Research Article

Teflon versus Titanium soft clip prostheses in stapedotomy

Mohammed R. Ghonem*, AbdelRahem A. AbdelKarem, Ahmed M. Youssef**, Mostafa T. AbdelHakem**, AbdelMoneem A. H. AbdelMoneem****

* Department of Otolaryngology, Faculty of Medicine, Mansora University

** Department of Otolaryngology, Faculty of Medicine, Minia University

Abstract

Background and objective: Otosclerosis is one of the most leading causes of conductive hearing loss with intact tympanic membrane in adults. Stapes prostheses have seen many changes in its shape, design and material. Both Teflon and Titanium prostheses used in this study having different method of application to compare the outcomes of use of Teflon and Titanium prostheses in stapedotomy surgery in patients with conductive hearing loss. **Subjects and methods:** The study was applied in Ear, Nose and Throat department at Mansora University Hospital and Minia University Hospital for 40 cases were operated upon: Stapedotomy with insertion of different two types of prostheses and then comparison study was applied for 20 ears with Teflon and 20 ears with titanium soft clip prostheses from August 2015 to August 2017. Air and bone conduction were tested preoperatively and one, three and 6 momths after surgery in all patients along with technique of prostheses application. **Results:** There was no significant difference between groups in hearing improvement. The mean postoperative air-bone gap was 2.7 dB for the teflon group and 3.4dB for the titanium group at 1 month follow up audiological evaluation postoperative, then mean postoperative air-bone gap was 1.6 dB for the teflon group and 4.5dB for the titanium group at 3 months and after 6 months then mean air-bone gap was 1.2 dB for the teflon group and 4.5dB for the titanium group. Neither group had a surgical complication. ABG was <10 dB for both groups at different follow up intervals. **Conclusion**: Both prostheses provide equal benefit to patients and there is no statistically significant difference between the uses of Teflon/Titanium prostheses. Long term results are still to be analyzed. The use of a newly designed titanium-clip stapes piston prosthesis gives good results in cases of stapedotomy for otosclerosis. The titanium-clip design is a new development in the evolution of stapes piston prostheses. Titanium soft clip piston is clipped for secure coupling which is associated with decreased risk of necrosis of long process of incus. It has easier application with lesser surgical time but needs experience.

Key Words: Titanium Soft, Clip Piston, stapes surgery

Introduction

Stapes surgery is a successful and safe treatment modality with high success and low complication rates in the management of otosclerosis[1]. The outcomes of stapes surgery are better in the hands of experienced otologic surgeon who are doing this surgery regularly[2]

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[3]. Teflon piston is the most commonly employed prosthesis in stapes surgery. 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[4]

The titanium soft clip stapes piston, a new type of stapes piston is a modification of the earlier a `Wengen clip piston and is designed to avoid the crimping onto the incus in stapedotomy[5]

Fixation of stapes prosthesis to long process of incus by crimping is one of the most difficult steps of stapes surgery. To address the problem of fixation of prosthesis to long process of incus various types of prosthesis have been designed. One of these newer prosthesis is a titanium clip piston designed by a `Wengen. This clip piston does not require crimping and at the same time does not encircle the long process of incus completely unlike other prosthesis, thus decreasing the chances of necrosis of the long process due to strangulation of the blood supply[6].

Patients and Methods

The study was applied in Ear, Nose and Throat department at Mansora University Hospital and Minia University Hospital for 40 cases were operated upon: Stapedotomy with insertion of different two types of prostheses and then comparison study was applied for 20 ears with Teflon and 20 ears with titanium soft clip prostheses from August 2015 to August 2017

Each case will subjected to the following:

- History taking including:
  1. Name, age, and sex.
  2. Hearing loss (unilateral or bilateral) its course and duration
  3. Previous ear surgery.
  4. Family history of otosclerosis
- In this study, all the selected patients were subjected to a thorough ear, nose and throat clinical examination including tuning fork tests. Pure tone audiogram and impedance audio-metry were done for all the patients.
- Otoscopic examination
- Complete Audiological evaluation (Pure Tone Audiometry and speech audio-metry): conductive or mixed hearing loss.

Immittancemetry using Zodiac 901 immittancemeter (GN Otometrics A/S, Taastrup, Denmark) to measure middle ear pressure and stapedial muscle reflex threshold at frequencies of 500, 1000, 2000 and 4000 Hz and to exclude other middle ear pathologies.

Pure tone and speech audiometry using audiometer Madsen Astera and sound treated room (amplisilence) to assess hearing sensitivity. Air conduction threshold was obtained for the frequency range 250–8000 Hz at single octave intervals using a TDH 49 ear phone (Telephonics Corporation, Farm ingdale, NY, U.S.A.), while bone conduction threshold was obtained for the frequency range 500–4000 Hz at single octave intervals using a B71 bone vibrator (Radio ear, New Eagle, PA, U.S.A). Speech reception threshold (SRT) and speech discrimination score were measured using bisyllabic and monosylabic phonetically balanced word respectively.

