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Original Article

Tympanoplasty with an Intact Stapes Superstructure in Chronic Otitis Media

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BACKGROUND: The objective of our study was to ascertain the functional results in terms of air bone gap (ABG) closure over 4 frequencies (0.5, 1, 2, 3 kHz) in patients with chronic otitis media (COM) that underwent tympanoplasty in the presence of a mobile stapes superstructure, and in particular excluding those cases in which the malleus was used in the reconstruction.

METHODS: A retrospective review of our database between January 1, 2006 and June 1, 2018 identified all cases that underwent one of 3 reconstructive options: the classic Type III tympanoplasty in an open-cavity setting; the "stapes augmentation" (SA) type reconstruction where the stapes superstructure is augmented to the drum by an interposing partial ossiculoplasty of either autologous bone, cartilage, or prosthetic material; and the use of a total articular replacement prosthesis (TORP) from the stapes footplate to the drum in the presence of an intact superstructure.

RESULTS: A total of 116 procedures in 112 patients were identified with a mean ABG reduction from 27 dB to 21 dB ($P < .05$). There was no significant difference in the mean post-operative ABG result between Type III (19.21 dB), TORP+ (24.90 dB), or SA (20.94 dB) reconstructions ($P = .368$). Overall, an ABG $\leq$20 dB or "surgical success" was achieved in 56% ($n = 65$) of cases. Only 20% ($n = 23$) of cases had "failure" or a post-operative ABG >30 dB.

CONCLUSION: Tympanoplasty with an intact stapes superstructure in COM is expected to provide acceptable levels of surgical success. We did not identify any particular risk factors associated with improved outcome.

KEYWORDS: Tympanoplasty, stapes, otitis media, risk factors

INTRODUCTION

Chronic otitis media (COM) refers to long-standing inflammation of the middle ear and mastoid with or without tympanic membrane perforation.[1] The ossicle most commonly involved by COM is the incus, and the surgeon is most commonly required to reconstruct the conductive mechanism between the tympanic membrane/handle of malleus and the stapes superstructure.[2] It is not uncommon that the handle of malleus cannot be used in the reconstruction of the ossicular chain because it is either too far anterior for a stable assembly, destroyed by extensive disease, the tensor tendon cut, or the malleus removed in its entirety by the surgeon for adequate access to the epi/protympanum.[2,3] The resultant ossiculoplasty now bridges between the mobile stapes superstructure and the tympanic membrane, with or without interposing cartilage for reinforcement. Therefore, 3 major groups may be encountered:

An open-cavity setting, where the tympanic membrane or temporal fascia is draped directly onto the mobile stapes superstructure, referred to as a classic Wullstein Type III reconstruction.[1]

An interposing graft between the stapes and the tympanic membrane, called a "stapes augmentation" (SA). Other synonyms in the literature include "partial ossiculoplasty"[4] type III with columella reconstruction,[5] and tympanic membrane to stapes head (TASH).[6]

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The use of a TORP from the footplate of the stapes to the tympanic membrane in the presence of an intact superstructure. This may be done because either the superstructure is inferiorly rotated and unfavorable for a stable reconstruction or the middle ear height is too short to accommodate a partial prosthesis between the capitulum of the stapes and the drum.[7]

The objective of our study was to ascertain what the functional results would be in terms of air bone gap (ABG) closure over 4 frequencies (0.5, 1, 2, 3 kHz) in patients with COM that underwent tympanoplasty where a mobile stapes superstructure was found. Various risk factors such as the status of the middle ear (inflammation/drainage) and ossicular chain (stapes/malleus presence), extent (mastoidectomy/canal wall removal) and timing (primary/revision/staged) of surgery have been associated with hearing outcomes in ossiculoplasty either individually[8,9] or as part of composite scoring systems.[10,11] An additional objective therefore was to assess the potential impact of some of these on our results.

This is a retrospective analytical observational study.

METHODS

All peri-operative information specific to each patient, including audiology and radiology assessments, intra-operative findings, and standardized drawings were prospectively entered into our electronic database (Innoforce ENT statistics, www.innoforce.com). A retrospective search of this database was performed to identify all possible cases of tympanoplasty where the stapes superstructure was found intact and mobile but where the malleus handle was not used in the reconstruction, between January 1, 2006 and June 1, 2018. All surgery was performed by 3 senior otologists. The surgeons had used and properly coded the following 3 ossicular reconstruction options:

The classic Type III tympanoplasty in an open-cavity setting, as described by Professor Fisch,[1] using temporalis fascia for the underlay reconstruction of the tympanic membrane in direct contact to the stapes superstructure in an open-cavity situation.

