Zagazig University Medical Journal
www.zumj.journals.ekb.eg

Manuscript ID ZUMJ-2101-2080 (R1)

DOI 10.21608/zumj.2021.57843.2080

ORIGINAL ARTICLE

COMPARATIVE STUDY BETWEEN TEFLON AND ROBINSON STAINLESS STEEL PROSTHESES IN OTOTSCLEROSIS SURGERY

Essam Fathy Mohamed[1], Said Abdmnem[2] ,Wael A. Alzamil [3]

[1,3]Ear, Nose and Throat Department, Hearing and Speech Institute, General Organization for Teaching Hospitals and Institutes, Egypt.

[2]Otorhinolaryngology Department, Faculty of Medicine Zagazig University.

Corresponding author.
Assist. Consultant
Essam Fathy Mohamed
Email:
essament2014@gmail.com
Telephone. No.
01227743007

Submit Date	2021-01-28
Revise Date	2021-03-13
Accept Date	2021-04-09

ABSTRACT

Background: The main cause of conductive hearing loss in the presence of a completely normal tympanic membrane is otosclerosis. There are different types of prostheses that could be used in the operation with different materials, designs, and shapes. The prostheses utilized in this study including both Teflon and Robinson are assessed. The aim of our work is to match and determine the surgical steps, postoperative results, and surgical complications of both Teflon piston and Robinson titanium prosthesis in line with the improvement in hearing and therefore the ability to decrease the air-bone gap.

Results: stapedotomy done for 40 patients with Teflon piston and Robinson stainless steel piston prosthesis, 20 patients for each type. Both groups were matched based on age and preoperative bone-conduction scores. Follow up for all patients were done up to 6 months postoperatively. We have excluded all revision cases. A comparison between both prostheses was assessed by differences in the Air Bone (AB) Gap and surgical difficulties and complications. Both groups showed no significant difference either in hearing improvement or postoperative decrease of an air-bone gap. The Robison titanium piston needs more surgical skills than Teflon one. Both groups had no surgical complications.

Conclusions: There is an equal benefit to patients with the use either of Teflon piston or Robinson protheses and there is no statistically significant difference between both of them. We need a long time of follow up the results to be analyzed.

Keywords: Teflon prosthesis, Robinson prostheses, otosclerosis, stapedectomy.

INTRODUCTION

People within the age of 15-50 years complaining of conductive hearing loss without any history of aural discharge and intact tympanic membrane mostly caused by otosclerosis, which is an inherited condition (1, 2, 3). It is an autosomal dominant form with incomplete penetrance (4, 5, and 6). Sixty percentages of otosclerotic patients are presented by bilateral conductive hearing loss (2, 6, and 7). These are slowly progressive at low frequency (500-2000 Hz) and sensorineural hearing loss could be the presenting picture (8). The surgery or hearing aids still the only management of otosclerosis. The surgery developed from total removal, partial removal, up to small fenestra (done by laser or micro drill) of the footplate of stapes (9). Many stapes prostheses are now available; they are preferred according to size, weight, materials of synthesis, and shape. The chosen prosthesis must fulfill the criteria of its ability to make a secure attachment to the incus without any inflammatory reaction. The cornerstone of the prosthesis is the method of fixation on the incus. So many modifications were applied to the prosthesis from, a piston with a wire loop at the end. A forceps is used to clamp the wire of the prothesis around the

incus that maintains the stability of the prosthesis, which has the disadvantage of loose or over crimping (10). Teflon is the most commonly applied prosthesis (11); it has popularity because of the low material reactivity and has a retractable memory on its ring (12), this memory guarantees fast implementation of recoil ensures easy application, and good stability without crimping dilemma. The prosthesis of the bucket handle is also another option, which was developed by Robinson in 1961, Lippy modified it with a notch to properly fit the incus. The available design has the lenticular process installed in the bucket, then the handle will be flipped over the incus. The bucket handle prosthesis is also equipped with a hole in the distal portion of the stem to facilitate tissue ingrowth. The rotating wire loop in the prosthesis acts as an extra anchor to the incus until tissue ingrowth is complete (13). The prosthesis is inert to tissue as it is made of 316L stainless steel. The architecture allows this prosthesis to be self-centered; it maintains an attachment to the lenticular process similar to a ball and socket joint. The holes encourage the existence of tissue and vascular in growth (13).