- Operative data of the procedure including usage of Teflon or Titanium prostheses.
- All operations were done under local anaesthesia.
- Postoperative pure tone audiometry and speech audiometry 1,3 and 6 months of stapes surgery
- Postoperative vestibular symptoms

Inclusion criteria:

1. Patients with conductive hearing loss (CHL) or mixed hearing loss with intact TM and absent acostic reflex with exclusion of other causes of CHL with intact TM as proved clinically, by tympanometry especially otitis media with effusion and then intraoperative exploratory tympanotomy with testing of ossicular mobility which might reveal other causes of CHL and these cases were excluded from the study as tympanosclerosis, incudo-stapedial dislocation, fixed malleus.
2. No history of stapes surgery

Exclusion criteria:

1. Patients with pure sensorineural hearing loss
2. Revision surgery

Results

Titanium soft clip prostheses:

Of the twenty patients included in this study the youngest was 23 years and the eldest was 50 years with the average age of 34.6 years. Air-bone gap was calculated using mean of audiometric values at 0.5, 1, 2 and 4 kHz. The minimum pre-operative air-bone gap was 21.3dB and the

maximum was 38.8dB with an average of 30.1 dB (SD 6.5). At 6 month's follow up mean postoperative air-bone gap was within 10 dB in all cases. The difference between preoperative and postoperative air-bone gap was found to be statistically significant with a P value <0.001 at 1, 3 and 6 months postoperative. Postoperative air conduction also showed significant improvement.

Teflon prostheses:
Of the twenty patients included in this study the youngest was 23 years and the eldest was 59 years with the average age of 34.9 years. Air-bone gap was calculated using mean of audiometric values at 0.5, 1, 2 and 4 kHz. The minimum preoperative air-bone gap was 17.5 dB and the maximum was 38.8dB with an average of 26.7dB (SD 6). At 6 month's follow up mean postoperative air-bone gap was within 10 dB in all cases. The difference between preoperative and postoperative air-bone gap was found to be statistically significant with a P value <0.001 at 1, 3 and 6 months postoperative. Postoperative air conduction also showed significant improvement

Although ABG closure is better with usage of Teflon prostheses than Titanium soft clip prostheses which was found to be statistically significant, both prostheses showed excellent results as regard closure of ABG<10dB but titanium soft clip piston does not require crimping and at the same time does not encircle the long process of incus completely unlike other prosthesis, thus decreasing the chances of necrosis of the long process due to strangulation of the blood supply.

Table 1: Demographic data in both groups

		Titanium (n=20)	Teflon (n=20)	*P value*
Age ¶	Range Mean ± SD	(23-50) 34.6±8.5	(23-59) 34.9±10.5	*0.922*
Sex μ	Male: n (%) Female: n (%)	4(20%) 16(80%)	6(30%) 14(70%)	*0.716*
Side μ	RT: n (%) LT: n (%)	14(70%) 6(30%)	16(80%) 4(20%)	*0.716*

¶: independent samples T test, μ: Fisher exact test, SD: standard deviation

Table 2: preoperative and postoperative air conduction at 0.5 kHz in both groups

	Titanium (n=20)	Teflon (n=20)	*P value* ¶
Air conduction at 0.5 kHz	***Range Mean ± SD***	***Range Mean ± SD***	***(between 2 groups)***
Preoperative	(50-80) 63±12.2	(45-75) 59.3±9.4	*0.282*
At 1 month postoperative	(15-40) 28±9.1	(20-40) 24±6.4	*0.117*
At 3 months postoperative	(15-40) 27.5±10.3	(20-40) 24±6.4	*0.207*
At 6 months postoperative	(15-40) 27.5±10.3	(20-40) 24±6.4	*0.207*
P values within each group μ			
Pre vs 1 m	***<0.001****	***<0.001****	
Pre vs 3 m	***<0.001****	***<0.001****	
Pre vs 6 m	***<0.001****	***<0.001****	

1 m vs 3 m	*0.666*	*1*
1 m vs 6 m	*0.666*	*1*
3 m vs 6 m	*1*	*1*

¶: independent samples T test, µ: paired samples T test, SD: standard deviation, *: significant difference

Table 3: preoperative and postoperative air conduction at 1 kHz in both groups

	Titanium (n=20)	**Teflon (n=20)**	***P value* ¶**
Air conduction at 1 kHz	***Range Mean ± SD***	***Range Mean ± SD***	***(between 2 groups)***
Preoperative	(50-85) 61.5±13.4	(35-80) 54.8±12	*0.101*
At 1 month postoperative	(15-35) 27±6.6	(15-45) 23.5±8.8	*0.161*
At 3 months postoperative	(15-35) 25±6.9	(10-45) 22.8±9.7	*0.402*
At 6 months postoperative	(15-35) 25±6.9	(15-45) 23.5±8.8	*0.550*
P values within each group µ			
Pre vs 1 m	***<0.001****	***<0.001****	
Pre vs 3 m	***<0.001****	***<0.001****	
Pre vs 6 m	***<0.001****	***<0.001****	
1 m vs 3 m	***0.042****	*0.083*	
1 m vs 6 m	***0.042****	*1*	
3 m vs 6 m	*1*	*0.083*	

