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The Effect of Two Different Footplate Perforation Techniques on Bone Conduction Hearing Thresholds in Stapedotomy

Stapedotomide İki Farklı Taban Perforasyonu Tekniğinin Kemik Yolu İşitme Eşikleri Üzerine Etkisi

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ABSTRACT Objective: Today, the preferred surgical technique in the treatment of otosclerosis is stapedotomy. While many techniques are used to create a small window at the footplate of stapes, there is no consensus on the best technique. Our study aims to investigate the effect of microdrill and manual perforator on bone conduction hearing thresholds. **Material and Methods:** The patients who underwent stapedotomy in our clinic were compared retrospectively dividing into 2 groups as those with a manual perforator (Group I) and a microdrill (Group II). The difference between the bone conduction thresholds at 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, and 8000 Hz from the preoperative and postoperative pure tone audiometry tests were recorded, and the 2 groups were compared for each frequency separately. **Results:** There were 34 in Group I and 18 patients in Group II. There was no statistically significant difference between the groups in terms of gender, age, demographic data and preoperative bone conduction hearing thresholds. The groups were compared separately for each frequency in terms of the mean difference between preoperative and postoperative bone conduction thresholds, and no statistically significant difference was found between the groups at any frequency. **Conclusion:** The data obtained from our study shows that both the manual perforator and the microdrill are safe methods that can be used in the sole perforation of the stapedotomy operation. We believe that more studies are needed to compare the differences between the 2 techniques.

Keywords: Otosclerosis; conductive hearing loss; stapes; stapes surgery; pure tone audiometry

ÖZET Amaç: Günümüzde otosklerozun cerrahi tedavisinde tercih edilen cerrahi teknik stapedotomidir. Stapes tabanında küçük bir pencere oluşturmak için kullanılan birçok teknik bulunmakla birlikte, en iyi teknik hakkında bir görüş birliği henüz yoktur. Çalışmamızın amacı, mikrodrill ve manuel perforatörün kemik yolu işitme eşikleri üzerine etkisini araştırmaktır. **Gereç ve Yöntemler:** Kliniğimizde stapedotomi yapılan hastaların dosyaları retrospektif olarak incelendi. Hastalar, taban perforasyonu manuel perforatör ile yapılanlar (Grup I) ile mikrodrill ile yapılanlar (Grup II) olarak 2 gruba ayrıldı. Hastaların preoperatif ve postoperatif saf ses odyometri testlerinden 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz ve 8000 Hz'deki kemik yolu eşikleri ve aradaki fark hesaplanarak kayıt altına alındı ve 2 grup her frekans için ayrı ayrı karşılaştırıldı. **Bulgular:** Grup I'de 34 hasta, Grup II'de ise 18 hasta vardı. Gruplar arasında cinsiyet, yaş, demografik veriler ve preoperatif kemik yolu işitme eşikleri açısından istatistiksel olarak anlamlı bir fark tespit edilmedi. Grupların her frekans için ayrı olarak preoperatif ve postoperatif kemik yolu eşikleri arasındaki ortalama fark karşılaştırıldı ve hiçbir frekansta gruplar arasında istatistiksel olarak anlamlı fark tespit edilmedi. **Sonuç:** Çalışmamızdan elde edilen veriler, stapedotomi operasyonunda hem manuel perforatör hem de mikrodrillin taban perforasyonunda kullanılabilecek güvenli yöntemler olduğunu göstermektedir. İki teknik arasındaki farkları karşılaştırmak için daha fazla çalışmaya ihtiyaç olduğuna inanıyoruz.

Anahtar Kelimeler: Otoskleroz; iletim tipi işitme kaybı; stapes; stapes cerrahisi; saf ses odyometre

Otosclerosis is a disease characterized by cancellous bone growth within the otic capsule and consequent fixation of the footplate, with progressive hearing loss.[1] Since stapes surgery, first performed by Shea in 1958, the technique has been modified to this day, surgery is still the best treatment option among the treatment options.[2,3] Besides attaching the prosthesis to the long arm of the incus, perforating the stapes footplate and opening the perilymphatic space of the cochlea require speacial attention. In recent years, stapedotomy, rather than classical stapedectomy, has come to the fore as the preferred

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technique because of fewer complications and better post-operative hearing results.[4,5]