Methods:

Ethical consideration: The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Consent is mandatory for all patients. We excluded all patients with a history of trauma, chronic otitis media and revision cases, congenital stapes fixation, otosclerosis with malleus head fixation. This is a retrospective study, the surgery done in hearing and speech institute and zagazig university hospitals, between the periods from 2015 to 2019. The recorded data of 20 patients, with age 25 to 49 years (mean 36.6), who scheduled a small-fenestra stapedotomy with a Teflon piston. We compared them out comes with those of 20 patients aged 24 to 56 years (mean 38.2), who have done a small-fenestra stapedotomy with a stainless-steel Bailey-modified Robinson prosthesis and a bone cement over the handle of the bucket to be more secure. We compared the degree of hearing improvement and the reduction of the air-bone gap to assess which prosthesis provided better results. We assess the audiological improvement by pre-and postoperative after 6 months with audiometry. The degree of hearing gain was calculated by comparing pre-and postoperative air conduction, while the decrease of an air-bone gap was monitored by comparing postoperative air conduction with preoperative bone conduction.

Surgical Techniques:

Stapedectomy in both groups done under general anesthesia. We infiltrate the external auditory meatus with 1% lignocaine soaked in 1/200,000 epinephrine. Both groups follow the same steps in surgery. Briefly, the tympanomeatal flap was elevated. The chorda tympani should be preserved, the posterosuperior bony part of the external ear canal was removed by curette until exposure of the pyramid and the tympanic segment of the facial nerve. We assess the stapes mobility firstly, then a small fenestra was done in the posterior portion of the stapes footplate, with a small needle tip perforating instrument, this fenestration was widened by a hand drill 0.6 followed by 0.8. The prosthesis was placed in this hole and fit along the long process of the incus subsequently, the incudostapedial joint was separated using a joint knife, the stapedius tendon was severed, and the superstructure of the stapes was removed. This step is done with talon processes but with Robinson processes the surgery is done classically by removal of the footplate of stapes firstly then insertion of the Robinson processes. Frequent suctions should be avoided, especially after opening the stapes footplate, so that to decrease post-operative complications, such as cochlear damage and vertigo. Following that, we reposition the tympanomeatal flap and insert Gelfoam® dressing in the external auditory canal.

Teflon- piston prosthesis;

The 0.4 mm thickness 4.5 long Teflon pistons were applied by its loop over a straight needle and sliding it to widen its loop to accommodate onto the distal end of the incus. After that, we insert the Teflon and depressed it into the vestibule 0.25 mm through the

fenestra. The prosthesis was secured into the distal end of the incus due to its elastic recoil.
Bailey-Modified Robinson Bucket Prosthesis; figure, 1, 2, 3
The prosthesis was inserted in the oval window; the prosthesis well was inserted under the lenticular process by smoothly elevating the incus while lowering the prosthesis slightly. After the bucket was set, the wire bale was rotated over the incus, and then bone cement was placed over the wire to be more secure. The incus was gently palpated to confirm the proper position and assess the mobility of the prosthesis. Both prostheses have the same options of avoiding mechanical crimping.
Data of bone-conduction were adequately identified as audiograms obtained within one month preoperatively and a minimum of four months postoperatively. Where the results are considered stable after that time (14).
Statistical analysis; The data were analyzed by the SPSS software. Data were expressed as means, standard deviations (SD), minimum and maximum for the numerical analysis; the correlation between two variables was done using correlation coefficient test. Comparison between two groups was done using student's t-test.
Ethics considerations: This study was approved by the local ethics committee. All included participants had to signed and agree to the written consent. We inform all participants included about the procedures to be done and what results to be expected.

