A Prospective Study of Efficacy of Small Fenestra Stapedotomy at a South Asian Center

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Abstract

Introduction The best surgical treatment for otosclerosis is stapedotomy. Various methods are used for creating fenestra, including manual pick, laser, and Skeeter drill. In India, despite several studies on the hearing outcomes of otosclerosis surgery, there exist few studies on small fenestra stapedotomy performed using a microdrill. Hence, we designed this study with the objectives of examining the demographic profile, hearing improvement after surgery, anatomical variations encountered at surgery, effect of microdrill use on bone conduction (BC), and postoperative complications of small fenestra stapedotomy.

Methods A prospective study was conducted for 63 patients of otosclerosis. Stapedotomy was performed by the same surgeon on all patients by a transcanal approach under local anesthesia. Small fenestra stapedotomy was performed using Skeeter microdrill. The study proforma included sociodemographic profile, clinical history, examination, audiometry, surgical details, and postoperative findings. Descriptive statistics was used to analyze the data.

Results Our study demonstrated a male preponderance (58.7%) over females (41.3%). Of the study population, 31.7% reported a family history of otosclerosis, whereas nine (14.28%) individuals had a history of measles. All four different types of footplates were identified. Most of them were either type 1 (52.4%) or 2 (34.9%). In most cases, the diameter was 0.4 mm (96.8%), a majority of the cases having either 4.25 (22.2%) or 4.5 mm (63.5%) long piston. After stapes surgery, the mean ABG reduced from 39.48 (±9.17) to 13.89 (±7.99) dB. The mean worsening in postoperative BC was only 3.035 dB. Use of microdrill caused only a slight and statistically insignificant decline in BC. Anatomical variation of a narrow oval window niche may require drilling of the bone. In practice, this drilling does not adversely affect the BC of the patient. Some facial nerve variation (partially overhanging facial nerve and exposed facial nerve) may be encountered, but it does not affect the facial nerve function or hearing improvement. On rare occasions, facial paresis may occur on the fifth to sixth postoperative day, even without facial nerve handling. This can be managed conservatively with oral steroids with favorable results. Taste alterations are seen even when the chorda handling is minimal. Complaints are most common in the first few weeks after surgery. Over a 6-month period, only 5% of the patients who underwent surgery were found to have altered taste sensation.

Conclusion Microdrill-assisted small fenestra stapedotomy, performed under local anesthesia, with placement of a 0.4-mm Teflon piston for patients with otosclerosis produces excellent results. The complication rates are low, and the surgery has a positive impact on the patient's hearing.

Keywords
- ► otosclerosis
- ► skeeter drill
- ► stapedotomy
- ► teflon piston

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Introduction

Otosclerosis is an exclusive disease of the otic capsule, characterized by disordered resorption and deposition of bone leading to conductive hearing loss from 5 to 60 dB. The incidence of otosclerosis varies between regions, as it is race dependent, besides depending on age and sex within the race. Management options include fluoride supplementation, hearing aids (conventional and bone anchored), and stapes surgery. The choice between surgery and using hearing aids depends on factors, such as the patient's age, attitude to risk, consideration of aesthetics, and quality of life.

The outcomes of various treatment modalities for otosclerosis must be measured both objectively and subjectively. In India, despite many studies on the hearing outcomes of otosclerosis surgery, there exist few studies on small fenestra stapedotomy performed using a microdrill. Hence, we designed this study with the objectives of examining the demographic profile, hearing improvement after surgery, anatomical variations encountered at surgery, effect of microdrill use on bone conduction (BC), and postoperative complications of small fenestra stapedotomy.

Methods

Sample Size Estimation

Analysis of long-term hearing gains after stapes surgery has shown an average air conduction (AC) hearing gain of 35 dB over the speech frequencies.[1-4] Similar to these studies, we expected an average postoperative AC gain of 30 dB in our study population. Hence, the sample size was estimated to be 63 dB with the following formula:

$$N = [2\,(Z_\alpha + Z_{1-\beta})^2 \times \sigma^2]/\Delta^2$$

where Z_α = 1.96 (at 5% significance); $Z_{1-\beta}$ = 0.8416 (at 80% power); σ = standard deviation = 1.5, Δ = effect size = [(40 − 10)/40] × 100 = 75%

Patients presenting to the outpatient department (OPD) of KKR ENT hospital fulfilling the following criteria were taken as study subjects.

