Stapedotomy: Does Titanium soft clip prostheses affect outcome?

Original Article

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ABSTRACT

Purpose: The aim of this study was to compare the postoperative hearing outcomes of stapes surgery with titanium soft clip stapes piston to those with Teflon in cases of otosclerosis.

Patients and Methods: 40 patients with otosclerosis. Twenty patients were operated with stapedotomy with the insertion of titanium soft clip prostheses and 20 patients were operated with the insertion of Teflon prostheses. All patients had conductive or mixed hearing loss. The mean air-bone gap (averaged across frequencies of 500, 1000, 2000 and 4000 Hz) was 28.4 dB HL ± SD of 6.3 dB HL. Air-bone gap was computed postoperatively at intervals of one, three and 6 months for all patients.

Results: The mean postoperative air-bone gap for the Teflon group was 2.7 dB HL, 1.6 dB HL, and 1.2 dB HL at one, three, and 6 months respectively. The mean postoperative air-bone gap for the titanium group was 3.4 dB HL, 4.5 dB HL, and 4.5 dB HL at one, three, and 6 months respectively. No statistically significant difference was found between the two groups as regards the preoperative or the postoperative air-bone gap at the different intervals. All patients in the two groups had air-bone gap less than 10 dB at the different follow up intervals.

Conclusion: Titanium prosthesis provide equal hearing improvement to the Teflon prosthesis for patient with otosclerosis with the advantages of secure coupling, decreased risk of necrosis of long process of incus, easier application, and lesser surgical time but needs experience.

Key Words: Otosclerosis, stapes surgery, teflon, titanium clip stapes piston prosthesis.

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INTRODUCTION

Stapes surgery is a 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 different materials 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.

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 prostheses is the titanium clip piston, which is a modification of the earlier Wengen clip piston and is designed to avoid the crimping into the incus in stapedotomy. 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[4-6].

For our best knowledge, a Study that compares the hearing outcome after stapedotomy with titanium prosthesis to that with Teflon prosthesis is not available. The aim of the current work was to compare the hearing outcome of stapedotomy with the two types of prostheses in cases of otosclerosis.

PATIENTS AND METHODS:

The study was applied in Ear, Nose and Throat (ENT) departments at Mansora University Hospital, Egypt and Minia University Hospital, Egypt for 40 patients with otosclerosis. Twenty patients had unilateral stapedotomy with insertion of Teflon prosthesis and 20 patients had unilateral stapedotomy with insertion of titanium soft clip prosthesis. Table 1 shows age, sex, and the operated ear for the patients under each group. Independent sample t test

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revealed no statistical significant difference between the groups as regards patient's age (*p value =0.92*). Similarly, Fisher exact test revealed no statistical significant difference between the two groups as sex distribution (*p value =0.75*) or the operated ear (*p value = 0.75*).

The study was carried in the period from August 2015 to August 2017. Preoperative assessment included full history, full clinical ENT examination, otoscopic examination, pure tone audiometry, speech audiometry, and Immittancemetry. History taking included hearing loss history, its course and duration, history of current or previous middle ear disease, ear discharge, history of previous ear surgery, and family history of hearing loss or otosclerosis. Postoperative pure tone audiometry and speech audiometry were performed at 1,3 and 6 months intervals of stapes surgery.

All cases had intact healthy tympanic membranes, A or As tympanogram, and absent acoustic reflex. Other causes of CHL were excluded through proper history taking, otoscopic examination, tympanometry, and intraoperative exploratory tympanotomy with testing of ossicular mobility which might reveal tympanosclerosis, incudo-stapedial dislocation, or fixed malleus. Any case with one of these pathologies or other cause of CHL was excluded from the study. Cases with previous stapes surgery or revision surgery were also excluded. Table 2 shows the preoperative audiometric air conduction thresholds at 500, 1000, 2000, and 4000 Hz and the air-bone gap (averaged gap of 500, 1000, 2000, and 4000 Hz) of the both groups. Averaged across frequencies and patients, both groups had moderately severe degree of hearing loss. Independent sample t test revealed no significant differences between the two groups as regards the preoperative audiometric threshold or the air-bone gap.