RESULTS

In this study, 40 patients including 27 females (67.5 %) and 13 males (32.5%) undergoing stapedotomy were assessed. Subjects were 25-49 years old with a mean age of 34.1 years. Bilateral involvement was registered in 32 (80%), with unilateral ear involvement was revealed in eight patients (20%). Right ear surgery was done in 25 (62.5%) and on the left side in 15 cases (37.5%). The research group consisted of 20 Teflon piston prostheses and 20 Robinson prosthesis. at the time of surgery, we assess the type of otosclerotic pathologic condition in the middle ear. There were no substantial changes in pathologic conditions between the two groups. Tiny fenestra procedure has been used in all patients. The fenestra was made by needle then dilated by a hand drill in all cases. There is no difference in the mean of the preoperative air and bone conduction thresholds for both groups (Table 1). The mean preoperative PTA bone conduction threshold for the Teflon group is 13.3 db HL and for the stainless steel prosthesis group is 13.9 db HL. The preoperative mean for the PTA air-conduction threshold was 50.4 dB HL for the Teflon group and 47.6 dB HL for the stainless steel group. The mean postoperative air conduction and bone conduction thresholds were similar for patients in the two groups (Table 2). The postoperative mean for the air-bone gap was 14.4 dB for the Teflon group and 11.7 dB for the stainless steel group. The mean hearing improvement was 37.1 dB for the Teflon group and 33.7 dB for the stainless steel group. No statistically meaningful distinction between the two groups (p=0.980). No hearing loss or any other complication was recorded in both groups. 96% of cases in both groups, postoperatively show ABG of 20 db or less. Significant closure of ABG at 500, 1000, 2000 Hz was detected by Pure tone audiometry and was clinically better than at 4000 Hz. There was no statistically meaningful distinction noted in ABG between both groups. However, the study sample size tested was small. Better closure of AB Gap was observed in the stainless steel group compared to the Teflon piston.

Table 1. Mean preoperative hearing results (dB HL) for patients of both group.

Frequency (Hz)	250	500	1000	2000	4000	8000	DISCRIMNATION
Teflon prosthesis							
Preop. air	55.3	54.8	51.6	45.9	41.3	53.9	97%
Preop. bone	1O.1	10.2	13.6	17.2	10.7	10	
Air-bone gap	45.2	44.6	38	28.7	30.6	43.9	

Frequency (Hz)	250	500	1000	2000	4000	8000	DISCRIMNATION
Robinson prosthesis							
Preop. air	55.1	52.9	50.8	42.6	40.3	48.9	97.3%
Preop. bone	10	10.3	14.3	19.2	11.6	9.8	
Air-bone gap	44.1	42.9	36.5	23.4	28.7	39.1	

Table 2. Mean postoperative hearing results (dB HL) for patients of both group

Frequency (Hz)	250	500	1000	2000	4000	8000	DISCRIMNATION
Teflon prosthesis							
Postop. air	19.8	17.1	17.9	21.1	25.9	26.9	95.6
Postop. bone	11.2	11	13.3	17.9	12.2	13.4	
Air-bone gap	11.6	8.1	5.6	5.2	13.7	43.5	
Robinson prosthesis							
Postop. air	24.1	20.1	18.7	17.7	28.2	46.9	98
Postop. bone	10.1	10.9	15.3	20	12.5	15	
Air-bone gap	14.1	9.2	3.4	2.3	15.7	31.9	