Inclusion Criteria

1. Intact tympanic membrane with pure tone audiometry (PTA) showing a conductive hearing loss with an air–bone gap (ABG) of at least 20 dB with impedance showing A or A's-type curve.
2. Age between 18 and 60 years.

Exclusion Criteria

1. Patients not consenting to the study.
2. History of previous surgery in the study ear.
3. Patients with conductive deafness not attributable to otosclerosis.
4. Patients with associated vertigo or aural fullness (coexisting Meniere's or benign paroxysmal positional vertigo [BPPV]).
5. Pregnant females.

Complete information regarding the treatment options was explained, and a written informed consent was obtained for surgery. A proforma was prepared for the study, which included demographic profile, clinical history, examination surgical details, and postoperative follow-up on first, third, and sixth month. Preoperative and postoperative PTA (GSI AudioStar Pro, Minnesota, United States) and impedance audiometry (Interacoustics AT235, Assens, Denmark) were recorded for BC and AC over the frequencies of 250, 500, 1,000, 2000, and 4,000 Hz.

Stapedotomy was performed by the same surgeon on all patients by a transcanal approach. To facilitate assessment of hearing improvement on table, surgery was performed under local anesthesia (a solution of 1:50,000 adrenaline prepared from 5 mL of 2% Xylocaine, 5 mL of distilled water, and 0.2 mL of 1 in 1,000 adrenaline, 2–3 mL infiltrated with a 1.5-in 26 G needle, in the posterior quadrant of the external auditory canal, approximately 1 cm from the annulus). A tympanomeatal flap was elevated, and any anatomical variations, such as narrow oval window niche, partial prolapse of facial nerve, were observed and recorded in the study proforma. Chorda tympani was identified and retracted anteriorly. Bone was curetted from the scutum to expose the incudostapedial joint, the stapedius tendon, the pyramid base, and the stapes footplate. The stapes footplate was inspected, and the ossicles were gently palpated, thus confirming the diagnosis. The stapedius tendon was cut with microscissors, and the incudostapedial joint was dislocated with a right-angled pick. The stapes suprastructure was downfractured gently and was removed. A microdrill (Skeeter system, Xomed-Treace, Jacksonville, Florida, United States; in all but one case, where the footplate was removed inadvertently while fracturing the crura) with a 0.5-mm diamond burr was used to make the fenestra (of approximately 0.6 mm) in posterior part of stapes footplate. Drilling was usually done for 30 to 40 seconds at 7,000 to 12,000 rpm depending on the type of footplate.[5,6] In patients who had a narrow oval window niche, the bone of the promontory was drilled with 0.7-mm Skeeter burr until footplate was visualized. A measuring jig was used, and a Teflon piston of appropriate length was used, supported with a small piece of blood-soaked Gelfoam. The loop of the piston was gently crimped to the long process of the incus. The tympanomeatal flap was repositioned, and the external ear canal was packed with absorbable Gelfoam soaked in antibiotic drops. Patients were reviewed on the fourth postoperative day for canal pack removal. Subsequently, patients were reviewed on the first, third, and sixth postoperative months. PTA was performed at each visit, and findings were recorded.

Results

Distribution of study population by footplate type, drill duration and speed, piston diameter, and length was done by chi-square test. The changes in mean values of PTA findings were assessed and compared between before and after surgery using paired *t*-test. Comparison of hearing outcomes in patients who underwent drilling for narrow niche with those with normal anatomy (hence no drilling of niche) was done using unpaired *t*-test (comparing means between two groups). Similar change in the mean value of PTA findings for 1, 3, and 6 months was assessed and compared using repeated measures analysis of variance (RMANOVA).

Demographic Profile and Examination Findings

Patients' age in the study population ranged from 18 to 67 years with a mean of 44.51 years (±11.989) and a median of 47 years. Of the total 63 patients, 37 were males (58.7%) and 26 were females (41.3%). Majority of patients were older than 35 years (►**Table 1**).

All patients had hearing impairment ranging from 5 to 360 months with a median of 36 months; 29 patients complained of tinnitus (46%), 20 (31.7%) had a family history of otosclerosis, and 9 (14.28%) had a history of measles (►**Fig. 1**). Thirteen (50%) women had a history of aggravation of the symptoms during pregnancy. In 53 (84.13%) patients, the disease was bilateral.

Air conduction was measured at 250, 500, 1,000, 2,000, 4,000, and 8,000 Hz, whereas BC was measured at 250, 500, 1,000, 2,000, and 4,000 Hz (►**Table 2**, ►**Fig. 2**). Impedance audiometry was A type in 45 (71.4%) patients and A's type in 18 (28.6%) patients.

