Research Article

Titanium Soft Clip Piston in stapes surgery

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

* Department of Otolaryngology, Faculty of Medicine, Mansora University

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

Abstract

Background and objective: The aim of the study was to gain the first clinical experience with new titanium soft clip prosthesis in stapes surgery. We placed particular emphasis on the practicability of fixing the prosthesis to the long process of the incus and on the postoperative improvement in hearing. **Subjects and methods:** The current study included 20 patients with atitanium Soft CliP Piston. 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:** We found a mean air-bone gap of 3.4±1.9dB in the frequencies 0.5, 1, 2, and 4 kHz for the patients with a Soft CliP piston at follow-up audiometry after an average of 1month, and of 4.5±2.9 dB after 3 months and of 4.5±2.9 after 6 months. All the prostheses were implanted without difficulty. **Conclusion**: The use of newly designed titanium-clip stapes piston prosthesis with a diameter of 0.6 mm 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

Right from the time when Shea first introduced modern stapes surgery in 1956, the procedure rapidly developed a high success rate. In experienced hands, little or no residual air-bone gap (the difference between air and bone conduction) has in the meantime become the standard. Over the years, many modifications of the surgical technique have constantly refined stapes surgery. For example, the stapedectomy originally performed was first modified to a partial stapedectomy and later to stapedotomy. With the introduction of more advanced appliances, the technique of stapes fenestration also moved on from manual perforators to microdrills and lasers[(1)]

Since the nineteenth century around 105 different types of prosthesis have been developed. The characteristics of acceptable stapes prostheses include the requirement that they produce a reasonable hearing result, are durable, do not cause an inflammatory reaction, and are secure to the long process of incus. Numerous materials and designs of stapes-replacement prostheses are currently available. Piston-style prostheses incorporating Teflon pistons with stainless steel or platinum wire loops are the two most common types. However, the new titanium prosthesis has a lower weight and is much softer, allowing for easier crimping around the incus[(2)]

Fixation of the stapes prosthesis onto the long process of the incus with crimping remains one of the most difficult and unpredictable steps in stapes surgery. Daniel a `Wengen also recognized this problem and came up with a design that eliminated the need for crimping. He designed a special clip that retains its position on the long process as a result of its shape and the memory of titanium. Initially, the clip initially is placed onto the long process of the incus; then it is slid onto the incus much like a tiny laundry pin. Once the clip is in place, no additional crimping is needed. Unlike conventional

prostheses, there is no circular enclosure around the complete circumference of the long process, the philosophy being that the risk for necrosis of the long process of the incus is diminished by minimizing any strangulating effects with this fixation[3]

Patients and Methods

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

Each case will subject 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 audiometry were done for all the patients.
- Otoscopic examination
- Complete Audiological evaluation (Pure Tone Audiometry and speech audiometry): 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 monosyllabic phonetically balanced word respectively.

- Operative data of the procedure including technique of prostheses insertion
- All operations were done under local anaesthesia: the local anaesthetic needle is introduced permeatal in poserosuperior quadrant of EAC at hair line (bony-cartilagenous junction). Lidocaine hydrochloride 2% with adrenaline 1:20,000 is infiltrated very slowly. Faster infiltration is more uncomfortable. Further injection of the needle are made towards the roof and then the floor of the ear canal. Infiltration in the canal is performed using a self retained aural speculum just lateral to the junction of the hair bearing and the normal meatal skin. Again, this is infiltrated slowly to avoid undue discomfort and also ballooning of the deep meatal skin. The sites of infiltration are superiorly into the vascular strip, posteriorly (at nine o'clock for a right ear) and, finally, anteroinferiorly
- Postoperative pure tone audiometry and speech audiometry 1,3 and 6 months of stapes surgery

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 tympa-notomy 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

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 meanof audiometric values at 0.5, 1, 2 and 4 kHz. The minimum preoperative air-bone gap was 21.3dB and the maximum was 38.8dB with an average of 30.1dB (SD 6.5). At 6 month's follow up mean postoperative air-bone gap was within 10 dB in all cases. On applying t test 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.