¶: independent samples T test, µ: paired samples T test, SD: standard deviation, *: significant difference

Table 4: preoperative and postoperative air conduction at 2 kHz in both groups

	Titanium (n=20)	**Teflon (n=20)**	***P value* ¶**
Air conduction at 2 kHz	***Range Mean ± SD***	***Range Mean ± SD***	***(between 2 groups)***
Preoperative	(35-75) 54.5±14.6	(35-75) 48.5±14.7	*0.203*
At 1 month postoperative	(15-30) 22.5±4.7	(15-45) 25.5±9.4	*0.215*
At 3 months postoperative	(15-30) 21.5±4.6	(10-45) 24±11	*0.356*
At 6 months postoperative	(15-30) 21.5±4.6	(10-45) 24±11	*0.356*
P values within each group µ			
Pre vs 1 m	***<0.001****	***<0.001****	
Pre vs 3 m	***<0.001****	***<0.001****	
Pre vs 6 m	***<0.001****	***<0.001****	
1 m vs 3 m	***0.042****	*0.083*	
1 m vs 6 m	***0.042****	*0.083*	
3 m vs 6 m	*1*	*1*	

¶: independent samples T test, µ: paired samples T test, SD: standard deviation, *: significant difference

Table 5: preoperative and postoperative air conduction at 4 kHz in both groups

Air conduction at 4 kHz	**Titanium (n=20)** *Range* *Mean ± SD*	**Teflon (n=20)** *Range* *Mean ± SD*	*P value ¶ (between 2 groups)*
Preoperative	(30-70) 49±15	(20-70) 43.5±16.6	*0.279*
At 1 month postoperative	(15-40) 27.5±6.6	(15-40) 23.8±7.8	*0.108*
At 3 months postoperative	(15-40) 26.5±7.3	(15-40) 23.8±7.8	*0.255*
At 6 months postoperative	(15-40) 26.5±7.3	(15-40) 23.8±7.8	*0.255*
P values within each group μ			
Pre vs 1 m	***<0.001****	***<0.001****	
Pre vs 3 m	***<0.001****	***<0.001****	
Pre vs 6 m	***<0.001****	***<0.001****	
1 m vs 3 m	***0.042****	*1*	
1 m vs 6 m	***0.042****	*1*	
3 m vs 6 m	*1*	*1*	

¶: independent samples T test, μ: paired samples T test, SD: standard deviation, *: significant difference

Table 6: preoperative and postoperative air bone gap in both groups

Air bone gap	**Titanium (n=20)** *Range* *Mean ± SD* *Median*	**Teflon (n=20)** *Range* *Mean ± SD* *Median*	*P value ¶ (between 2 groups)*
Preoperative	(21.3-38.8) 30.1±6.5 32.5	(17.5-38.8) 26.7±6 26.9	*0.157*
At 1 month postoperative	(0-7.5) 3.4±1.9 3.8	(0-10) 2.7±3.2 1.3	***0.021****
At 3 months postoperative	(0-10) 4.5±2.9 3.8	(0-2.5) 1.6±0.8 1.3	***<0.001****
At 6 months postoperative	(0-10) 4.5±2.9 3.8	(0-2.5) 1.2±0.9 1.3	***<0.001****
P values within each group μ			
Pre vs 1 m	***<0.001****	***<0.001****	
Pre vs 3 m	***<0.001****	***<0.001****	
Pre vs 6 m	***<0.001****	***<0.001****	
1 m vs 3 m	***0.024****	*0.083*	
1 m vs 6 m	***0.024****	*0.083*	
3 m vs 6 m	*1*	*0.083*	

¶: Mann Whitney test, μ: Wilcoxon test, SD: standard deviation, *: significant difference

Discussion

Thanks to modern technology, with the introduction of new biocompatible prostheses in the field of otology, otologists have the opportunity to trial various types of device; although there is conflicting evidence in the literature with regards to the superiority of one prosthesis over another Even though the soft-clip prosthesis does

not need manual crimping, the narrow opening at the anterior end of its loop means that it does need to be clicked onto the long process of the incus with a gentle push. Hence, if the force applied by the surgeon is excessive, it may dislocate the incus, leading to serious consequences in terms of hearing results. In contrast, due to the nature of Teflon, its loop spontaneously returns back to its original closed shape[7] 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 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[8]

Durko et al., experience with Teflon-piston prosthesis shows the lowest post-op mean value of the air–bone gap[3] While comparing 2 pistons designated 0.6 mm in diameter, Mangham 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[9]. Casale et al., data shows that titanium piston is as good as fluoro-plastic piston in stapes surgery for otosclerosis[2].

Conclusion

Both Teflon and Titanium prostheses provide almost equal benefits to patients in terms of ABG. Teflon prostheses are, however cheaper than Titanium. The clipping and crimping of prostheses requires experience. New titanium soft clip prosthesis does not require crimping and at the same time does not encircle the long process of incus completely unlike other prosthesis, thus decreasing the chances of necrosis of the long process. Long term audiometric results and post-operative complications are yet to be analyzed.

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