Intraoperative Findings

The chorda tympani nerve was minimally manipulated in 59 (93.6%) patients, completely sectioned in 3 (4.8%), and partially injured in 1 (1.6%) patient.

Other anatomical variations included narrow oval window niche in seven (9.5%) patients, partial facial nerve overhang in two (3.2%) patients, persistent stapedial artery in one (1.6%), and exposed horizontal facial nerve in one (1.6%) patient.

Footplate was type I in 33 (52.4%), type II in 22 (34.9%), type III in 6 (9.5%), and type IV in 2 (3.2%) patients. However, the association between sex and the type of footplate was statistically not significant ($\chi^2 = 2.676$, $p = 0.444$; ►**Table 3**).

The piston diameter varied from 0.4 to 0.6 mm. In 61 (96.8%) patients, the diameter of piston was 0.4 mm. The length of the piston varied from 3.75 to 4.75 mm, with majority of patients (40 [63.5%]) requiring piston of 4.5 or 4.25 mm (22.2%).

Postoperative Hearing Outcomes

The mean values for AC, BC, and ABG at each frequency were compared before and 1 month after surgery using paired *t*-test (►**Tables 4-6**).

Comparison of mean values of BC by the duration of drilling is shown in (►**Table 7**). The mean worsening in postoperative BC was only 3.035 dB. Comparison of mean values of BC by the speed of drilling is shown in (►**Table 8**).

Comparison of the hearing parameters for seven patients who had a narrow oval window niche (the bone of the promontory was drilled with 0.7-mm Skeeter burr until

Table 1 Distribution of the study population by age and sex

Age groups	Sex		Total
	Male	Female	
< 35 y (%)	8 (21.6)	4 (15.4)	12 (19.0)
35–49 y (%)	12 (32.4)	13 (50.0)	25 (39.7)
> 50 y (%)	17 (45.9)	9 (34.6)	26 (41.3)
Total	37 (58.7)	26 (41.3)	63 (100.0)

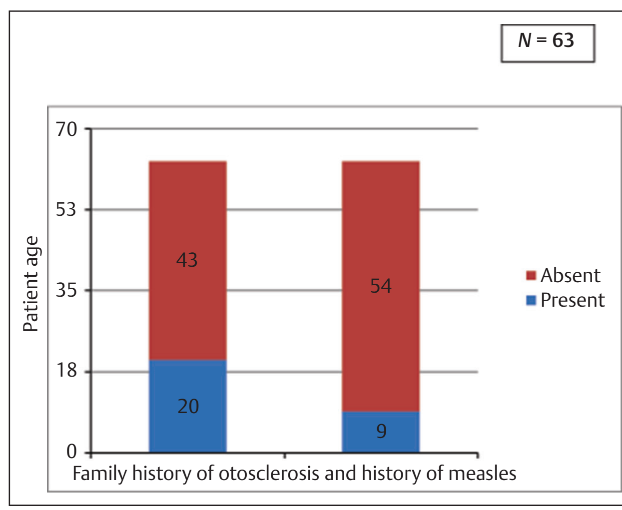

Fig. 1 Proportion of the study population with family history of otosclerosis and history of measles.

Table 2 Baseline mean (±SD) air conduction, bone conduction, and air–bone gap values at different frequencies

Frequency (Hz)	Mean (±SD) AC at baseline	Mean (±SD) BC at baseline	Mean (±SD) ABG at baseline
250	49.37 (±12.427)	8.33 (±5.750)	41.03 (±9.165)
500	52.06 (±12.529)	9.21 (±7.252)	42.86 (±9.277)
1,000	55.63 (±14.298)	14.52 (±9.702)	41.11 (±10.098)
2,000	53.73 (±15.912)	17.46 (±12.044)	36.27 (±11.708)
4,000	56.93 (±19.98)	18.63 (±13.58)	37.70 (±12.915)
8,000	58.05 (±18.98)	–	–

Abbreviations: ABG, air–bone gap; AC, air conduction; BC, bone conduction; SD, standard deviation.

