater improvement in the hearing threshold at low frequencies, while a decrease of diameter results in a greater improvement in the hearing threshold at high frequencies, as indicated by previous international studies [2].

When comparing technical factors in stapes surgery, closure of air–bone gap is a satisfactory measure. However, from the patients' perspective the reduction in their auditory disability is important. Cavaliere et al. [7] concluded that in stapedotomy surgery, functional recovery is not affected by the diameter of the prosthesis used. Smaller diameter prosthesis is, however, the one of choice when the facial nerve is prominent or the oval window particularly narrow [7]. Some studies show that heavier pistons (steel, 12.5 mg, or gold, 10 mg) give better outcomes in the lower frequencies, whilst lighter pistons (Teflon, 3 mg) may be better in higher frequencies [3, 10].

The time-tested, readily available, and cost-effective Teflon® piston continues to have equivocal results to the newer Nitinol piston [13]. Implantation of the new Nitinol piston stapes prosthesis is facilitated due to the superelasticity and the design of the prosthesis. Crimping is not needed anymore [15]. However the surgeon needs adequate experience to insert the Soft-CliP Piston [16].

Because of the different properties of the two titanium piston studied (CliP-piston àWengen Titanium type, no crimping and K-piston Titanium crimping necessary) a difference in the closure of the air–bone gap could be suspected. The comparative study of Tange and Grolman [6] could not demonstrate a statistical better air–bone gap closure for one of the titanium pistons. Both stapes prostheses showed good results in reconstruction of the hearing loss due to otosclerosis [6].

Durko et al. [9] experience with Teflon-piston prosthesis shows the lowest post-op mean value of the air–bone gap [9]. Rajan et al. [14] in their multicenter prospective study observed that the self-crimping shape memory alloy Nitinol stapes piston overcomes the limitations of manual malcrimping in stapedotomy, thus simplifying and optimizing the surgical procedure [14]. Results of Harris and Gong study [11] demonstrated that experienced surgeons might achieve comparable results with both prostheses; however, the ease of self-crimping and the tightness of the

crimp may provide advantages that may have long-term benefits. The potential issue of nickel allergy is important when considering patients for nitinol prosthesis [11].

While comparing 2 pistons designated 0.6 mm in diameter, Mangham [12] found that Teflon piston produced better hearing results than the titanium device. However, actual piston diameter differed between devices that contributed to the superior results with the larger Teflon piston. In addition, the titanium piston performed better with a small stapes fenestra diameter that suggests an advantage for titanium over Teflon in certain conditions. The clip design was problematic for a few patients [12]. Casale et al. [2] data shows that titanium piston is as good as fluoroplastic piston in stapes surgery for otosclerosis.

Conclusion

This review study shows that titanium piston is as good as Teflon piston in stapes surgery for otosclerosis. The surgical correction of hearing loss is one of the great drivers in the progress of otology. Stapes surgery usually offers gratifying outcomes for both hearing loss and tinnitus in patients with otosclerosis. Stapedotomy generally leads to fewer complications than stapedectomy. Stapes surgery should be performed by surgeons who do these operations regularly and must be aware about the controversies regarding when not to operate. The published data which was reviewed did not reveal any significant difference in surgical outcomes between the use of Teflon and titanium stapes prostheses. More accurate and standardized data are required to facilitate comparison between techniques and types of stapes prosthesis. Randomized trials are required to assess variations in surgical techniques and the diameters and the materials of stapes pistons and the metaanalysis of these studies would eventually result into the clear guidelines.

Compliance with Ethical Standards

Conflict of interest Author declares that he has no conflict of interest.

Ethical Approval This article does not contain any studies with human participants or animals performed by any of the authors.

References

1. Topdağ DO, Topdağ M, Aydın O et al (2014) Evaluation of efficacy of otosclerosis surgery on hearing outcomes. *Kulak Burun Bogaz Ihtis Derg.* 24(3):137–147
2. Casale M, De Franco A, Salvinelli F et al (2003) Hearing results in stapes surgery using two different prosthesis. *Rev Laryngol Otol Rhinol (Bord).* 124(4):255–258
3. Causse J, Causse JB (1980) Eighteen year report on stapedectomy. Problems of stapedial fixation. *Clin Otolaryngol* 5:49–59
4. Gjurić M (1990) Microdrill versus perforator for stapedotomy. *Clin Otolaryngol Allied Sci* 15:411–413
5. Shea J Jr (1958) Fenestration of the oval window. *Ann Otol Rhinol Laryngol* 67:932–936
6. Tange RA, Grolman W (2008) An analysis of the air–bone gap closure obtained by a crimping and a non-crimping titanium stapes prosthesis in otosclerosis. *Auris Nasus Larynx* 35(2):181–184
7. Cavaliere M, Ricciardiello F, Mesolella M et al (2012) Stapedotomy: functional results with different diameter prostheses. *ORL J Otorhinolaryngol Relat Spec* 74(2):93–96
8. Teig E, Lindeman H (1999) Stapedotomy piston diameter: Is bigger better? *Otolaryngol Nova* 9:252–256
9. Durko M, Pajor A, Jankowski A et al (2008) Does the material of stapes prosthesis influence hearing improvement in stapes surgery—retrospective analysis of 350 cases]. *Otolaryngol Pol* 62(4):480–482
10. de Bruijn AJ, Tange RA, Dreschler WA (1999) Comparison of stapes prostheses: a retrospective analysis of individual audiometric results obtained after stapedotomy by implantation of a gold and Teflon piston. *Am J Otol* 20:573–580
11. Harris JP, Gong S (2007) Comparison of hearing results of nitinol SMART stapes piston prosthesis with conventional piston prostheses: postoperative results of nitinol stapes prosthesis. *Otol Neurotol* 28(5):692–695
12. Mangham CA Jr (2008) Titanium CliP piston versus platinum-ribbon Teflon piston: piston and fenestra size affect air–bone gap. *Otol Neurotol* 29(1):8–12
13. Brar T, Passey JC, Agarwal AK (2012) Comparison of hearing outcome using a Nitinol versus Teflon prosthesis in stapedotomy. *Acta Otolaryngol* 132(11):1151–1154
14. Rajan GP, Diaz J, Blackham R et al (2007) Eliminating the limitations of manual crimping in stapes surgery: mid-term results of 90 patients in the Nitinol stapes piston multicenter trial. *Laryngoscope* 117(7):1236–1239
15. Reineke U, Ebmeyer J, Plett D et al (2010) Superelastic nitinol stapes prostheses. *Laryngorhinootologie* 89(5):271–275
16. Bast F, Schrom T (2009) First experiences with the new soft-clip piston as an alloplastic prosthesis during stapedotomy. *Laryngorhinootologie* 88(5):304–308
17. Somers T, Marquet T, Goverts P et al (1994) Statistical analysis of otosclerosis surgery performed by Jean Marquet. *Ann Otol Rhinol Laryngol* 103:945–951