Pure tone and speech audiometry were performed using audiometer Madsen Astera and sound treated room (amplisilence). 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 bi-syllabic and monosyllabic phonetically balanced word, respectively. Immittancemetry was performed using Zodiac 901 immittancemeter (GN Otometrics A/S, Taastrup, Denmark) to measure middle ear pressure and stapedial muscle reflex at frequencies of 500, 1000, 2000 and 4000 Hz

All operations were done under local anaesthesia. Initially, the local anaesthetic needle is introduced permeatal in posterosuperior quadrant of external auditory canal (EAC) at hair line (bony-cartilagenous junction). Lidocaine hydrochloride 2% with adrenaline 1:20,000 was infiltrated very slowly. Faster infiltration is more uncomfortable. Further injection of the needle were made towards the roof and then the floor of the ear canal. Infiltration in the canal was performed using a self-retained aural speculum just lateral to the junction of the hair bearing and the normal meatal skin. This was 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.

Operative procedures were as follow:

1- The surgical technique was a standard permeatal stapedotomy. The aural speculum was held in place and fixed with towel clips. This had the advantage that the patient is able to move his or her head without displacing the speculum. 2- Incision and elevation of tympanomeatal flap by double-curved round knife. 3- Identification of Chorda Tympani Nerve. 4- Curetting of the Posterosuperior Bony Meatal Wall. 5- Inspection of the Ossicular Chain The middle ear cleft. 6- Reversal of steps of classic stapedotomy.

According to this method, the dislocation of the incus and, the luxation and fracture of the footplate were avoided by performing the footplate hole and fixing the prosthesis to the incus before removing the stapes superstructure. Footplate was perforated by handheld perforator in the posterior 1/3 of the oval window before the division of stapedius tendon, disarticulation of incudo-stapedial joint and subsequently removal of stapes superstructure by fracturing the crura after fixing the prosthesis.

Figures 1 and 2 show the insertion of the Teflon prosthesis and the required crimping and the titanium soft clip prosthesis by hook without the need for crimping.

The study was approved by the ethical research committee at Minia and Mansora universities. Participated patients gave written consent to approve their participation in the study and publication of the operation results.

Table 1: Age, sex, and the operated ear for the otosclerosis patients treated with Titanium and Teflon prosthesis.

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

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

Table 2: Pre-operative air conduction threshold and air-bone gab in the titanium and Teflon groups.

Audiometric thresholds	Titanium	Teflon	*P value*
500 Hz	Range =50-80 dB HL Mean ± SD = 63 ± 12.2	Range =45-75 dB HL Mean ± SD = 59.3 ± 9.4	0.282
1000 Hz	Range =50-85 dB HL Mean ± SD = 61.5 ± 13.4	Range =35-80 dB HL Mean ± SD = 54 ± 12	0.101
2000 Hz	Range =35-75 dB HL Mean ± SD = 54.5 ± 14.6	Range =35-75 dB HL Mean ± SD = 48.5 ± 14.7	0.203
4000 Hz	Range =30-70 dB HL Mean ± SD = 49 ± 15	Range =20-70 dB HL Mean ± SD = 43.5 ± 16.5	0.279
Averaged air-bone gap	Range =21.3-38.8 dB HL Mean ± SD = 30.1 ± 6.5	Range =50-80 dB HL Mean ± SD = 26.7 ± 6	0.157

Fig. 1: Insertion (A) and crimping (B) of the Teflon prosthesis

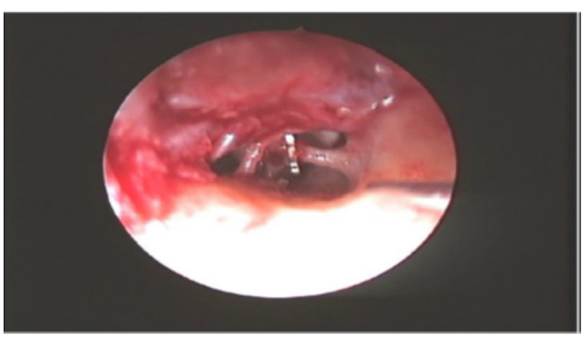

Fig. 2: Insertion of the titanium soft clip prosthesis by hook without the need for crimping

RESULTS:

Tables 3-6 show the postoperative air conduction thresholds at different audiometric frequencies at 1, 3, and 6 month intervals postoperatively, compared to the preoperative audiometric threshold. For both groups, there was considerable and statistically significant hearing improvement at each frequency at one month postoperatively. For the titanium group, hearing improved by 35 dB HL, 34.5 dB HL, 32 dB HL, and 21.5 dB HL at 500, 1000, 2000, and 4000 Hz respectively. For the Teflon group, hearing improved by 35.3 dB HL, 31.3 dB HL, 23 dB HL, and 19.7 dB HL at 500, 1000, 2000, and 4000 Hz respectively. Independent sample t tests revealed no statistical significant difference between the two groups as regards the magnitude of hearing improvement. For both groups, paired samples t tests revealed no statistical significant hearing change at any of the tested frequency at 3 and 6 month postoperatively compared to hearing threshold at 1 month postoperative.

Table 7 shows the averaged air-bone gap (500, 1000, 2000, and 4000 Hz) at 1 month postoperative. One month postoperative, mean air-bone gap was 3.8 dB HL for the titanium group, and 1.3 dB HL for dB the Teflon group. For both groups, the air-bone gap decreased considerably and statistically significant. There was a reduction in the air-bone gap of 28 dB HL for the titanium group and of 23.3 dB HL for the Teflon group. For both groups, all patients had reduction of the air-bone gap to less than 10 dB HL. Similar to the hearing improvement, Independent sample t tests revealed no statistical significant difference between the two groups as regards the magnitude of air-bone gap reduction. For both groups, paired samples t tests revealed no statistical significant change in the air-bone gap at 3 and 6 month postoperatively compared to hearing threshold at 1 month postoperative.

Table 3: Pre-operative and 1, 3, and 6 month post-operative air conduction threshold at 0.5 kHz in the titanium and Teflon groups

Air conduction at 0.5 kHz	Titanium (n=20)	Teflon (n=20)	*P value* ¶
	Range Mean ± SD	Range Mean ± SD	(between 2 groups)
Preoperative	(50-80)	(45-75)	0.282
	63±12.2	59.3±9.4	
At 1 months postoperative	(15-40)	(20-40)	0.117
	28±9.1	24±6.4	
At 3 months postoperative	(15-40)	(20-40)	0.207
	27.5±10.3	24±6.4	
At 6 months postoperative	(15-40)	(20-40)	0.207
	27.5±10.3	24±6.4	
P value within each groups			
Pre vs 1 ms	*<0.001**	*<0.001**	
Pre vs 3 ms	*<0.001**	*<0.001**	
Pre vs 6ms	*<0.001**	*<0.001**	
1 ms vs 3 ms	0.666	1	
1 ms vs 6 ms	0.666	1	
3 ms vs 6 ms	1	1	

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

Table 4: Pre-operative and 1, 3, and 6 month post-operative air conduction threshold at 1 kHz in the titanium and Teflon groups

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

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

Table 5: Pre-operative and 1, 3, and 6 month post-operative air conduction threshold at 2 kHz in the titanium and Teflon groups

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

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

Table 6: Pre-operative and 1, 3, and 6 month post-operative air conduction threshold at 4 kHz in the titanium and Teflon groups

Air conduction at 4 kHz	Titanium (n=20)	Teflon (n=20)	*P value* ¶
	Range Mean ± SD	Range Mean ± SD	(between 2 groups)
Preoperative	(30-70)	(20-70)	0.203
	49±15	43.5±16.6	
At 1 months postoperative	(15-40)	(15-40)	0.108
	27.5±6.6	23.8±7.8	
At 3 months postoperative	(15-40)	(15-40)	0.255
	26.5±7.3	25.8±7.8	
At 6 months postoperative	(15-40)	(15-40)	0.356
	26.5±7.3	25.8±7.8	
P value within each groups			
Pre vs 1 ms	*<0.001**	*<0.001**	
Pre vs 3 ms	*<0.001**	*<0.001**	
Pre vs 6ms	*<0.001**	*<0.001**	
1 ms vs 3 ms	0.042*	1	
1 ms vs 6 ms	0.042*	1	
3 ms vs 6 ms	1	1	

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

Table 7: Pre-operative and 1, 3, and 6 month post-operative averaged air-bone gap in the titanium and Teflon groups