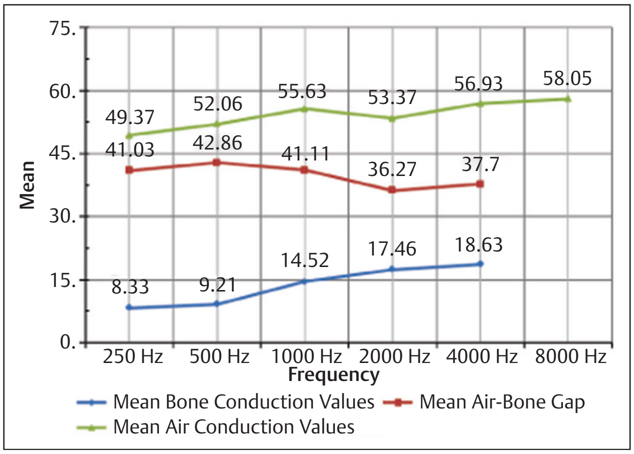

Fig. 2 Baseline mean air conduction, bone conduction, and air–bone gap values at different frequencies.

footplate was visualized) with seven randomly selected controls (with normal anatomy, no drilling of niche done) from the study group was performed (►**Table 9**). The unpaired *t*-test revealed no difference in hearing outcomes between these two groups.

Postoperative Complications

(►**Table 10**) enlists the complaints patients had at different postoperative visits. One patient developed sensorineural hearing loss as a complication of surgery. One patient developed facial paresis (House–Brackmann grade 4) on the sixth postoperative day and recovered completely with conservative treatment. (►**Table 11**) details the intraoperative handling of the chorda and its relation to the postoperative taste sensation.

Table 3 Distribution of the study population by sex and the type of footplate

Type of footplate	Sex		Total	Statistical significance
	Male	Female		
Type 1 (%)	22 (59.5)	11 (42.3)	33 (52.4)	$\chi^2 = 2.676$ $p = 0.444$
Type 2 (%)	12 (32.4)	10 (38.5)	22 (34.9)	
Type 3 (%)	2 (5.4)	4 (15.4)	6 (9.5)	
Type 4 (%)	1 (2.7)	1 (3.8)	2 (3.2)	
Total	37 (58.7)	26 (41.3)	63 (100.0)	

Table 4 Mean air conduction values at baseline (before surgery) and at 1 month after surgery: comparison using paired *t*-test

Frequency (Hz)	Baseline	1 mo after the surgery	*t*-Value	Statistical significance
250	49.37 (±12.427)	22.62 (±10.075)	17.563	0.000
500	52.06 (±12.529)	23.65 (±11.043)	19.802	0.000
1,000	55.63 (±14.298)	27.62 (±11.943)	17.753	0.000
2,000	53.73 (±15.912)	30.56 (±13.384)	16.128	0.000
4,000	56.93 (±19.98)	39.76 (±19.353)	11.968	0.000

Table 5 Mean bone conduction values at baseline (before surgery) and at 1 month after surgery: comparison using paired *t*-test

Frequency (Hz)	Baseline	1 mo after the surgery	*t*-Value	Statistical significance
250	8.33 (±5.750)	9.37 (±5.922)	−1.496	0.140
500	9.21 (±7.252)	11.03 (±7.681)	−1.924	0.059
1,000	14.52 (±9.702)	14.68 (±9.196)	−0.174	0.862
2,000	17.46 (±12.044)	18.33 (±10.999)	−0.737	0.464
4,000	18.63 (±13.58)	21.31 (±13.475)	−3.245	0.002

Table 6 Mean ABG values at baseline (before surgery) and at 1 month after surgery: comparison using paired *t*-test

Frequency (Hz)	Baseline	1 mo after the surgery	*t*-Value	Statistical significance
250	41.03 (±9.165)	13.25 (±7.249)	20. 061	0.000
500	42.86 (±9.277)	12.62 (±6.467)	23.402	0.000
1,000	41.11 (±10.098)	12.94 (±7.050)	20.178	0.000
2,000	36.27 (±11.708)	12.22 (±6.207)	15.507	0.000
4,000	37.70 (±12.915)	19.13 (±15.620)	8.394	0.000

Abbreviation: ABG, air–bone gap.

Table 7 Mean bone conduction values distributed by the duration of drilling

Drill duration	Total no. of patients	Mean preoperative BC	Mean postoperative BC
< 30 s	55 (87.3 %)	13.56 (±8.690)	16.77 (±10.878)
30–60 s	5 (7.9%)	12.40 (±7.829)	17.00 (±7.213)
> 60 s	2 (3.2%)	14.00 (±11.314)	22.50 (±15.910)
No drill	1 (1.6%)	37.00	51.25

Abbreviation: BC, bone conduction.

