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TEFLON VS TITANIUM PROSTHESES IN STAPES SURGERY

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ABSTRACT

BACKGROUND: 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 are reviewed in detail.

OBJECTIVE: To compare the outcomes of use of Teflon and Titanium prostheses in stapedotomy surgery in patients with conductive hearing loss.

STUDY DESIGN: Prospective study

SETTING: Tertiary referral centre

METHODS: A prospective study of 50 patients of otosclerosis, who underwent stapedotomy at B.J.Medical College, Civil Hospital, Ahmedabad, with Teflon/Titanium prostheses, from June 2009-February 2012 was done. Follow up was done for a minimum period of 6 months. Revision cases were excluded. A comparison of prostheses was concluded by differences in AB (Air Bone) Gap.

RESULT: Postoperative ABG of 20db or less was seen in 96% in both groups. The mean postoperative ABGap was 8.2 dB and 11.5 dB for Teflon and Titanium group respectively. There was no statistically significance difference noted in ABGap between Teflon and Titanium pistons at 95% confidence limit at $P<0.05$. There was significant improvement of AC thresholds at each frequency except for above 4 kHz, in postoperative period.

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.

Key Words: Otosclerosis, Stapedotomy, Prostheses, Air Bone Gap

INTRODUCTION:

Evolution of stapes surgery began since Shea did the first stapedectomy in 1956(1). Since then there have been many changes in the design and materials used for stapes surgery. An ideal stapes piston should have a good biocompatibility and adequate transmission of sound. Most common materials used for stapes surgery are of teflon (flouroplastic), titanium, stainless steel, platinum and nitinol. Any stapes piston should easily adjust itself to the long process of incus and should not get distorted during crimping. In India, Teflon and Titanium are two most common prostheses in use.

Teflon piston is now the most widely used prosthesis for reconstruction of the ossicular chain in cases of otosclerosis (2). Titanium is widely used in total and partial ossicular chain reconstruction in ossiculoplasty.The major difference between the two prostheses is their design and mode of application. The most insecure step in stapes surgery is to fix the stapes prostheses on long process of Incus. Stable fixation of the stapes prosthesis on the long process of the incus is one of the important aims in stapes surgery because it is needed for a reliable, long-lasting hearing result.

Teflon was the first material to be used in stapedectomy by John Shea in 1956(1). Titanium prosthesis was introduced by Kurz Medical Inc. in 1996(3). The purpose of this study is to compare the effectiveness of Teflon piston- (type causse xomed surgical products, Jacksonville, FL) to Titanium piston(Clip Piston a`Wengen, KURZ-Medizintechnik, Dusslingen, Germany) in hearing improvement in form of Air Bone Gap(ABG) in patients, undergoing stapedotomy.

MATERIALS AND METODOLOGY:

A prospective study was conducted on 50 patients, undergoing stapedotomy at B.J Medical College, Civil Hospital, Ahmedabad from June 2009 to June 2012. Only patients with conductive hearing loss and intact drum were included in study. Revision cases were excluded. Age group of patients ranged between 16 to 57 years. Patients were given option of both prostheses.

Random patients were selected from the total group of 76 patients with Teflon prostheses and 34 patients with Titanium prostheses. Manual Stapedotomy was performed by endomeatal approach by an experienced surgeon. Minimum period of follow up was 6 months. Average period of follow up was 18 months and maximum follow up was for 36 months. 25 patients in study had Teflon prostheses and rest 25 had Titanium prostheses. Length of the prostheses ranged from 4.0 to 4.75mm. Shaft diameter of both prostheses was 0.6mm. The piston was stabilized with the help of fat from ear lobule in each case. Fat was placed adjacent to piston.

Preoperative and postoperative Air and Bone conduction values were recorded at 250, 500, 1000, 2000, 3000, 4000 Hz. AB Gap was compared at the period of successive 6 months postoperatively. Difference in postoperative complications was evaluated at first postoperative day and after 1 month. Paired t test was applied to compare the outcomes of the two groups. The outcomes were analyzed as the following groups

AB Gap	**OUTCOME**
0-10	SUCCESSFUL OUTCOME
11-20	SATISFACTORY OUTCOME
>20	FAILURE

RESULTS:

Out of 50 patients who underwent stapedotomy irrespective of prostheses, 64% were female and 36% male. Most common complain of their presentation was bilateral decreased hearing (44%), followed by tinnitus. Right ear was explored in 68% of cases and left ear in 32% of cases. There was no difference in characteristics of age, sex, follow up period, operated ear. Otosclerosis was confirmed intraoperatively. The ideal length of piston was selected intra-operatively. The most common length of piston used was of 4.5mm (72%). There was no infection, sensorineural hearing loss or vertigo in immediate post-operative period in the groups compared.

