Hearing Gain with Tailor-made Polyethylene Strut in Total Stapedectomy

Kanthong Thongyai, M.D., Sarun Prakairungthong, M.D., Samut Chongvisal, M.D., Siriporn Limviriyakul, M.D., Prasit Srisomboon, M.D., Kanokrat Suvarnsit, M.D.

Department of Oto-Rhino-Laryngology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand.

ABSTRACT

Objective: To study audiometric changes after total stapedectomy with tailor-made polyethylene strut.

Methods: A retrospective analysis of preoperative and postoperative hearing results. One hundred and ninety-eight patients underwent total stapedectomy during 2009-2014. Stapedectomy was performed with tailor-made polyethylene strut prosthesis on vein or perichondrium graft over oval window. Changes of preoperative and postoperative pure tone average (PTA) were calculated from 4 frequencies after stapedectomy.

Results: Ninety percent success rate in the air-bone gap closure within 10 dB after stapedectomy.

Conclusion: Tailor-made polyethylene strut prosthesis is a cheap and cost-effective prosthesis, which is an alternative option for surgeons instead of the commercial prosthesis.

Keywords: Stapedectomy; otosclerosis; polyethylene strut; ossicular prosthesis (Siriraj Med J 2017;69:18-23)

INTRODUCTION

Otosclerosis is a disease of abnormal remodeling of complex bone in a human otic capsule with unknown etiopathogenesis.[1] Antonio Valsalva (1703) described stapes fixation and the concept of stapes removal was introduced by Clarence Blake and Frederick Jack (1892). Later, that concept was abandoned for over half of century until Dr. Samuel Rosen accidentally mobilized stapes in 1952 leading to temporary hearing improvement.[2]

At present, surgery is the mandatory treatment for hearing impairment in otosclerotic patients. The current surgical method was developed by Dr. John Shea[3] in 1956 including the first stapes prosthesis: a replica (Teflon copy of the stapes).

Nowadays, various surgical steps[4], technologies[5] and techniques have been modified and adapted, for example, total stapedectomy versus stapedotomy, choices of a wide variety of sizes of stapes footplate operation,[6,7] and options for tissue sealing the perforation,[8-10] and etcetera. All of these were invented to improve surgical outcome. However, stapes prosthesis plays the major role in the surgical procedure to achieve the better hearing.

There are two types of the prostheses which are piston and bucket types. The piston type prosthesis connects to the long process of incus whereas the bucket type prosthesis connects to the lenticular process of incus. The first prosthesis launched in the market was Teflon used by Dr. John Shea.

In 1968, Doctor Frederick R. Guildford started using polyethylene-strut bucket prosthesis during surgery, which was made of 2 different sizes of PolyEthylene (PE) tube (no. 90 and 50). His work was published in 1972.[11] Until now, quantities of newer prostheses generation have been exploited with high cost.[12]

Dr. Prasit Srisomboon who was Dr.Guildford's fellow introduced the polyethylene strut prosthesis to Siriraj Hospital in 1968. This prosthesis is economical and simplicity. With its worthiness of total price of only 1 Thai baht, thus it is the main stapes prosthesis used in our hospital.

To date, over thousands of tailor-made prostheses have been used in stapes operation in Siriraj Hospital. This study is to demonstrate the results of our recent 5-year experience in stapes surgery.

Correspondence to: Sarun Prakairungthong
E-mail: tiksarun99@yahoo.com
doi:10.14456/smj.2017.4

MATERIALS AND METHODS

Patient Selection

A retrospective chart review of primary stapedectomy, which was performed by experienced surgeons at Siriraj Hospital from January 2009 to December 2014. There were 198 operations, which are 136 women (68.7%) and 62 men (31.3%). Revision cases were excluded from the study. Data collection included age at the time of surgery, sex, operative time, duration of hospital stay, the length of stapes prosthesis, preservation of chorda tympani nerve, pre and postoperative audiograms.