The SA type reconstruction, where the stapes superstructure is augmented to the drum by an interposing partial ossiculoplasty, and where possible, the surgeon aimed to use autologous bone (incus/malleus head), if available and not involved by disease or cartilage (tragal/conchal) as a primary option. However, should there be an increased risk of fixation to surrounding bone (facial ridge) or in case of revision surgery, alternative titanium prostheses were chosen.

MAIN POINTS

- A number of reconstructive options exist when considering tympanoplasty in COM in the presence of a mobile stapes superstructure.
- In our experience, comparable functional results (ABG) were obtained in type III stapes augmentation and total ossicular replacement prosthesis reconstructions.
- Overall, acceptable levels of surgical success and low levels of failure are expected.
- No specific risk factors were identified to be statistically dominant.

The use of a TORP (Fisch or KURZ) from the stapes footplate to the drum in the presence of an intact superstructure, without use of the malleus handle. We use the abbreviation of TORP+ so as not to be confused with a footplate-only situation.

In addition, the following data were collected: Patient age, gender, side of procedure, air and bone conduction thresholds pre- and post-operatively (with a minimum interval of 3 months from the time of intervention), complications, and duration of follow-up. In terms of risk factors, we recorded whether the surgery was in an open (canal wall down) or closed (canal wall up) cavity setting and the presence or absence of a malleus handle at the time of reconstruction. We particularly excluded those cases in which the malleus was used in the reconstruction, as the results of incus interposition have been shown to be significantly better than stapes augmentation and we did not want the selection bias to affect our results.[1,6,12,13]

Additionally, we divided our patients into those that were undergoing ossiculoplasty for the first time (primary), those that had had previous ossiculoplasty (revision), and those that were undergoing a planned ossiculoplasty following a previous procedure (staged). In keeping with evolving evidence[8,14] we aimed to reconstruct the ossicular chain at the primary setting if possible.

Audiometric data were recorded during the pre-operative evaluation and the most recent follow-up. For the study, 5-frequency (500, 1000, 2000, 3000, and 4000 Hz) air and bone conduction thresholds were collected in every patient but only the first 4 frequencies were used for ABG calculations, as per the AAO-HNS guidelines.[15] Unfortunately, the word recognition score and scattergram plot format of data collection as outlined in the updated AAO-HNS Hearing Committee guidelines of 2012[15] were only implemented approximately half way during our study period; therefore incomplete data prevented us from including this information at this time. All cases with incomplete information or less than 3 months audiological follow-up were excluded.

Statistical Analysis

Innoforce ENT statistics and SPSS Statistics (2019) were used to calculate the descriptive and analytical results of the non-parametric data. The Wilcoxon signed-rank test was used to compare ABG changes at each frequency. The Mann–Whitney *U*-testwas used to compare means across 2 independent groups, and the Kruskal–Wallis test with post-hoc pairwise comparison and Bonferroni correction for multiple tests where the means of comparison of more than 1 independent group. The Pearson chi-square test was used to assess differences between ABG "bins." A *P*-value set at $< .05$ was considered to be significant.

RESULTS

A total of 116 procedures in 112 patients were identified. The mean age at the time of surgery was 41 years (range: 5-82 years) with 66 (59%) males and 46 (41%) females. There were 70 (60%) left and 46 (40%) right ears treated, with an average follow-up from the time of surgery to the last available audiogram of 2 years (range 3.5-116.5 months). There were 48 primary, 52 revision, and 16 staged cases. There were 34 Type III reconstructions, 23 TORP+, and 59 SAs, the latter further subdivided according to the material used for the augmentation.

Table 1. Overall Results

Grouping	*n* = 116	Pre-op 0.5-3 kHz (dB)	SD	Post-op 0.5-3 kHz (dB)	SD	Improvement	SD	*P*
Type III	*n* = 34 (29%)	24.25	11.12	19.21	8.2	5.04	12.73	.038*
TORP+	*n* = 23 (20%)	**34.95**	11.19	24.89	14.6	10.05	16.89	.009*
SA	*n* = 59 (51%)	26.34	13.55	20.94	10.49	5.4	13.8	.004*
P		.002*		.368		.131		
Overall	*n* = 116 (100%)	27.42	12.9	21.36	10.9	6.6	14.13	.000*

*denotes $P < .05$.

