Original Study

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Modified Power Piston Versus Simultaneous Stapedotomy With Hearing Aids in Otosclerosis: A Follow-Up Study Exploring Speech Recognition, Quality of Life and Usage of Device

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Objective: To compare audiologic outcomes, quality-of-life (QoL) and usage-of-device (UoD) between case-matched, otosclerotic patients with mixed hearing loss (MHL) which received (a) stapedotomy and postoperative amplification with hearing aids (SDT+HA) or (b) short-incudial process coupled active middle ear implant with simultaneous stapedotomy (mPP).
Study design, setting, and patients: Prospective, matched case-control, follow-up study conducted at two tertiary otologic referral centers. Eligible were all otosclerotic patients with MHL, which received mPP at either of the two institutions. A case-matched-cohort of SDT+HA-patients was generated from the hospitals database based on preoperative audiologic findings.
Main outcome measures: For sound- and speech perception, primary outcome parameters were the mean postoperative, aided air-conduction pure tone average (mpa-AC-PTA) and word recognition score at 80 dB speech level (mpa-WRS), for QoL the mean Nijmegen-Cochlear-Implant-Questionnaire (NCIQ) total-score, and for UoD the mean score rated on a 10-point Likert-scale.
Results: A total of 28 patients were included; 14 received mPP; mpa-AC-PTA and mpa-WRS significantly improved from 47.1 dB-HL to 34.3 dB-HL (−12.8 dB-HL; $p < 0.001$) and from 75.0% to 93.2% (+18.2%; $p = 0.002$) compared to 46.5 dB-HL to 31.9 dB-HL (−14.8 dB-HL; $p < 0.008$) and 75.0% to 93.2% (+18.2%; $p = 0.002$) for SDT+HA. No significant difference between groups was observed (all $p > 0.1$). NCIQ total-score between groups did not significantly differ (70.4 vs. 69.9; $p = 0.93$). UoD for mPP was significantly higher (6.1 vs. 3.0; $p < 0.001$).
Conclusions: If medical/technical problems prevent usage of HA in otosclerosis with MHL, mPP can be considered as effective treatment option with similar audiological outcome and QoL. A significantly higher UoD for mPP was observed. **Key Words:** Hearing aids—Otosclerosis—Quality of life—Stapes surgery—Treatment outcome.

Otol Neurotol **43:**429–436, 2022

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Joachim Schmutzhard is currently receiving a research grant from MedEl (Innsbruck, Austria). None of the other authors named in the submitted work have any conflict of interest including financial, consultant, institutional and or personal relationships that inappropriately bias his or her actions within 3 years of the work beginning. The open access charges have been covered by MED-EL Medical Electronics.

The authors disclose no conflicts of interest.

DOI: 10.1097/MAO.0000000000003514

Otosclerosis is associated with conductive hearing loss (CHL) in most patients (1). In these patients, hearing aids (HA) are the standard treatment (2). Occasionally, patients are unable to wear HA because of medical (i.e., chronic otitis externa) or technical problems (i.e., feedback) (2). In otosclerosis with pure CHL, stapedotomy (SDT) is considered as an alternative to HAs (2), which attempts to close the air-bone-gap (ABG). If otosclerosis progresses, hearing loss of mixed type (MHL) emerges (1). Since STD is not sufficient to compensate for MHL additional postoperative HA support after SDT is necessary to address the sensorineural part (SNHL) of the MHL (3). A fraction of these patients cannot wear a HA due to medical or technical problems (4). In such cases combination of active middle ear

implants (AMEI) with STD might be considered an option to restore hearing (4–9). While the SDT aims at closing the ABG, the AMEI addresses the sensorineural part of the MHL (4–7,9). The combination of these techniques was first described by Dumon and colleagues in a case report including one otosclerotic patient in 2007 (4). Kontorinis and colleagues were the first to refer to this operation as ''power piston'' surgery (7).