Figures

Fig. 1. Lippy-modified Robinson prosthesis

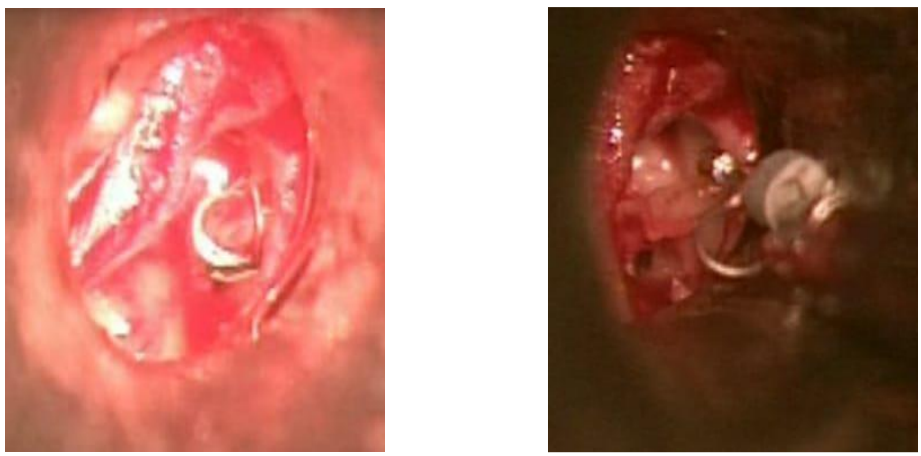

Fig. 2. Lippy-modified Robinson prosthesis. Left ear

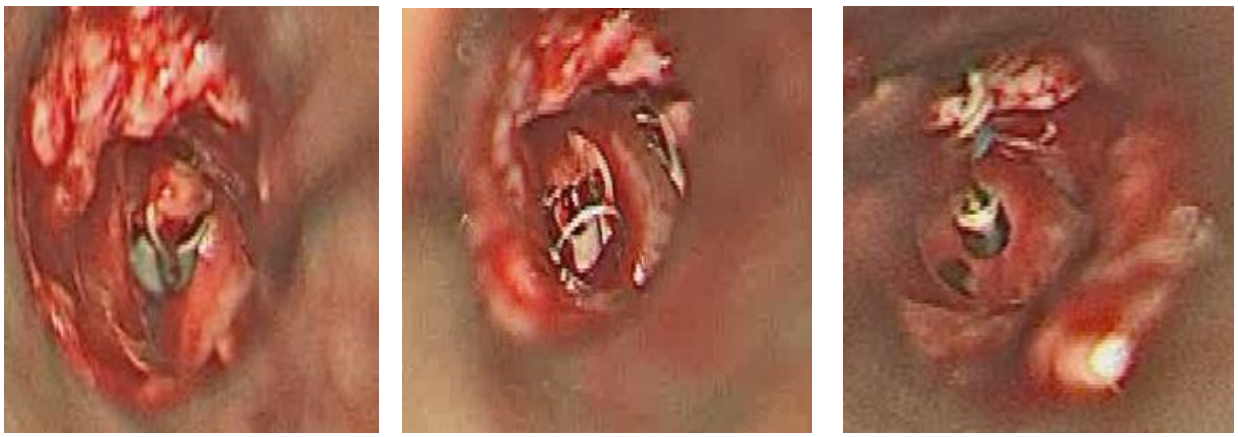

Fig.3. Lippy-modified Robinson prosthesis. Right ear

DISCUSSION

Agreeing to the writing, it is well known that a small-fenestra stapedotomy results in a superior hearing outcome and confers a lower chance of trauma to the labyrinth than does partial or total removal of the footplate of the stapes. The main object of this study was to decide whether the Robinson stainless steel prosthesis would be an efficient substitute for the Teflon prosthesis or not. Teflon has been the foremost-utilized stapes prosthesis in our institute. The perfect stapes prosthesis can regain the hearing chain framework to supply physiologic hearing in a longstanding way without evoking a remote body reaction. The main properties of the prosthesis are to be malleable enough for a traumatic, easy insertion and maintain adherence to the incus smoothly without causing the long process of incus necrosis; Ideally, the perfect prosthesis should be in the same shape, configuration, and weight of the stapes to avoid any overload over the oval window. Both the Teflon and Robinson stainless steel prostheses accomplish these aims. Elonka et al. (19) reported that the gain rates obtained by using the House stainless steel wire and Robinson stainless steel prosthesis were 88% and 94%, respectively. Robinson compared a stainless steel prosthesis (12.5 mg) with the Teflon prosthesis (3.3 mg), he found better hearing results in low and high frequencies, and increased overclosure rates were achieved with the heavier prosthesis (20). Recently, de Bruijn et al. evaluated gold prosthesis (10.2 mg) with Teflon prosthesis (3.2 mg) to determine disparities based on prosthesis mass. The overall finding indicated an improvement in overclosure with a heavier prosthesis but no difference in successful air-bone gap closure (21). for a successful surgery, a stable connection and a secured link between the long process of incus and the prosthesis is obligatory. Inability to make this may lead to both necrosis of the incus and incomplete hearing improvement secondary to cut-off the vibration between the incus and prosthesis (21). We assume that an experienced stapes surgeon will have the same results in the amount of over closure of the preoperative air-bone gap or the hearing gain between stainless-steel bucket surgery and a Teflon-wire surgery, although the stainless-steel bucket surgery could decrease the gap more efficiently. Others have already noticed this statement, in particular by House (22). We have always assumed that it is not a special technique, but a technique implemented by the experience and judgment of the