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Original Article

A Comparison Study of Partial Ossicular Reconstruction Prosthesis (PORP) Placement under the Malleus or Tympanic Membrane Graft in the Presence of the Malleus

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OBJECTIVE: The aim of this study was to compare the hearing results of embedding the partial ossicular reconstruction prosthesis (PORP) underneath the malleus with the malleus relocation technique and tympanic membrane graft in the presence of the malleus.

MATERIALS and METHODS: A retrospective review of patient charts and audiometric results in a tertiary referral center was conducted. In total, 83 patients who underwent intact canal tympanoplasty with mastoidectomy between 2010 and 2015 were included and divided into two different groups: malleus assembly to the stapes head (MASH) and tympanic membrane assembly to the stapes head (TASH). Pre- and postoperative audiometric results were assessed. The air-bone gap (ABG) and hearing gains were evaluated according to the groups.

RESULTS: In MASH, 86.1% (n=31) of the patients were received successful surgery and the postoperative average ABG was 10.41 dB. In TASH, 82.9% (n=39) of the patients were considered successful and the postoperative ABG was 13.27 dB. According to the overall data, MASH was more statistically successful than TASH, and hearing gains at 500 Hz ($p<0.036$), 2000 Hz ($p<0.031$), and PTA ($p<0.22$) were statistically significant better in the MASH group.

CONCLUSION: Malleus relocation is a successful technique with the presence of the malleus and provides better hearing outcomes than direct placement under the tympanomeatal flap. Both malleus- and tympanomeatal flap-linked groups were successful, but the malleus-linked group showed better ABGs.

KEYWORDS: Ossiculoplasty, malleus, ossicular replacement prostheses, PORP, tympanic membrane, tympanoplasty

INTRODUCTION

The middle ear ossicles are uniquely shaped structures that collect sound waves from the tympanic membrane (TM) and conduct them to the inner ear. For this reason, the ossicles are thought to be the most important structures in the middle ear for hearing. Infective agents, inflammatory processes, and trauma can prevent the normal functions of these structures. Chole [1] reported that ossicular involvement might be detected at more than half the chronic middle ear diseases. The long process of the incus is the most commonly affected part and causes disruption of ossicular chain integrity [2]. Therefore, it becomes a challenge for otologists to provide the best hearing results for patients who have ossicular problems.

Various materials have been described, and different success rates have been reported for this purpose [3]. Titanium ossicular replacement prostheses are some of the most popular materials within this prostheses group [4, 5]. In spite of the lightness in weight, titanium can show a tensile strength and reliable biocompatibility over other materials [6]. The presence of the stapes determines the concept of ossicular reconstruction and partial ossicular replacement prosthesis (PORP) that can be used successfully between the intact stapes and TM graft or malleus handle. Dornhoffer and Gardner [7] reported that the absence of the malleus had a significant detrimental influence on hearing results in a large study group, and Meulemans et al. [6] also showed that the pure tone average (PTA) air–bone gap (ABG) was smaller in the malleus-preserved group than in the malleus-absent group.

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Vincent et al. [8] described the malleus relocation technique for both PORP and TORP applications and discussed the beneficial effects. According to our knowledge, none of the current studies documented comparisons in the hearing results of PORP placement options in the presence of the malleus. In this study, we compared the hearing results of embedding the PORP underneath the malleus with the malleus relocation technique and TM graft in the presence of the malleus.

MATERIALS and METHODS

Patient Selection

This study was designed as a retrospective descriptive study, and data was obtained from the medical records of patients who underwent intact canal wall tympanoplasty with mastoidectomy (ICWT) in Kocaeli University School of Medicine otolaryngology department. All surgeries were performed under the consultation of a senior otologist between 2010 and 2015.