Table 8 Mean values distributed by the speed of drilling

Speed of drilling	Total no. of patients	Mean preoperative BC	Mean postoperative BC
No drill	1 (1.59%)	37.00	51.25
Less than full (around 7,000 rpm)	54 (85.71%)	13.56 (±8.690)	16.77 (±10.878)
Full speed (around 12,000 rpm)	8 (12.70%)	12.86 (±7.925)	18.57 (±9.169)

Abbreviation: BC, bone conduction.

Table 9 Comparison of hearing outcomes in patients who underwent drilling for narrow niche with randomly selected control group

	Total no. of cases	Average gain in AC at 0.5, 1, 2, and 4 kHz	Postoperative ABG	Mean increase in postoperative BC
Narrow niche (promontory bone drilled with 0.7-mm burr and Skeeter drill)	7	25 (±12.22) dB	12.63 (±4.54) dB	3.035 (±5.81) dB
Normal anatomy (drilling not done)	7	20.71 (±7.93) dB	11.38 (±4.329) dB	1.428 (±4.86) dB
t-Value using unpaired *t*-test	–	0.7780	0.5610	0.5275
p-Value	–	0.456	0.585	0.6075

Abbreviations: ABG, air–bone gap; AC, air conduction; BC, bone conduction.

Table 10 Patient complaints at different follow-up visits

	First wk *(N)*	First mo *(N)*	Third mo *(N)*	Sixth mo *(N)*
Tinnitus (%)	8 (12.7)	10 (15.9)	7 (11.1)	3 (4.8)
Altered taste (%)	10 (15.9)	11 (17.5)	5 (7.9)	3 (4.8)
Giddiness (%)	4 (6.4)	1 (1.6)	1 (1.6)	0 (0.0)
Discomfort in loud noise (%)	4 (4.8)	12 (19.0)	11 (17.5)	9 (14.3)
Hard of hearing (%)	1 (1.6)	4 (6.4)	5 (8.0)	3 (4.8)
Ear-blocked sensation (%)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)
Facial palsy (%)	1 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)
Patients without any complaints (%)	39 (61.9)	31 (49.2)	37 (58.73)	44 (69.84)

N = 63, but the numbers in each category are not mutually exclusive, and hence the total will not come up to 63.

Discussion

The distribution of otosclerosis in western studies among men and women has been found to be in the ratio of 1:1.4. In our study, this ratio was found to be 1.4:1.[7] This apparent difference in distribution may be indicative of the poorer health-seeking behavior among Indian women, in comparison with western women. It may also be due to the relatively smaller sample size in our study. Familial cases of otosclerosis constituted 31.7% of the study population, supporting the strong genetic association.[8,9] In addition, 14.28% had a history

Table 11 Chorda tympani handling and taste sensation

Type of chorda handling	No. and % of patients	No. and % with altered taste at 1 mo	No. and % with altered taste at 3 mo	No. and % with altered taste at 6 mo
No or minimal handling (%)	59 (93.6)	8 (13.5)	5 (8.4)	3 (5)
Injury with Skeeter burr (%)	1 (1.6)	0	0	0
Chorda sectioned (%)	3 (4.8)	1 (33.33)	0	0
Total	63	9	5	3

of measles. The incidence of tinnitus in our study population was 46%, as compared with other studies reporting incidence from 65 to 74%.[10,11]

A narrow oval window niche was encountered in 9.5% of patients. Drilling was done with a 0.7-mm Skeeter drill burr to access the footplate. Theoretically, this procedure may result in damage to the cochlear endosteum and thus cause sensorineural hearing loss.[12] The worsening in BC thresholds was 3.5 dB that was comparable to that of other patients who did not have this anatomical variation, and no significant deleterious effect was observed in the BC of these patients.

Facial nerve variations (4.8%) included partial overhang (3.2%) and exposed tympanic segment (1.6%). Prosthesis was placed in the segment of the footplate that was away from the facial nerve. Ballestar et al[13] found that 6.7% of the cases of stapedotomies had variations of the facial nerve including prolapse and exposed tympanic segment. No audiologic or neurologic complications were encountered among these patients in the postoperative period.

A persistent stapedial artery is a rare surgical finding and was seen in one patient. This artery can cause troublesome bleeding, if violated. It is advised to coagulate or cauterize the vessel, if not too large. Another option is to move the artery to one side, which was the technique used in our study.