Overall

When looking at all 116 cases together, the mean ABG reduced from 27 dB (0.5-3 kHz) pre-operatively to 21 dB, with a mean reduction of 6.6 dB ($P < .05$) (Table 1). Each type of reconstruction achieved a significant reduction in the respective ABG. Although the TORP+ cases started with a significantly larger ABG pre-operatively, there was no significant difference in the mean post-operative ABG result between Type III, TORP+, or SA reconstructions ($P = .368$) (Table 1).

Overall, an ABG ≤ 20 dB or "surgical success" was achieved in 56% ($n = 65$) of cases. Only 20% ($n = 23$) of cases had "failure" or a post-operative ABG >30 dB. There was no significant difference in either "surgical success" or "failure" between Type III, TORP+, or SA cases (Table 2).

Risk Factors

With regard to surgical timing, significant improvements in ABG were found in both primary and revision cases, but not in those that were staged. When comparing all 3 together, primary cases performed significantly better than staged cases, both pre and post-operatively. Significant improvements in ABG were found in all cases, regardless of whether the malleus handle was present or absent, but their post-operative results across the 4 frequencies were not significantly different. Interestingly however, a significantly greater pre-operative ABG was found in those cases with an absent malleus handle, and a significantly greater improvement in ABG was required in these cases to achieve this result. Significant ABG closure was again achieved irrespective of whether an open or closed-cavity approach was used, with no difference in outcome between the 2. A univariate analysis of all the risk factors taken together revealed that none of them proved to be stochastically dominant (Table 3).

Stapes Augmentation

We found in our series that only the use of cartilage for the augmentation, and not autologous incus or titanium, resulted in a significant improvement in ABG (Table 4). Of note is that there were no extrusions in our cohort of SA, but there were 6 cases of titanium prosthesis "failure" (ABG >30 dB), 3 each for KURZ and FISCH titanium incus

Table 2. ABG "Bins"

ABG «bin» AAO-HNS 0.5-3 kHz	*N* = 116 (100%)	Type III, *n* = 34 (100%)	TORP, *n* = 23 (100%)	SA, *n* = 59 (100%)	*P*
0-10 dB	16 (14%)	4 (12%)	2 (9%)	10 (17%)	
11-20 dB	49 (42%)	17 (50%)	9 (39%)	23 (39%)	.582
21-30 dB	28 (24%)	10 (29%)	6 (26%)	12 (20%)	
>30 dB	23 (20%)	3 (9%)	6 (26%)	14 (24%)	.156

*denotes $P < .05$.

Table 3. Risk Factors

Grouping	*n* = 116 (100%)	Pre-op 0.5-3 kHz (dB)	SD	Post-op 0.5-3 kHz (dB)	SD	Improvement	SD	*P*
Primary	48 (41%)	**23.35**	11.63	17.8	7.34	5.55	13.19	.005*
Revision	52 (45%)	29.18	13.47	22.09	11.7	7.09	15.63	.001*
Staged	16 (14%)	33.9	11.78	29.65	13.21	4.26	12.67	.204
P		.004*		.004*				
Malleus Present	69 (59%)	24.77	13.12	20.58	10.35	4.19	14.59	.027*
Malleus Absent	47 (41%)	31.3	11.82	22.5	11.87	8.8	13.3	.000*
P		.003*		.583		.031*		
Open cavity	68 (59%)	26.83	12.57	21.36	9.43	5.48	12.06	0.000*
Closed cavity	48 (41%)	28.24	13.59	21.35	12.97	6.89	16.89	.027*
P		.676		.488				
All risk factors					.064			

*denotes $P < .05$.

Table 4. Stapes Augmentation

SA Material Sub-group	*N* = 59 (100%)	Pre-op 0.5-3 kHz (dB)	SD	Post-op 0.5-3 kHz (dB)	SD	Improvement	SD	*P*
Cartilage	29 (49%)	26.44	14.04	18.49	10.59	7.95	9.95	0.000*
Incus	16 (27%)	25.94	15.37	19.92	8.21	6.01	18.08	.271
Titanium	14 (24%)	26.47	10.98	23.85	8.22	2.45	10.26	.196
P				.173				
SA Open vs. Type III		Pre-op 0.5-3 kHz (dB)	SD	Post-op 0.5-3 KHz (dB)	SD	Improvement	SD	*P*
Type III	*N* = 34	24.25	11.12	19.21	8.3	5.04	12.73	0.038*
SA Open	*N* = 27	27.48	13.93	22.8	10.43	4.68	2.27	0.065
P		.326		.163				

*denotes $P < .05$.

respectively. However, considering the relatively small number of titanium SA cases ($n = 14$), this may be a confounding factor (Table 4). We found no difference in the outcomes between our open-cavity SA and our classic Type III reconstructions (Table 4).