Table 1: Demographic data

Age ¶	**Range** **Mean ± SD**	**(23-50)** **34.6±8.5**
Sex μ	Male: n (%) Female: n (%)	4(20%) 16(80%)
Side μ	RT: n (%) LT: n (%)	14(70%) 6(30%)

μ: Fisher exact test, SD: standard deviation

Table 2: preoperative and postoperative air conduction at 0.5 kHz

	Range ***Mean ± SD***			
	Range ***Mean ± SD***	**At 1 month postoperative**	**At 3 months postoperative**	**At 6 months postoperative**
Preoperative	(50-80) 63±12.2	(15-40) 28±9.1	(15-40) 27.5±10.3	(15-40) 27.5±10.3
Pre vs 1 m			***<0.001****	
Pre vs 3 m			***<0.001****	
Pre vs 6 m			***<0.001****	
1 m vs 3 m			*0.666*	
1 m vs 6 m			*0.666*	
3 m vs 6 m			***1***	

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

Table 3: preoperative and postoperative air conduction at 1 kHz

Air conduction at 1 kHz	***Range*** ***Mean ± SD***			
	Preoperative	**At 1 month postoperative**	**At 3 months postoperative**	**At 6 months postoperative**
	(50-85) 61.5±13.4	(15-35) 27±6.6	(15-35) 25±6.9	(15-35) 25±6.9
Pre vs 1 m			***<0.001****	
Pre vs 3 m			***<0.001****	
Pre vs 6 m			***<0.001****	
1 m vs 3 m			***0.042****	
1 m vs 6 m			***0.042****	
3 m vs 6 m			*1*	

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

Table 4: preoperative and postoperative air conduction at 2 kHz

Air conduction at 2 kHz	*Range Mean ± SD*			
	Preoperative	**At 1 month postoperative**	**At 3 months postoperative**	**At 6 months postoperative**
	(35-75) 54.5±14.6	(15-30) 22.5±4.7	(15-30) 21.5±4.6	(15-30) 21.5±4.6
Pre vs 1 m			***<0.001****	
Pre vs 3 m			***<0.001****	
Pre vs 6 m			***<0.001****	
1 m vs 3 m			***0.042****	
1 m vs 6 m			***0.042****	
3 m vs 6 m			*1*	

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

Table 5: preoperative and postoperative air conduction at 4 kHz

Air conduction at 4 kHz	*Range Mean ± SD*			
	Preoperative	**At 1 month postoperative**	**At 3 months postoperative**	**At 6 months postoperative**
	(30-70) 49±15	(15-40) 27.5±6.6	(15-40) 26.5±7.3	(15-40) 26.5±7.3
Pre vs 1 m			***<0.001****	
Pre vs 3 m			***<0.001****	
Pre vs 6 m			***<0.001****	
1 m vs 3 m			***0.042****	
1 m vs 6 m			***0.042****	
3 m vs 6 m			*1*	

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

Table 6: preoperative and postoperative air bone gap

Air bone gap	*Range Mean ± SD Median*			
	Preoperative	**At 1 month postoperative**	**At 3 months postoperative**	**At 6 months postoperative**
	(21.3-38.8) 30.1±6.5 32.5	(0-7.5) 3.4±1.9 3.8	(0-10) 4.5±2.9 3.8	(0-10) 4.5±2.9 3.8
Pre vs 1 m			***<0.001****	
Pre vs 3 m			***<0.001****	
Pre vs 6 m			***<0.001****	
1 m vs 3 m			***0.024****	
1 m vs 6 m			***0.024****	
3 m vs 6 m			*1*	

µ: Wilcoxon test, SD: standard deviation, *: significant difference

Table 7: frequency of preoperative and postoperative abnormal air bone gap

Air bone gap	*N (%)*							
	Preoperative		**At 1 month postoperative**		**At 3 months postoperative**		**At 6 months postoperative**	
	≤10	>10	≤10	>10	≤10	>10	≤10	>10
	0(0%)	20(100%)	20(100%)	0(0%)	20(100%)	0(0%)	20(100%)	0(0%)
Pre vs 1 m	***<0.001****							
Pre vs 3 m	***<0.001****							
Pre vs 6 m	***<0.001****							
1 m vs 3 m	*1*							
1 m vs 6 m	*1*							
3 m vs 6 m	*1*							