Today, otosclerosis surgery has been performed with a similar technique around the world, except for minor differences. Small fenestra stapedotomy is widely used with less iatrogenic trauma and postoperative complications.[6] Although many methods such as laser, microdrill, and manual perforator can be used to create a small window at the footplate of stapes, there is no consensus on the best method yet.[7] Although the laser technology is ahead of the other 2, the fact that it is not easily accessible by all centers, its complications such as heat and pressure trauma allow the other 2 techniques to be still widely used options.[8]

While manual perforator is thought to be more traumatic than microdrilling; microdrilling is a technique that is more likely to cause acoustic trauma.[9,10] Even a gentle opening of the cochlea can result in trauma to the inner ear. Although this usually improves over time, it may cause deterioration of postoperative bone conduction.[11] The aim of our study is to examine the postoperative bone conduction thresholds in patients who underwent stapedotomy in our clinic, as well as to investigate the effects of microdrill and manual perforator on bone conduction hearing thresholds and the difference between the 2 techniques.

MATERIAL AND METHODS

The data of 60 patients who underwent primary stapedotomy surgery by confirming the diagnosis of otosclerosis by exploratory tympanotomy between October-2011 and September-2021 in the Ear-Nose-Throat Clinic of Bakirköy Dr. Sadi Konuk Training and Research Hospital, a tertiary center university hospital, were retrospectively analyzed. The pure tone audiometry (PTA) test results of the patients preoperatively and at least 3 months postoperatively were reviewed. Demographic data of the patients, bone conduction thresholds at 500, 1000, 2000, 4000, and 8000 Hz were recorded. Eight patients were excluded from the study due to the unavailability of preoperative or postoperative PTA results. The remaining 52 patients were seperated into 2 groups as those with a manual perforator (Group I) and those with a microdrill (Group II). While all of the operations were primary surgeries, revision surgeries were not included in this study.

The bone conduction hearing thresholds at 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, and 8000 Hz from the preoperative and postoperative PTA tests of the patients were calculated and recorded, and the 2 groups were compared for each frequency separately. Mean bone conduction gains were calculated for the 2 groups by averaging the differences at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz, and the mean bone conduction gains of the two groups were statistically compared.

All operations were performed through a transcanal approach using a Leica M525 F20 (Leica Microsystems®, Wetzlar, Germany) surgical microscope under general anesthesia. Before the incision, 2% lidocaine+epinephrine (0.125 mg/mL) solution was infiltrated into the ear canal wall subperiosteally in 4 quadrants. Incisions were then made perpendicular to the tympanic membrane allowing elevation of the tympano-meatal flap to access the middle ear, and the 2 incisions were joined in the posterior quadrant approximately 5 mm lateral to the tympanic membrane. In order to have the footplate of stapes visible, the posterior wall of the external auditory canal curetted. Following the observation of the entire ossicular chain, footplate fixation was checked. An articular knife was used to separate the incudostapedial joint and the stapedial tendon was cut. Before puncturing the footplate of the stapes, the cruras were broken and the stapes superstructure was removed. In the group in which the perforation was made with a 0.7 mm diameter diamond drill tip attached microdrill (Skeeter Otologic Drill System, Medtronic Xomed Surgical Products, Inc.) was used at a rotation speed of 7,000 rpm (max). In the manual perforator group, the fenestra diameter was 0.8 mm. A 0.6 mm diameter Fluoroplastic piston (Causse Loop Piston Fluoroplastic, Medtronic Xomed, Jackonville, FL, USA, REF: 1129055) was used in all patients. After the piston was placed in both groups, the surrounding of the piston was supported with adipose tissue taken from the ear lobule or subcutaneous connective tissue.

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After the prosthesis was placed, the tympanomeatal flap was replaced and the external auditory canal was stuffed with Gelfoam. In the 2nd postoperative week, Gelfoam was cleared from the external auditory canal. Follow-up examinations at 1 month, 3 months, and 6 months after surgery were made. Postoperative PTA tests were performed at the 3rd and 6th months.

We conducted our study in accordance with the "Good Clinical Practices" and ethical standards specified in the Declaration of Helsinki. The study protocol was approved Bakırköy Dr. Sadi Konuk Training and Research Hospital Clinical Research Ethics Committee (date: January 3, 2022, protocol no: 2022/06, decision no: 2022-01-15).