specialist and Sheehy Saied; “If a technique is working for you, do not change for change's sake” (23). There is no reason for a skilled stapes surgeon who has high success results with a certain prosthesis to believe that moving to another prosthesis would dramatically change these outcomes. In one of the largest reviews, the surgical and pure tone audiometry data of 1,800 patients (3,600 ears), were analyzed by Daniels and colleagues who had done bilateral stapedectomy with a Robinson bucket prosthesis; 95% of patients with otherwise average morphology achieved a decrease in the air-bone gap (ABG) less than 10 dB in both ears (24). Robinson stainless steel and Gyrus titanium were assessed by Lippy that

found no significant changes between both prosthesis with a mean 4-tone improvement of 27.8dB versus 27.7dB and postoperative ABG of 2.60dB versus2.60 dB (23). We report that; both prostheses often differ in their prices, Teflon prothesis is cheaper than the Robinson prostheses also the Teflon model easy to be available and technically easy to be inserted. MRI could be done for any patient who underwent any of both surgeries. Prosthesis made of 316L stainless steel to be comparatively nonferromagnetic, as these prothesis are safe in the current MRI use, but the more advanced technology for MRI needs more and careful assessment.

CONCLUSION

Our analysis has shown that both prostheses provide appropriate outcomes in patients with otosclerosis. While the findings were identical, the Robinson prosthesis produced better results relative to the Teflon prosthesis results, The Robinson prosthesis can also require slightly higher surgical skills to be applied. But, the more available, cheaper, and simpler application is the Teflon prosthesis. MRI compatibility of the Robinson stainless prosthesis requires more research.

DECLARATIONS

Ethics approval and consent to participate :

Local ethics committee approved,no nomber available ,the consent obtained from our EAR, NOSE AND THROAT DEPARTMENT, HEARING AND SPEECH INSTITUTE, GENERAL ORGANIZATION FOR TEACHING HOSPITALS AND INSTITUTES, EGYPT

the study not expirmental nor clinical trial.

Consent for publication :

Written Consent for study publication was obtained from all study participants.

Availability of data and materials :

The datasets used and/or analyzed in the current study are available from the corresponding author on reasonable request.

Competing interests:

The authors declare that they have no competing interests

Funding :

None

Authors' contributions:

All operations were done by EF and WE and observed by both. EF and WE shared in the data collection and interpretation of the results. EF was main contributors in writing the manuscript. both authors finally read and approved the final manuscript.