Those who underwent ossiculoplasty for Austin–Kartush group A impairments with PORP (Vario Bell PORP; Heinz Kurz® Medizintechnik GmbH, Dusslingen, Germany) during ICWT operations were the main patients. Stapes fixation, cholesteatoma involvement of the malleus, ineligible mucosal inflammation, wet middle ear, and accompanying bony canalplasty were the intraoperative exclusion criteria for this study and were checked from operation notes. Otoscopic and audiometric examinations were performed 6 months postoperatively. Patients who had re-perforations and/or prosthesis extrusions were excluded from the study.

In total, 83 participants were included and divided into two different groups: malleus assembly to the stapes head (MASH), and TM assembly to the stapes head (TASH). The same terminology from previously published studies was used [9]. Thirty-six (44.4%) patients (females: 19, males: 17) were included in the MASH group, and their ages ranged from 18 to 62 years (mean: 31.9, median: 29, std dev: 13.1). Forty-seven (56.6%) patients (females: 24, males: 23) were included in the TASH group, and their age distribution ranged from 18 to 64 years (mean: 34.8, median: 32, std dev: 13.5).

Surgical Technique

All patients were operated upon by retroauricular intact canal tympanoplasty with mastoidectomy under general anesthesia. After elevation of the tympanomeatal flap, discontinuity between the incus and stapes was evaluated. The disconnected incus was removed gently, and the malleus was dissected from the TM. Anterior ligaments, superior ligaments, and tensor tympani muscles were preserved. The TM was reconstructed with temporal muscle fascia or conchal perichondrium with a little cartilage groove according to the classic over-underlay technique.

The ossicular reconstruction technique was considered due to the position of the malleus and stapes. In the MASH group, the malleus was gently retracted to the head of the stapes to maintain a favorable vertical position and the PORP was interposed between the stapes capitulum and malleus manubrium. Some of the patients had a narrow middle ear or severely medialized malleus; however, the PORP was used to reconstruct the hearing. The PORP was interposed on the lateral aspect of the stapes capitulum and anchored to the posterior superior quadrant of the TM flap to maintain vertical tension for better sound transmission. These surgical interventions were considered in the TASH group. Small cartilage fragments were placed on the head of the prostheses in order to avoid extrusion. Before the placement of the PORP, the proper size was adjusted in all cases for the essential tension with a plastic dummy, which was provided by the manufacturer.

Audiometry

All patients underwent a preoperative hearing test, and an AC 40 audiometer (AS DK-5610 Interacoustics®, Assens, Denmark) was used. Pure tone thresholds (PTTs) of the air conduction (AC) and bone conduction (BC) were determined at frequencies of 500, 1000, 2000, and 4000 Hz according to the criteria of the International Bureau of Audiophonology (BIAP) [10]. Postoperatively (6 months after the surgery), AC-BC levels were determined and the ABG was calculated for each related frequency. If the ABG was 20 dB or less, the operation was considered successful.

Statistical Analysis

All statistical analyses were performed using Statistical Package for the Social Sciences v.20.0 (SPSS, IBM®, Chicago, IL, USA). Kolmogorov–Smirnov tests were used to detect the normality of data distribution. Related variables were expressed as median (25^{th}–75^{th} percentiles). Comparisons of groups were performed using the Mann–Whitney U test (non-normal distribution). A two-sided p value of <0.05 was considered statistically significant.

Ethics Statement

The local ethics committee of the Kocaeli University School of Medicine approved this clinical study (KU GOKAEK: 2016/219). Participants gave their informed consent on attending the requested hearing tests within a particular time frame.

RESULTS

Related data were evaluated and continuous variables were not distributed normally. Preoperative and postoperative hearing levels and the PTA of AC and BC were determined (Table 1). ABG values were calculated and classified according to the success rates (Table 2).

In the MASH group, 86.1% (n=31) of the patients were considered successful and the postoperative average ABG was 10.41 dB. In the TASH group, 82.9% (n=39) of the patients were considered successful and the postoperative average ABG was 13.27 dB. According to the overall data, MASH was statistically more successful than TASH.