For statistical analysis, IBM SPSS v.23 (IBM Corp., Armonk, NY, USA) was utilized. Gender and side distribution between the groups were compared with the chi-square test. Because the data distribution was not normal and the sample size was insufficient, nonparametric tests were used. Age, preoperative mean distribution of bone conduction hearing threshold values, and postoperative changes were analyzed using the Mann-Withney U test. Both groups were evaluated with the Kruskal-Wallis test in terms of hearing gains according to frequencies.

RESULTS

Fifty-four ears of 52 patients who fulfilled the criterias were recruited in the study. Both ears of 2 patients were operated with at least 6 months between surgeries. Twenty-four (46.2%) patients were male, whereas 28 (53.8%) were female. The mean age was 37.12±11.11 (15-61 years). While 26 (48%) right ear operations were performed, 28 (52%) left ears were operated. During stapedotomy, using a manual perforator in 36 (66.6%) ears for footplate perforation (Group I); microdrill (Group II) was used in 18 (33.3%) ears.

Whereas there were 16 male and 18 female patients in Group I; in Group II, there were 8 male and 10 female patients. While the mean age was 37.80±10.64 years in Group I, it was 35.88±12.39 years in Group II. In terms of gender distribution, side distribution, mean age, and preoperative bone conduction hearing thresholds, no statistically significant difference was detected between the groups (Table 1). Since the same piston type was used in all patients, the groups were not statistically compared in terms of piston effect on bone conduction hearing thresholds.

When the preoperative bone conduction hearing thresholds at 500, 1000, 2000, 4000, 8000 Hz and the differences between preoperative and postoperative bone conduction hearing thresholds according to the mean and frequencies were compared, it was seen that there was no statistically significant difference between the groups (Table 2). The groups were compared among themselves in terms of hearing gains according to frequencies. In both groups, the highest gain was obtained at 1000 and 2000 Hz, and the gains between frequencies were found to be statistically significantly different. The p values for Group I and Group II were p=0.001 and p=0.003, respectively. In Group I, the gain in the bone conduction was found to be lower at 8000 Hz compared to the other frequencies. In Group II, there was an increase in bone conduction thresholds at 8000 Hz compared to the preoperative period; however, the difference between the groups was not statistically significant.

DISCUSSION

In our study, the bone conduction thresholds of patients who underwent stapedotomy were evaluated

TABLE 1: Demographic characteristics of the groups.

	Group I (Manual perforator n=36)	Group II (Mikrodrill n=18)	p value
Age	37.80±10.64	35.88±12.39	0.563[a]
Sex	M=16, F=18	M=8, F=10	0.440[b]
Side	R=14, L=22	R=12, L=6	0.123[b]

n: Number; M: Male; F: Female; R: Right; L: Left; aMann-Whitney U test; bChi-square test.

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TABLE 2: Comparison of bone conduction hearing thresholds of the groups in terms of preoperative and pre-postoperative differences.

		Group I (Manual perforator n=36)	Grup II (Microdrill n=18)	p value*
500 Hz	Preoperative BCHT	20.13±8.65	20.55±9.83	0.757
	Pre-Postoperative Difference	3.47±7.25	5.27±8.98	0.657
1000 Hz	Preoperative BCHT	22.30±6.73	21.66±7.85	0.494
	Pre-Postoperative Difference	7.58±7.40	6.94±8.06	0.714
2000 Hz	Preoperative BCHT	24.02±8.35	23.61±10.26	0.744
	Pre-Postoperative Difference	8.33±7.07	6.11±8.83	0.433
4000 Hz	Preoperative BCHT	24.58±11.73	24.44±14.23	0.831
	Pre-Postoperative Difference	3.47±9.54	0.27±7.94	0.191
8000 Hz	Preoperative BCHT	25.27±12.70	26.11±14.09	0.911
	Pre-Postoperative Difference	2.22±10.03	-1.38±6.81	0.090
Average difference		5.71±8.86	3.12±10.54	0.112

*Mann-Whitney U test; BCHT: Bone conduction hearing threshold.