REFERENCES

1. Jenkuns H, Abbasi O. Otosclerosis.In: B. Snow Jr J, Flint et al, Ballenger's Editor, otorhinolaryngology Head & Neck surgery. 16th ed. spain: BC Cecker; (2003), p.317-24.
2. Kileny P, Zwolan T. Otosclerosis. In: Cummings W, Flint C, Editors. Otolaryngology Head & Neck Surgery. 5th ed. USA: Mosby ;(2010) p.1887-1903.
3. Kos ML, Montandon PB, Guyot JP. Short and long-term results of stapedotomy and stapedectomy with Teflon-wire piston prosthesis. *Ann Otol Rhin Otolaryngol*; (2001) 10: 907–911.
4. Daniels R, Krieger L, Lippy W. The other ear: findings and results in 1,800 bilateral stapedectomies. Otol Neurotol ;(2001) 22:603–607.
5. Perez-Lazaro JJ, Uruiza R, Cabrea A., Guerrero C, Navarro E. Effectiveness assessment of otosclerosis surgery. Acta Otolaryngol. (2005), 125 (9): 935-45.
6. Vincent R, Sperling NM, Oates J, Jindal M. Surgical findings and long-term hearing results in 3,050 stapedotomies for primary otosclerosis: a prospective study with the otology-neurotology database. Otol Neurotol. ;(2006) 27(8): 25-47.
7. Ahmed S, Raza N, Ali L, Ullah S, Iqbal S .Hearing improvement after stapedotomy using Teflon loop prosthesis. JCPSP; (2006)16(10): 659-61.
8. Freitas VA, Becker CG, Guimaraes RE, Crosara PFTB, Morais GAN, Moura M Surgical treatment of otosclerosis in medical residency training. Rev Bras Otorrinolaringol.; (2006). 72(6): 727-30.
9. Morshed K, Siwiec H,Szymanski M,Golabek W. Bone and air conduction after stapedectomy,Ann univ Mariae Curie Skoldowaska.; (2003). 58(1):33-37.
10. Ruckenstein and Nicolli : Best Stapes Prosthesis, Laryngoscope (2012) 122: October;2123-2124
11. Robinson M. Stapes prosthesis: stainless steel vs. Teflon. *Laryngoscope*; (1974) 84:1982–1995.
12. Causse JB, Gheri ni S, Horn KL. Surgical treatment of stapes fixation by fibero ptic argon laser stapedotomy with reconstruction of the annular ligament. Otol aryngol Clin North Am; (1993). 26:395- 4 I 6.
13. Lippy WH, Burkey JM, Schuring AG, et al .Comparison of titanium and Robinson stainless steel stapes piston prostheses. Otol Neurotol; (2005). 26:874–7.
14. Raske M, Welling JD, Gillum T, Welling DB .Long-term stapedectomy results with the McGee stapes prosthesis. *Laryngoscope*; (2001) 111:2060–2063.
15. Causse JB, Gheri ni S, Horn KL. Surgical treatment of stapes fixation by fibero ptic argon laser stapedotomy with reconstruction of the annular ligament. Otol aryngol Clin North Am; (1993) 26:395- 4 I 6.
16. Raske M, Welling JD, Gillum T, Welling DB. Long-term stapedectomy results with the McGee

stapes prosthesis. *Laryngoscope*; (2001) 111:2060–2063.
17. Mangham CA. Platinum ribbon-Teflon piston reduces device failure after stapes surgery. *Otolaryngol Head Neck Surg*;(2000) 123:108–113.
18. Kos ML, Montandon PB, Guyot JP .Short and long-term results of stapedotomy and stapedectomy with Teflon-wire piston prosthesis. *Ann Otol Rhin Otolaryngol*; (2001). 10: 907–911.
19. Elonka DR, Derlacki EL, Harrison WH .Stapes prosthesis comparison. *Otolaryngol Head Neck Surg*; (1982). 90: 263–265.
20. Robinson M .Stapes prosthesis: stainless steel vs. Teflon. *Laryngoscope*; (1974). 84:1982–1995.
21. McGee TM .The loose wire syndrome. *Laryngosco (1981). pe*; 91: 1478–1483. 16.
22. House HP. The evolution of otosclerosis surgery. Otolaryngol Clin North Am; (1993). 26:323-33.
23. SlatteryWH,HouseJW .Prostheses for stapes surgery.Otolaryngol Clin North Am 1995; 28:253-264.
24. Daniels R, Krieger L, Lippy W .The other ear: findings and results in 1,800 bilateral stapedectomies. Otol Neurotol; (2001). 22:603–607.

CITE THIS ARTICLE
mohammed, E., Abdmnem, S., Alzamel, W. Comparative study between Teflon and Robinson stainless steel Prostheses in ototsclerosis surgery. *Zagazig University Medical Journal*, 2021; (1575-1581): -. doi: 10.21608/zumj.2021.57843.2080