The postoperative ABG for each frequency were evaluated according to the related groups. The hearing gains at 500 Hz ($p<0.036$), 2000 Hz ($p<0.031$), and PTA ($p<0.22$) were statistically significantly better in the MASH group (Table 3). In fact, 1000 Hz ($p<0.083$) and 4000 Hz ($p<0.279$) did not differ statistically.

DISCUSSION

The main objectives of tympanoplasty operations are to ensure a disease-free middle ear with a favorable sound transmission between the TM flap and inner ear. Various prostheses and different stabilization techniques have been described for different conditions. PORPs are some of the most common tools available for otologists. Bance et al. [9] first reported that the malleus to stapes assembly showed a

Table 1. Preoperative and postoperative hearing results (dB)

			500 Hz AC	1000 Hz AC	2000 Hz AC	4000 Hz AC	PTA AC	500 Hz BC	1000 Hz BC	2000 Hz BC	4000 Hz BC	PTA BC	ABG
MASH	Mean	Preop	50.13	44.44	44.58	38.88	44.63	18.19	11.80	17.63	18.88	16.77	27.88
n=36		Postop	28.19	31.11	25.27	22.08	26.79	16.38	11.66	16.11	20.83	16.33	10.41
(44.4%)	Median	Preop	29	40	42.5	35	44	15	10	15	15	13.5	27.5
		Postop	25	25	20	20	23.5	15	10	10	17.5	15	8.75
	Std Dev	Preop	13.16	14.72	14.70	16.12	12.64	8.79	8.20	12.09	10.21	8.55	8.27
		Postop	14.09	17.36	14.43	14.26	13.01	7.33	8.10	11.21	11.49	7.71	7.26
	Percentile 25–75	Preop	20–40	35–53.75	31.25–55	30–45	34–52.5	15–23.75	5–15	10–20	11.25–20	11–19.75	20.31-34.68
		Postop	15–38.75	16.25–43.75	15–35	15–23.75	18.25–32.5	10–20	5–15	10–20	10–25	11–19	5–13.75
TASH	Mean	Preop	51.48	44.04	48.19	41.17	46.31	17.34	12.97	19.36	22.12	18.06	28.27
n=47		Postop	31.59	34.04	28.72	25.10	29.95	16.17	11.91	16.06	22.23	16.72	13.27
(56.6%)	Median	Preop	50	40	50	40	44	15	10	15	20	15	28.75
		Postop	30	30	30	20	28	15	10	15	20	15	12.5
	Std Dev	Preop	14.63	19.10	13.40	13.03	12.57	7.65	8.31	10.30	13.97	8.28	8.26
		Postop	11.47	15.13	12.17	13.33	11.09	7.08	6.80	9.32	12.92	7.32	6.55
	Percentile 25–75	Preop	45–65	30–60	40–55	30–45	39–53	10–25	5–15	10–25	10–25	11–23	21.25–35.00
		Postop	20–35	25–45	20–30	15–30	23.33	10–20	5–15	10–20	15–25	11–21	10–16.25

MASH: malleus assembly to the stapes head; TASH: tympanic membrane assembly to the stapes head; Std Dev: standard deviation; Per: percentile; Hz: Hertz; PTA ABG: pure tone average air–bone gap; AC: air conduction; BC: bone conduction; Preop: Pre operative; Postop: Post operative

Table 2. Number of postoperative air–bone gaps (dB) according to different frequencies

		500 Hz	1000 Hz	2000 Hz	4000 Hz
MASH	0–10 dB	21 (58%)	17 (47%)	32 (88%)	24 (66%)
	11–20 dB	11 (30%)	14 (38%)	2 (6 %)	9 (25%)
	>20 dB	4 (12%)	5 (15%)	2 (6%)	3 (9%)
TASH	0–10 dB	20 (42%)	13 (28%)	33 (70%)	25 (53%)
	11–20 dB	20 (42%)	23 (48%)	11 (23%)	16 (34%)
	>20 dB	7 (16%)	11 (24%)	3 (7%)	6 (13%)

MASH: malleus assembly stapes head, TASH: tympanic membrane assembly stapes head

Table 3. Comparison results of postoperative hearing outcomes between the MASH and TASH groups

	500 Hz	1000 Hz	2000 Hz	4000 Hz	ABG
p	0.036*	0.083	0.031*	0.279	0.022*

*Statistically significant (p<0.05)

better vibration transmission than the TM to stapes on cadaver temporal bone models and significantly related with tension. Since then, different studies have clinically shown that the preservation of the malleus maintains better hearing outcomes [6].