Open Cavity High Frequency

We noted that our Type III reconstruction in particular achieved significantly poorer results at trying to close the ABG at 4 kHz than either the SA or the TORP+ reconstructions (Table 5).

Complications and Failures

There was no significant change in bone conduction thresholds in our patients during the study period, either over 0.5-4 kHz (17.6 dB vs. 17.5 dB) ($P = .141$) or at 4 kHz (23.2 dB vs. 20.8 dB) ($P = .281$). There were no extrusions in the stapes augmentation group, but 3 in the TORP+ group, all in open-cavity reconstructions.

DISCUSSION

The mean result of reconstruction between a mobile stapes superstructure and the tympanic membrane in our study at 21.36 dB was marginally more than one would expect with an incus interposition (15-20 dB)[6,12,13] but better than a classic type IV or TORP reconstruction (25-30 dB).[1]

Type III

Clinical results of type III tympanoplasty have traditionally been expected to result in an ABG of between 30 and 40 dB.[1] The smallest ABG is found at 2 kHz and is similar to that expected even with a simple perforation of the tympanic membrane.[16] Few comparable clinical studies exist, but some of the more recent have shown an average outcome of between 24.7 dB and 33.57 dB; and those reporting "success" of between 2% and 43%[5,17] and "failure" of between 31 and 89%.[1,18] Several of the studies specific to type III tympanoplasty noted that overall results and frequencies up to 2 kHz in particular may be improved by the addition of a "minor columella" to the stapes superstructure.[17-21]

Our results then in context appear to be quite favorable, with this also being the "safest" of our 3 reconstruction options, with "failure" only at 9% (Table 2). We found no difference between our Type III reconstruction and that of our open-cavity SA (Table 4).

One of the interesting findings of the type III tympanoplasty in our experience was that in contrast to the TORP+ and SA reconstructions, we found an increase in the ABG at 3 kHz and 4 kHz postoperatively. Even if we control for open-cavity reconstructions, we find a negative change in conductive hearing at 4 kHz and argue against ascribing this to the resonant frequency of the mastoid cavity[20] (Table 5).

In summary, we prefer the type III tympanoplasty reconstruction in open cavities with an intact and mobile stapes, although better closure at 3 and 4 kHz remains a challenge.

SA

Studies in keeping with stapes augmentation that specify the use of cartilage report the rate of surgical "success" (post-operative ABG ≤20 dB) to range between 50 and 94%[4,19,22,23] and "failure" (ABG >30 dB) of between 8.2 and 35%[4,19,22] with a mean post-operative ABG of 13-23.8 dB.[19,22] Autologous bone is reported to give "success" of 66-77%[4,24-26] and "failure" of 9-34%,[4,24,25] and a mean post-op ABG of 17.5-20.3 dB.[24,25] "Success" is achieved when using titanium in 43.8-69.1% of cases,[23,27] and "failure" in 18.8%, and a mean ABG of 16.8-24.1 dB.[23]

Our "surgical success" within this SA group of 56% is probably fair considering we used all 3 materials. Displacement of the titanium prosthesis was the reason for columella failure in 60% of our cases, and as previously mentioned, there were no extrusions.

In summary, a well-performed type III tympanoplasty is equal or superior to a SA in open cavities. If a columella is chosen in either

Table 5. High-Frequency Comparison

Open cavity Sub-group	68/116 (59%)	Pre-op 4 kHz (dB)	SD	Post-op 4 kHz (dB)	SD	Improvement	SD
TORP + Open	7/23 (30%)	43.57	15.47	38.57	19.73	5	5.77
SA Open	27/59 (44%)	34.65	15.06	32.12	13.8	1.92	20.93
Type III	34/34 (100%)	25.44	12.02	30	14.67	−4.56	16.98

closed or open cavities with a lateralized ear drum, we suggest placement of cartilage in a primary (first-stage) setting.

TORP+

There are numerous studies in the literature comparing partial with total ossicular replacement prostheses. In essence, their outcome on metanalysis reveals that PORP will achieve better results than TORP.[28] These studies however almost exclusively include TORP reconstructions where the stapes superstructure is absent.

Clinically, there have been few studies that have specifically looked at the results of reconstructions where a TORP was used in the presence of an intact stapes superstructure.