and compared with the changes in postoperative bone conduction thresholds in patients whom were used microdrills or manual perforators in the footplate perforation. In patients with otosclerosis, due to the fixation of the stapes footplate, sound waves cannot be transmitted to the cochlea, and air conduction thresholds rise, resulting in conductive hearing loss. However, it is frequently observed that conductive hearing loss is accompanied by sensorineural hearing loss. The loss of conduction in bone conduction is more difficult to explain. Eventhough an air-bone gap in PTA is expected to be seen in patients with conductive hearing loss, in case of otosclerosis, it might disappear around 2000 Hz with an increase in bone conduction threshold. This is a clinical phenomenon named the Carhart notch, which is a predictor of stapes footplate fixation, especially when it presents at 2000 Hz compared to 1000 Hz.[12] The Carhart effect was initially described by Carhart in 1950 in patients who demonstrate a recovery in bone conduction thresholds in the frequency range of 500 to 4000 Hz, with a maximum at 2000 Hz, following a successful fenestration surgery for otosclerosis.[13] Although the mechanism of the Carhart effect has yet to be fully understood, conventionally it is attributed to mechanical factors. It is thought that the additional energy lost through the external and middle ear due to conductive hearing loss leads to an increase in the bone conduction threshold.[14] Sabbe et al. reported that bone conduction was best observed at ossicular chain resonance (2000 Hz) after stapedotomy.[15] Ginsberg et al. stated that this improvement in bone conduction thresholds was observed mostly in the range of 500 to 2000 Hz.[16] Kos et al. found a decrease of 3±9.1 dB in bone conduction averages at 500, 1000, and 2000 Hz. However, they found that the bone conduction thresholds increased at 4000 Hz.[17] Ksilevsky et al. claimed that there was a decrease in bone conduction at all frequencies except 4000 Hz, and they attributed this to the increase in the bone conduction thresholds at high frequencies due to surgical trauma of the inner ear.[18] In this study, the decrease in the postoperative bone conduction hearing thresholds was 5.71±8.86 dB in Group I, and 3.12±10.54 dB in Group II, as it was found 4.41±9.7 dB in all patients. The highest bone conduction gain was at 1000 and 2000 Hz in both groups. While no statistical difference between the groups existed, the difference between frequencies was statistically significant, which supports previous studies.

The goal of otosclerosis surgery is to improve hearing and minimize the risk of hearing damage or other complications related to the stapes footplate fenestration that provides access to the inner ear.[10] Even though stapedotomy is generally considered a safe procedure with good results and few complications, it may result in sensorineural hearing loss in some cases.[19] There are studies reporting negative re-

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sults against the use of microdrill in otologic surgery because of complications such as mechanical or acoustic trauma, vibration, and as a result, hearing deterioration especially at high frequencies.[20-22] In addition to the fact that it takes longer and requires more care during the operation, the possibility of bone fragments escaping into the vestibule is a handicap of the manual perforator.[6]

Both Yavuz et al. and Gjuric et al. reported in their studies that the 2 methods provided similar postoperative hearing gain, while the microdrilling method did not cause more inner ear trauma than the manual perforator.[6,23] Likewise, Palacios-Garcia et al., when they compared the 2 methods, stated that the hearing thresholds did not differ significantly between the 2 methods and that one of them was not superior to the other in this respect.[24]

In our study, the fact that bone conduction hearing thresholds did not worsen, except for postoperative 8000 Hz bone conduction thresholds in the microdrill group, and that no statistically significant difference between the groups were detected comparing changes before and after surgery, supports the data obtained in previous studies.

The main constraint of our study was its retrospective nature. Moreover, other limitations are that bone conduction thresholds were not evaluated at frequencies above 8000 Hz, the effects of the perforation technique in the long term were not evaluated, and the surgeons performing the operations were different.

CONCLUSION

The data we obtained from our study show that both the manual perforator and the microdrill are safe methods that can be used for footplate perforation in the stapedotomy operation. We believe that more studies with a high number of patients are needed to compare the 2 techniques in terms of superiority to each other.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

***Idea/Concept:** Filiz Gülüstan, Zahide Mine Yazıcı; **Design:** Filiz Gülüstan, Nusret Solak; **Control/Supervision:** İbrahim Sayın, Zahide Mine Yazıcı; **Data Collection and/or Processing:** Filiz Gülüstan, Nusret Solak; **Analysis and/or Interpretation:** Mehmet Akif Abakay; **Literature Review:** Filiz Gülüstan, Nusret Solak; **Writing the Article:** Filiz Gülüstan, Nusret Solak; **Critical Review:** İbrahim Sayın, Mehmet Akif Abakay; **References and Fundings:** Filiz Gülüstan, Mehmet Akif Abakay; **Materials:** Filiz Gülüstan, Mehmet Akif Abakay.*

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