The presence of the malleus may not be the only reason for a better hearing outcome. In our study, we compared two different conditions of lateral linkage of the PORP in the presence of the malleus. In the first group, the PORP was embedded between the stapes capitulum and slightly lateralized malleus. The position of the PORP was stabilized vertically, and the curvature of the tympanomeatal flap was more conical. In the second group, the malleus lateralization was not sufficient for the placement of a prosthesis underneath the malleus; thus, the lateral aspect of the PORP was embedded underneath a flat tympanomeatal flap with a cartilage island.

Postoperative hearing results showed that direct malleus contact of the PORP provides better hearing results. This may be associated with different reasons. The vertical placement of the prosthesis is a favorable position for a better hearing outcome [11]. Bance et al. [9] reported the angulation of the prosthesis decreased the force transmission and better hearing outcomes of the MASH group on cadavers. Sacrificing the tensor timpani muscle to lateralize the malleus may help place the prosthesis in a proper vertical position, but it is vital to detect sufficient malleus stability.

The tympanic membrane has a relation with the malleus, and this relation causes a natural conical shape. This anatomical specialty is part of the lever effect in the middle ear. The placement of the PORP underneath the malleus could be more functional because it provides a conical tympanomeatal flap, which is directly related to the malleus. Otherwise, the utilization of the prosthesis head and malleus can cause a flat tympanomeatal flap and this issue may decrease hearing gains.

Cartilage size and thickness may also affect hearing outcomes. Shimizu and Goode [12] mentioned that a decrease in the cartilage size could cause a loss in higher frequencies, and Zahnert et al. [13] recommended the cartilage thickness should be 0.5 mm. In our study, we preferred to use the conchal cartilage island to reinforce the head of the PORP to avoid extrusion. The size of the cartilage was limited as the PORP's head and thickness were used as recom-

mended. In fact, the cartilage island is another tissue between the graft and prosthesis. This cartilage interface may reduce vibrations and compromise the sound transmission with a mass effect. For this reason, hearing gains may be decreased more than expected for particular frequencies.

The head of the PORP was designed to carry the tympanomeatal graft with the aim of transmitting the vibrations to the stapes. Various sizes were tested, and no substantial difference was revealed. Moreover, the small-headed prosthesis was suggested for easy manipulation in the literature [14]. The head position was another important factor for success in the TASH group. The prosthesis head may interact with the narrow bony canal or annulus on the posterior quadrant. Interaction may cause fibrosis and decreased hearing outcomes in the long term [9]. Previous hearing results may be related to the early fibrotic process in the TASH group.

In our study, all participants were followed for six months, but this period was shorter than that in related studies [8, 10]. Otoscopic examinations were normal, and none of the patients were accepted for revision surgery. Fibrotic processes in the middle ear, vibratory loss between the middle ear structures, and possible deformations on the stapes capitulum may be possible factors for unsuccessful operations. Due to the results of the short-term follow-up, the malleus relocation technique was a successful method, and embedding the PORP underneath the malleus was better for hearing. Long-term follow-ups and standardized prospective studies are required for the future.

CONCLUSION

In this report, we examined the hearing results of PORP placement in the presence of the malleus. Both malleus- and tympanomeatal flap-linked groups were successful, but the malleus-linked group showed better ABGs. The similarity of normal bony structures, conical shape of the tympanomeatal flap, fewer support materials needed, and less fibrotic interactions with the bony canal may be advantages for the MASH technique.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Kocaeli University School of Medicine (KU GOKAEK: 2016/219).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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