Tailor-made polyethylene prosthesis is made of two different sizes of polyethylene tube; no.50 (PE50) and no.90 (PE90), as shown in Fig 1. The top of PE 90 is cut in beveled shape with 1 millimeter long and placed over PE50 (Fig 2). The inner diameter of PE 90 is 0.86 millimeter and its superior end fits the lenticular process of incus whereas the smaller PE50 has an outer diameter about 0.965 millimeter and its inferior end is placed over the oval window. The average oval window size is about 3*2 mm[13] so the PE50 could easily be placed even with the narrow footplate. The proper length of the PE50 is the actual height, measured during the operation, between the lenticular process of incus and oval window. (Fig 2 and 3)

Fig 1. Polyethylene no. 90 and no. 50

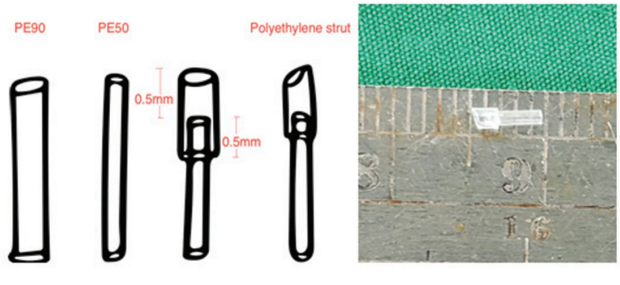

Fig 2. Demonstration of polyethylene-strut prosthesis used in stapedectomy

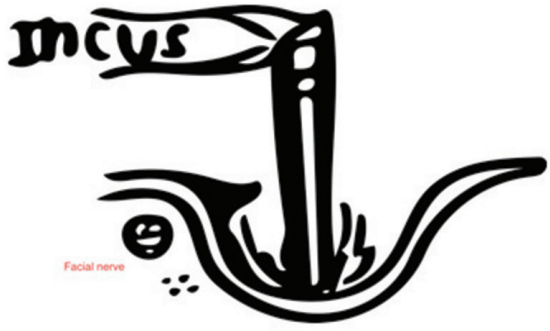

Fig 3. Proper position of tailor-made polyethylene strut prosthesis connected between lenticular process of incus and oval window

Surgical Technique

Stapes surgery was performed via transcanal approach under local or general anesthesia which depended on patient's decision. The middle ear space was entered by classical endomeatal incision. Chorda tympani nerve would rather be preserved as a first priority. Posterosuperior canal wall was curetted for good exposure. Stapes fixation was confirmed then followed by the creation of the control hole on the fixed footplate to ensure no perilymphatic gusher.

The distance between the lenticular process of the incus and footplate was measured by a measuring rod. Its lengthwas the length of PE50. Either tragal perichondrium graft or vein graft was harvested. Stapedius tendon was cut and stapes suprastructure was removed by mobilizing it back and forth with heavy angle pick. Total footplate should be removed in one piece if possible. In case of fragmented stapes footplate, a small hook was inserted into the control hole and pieces of footplate were removed gently. Next, the prepared graft is placed to cover the oval window. Polyethylene strut is then inserted below the lenticular process and hooked with beveled end of PE90. The end of PE50 touched the graft beneath. The graft was then checked to ensure that the entire oval window was fully covered. If an unexpected narrow footplate was faced, the end of PE50 was trimmed in a beveled manner.

MATERIALS AND METHODS

The study was approved by Siriraj Institutional Review Board (Si.176/2015). The representative hearing was calculated using 4 frequencies: 0.5, 1, 2 and 4 kHz at preoperative period, 1-month postoperation, and 6-month postoperation. The pure tone threshold at 3 kHz was obtained from the calculation of the mean of 2 and 4 kHz since the 3 kHz threshold is not included in our standard audiometry.