Hearing outcomes showed a statistically significant improvement in the mean AC values at all the frequencies. The gain was highest in the low frequencies followed by that in the speech frequencies and at 4,000 Hz. Overall four frequency AC gains were found to be very similar to the four frequency AC gain seen in other studies.[3,14,15] Similar statistically significant improvement was observed in the mean ABG. In our study, 90.48% of the patients demonstrated a postoperative ABG of 41.27% in the 0 to 10 dB group and 49.21% in the 11 to 20 dB group. This indicates that small fenestra stapedotomy gives good closure of ABG in a larger number of patients.

There was a slight worsening in the BC values at all frequencies, which was not statistically significant. The worsening was higher when the drilling was done at full speed (12,000 rpm).[6] However, the number of patients in the groups in which drill duration was between 30 and 60 seconds and more than 60 seconds was too small to perform statistical analysis. Perhaps prolonged duration and higher speed of drill could be more deleterious to the delicate inner ear structures. To our knowledge, no study has analyzed the effect of microdrill duration and effect of drill speed on BC. Further studies in a larger number of patients, distributed evenly in the various subgroups of drill duration and drill speed, may provide more clarity on the effect of these particular aspects of drill use.

We compared our overall hearing results based on piston diameter versus another study done by Marchese et al,[16] in which Schuknecht Teflon wire prosthesis was used at two diameters: 0.6 and 0.4 mm. Based on hearing outcomes, the study concluded that the 0.6-mm piston gave better results. In an overwhelming majority of our study population (96.8%), a Teflon piston of diameter of 0.4 mm was used. The values of ABG and AC gains (both AC PTA and at individual frequencies) from our study (0.4-mm Teflon piston) remain better than those obtained with a 0.6-mm Teflon wire prosthesis in the study by Marchese et al. Apart from the difference in piston diameter, use of different types of prostheses and the variations in surgical techniques employed in each of these studies could have influenced the hearing outcome.

Postoperative Complications

In one (1.6%) patient, part of the footplate was removed while fracturing the crura, and the patient developed sensorineural hearing loss after surgery. This number is comparable to the incidence of sensorineural hearing loss of 0.5 to 3% in other series.[3,17]

One patient developed facial paresis (House–Brackmann grade 4) on the sixth postoperative day. He did not have any significant intraoperative findings and had an uneventful surgery. He was treated with a tapering course of oral corticosteroids and recovered completely in a few weeks. This rare complication has been reported to occur in approximately 0.5% of the population between the 5th and 20th day. It resolved within 1 to 2 months of treatment on the lines of Bell's palsy management.[18]

Four patients complained of giddiness within the first week. They were treated with labyrinthine sedatives. One of these patients complained of mild giddiness occasionally for up to the third month and improved thereafter; 14.3% patients complained of improvement in hearing but discomfort in noisy environments. This is a known complication of cutting the stapedius tendon.

Damage to the chorda tympani occurred in around 30% of the patients and caused dry mouth, soreness of tongue, and metallic taste.[19] In our study, the most common complaints included altered taste, metallic taste, and numbness over the tongue. Chorda tympani underwent minimal manipulation, that is, it was gently moved away from the field without stretching or injuring it in 93.6% patients. In this subgroup, by the end of the first month, 13.5% had taste-related complaints. By 3 and 6 months, the percentage reduced to 8.4 and 5%, respectively, in this group. Chorda was injured with the Skeeter drill in one patient. However, the patient did not have any taste-related complaints postoperatively. Chorda was sectioned in 4.8% of patients who underwent surgery, and 25% of patients in this subgroup had altered taste sensation in the first month. The complaint did not persist in the subsequent follow-ups.

In a study by Just and colleagues,[20] the postoperative taste sensation was assessed subjectively and also by regional chemical taste test and electrogustometry in which the percentage of patients diagnosed to have taste dysfunction was found to be higher. Electrogustometry was found to be superior to regional chemical taste tests. In our study, the taste sensation was assessed only subjectively. In both our study and the above-mentioned study, the complaints were found to decline over time, although a small percent of patients continued to have troublesome symptoms.

Conclusion

Microdrill-assisted small fenestra stapedotomy, performed under local anesthesia, with placement of a 0.4-mm Teflon piston, causes good closure of ABG with minimum complication or long-term sequelae in patients with otosclerosis. Microdrill used for fenestration is safe when used for short duration and at lower speed. The complication rates are low, and the surgery has a positive impact on the patient's hearing.

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