Silastic banding, described where the TORP was placed between the footplate and drum immediately superior to the superstructure and "bound" to it, achieving markedly good results with a mean ABG of 11.75 dB and 77% "success."[29] In a further evaluation of this technique, the same authors looked at comparing TORP with PORP reconstructions, but this time in the presence of the malleus handle, even if it meant "relocating" it for the reconstruction. Interestingly they found their TORP reconstructions with silastic banding achieved better results than those using PORP (mean ABG 8.9 vs. 13.1 B).

We know from the literature and from own results that the TORP or TORP+ reconstructions outperform the PORP, or in our case, the SA and type III reconstructions, in the higher frequencies[30] (Table 5). This may have to do with the increased tension inherent to this type of reconstruction However, while it may assist in high-frequency sound transfer, this may be an underlying risk factor for extrusion which ranges from 4.2 to 5.2%.[30]

In summary, TORP+ reconstructions appear to perform better than type III or SA reconstructions in the higher frequencies, but as they do not appear to provide an overall benefit in terms of ABG closure, the increased risk of extrusion should be taken into account.

Risk Factors in Tympanoplasty

Handle of Malleus

A systematic review and metanalysis looking at pre-operative ossicular chain status in ears undergoing surgery for COM found the presence of the malleus a significant predictor of improved outcome.[2] It was however not specified whether the malleus was used in the reconstruction or not. Preservation of the malleus and in particular the handle and tensor tendon may prevent lateralization of the graft, and also preserve its catenary effect and impedance-matching function.[31] The presence of the malleus is seen as significant in both the surgical, prosthetic, infection, tissue ,and eustachian tube (SPITE) as well as the ossiculoplasty outcome parameter-staging indices, and was found to be significant in cohorts assessing short-term[31-33] and long-term (>5 years)[8,9] outcome in surgery for COM (all included cholesteatoma).

Our results revealed very similar outcomes across all reconstructive options, whether the malleus was present or not (Table 3). The significance however was found when looking at the degree of improvement between the cases where the malleus handle was present or absent, in keeping perhaps with the latter presenting with more severe or advanced disease and with more to gain from the procedure.

In summary, preservation of the malleus does improve the final hearing outcome if its final position allows a proper incus interposition, but otherwise, its preservation may not add additional benefit in open or closed-cavity settings.

Primary Surgery

In our experience, staged cases seemed to fare the worst of all and were significantly poorer than primary, both pre and post-operatively, perhaps again selecting themselves as the worst ones clinically where reconstruction was just not possible at the time due to unfavorable conditions. We found our primary cases to have the lowest ABG results post-operatively, but they also started as such and were not significantly different to our revision cases. Reviewing the literature, primary surgery was reported to be favorable, in both long-term (>5 years) univariate[9] and multivariate risk factor analyses[8] (Table 3).

Canal Wall

Our classic type III reconstruction is synonymous with an open cavity or canal wall-down approach, but the SA or TORP+ were completed in either an open or closed-cavity situation. Comparing all 3 options, we found no significant difference between either open or closed-cavity reconstructions.

Complications

An increase in bone conduction threshold of >20 dB ranges between 0.4 and 6.6%.[23,26] As mentioned above, we had no significant deterioration in BC thresholds overall, though if one includes long periods of follow-up in older patients, factors such as age-associated hearing loss and decreasing reliability of high-frequency testing should also be kept in mind.[24]

Shortcomings of this Article

Despite the data being prospectively acquired, the retrospective nature of our study is not ideal. There is a certain amount of heterogeneity in our patient cohort in terms of etiology and age, which we cannot control, and of course, it is not possible to randomize surgical interventions. We also unfortunately could not add the speech discrimination information, which had to be omitted due to incomplete data.

CONCLUSION

Tympanoplasty with an intact stapes superstructure using a classic Type III, TORP+, or SA reconstruction in COM is expected to provide acceptable levels of surgical success (56% ≤ 20 dB) and low levels of failure (80% <30 dB). Most patients will achieve a post-operative ABG of between 20 and 25 dB. We did not identify any particular risk factors associated with significantly improved outcome. A classic Wullstein type III operation remains a safe, reliable option in all open cavities, and if considering a stapes augmentation or major columella reconstruction, cartilage followed by autologous incus are more favorable choices than titanium, in our experience. An open cavity per se does not imply a poorer result than a closed-cavity setting.

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of EKNZ (Ethikkommission Nordwest- und Zentralschweiz), (Approval No: 2017-01289).

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