µWilcoxon test, *: significant difference

Discussion

Different types of stapes prosthesis have been developed since introduction of stapes surgery by Shea. Most commonly used is the Teflon piston, other materials which have been used to design a stapes prosthesis are gold, stainless steel, platinum, titanium and nitinol to name a few. The most contentious issue in otosclerosis surgery has been the fixation of stapes prosthesis to the long process of incus. A prosthesis which into otight cuts through the incus as was demonstrated by Marquetinre vision surgeries where earlier a wireloop prosthesis was used. Lesinski saw in revision surgeries that a loose prosthesis can also cause notching of the long process leading to incus erosion and necrosis[4]

To obviate these problems of improper crimping of stapes prosthesis onto long process of incus, a `Wengen designed a titanium clip piston prosthesis (manufactured by Kurz) which has been in use during the last decade. Advantage of this prosthesis is that it does not require any crimping and at the same time does not compress the long process circum-ferentially[5]. Schimanski et al. retrospectively evaluated surgical records of 275 stapes surgeries done using a `Wengen clip piston. It was found that using this piston was problematic in cases where long process was either too thin or too thick. They also studied 100 incudes intraoperatively to measure the diameter of long process at the application site of stapes prosthesis. They measured the antero-posterior and the latero-medial diameter of the long process and found that both the diameters ranged from 0.5 to 0.9 mm. They modified the design of the older a `Wengen clip prosthesis taking into account various factors like diameter of long process, stiffness of the prosthesis, application force and clamping force. Stiffness of this new clip piston was reduced by 25% in comparison toa. We ngen clip is tonthatis why this new clip prosthesis is also referred to as the soft clip piston. The application force was also reduced by up to 45% makingiteasiertoclipontothelongprocessofin cuswithout any risk of dislocation of the malleo-incudal joint[6].

Zurr et al.,[7] retrospectively evaluated the results of 58 stapedotomies done using titanium stapes prosthesis. They reported an average postoperative air-bone gap of 8.4 dB,in 79% of the patients the postoperative air-bone gap was less than 10 dB.Tange and Grolman[8] on comparing the results of a `Wengen clip piston with a crimping type titanium stapes prosthesis in 126 patients (63 in each group) found no difference in the postoperative results between the two groups. The hearing results of the present study are comparable to the results reported in the literature using other types of stapes prostheses. Chances of a soft clip piston getting twisted while implanting onto the long process of incus are also much less as the force required to clip it on to incus is considerably less[5].

Conclusion

Titanium soft clip piston gives excellent results as regard closure of air-bone gap in

addition to different technique of insertion which does not require crimping over lenticular process of incus and therefore decrease chance of long term necrosis of incus.

References

1. Hornung JA, Brase C, Bozzato A, Zenk J, Iro H. First experience with a new titanium clip stapes prosthesis and a comparison with the earlier model used in stapes surgery. The Laryngoscope. 2009;119(12):2421-7.
2. Faramarzi M, Gilanifar N, Roosta S. Comparison of Fluoroplastic Causse Loop Piston and Titanium Soft-Clip in Stapedotomy. Iranian journal of otorhinolaryngology. 2017;29(90):23.
3. Grolman W, Tange R. First experience with a new stapes clip piston in stapedotomy. Otology & Neurotology. 2005;26(4):595-8.
4. Lesinski SG. Causes of conductive hearing loss after stapedectomy or stapedotomy: a prospective study of 279 consecutive surgical revisions. Otology & neurotology. 2002;23(3):281-8.
5. Singh P, Goyal A. Our experience with the titanium soft clip piston stapedotomy. Indian Journal of Otolaryngology and Head & Neck Surgery. 2013;65(3):280-2.
6. Schimanski G, Steinhardt U, Eiber A. Development of a new clip-piston prosthesis for the stapes. Middle ear mechanics in research and otology: World Scientific; 2007. p. 237-45.
7. Zuur C, de Bruijn A, Lindeboom R, Tange R. Retrospective analysis of early postoperative hearing results obtained after stapedotomy with implantation of a new titanium stapes prosthesis. Otology & neurotology. 2003;24(6):863-7.
8. Tange RA, Grolman W. An analysis of the air-bone gap closure obtained by a crimping and a non-crimping titanium stapes prosthesis in otosclerosis. Auris Nasus Larynx. 2008; 35(2):181-4.