The pre- and post-operative pure tone average (PTA) values were calculated for the hearing test results in consideration of the mean air conduction threshold (ACT) of 0.5, 1, 2 and 3 kHz (From the recommendations of the Committee on Hearing and Equilibrium).[14] The air-bone gap (ABG) was the ACT minus the bone conduction threshold (BCT) for each frequency. The average air-bone gap (A-ABG) was calculated and reported as the mean ABG of 0.5, 1, 2 and 3 kHz.

Preoperative audiometry was done within 3 months prior to surgery. The audiometry recorded during 2 to 8 weeks postoperation was accounted for 1-month postoperative audiometry while the audiometry recorded during 6 to 12 months postoperation was reported as 6-month postoperative audiometry.

The residual A-ABG after surgery was subdivided into three groups:

Group A: A-ABG ≤ 10 dB
Group B: A-ABG 10-20 dB
Group C: A-ABG > 20 dB

Other data recorded were preservation of chorda tympani nerve, details of the end of prostheses, operative time and dizziness at the discharge date (patient's complaint). Postoperative A-ABG ≤ 10 dB were considered as a successful operation.

Statistical Analysis

SPSS version 21 for MAC was used for the analysis. The results were reported in number of patients and percentage. Wilcoxon sign rank test was used to compare pre and postoperative hearing outcomse. P values <0.05 were considered as statistically significant.

RESULTS

There were 136 females (68.7%) and 62 male (31.3%), which showed female preponderance nearly 2 times greater than male. The laterality was almost equal on both sides (108 right ears and 90 left ears). Age ranged between 9 to 69 years old (median: 48 years; interquartile range (IQR): 39, 54) (Table 1).

Some of the patients had incomplete data recorded. Four patients had missing preoperative audiometry. However, these patients had at least one postoperative follow-up audiometry. Three patients missed the 1-month period audiometry and 28 patients missed the 6-month period audiometry.

Surgical results

Chorda tympani nerve was preserved in 149/188 (79.3%) patients. Beveled prosthesis tip was recorded in 47/194(24.2%) patients. Operative time ranged from 20 minutes to 250 minutes (median: 65 minutes; IQR: 55, 85). One hundred and sixty-one patients (81.3%) were discharged within 24 hours post-operation.

TABLE 1. Demographic data and clinical characteristics of 198 post-stapedectomy patients.

	Number (%)	Median (Min,Max)
No. of patients		198
Female	136 (68.7)	
Male	62 (31.3)	
Age (years)		48 (9,69)
Side	198	
Right	108 (54.5)	
Left	90 (83.3)	
Preservation of chorda tympani nerve	188	
Yes	149 (79.3)	
No	39 (20.7)	
End of prosthesis	194	
Straight	147 (75.8)	
Beveled	47 (24.2)	
Operative time (minutes)		65 (20,250)
Hospital stay	198	
Discharge within 24 hours	161 (81.3)	
Discharge within 48 hours	192 (97)	

Hearing results

Hearing results were calculated using 2 main outcomes. First, the gap closure in postoperative A-ABG. Second, the improvement of the PTA.

Three patients (1.5%) had worsened hearing.

Gap closure (Table 2)

One month after surgery, one hundred and fifty-one patients (78.65%) accomplished a successful result (A-ABG within 10 decibels), and the fair result (A-ABG 10-20 decibels) in 26/192 (13.54%) patients.

Six months after surgery, one hundred and forty-eight patients (90.24%) accomplished a successful result (A-ABG within 10 decibels), and fair result (A-ABG 10-20 decibels) in 9/164 (5.49%) patients.

Improvement of hearing (Table 3) (Diagram 1-3)

One month after surgery, the improved PTA greater than 20 dB was demonstrated in 159/188 (84.57%) patients.

Six months after surgery, the improved PTA

TABLE 2. Hearing outcome after stapes surgery using tailored-made polyethylene strut prosthesis.