There was a failure rate of 4%, due to displacement of prostheses from its position in both pistons.

In Teflon prostheses displacement of prostheses was found immediately in the postoperative period within 7 days. In Titanium prostheses there was initial success with late failure. In the latter case, patient had sudden loss of hearing from the operated ear soon after fall from stairs. Both cases were re-explored immediately and findings were confirmed.

Preoperatively there was no significant difference in the mean air and bone conduction values between the two prostheses on pure tone audiometry (Table1). Mean postoperative Hearing results (db HL) for patients who underwent stapedotomy with Teflon and Titanium prostheses are shown in Table 2. The mean preoperative PTA bone conduction threshold is 13.3 db HL for the Teflon group and 13.9 db HL for the Titanium group. The mean preoperative PTA air conduction threshold was 57.05 db HL for the Teflon group and 56.7 db HL for the Titanium group. The mean postoperative air conduction and bone conduction threshold were similar for patients in two groups (Table 2). The mean postoperative ABGap was 8.2 dB and 11.5 dB for Teflon and Titanium group respectively, at the end of 6 months. In Titanium group, closure of ABGap as successful outcome was seen in 62%, while satisfactory results were seen in 34%. In Teflon group, closure of ABGap as successful outcome was seen in 60%, while satisfactory results were seen in 36%. There was no significant difference in the ABGap of patients over a period of time after initial survey of 6 months.

Postoperative ABG of 20db or less was seen in 96% of cases in both groups. (Table 3) Pure tone audiometry showed significant closure of ABG at 500, 1000, 2000 Hz and were clinically better than 4000 Hz. There was no statistically significant difference noted in ABG between Teflon and Titanium prostheses at 95% confidence limit with $p<0.05$. However, the sample size used for this study was small. Postoperative there was significant improvement of AC thresholds at each frequency except for above 4 kHz. Teflon piston however showed better closure of ABGap compared to Titanium piston at 4 kHz.

Table 1: Mean preoperative hearing results (db HL) for patients who underwent stapedotomy with Teflon and Titanium prostheses:

	Frequency (Hz)					
	250	500	1000	2000	4000	8000
Teflon prostheses						
Pre-op AC	50.8	52.5	61.6	55	59.1	68.2
Pre-op BC	10	10	14.2	18.3	10.8	10
ABGap	40.8	42.5	47.4	36.7	48.3	58.2
Titanium Prostheses						
Pre-op AC	45.6	51.9	60.2	54.8	60.1	66.9
Pre-op BC	10	10	14.5	19.1	11.6	9.6
ABGap	35.6	41.9	45.7	35.7	48.5	57.3

*AC: Air conduction

*BC: Bone conduction

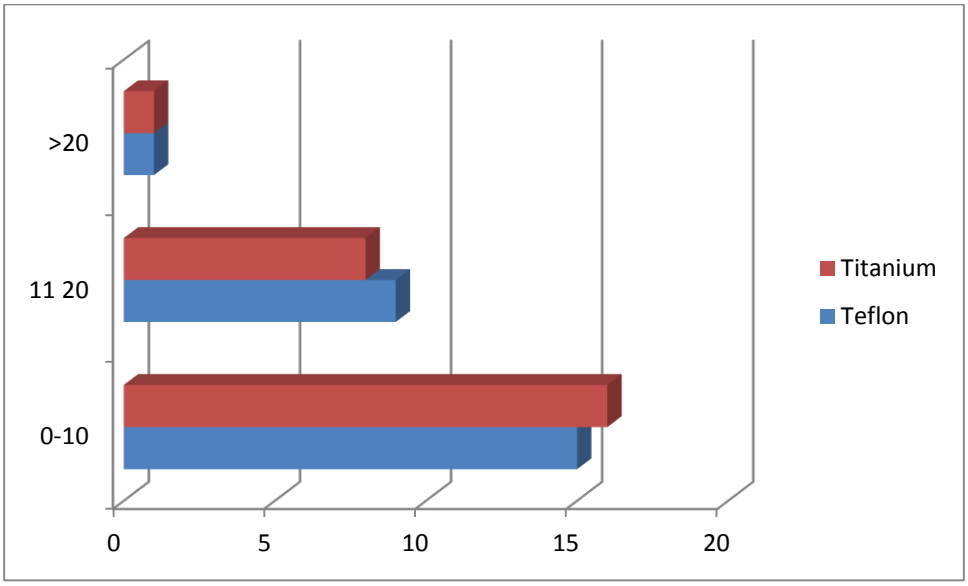
Table 2: Mean postoperative Hearing results (db HL) for patients who underwent stapedotomy with Teflon and titanium prostheses at a period of 6 months:

	Frequency (Hz)					
	250	500	1000	2000	4000	8000
Teflon prostheses						
Post-op AC	19.8	16.4	21.1	24.9	26.1	31.1
Post-op BC	11.1	11.1	13.9	18.1	12.5	13.3
ABGap	8.7	5.3	7.2	6.8	13.6	17.8
Titanium Prostheses						
Post-op air	24.3	20.4	24.1	28.1	44.3	48.1
Post-op BC	10.1	10.9	15.3	20	24.4	40
ABGap	14.2	9.5	8.8	8.1	19.9	8.1

Table 3: Comparison of ABGap of Teflon and Titanium pistons at 6 months in terms of number and percentage.

	Teflon	**Titanium**
0-10 (Successful Outcome)	15 (60%)	16 (64%)
11-20 (Satisfactory Outcome)	9 (36%)	8 (32%)
>20	1 (4%)	1 (4%)

Fig: 1 Comparison of Teflon and Titanium prostheses in closure of ABGap. The horizontal axis represents the ABgap at an interval of 10 dB HL. The vertical cases represent the number of patients.



DISCUSSION:

Both Teflon and Titanium prostheses are biocompatible and permits adequate transmission of sound.

The difference in design makes the operative steps differ during placement of prostheses Titanium 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. It covers 60% of circumference of Incus. Teflon piston is crimped completely around the long process of incus. (4, 5) However both these prostheses also differ in its cost, Teflon model being much cheaper than the Titanium prostheses.

The first implantation of the a'Wengen type of Titanium stapes piston was performed in September 2000, and U.S. Food and Drug Administration approval was received in June 2002.

(6) A'wengen prostheses has been used successfully by several surgical teams. The results of their efforts showed that outcomes of this prostheses are comparable to standard prostheses, but not significantly better. (7-10)

Massey et al. studied the effect of Titanium and Teflon wire prostheses which showed that both prosthesis give acceptable results with postoperative ABG of 20db or less in 97.8% of Teflon pistons and 97.1% of Titanium prostheses. (11) Hornung et al. studied the comparison of titanium clip aWengen prostheses to soft clip prostheses and showed that ABG was better than 10 db in 60.9% of first group and 52.3% of soft clip group. (12)

The difficulty in using the W clip(aWengen) model was described by Schimanski(13). The design of the piston makes its head, occupy a greater space in middle ear. Hence, experience is also an important factor in insertion of titanium prostheses.(14)

Kurz medizmentechnik has further modified the soft clip piston in which the head protrudes less and takes up less space in middle ear. (13)

Displacement of prostheses shows that proper experience and postoperative care play a very crucial role in stapes surgery. The study, however, has a comparison of two materials Teflon and Titanium, yet the design of the two prostheses being different, acts as a confounding factor. Random number of patients has been selected from a group of patients undergoing stapedotomy surgery. But in order to apply pair t test equal numbers of patients were selected from both groups. This also encounters bias in study. The sample size in study is also small. Follow up done at an interval of 6 months, reveals that after initial survey of 6 months in each case, postoperative ABGap doesnot change much statistically. Hence an average time for audiometery for a successful stapes surgery can be supported as ideal at 6 months. However, long term studies are still required to watch for delayed necrosis of long process of incus in both prostheses.

CONCLUSION:

Both Teflon and Titanium prostheses provide almost equal benefits to patients in terms of ABGap, and there is no statistically significant difference between them. Teflon prostheses are, however cheaper than Titanium. The clipping and crimping of prostheses requires experience. Long term audiometric results and post-operative complications are yet to be analyzed.

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