Air bone gap	Titanium (n=20)	Teflon (n=20)	*P value* ¶
	Range Mean ± SD Median	Range Mean ± SD Median	(between 2 groups)
Preoperative	(21.3-38.8)	(17.5-38.8)	0.203
	30.1±6.5	26.7±6	
	32.5	26.9	
At 1 months postoperative	(0-7.5)	(0-10)	0.021*
	3.4±1.9	2.7±3.2	
	3.8	1.3	
At 3 months postoperative	(0-10)	(0-2.5)	*<0.001**
	4.5±7.3	1.6±0.8	
	3.8	1.3	
At 6 months postoperative	(0-10)	(0-2.5)	*<0.001**
	4.5±7.3	1.6±0.8	
	3.8	1.3	
P value within each groups			
Pre vs 1 ms	*<0.001**	*<0.001**	
Pre vs 3 ms	*<0.001**	*<0.001**	
Pre vs 6ms	*<0.001**	*<0.001**	
1 ms vs 3 ms	0.024*	0.083	
1 ms vs 6 ms	0.024*	0.083	
3 ms vs 6 ms	1	0.083	

DISCUSSION

For stapedotomy in cases of otosclerosis, 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 into the long process of the incus with a gentle push. However, 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].One important advantage of soft clip prosthesis that does not require crimping is that it does not encircle the long process of incus completely unlike other prosthesis, thus decreasing the chances of necrosis of the long process. However, this kind of prosthesis requires surgical experience.

In the current study, the hearing results after stapedotomy with the use of traditional Teflon prosthesis was compared to that after stapedotomy with the use of titanium soft clip prosthesis, that does not require crimping. Results showed that both prostheses had excellent results as regards hearing improvement and reduction of the air-bone gap. One month postoperative, there was a mean reduction in the air-bone gap of 28 dB HL for the titanium group and of 23.3 dB HL for the Teflon group. One month postoperative, mean air-bone gap was 3.8 dB Hl for the titanium group, and 1.3 for the Teflon group. For both groups, all patients had reduction of the air-bone gap to less than 10 dB HL. For the titanium group, hearing improved by a mean of 35 dB HL, 34.5 dB HL, 32 dB HL, and 21.5 dB HL at 500, 1000, 2000, and 4000 Hz respectively. For the Teflon group, hearing improved by a mean of 35.3 dB HL, 31.3 dB HL, 23 dB HL, and 19.7 dB HL at 500, 1000, 2000, and 4000 Hz respectively. Relevant to the study objective, our results showed that had benefit as regards hearing improvement and reduction of the air bone gap. Moreover, there was no hearing change at intervals of 3 and 6 month postoperative for both groups.

Lippy *et al*.[8] performed stapedodomy with use of titanium soft clip piston prosthesis and reported a mean hearing improvement of 27. 8 dB HL averaged across frequencies 500-4000 Hz and a mean reduction of 2.6 the air-bone gap to dB HL. These results are quite comparable to the current study results. In fact, hearing improvement was more in the current results. Further, Lippy *et al*.[11] compared hearing outcome of stapedotomy with use of a Robinson stainless steel piston to that of stapedotomy with use of a titanium soft clip piston and found no statistical significant difference in hearing improvement or the reduction of the air bone gap between the two prostheses. No surgical complications were reported with either prosthesis. Lippy *et al*.[11] concluded that the titanium stapes prosthesis is a good alternative to stainless steel prosthesis. Current study supports the titanium prosthesis as good and better alternative to Teflon prosthesis.

Tange and Grolman[9] 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[10]. In the current study non crimping Titanium soft clip prostheses were compared to Teflon prostheses, which require crimping, in stapes surgery and reveals also comparable hearing results. The study supports the use of titanium prosthesis for the proposed benefit of less necrosis of long process of the incus.

CONCLUSION

Titanium prostheses provide comparable hearing improvement and reduction of the air-bone gap to Teflon prosthesis in cases of otosclerosis. The non-crimping property of Titanium prosthesis give it the advantage of not encircle the long process of incus completely, thus decreasing the chances of necrosis of the long process. Long term audiometric results and post-operative complications are yet to be analyzed for the titanium prosthesis.

CONFLICT OF INTEREST

There are no conflicts of interest.

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