Hearing outcomes	1 month post-operation			6 months post-operation		
	Complete data	Number	Percentage	Complete data	Number	Percentage
Good results (A-ABG within 10 dB)	192	151	78.65	164	148	90.24
Fair results (A-ABG 10-20 dB)	192	26	13.54	164	9	5.49
PTA improved greater than 20 dB	188	159	84.57	163	145 8	8.96

TABLE 3. Comparison of hearing outcomes between pre- and post-operative at 1 month and pre- and post-operative at 6 months.

	Pre-operative	1 month post-operative	6 months post-operative
		Median (Min, Max)	
Pure Tone Average (dB)	59.06 (38.13,90.63)	27.50 (8.13,85.63)	24.38 (10.63,89.38)
Average Air-Bone Gap (dB)	29.38 (11.25,51.88)	2.50 (0,39.38)	0.31 (0,27.50)
Hearing Threshold at 8 kHz (dB)	60.00 (20.00,110.00)	60.00 (5.00,120.00)*	50.00 (0,110.00)

P<0.001 all except for hearing threshold at 8 kHz between pre- and post- operative at 1 month*: p=0.052

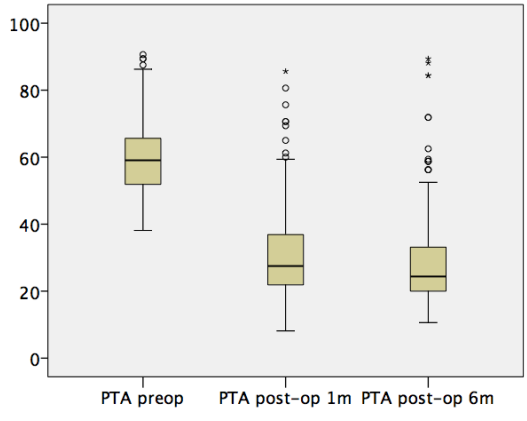

Diagram 1. Comparison of PTA between pre- and post-operation at 1month and pre and post-operation at 6 months.

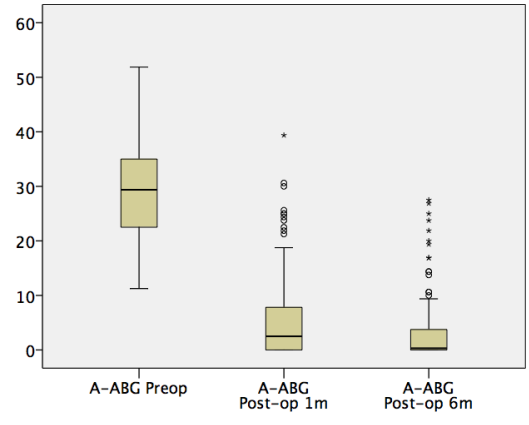

Diagram 2. Comparison of A-ABG between pre- and post-operation at 1 month and pre- and post-operation at 6 months.

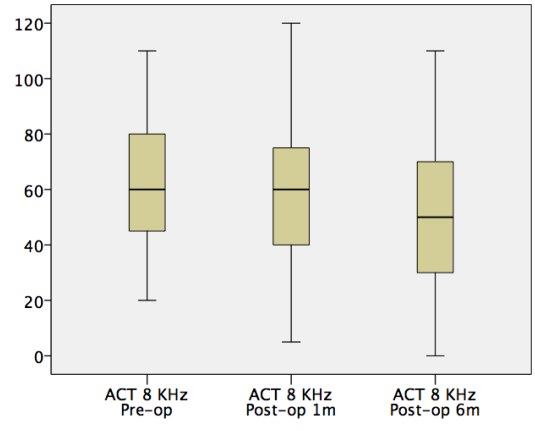

Diagram 3. Comparison of hearing threshold at 8 kHz between pre- and post-operation at 1 month and pre- and post-operation at 6 months.

greater than 20 dB was demonstrated in 145/163 (88.96%) patients.

