Our Experience with the Titanium Soft Clip Piston Stapedotomy

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Abstract The crimping of stapes prosthesis to the long process of incus has always been the bugbear of an otologist. Malcrimping on one hand can lead to necrosis of the long process on the other it can lead to a residual air-bone gap or a postoperative reappearance of the conductive hearing loss. To solve these problems different types of stapes prostheses having different techniques to achieve a secure attachment to incus have been devised. Retrospective analysis of patient data. Tertiary care hospital. Case records of 20 patients of otosclerosis who had undergone stapedotomy using titanium soft clip stapes piston (Kurz, Germany) were retrospectively analysed. This new type of stapes piston is a modification of the earlier àWengen clip piston (Kurz, Germany) which was designed to avoid the crimping onto the incus in stapedotomy. Hearing results were analyzed using American Academy of Otolaryngology-Head and Neck Surgery guidelines including 4 frequency pure tone average. The mean postoperative air-bone gap was within 10 dB in 8 (40% of cases), up to 15 dB in another 8 (40%) cases and in rest 4 (20%) was within 20 dB. No adverse reactions occurred during follow-up. The use of the titanium soft clip stapes piston gives good results in cases of stapedotomy for otosclerosis. The soft clip design is a new development in the evolution of stapes piston prostheses. Surgical introduction, placement,

and fixation are easier than the earlier àWengen design of clip piston.

Keywords Otosclerosis · Stapedotomy · Clip piston

Introduction

Historically many techniques have been used for treatment of otosclerosis but the most widely used has been the surgical technique introduced by Shea [1] in 1958. This original technique of stapedectomy has undergone refinement over the years and has been more or less replaced by stapedotomy. Along with modification of the surgical technique the prosthesis has also evolved resulting in a better post surgical hearing outcome. Most widely used stapes prosthesis is the Teflon piston [2]. Achieving stable fixation of the stapes prosthesis to the long process of incus is the bugbear of stapes surgery. A loose prosthesis will result in a poor postoperative hearing result and a higher incidence of displacement. Too tight an attachment onto the incus will result in incus erosion [3]. 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 àWengen [4]. 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. This clip piston was later on modified by Schimanski et al. [5] to decrease the force of application of the prosthesis and to fit various anatomical variations of the long process of incus (Fig. 1).

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Fig. 1 Wengen and soft clip titanium piston prostheses

Our experience of using this new soft clip stapes piston prosthesis is presented in this study.

Materials and Methods

Case records of 20 patients of otosclerosis who had undergone stapedotomy over a period of 1 year using titanium soft clip piston (KURZ-Medizintechnik, Germany) were reviewed. Out of 20 patients 13 were males and 7 were females. Right ear was operated upon in 14 cases and left in 6 patients. In all cases a piston of 0.4 mm diameter was used. In all the cases a fenestra of 0.6 mm was made in the stapes footplate using a Skeeter drill. In majority (13 patients) a 4.5 mm long piston was used, 3 required a piston of 3.75 mm length another 3 had 4.25 mm and only 1 was implanted with a 4.0 mm long piston. After implantation the opening in stapes footplate around the piston was sealed with blood clot in all the cases (Table 1).

The patients were followed for a minimum of 6 months and all the audiometric data was collected and analyzed according to the American Academy of Otolaryngology-Head and Neck Surgery guidelines [6] using Microsoft Excel software.

Results

Of the twenty patients included in this study the youngest was 16 years and the eldest was 48 years with the average age of 29.1 years. Air-bone gap was calculated using mean

Table 1 Demographic data of the patients

Serial no.	Age	Sex	Laterality	Piston size (mm)
1	23	Female	Left	4.25
2	40	Female	Right	3.75
3	20	Male	Right	4.50
4	16	Male	Right	4.50
5	28	Male	Right	4.25
6	20	Male	Right	3.75
7	36	Male	Left	4.50
8	30	Female	Right	4.50
9	38	Male	Right	4.50
10	48	Male	Right	4.50
11	43	Male	Right	4.25
12	27	Male	Right	4.50
13	20	Female	Left	4.00
14	28	Female	Left	4.50
15	24	Male	Right	4.50
16	22	Female	Left	4.50
17	40	Female	Right	3.75
18	16	Male	Right	4.50
19	36	Male	Left	4.50
20	27	Male	Right	4.50

of audiometric values at 0.5, 1, 2 and 3 kHz. The minimum preoperative air-bone gap was 29 dB and the maximum was 56 dB with an average of 41.5 dB (SD 7.39). At 6 month's follow up mean postoperative air-bone gap was within 10 dB in 8 (40% of cases), up to 15 dB in another 8 (40%) cases and in rest 4 (20%) was within 20 dB, the average air-bone gap was 13 dB (SD 4.37) with a range from 7 to 20 dB (Table 2). So the average closure of air-bone gap was found to be 28.5 dB. 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.

Bone conduction threshold mean was calculated using audiometric values at 1, 2 and 4 kHz. The average value of preoperative and postoperative bone conduction was 13 dB (SD 8.70) and 15.5 dB (SD 7.94) respectively. Sensorineural hearing loss of more than 5 dB was seen in only one patient who had a loss of 12 dB. In 5 cases slight improvement (2–5 dB) was found in bone conduction thresholds postoperatively.

Table 2 Audiometric data at 6 months follow up

A-B gap (dB)	No. of cases	Percentage
10	8	40
15	8	40
20	4	20

The average value of postoperative air conduction threshold was found to be 25.65 dB (SD 8.58) with a range from 18 to 48 dB.

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 in too tight cuts through the incus as was demonstrated by Marquet [7] in revision surgeries where earlier a wire loop prosthesis was used. Lesinski [8] saw in revision surgeries that a loose prosthesis can also cause notching of the long process leading to incus erosion and necrosis.

To obviate these problems of improper crimping of stapes prosthesis onto long process of incus, àWengen 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 circumferentially.

Schimanski et al. retrospectively evaluated surgical records of 275 stapes surgeries done using àWengen 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 àWengen 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 to àWengen clip piston that is why this new clip prosthesis is also referred to as the soft clip piston. The application force was also reduced by up to 45% making it easier to clip onto the long process of incus without any risk of dislocation of the malleo-incudal joint.

Zurr et al. [9] 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 [10] on comparing the results of àWengen 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 [8, 9]. We found that the new soft clip piston is easier to implant than the àWengen clip piston because of the changes in the design of the clip. 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 than that required for an àWengen clip piston.

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