The pure tone average pre-operative was improved from 59.06 dB (IQR: 51.88, 65.78) to 21.50 dB (IQR: 21.88, 37.19) post-operative at 1 month and to 24.38 dB (IQR: 20, 33.75) post-operative at 6 months

The average Air-Bone gap was improved from 29.38 dB (IQR: 22.5, 35.0) to 2.5dB (IQR: 0, 8.12) post-operative at 1 month and to 0.31(IQR: 0, 3.75) post-operative at 6 months

The hearing threshold at 8 kHz remained the same at 1 month (preoperative: 60 dB (IQR: 45, 80) and

1 month postoperative: 60 dB (IQR: 40, 75)), but slightly improved at 6 months post-operatively (50 dB (IQR: 30, 70)

DISCUSSION

Since Dr. John Shea's first operation in 1956, stapes surgery has evolved the same as the prosthesis usage. Nowadays, stapedotomy with piston type prosthesis has become the most popular method,[15] despite the expensive accessories such as LASER and commercial piston prostheses.

In 2011, Schimanski et al[16] reviewed prosthesis usage during the past 26 years, and the top 3 prostheses being used were Teflon platinum, gold, and titanium pistons. Other prostheses were included such as the Schucknecht prosthesis and polyethylene strut which was created from 1 size of polyethylene tube, while our polyethylene strut, which was made from 2 sizes of polyethylene tube, were uncommonly used. The reason why self-fabricated Schuknecht prosthesis was rarely used, was due to its failure rate. It is not recommended to use because of the increased chance of revision surgery.

Recently, otosclerosis surgery is primarily stapedotomy with or without LASER. Prosthesis that yields the good reconstruction is the piston prosthesis with the diameter approximately 0.5 to 0.6 mm. The success rate (residual ABG within 10 dB), among most studies, was nearly 80 to 90% (Table 4).

TABLE 4. Comparison the outcome of stapedotomy and prostheses used among several studies

Authors	Cases	Stapedotomy cases	Prosthesis diameter (mm.)	Gap within 10 dB (%)
Sperling et al 2013[17]	45	45	0.6	91
Poletti et al 2014[18]	179	179	0.6	89
Freni et al 2014[4]	84	84	0.5	80
Sakamoto et al 2015[19]	99	77	0.6	59-64
Andersen et al 2015[20]	166	166	Not mention	85

Our tailored-made polyethylene strut prosthesis has the benefit in that it has bigger diameter compared with those commercial piston prostheses. Although this type of prosthesis has a big shaft, it can be trimmed in beveled shape in case that we are faced with intraoperative narrow stapes footplate (Our study showed a successful operation in one-quarter of cases).

Tailored-made polyethylene strut prosthesis use can proficiently close the postoperative A-ABG (within 10 dB). The success rate at 1-month period was 78.65% and reached 90.24% at 6-month period. Also, PTA could be improved over 20 dB at 6-month period by nearly 90%. Our hearing results were comparable with those of other traditional or laser stapes surgery series reported in the prior literature.

Generally, we have used the standard surgical method and have got a good result of hearing improvement. The PTA was improved along with the A-ABG which was significantly decreased. We performed total stapes footplate removal. Even though this may risk inner ear injury, such problems were not identified in our patients confirmed by the audiometric threshold at 8 kHz. The hearing level did not differ or worsen in comparison with the preoperative audiometry. However, the deterioration in hearing after surgery occurred in 3 of our patients (1.5%).

We did not find any complication caused by the rejection of the prosthesis. Polyethylene is one of the most non-reactive materials known and tested in simulated biochemical exposure to pseudoextracellular fluid.[21] Microscopic examination of Polyethylene section, removed after many months in the middle ears of human patients, showed that an interlacing network of fibrous connective tissue invaded it. Occasionally, multinucleated giant cell was seen around the implant. However, foreign body reaction of an implanted plastic material has never been shown to be related to the number of giant cells presented.

CONCLUSION

Tailor-made polyethylene strut prosthesis is a cheap and effective prosthesis. It is an alternative option for surgeons instead of the commercial prosthesis with a very cost-effective material.

REFERENCES

1. Karosi T, Sziklai I. Etiopathogenesis of otosclerosis. Eur Arch Otorhinolaryngol 2010;267(9):1337-49.
2. Beales PH. Otosclerosis-past and present. J R Soc Med 1979;72(8): 553-61.
3. Shea JJ Jr. A personal history of stapedectomy. Am J Otol 1998;19 (5 Suppl):S2-12.
4. Freni F, Mannella VK, Cammaroto G, Azielli C, Cappuccio C, Galletti F. Classic and reversal steps stapedotomy performed with CO2 laser: a comparative analysis. Eur Arch Otorhinolaryngol 2014;271(5):981-6.
5. Kojima H, Komori M, Chikazawa S, Yaguchi Y, Yamamoto K, Chujo K, et al. Comparison between endoscopic and microscopic stapes surgery. Laryngoscope 2014;124(1):266-71.
6. House HP, Hansen MR, Al Dakhail AA, House JW. Stapedectomy versus stapedotomy: comparison of results with long-term follow-up. Laryngoscope 2002;112(11):2046-50.
7. Cavaliere M, Ricciardiello F, Mesolella M, Iengo M. Stapedotomy: functional results with different diameter prostheses. ORL J Otorhinolaryngol Relat Spec 2012;74(2):93-6.
8. Schmerber S, Cuisnier O, Charachon R, Lavieille JP. Vein versus tragal perichondrium in stapedotomy. Otol Neurotol 2004;25(5):694-8.
9. Causse JB, Causse JR. Technique for otosclerosis. Am J Otol 1984;5(5):392-6.
10. Bittermann AJ, Vincent R, Rovers MM, van der Heijden GJ, Tange RA, Dreschler WA, et al. A nonrandomized comparison of stapes surgery with and without a vein graft in patients with otosclerosis. Otol Neurotol 2013;34(5):827-31.
11. Draper WL, Herndon JW. A new prosthesis for stapes surgery. Laryngoscope 1972;82(5):864-7.
12. Roosli C, Huber AM. Mid-term results after a newly designed nitinol stapes prosthesis use in 46 patients. Otol Neurotol 2013;34(7):e61-4.
13. Peter D. Phelps GASL. Diagnostic Imaging of The Ear London: Springer-verlag; 1990.
14. Committee on Hearing and Equilibrium guidelines for the evaluation of results of treatment of conductive hearing loss. AmericanAcademy of Otolaryngology-Head and Neck Surgery Ffoundation, Inc. Otolaryngol Head Neck Surg 1995;113(3):186-7.
15. Goldenberg RA, Emmet JR. Current use of implants in middle ear surgery. Otol Neurotol 2001;22(2):145-52.
16. Schimanski G, Schimanski E, Berthold MR. Diagnostic findings in stapes revision surgery--a retrospective of 26 years. Otol Neurotol 2011;32(3):373-83.
17. Sperling NM, Sury K, Gordon J, Cox S. Early postoperative results in stapedectomy. Otolaryngol Head Neck Surg 2013; 149(6):918-23.
18. Poletti AM, Miceli S, Rossi V, Di Pietro S, Tosi G, Colombo G. The "One Shot" Diode Laser Stapedotomy. Photomed Laser Surg 2015;33(12):598-603.
19. Sakamoto T, Kikuta S, Kikkawa YS, Tsutsumiuchi K, Kanaya K, Fujimaki Y, et al. Differences in Postoperative Hearing Outcomes and Vertigo in Patients with Otosclerosis Treated with Laser-Assisted Stapedotomy versus Stapedectomy. ORL J Otorhinolaryngol Relat Spec 2015;77(5):287-93.
20. Andersen SA, Ohman MC, Sorensen MS. The stability of short-term hearing outcome after stapedotomy: a prospective database study. Acta Otolaryngol 2015;135(9):871-9.
21. Emmett JR. Plasti-pore implants in middle ear surgery. Otolaryngol Clin North Am 1995;28(2):265-72.