One possible device for this type of surgery is the Vibrant Soundbridge® (VSB, MedEl; Innsbruck, Austria). The main part of the VSB is the floating mass transducer (FMT), which allows attachment and transmission of vibratory motion to various structures of the middle ear (6). Introduced in the 1990s (10), the VSB obtained its original indication for SNHL in 2002 (11), which was expanded to MHL in 2006 (12). Originally the FMT was coupled to the long incudial process (12). Additional coupling sites with various advantages, including the round window, oval window and short incudial, process were proposed (6,12–15). While these alternative coupling site are established for the treatment of chronic otitis media (COM) (15–17), for otosclerotic patients with MHL, primarily long incudial process coupling following STD was performed (4,7,9). Thus, a wide posterior tympanotomy for coupling is required, which bears the risk of injury to the Chorda tympani, the facial nerve and the horizontal semicircular canal (6). Moreover, the FMT has to be clipped over the positioned stapes piston, additionally endangering the open inner ear (6).

In a previous publication, a modified approach of power piston surgery (mPP) for otosclerotic patients with MHL was proposed. The modification implied the short incudial process coupling followed by simultaneous SDT. Through this modification the extent of surgery was reduced from a wide posterior tympanotomy to an extended antrotomy, which minimizes the risk for anatomical structures such as the facial nerve. The mPP approach was investigated in a sample of 28 patients (matched cohort study) and was observed to be equally safe and effective as conventional SDT (6).

In the present work, the audiological outcome in patients with MHL treated with the new mPP approach is analyzed. The particular aim of the present follow-up study is to explore whether matched otosclerotic patients with MHL undergoing mPP equally benefit in terms of sound- and speech recognition with activated devices in comparison to patients treated with the standard option with STD and HA. In addition, the postoperative quality of life (QoL) and the usage of device was assessed.

MATERIALS AND METHODS

Study Population

This prospective, matched case-control, follow-up study was conducted at *blinded* and at *blinded*. All patients were eligible, which were included in the original, retrospective study exploring the efficacy and safety of mPP (6). In short, charts of adult otosclerosis patients with moderate to profound MHL (18), which underwent mPP at either of the two institutions, were retrospectively reviewed. A case-matched-cohort was generated from a larger sample of patients undergoing SDT at *blinded*. All eligible patients were invited to one follow-up visit to either of the two institutions. After written informed consent was obtained, audiologic performance, QoL and the usage of device was raised. Detailed inclusion and exclusion criteria are provided in Table 1. All mPP patients included in this study were previously fitted with HA. Reasons upon which patients opted for mPP instead of SDT followed by continuing to wear HA were medical (chronic external otitis) or technical (feedback, dissatisfaction with HA). These reasons are detailed in Table 2. The study was approved by the local ethics committee's (ethics committees reference number 1174/2019).

TABLE 1. *Detailed inclusion criteria*

Age $\geq$ 18 years
History of otosclerosis
Moderate to profound mixed hearing loss
Modified power piston surgery
Air-conductive pure-tone-average of $\geq$40 decibel hearing level
Bone-conductive pure-tone-average of $\geq$20 decibel hearing level

Audiologic Performance Testing

Sound Perception

Postoperative pure tone hearing thresholds were measured according to audiometric standards (ENISO8253 1–3) in a sound treated booth. Air-conduction thresholds were determined for audiometric frequencies ranging from 0.125 to 8 kHz. If necessary, the contralateral ear was plugged or masked by narrow-band noise signals. The air-conduction pure-tone-average (AC-PTA) was calculated as mean of the thresholds obtained at 0.5, 1.0, 2.0, and 3.0 kHz as recommended by the Committee on Hearing and Equilibrium previously (19). Unaided AC-PTA were measured postoperatively via headphones while the audio-processor of the VSB or the HA was not worn. Aided AC-PTA were measured in free sound field while the patients were sitting in front of a loudspeaker at one meter distance (0-degree azimuth).

Speech Perception

The Freiburg monosyllabic speech test in quiet was used to assess the word recognition scores (WRS) of the patients. The latter were determined at 80 dB speech level while wearing the activated audio-processor in free sound field. During the measurements, the contralateral ear was plugged. The Unaided WRS was measured while the audio-processor or HA was not worn, whereas the aided WRS was measured with active VSB or HA.

TABLE 2. *Reasons upon which patients opted for mPP*

	Department at Which Surgery Was Performed	
Reason	Innsbruck	Wels-Grieskirchen
Chronic external otitis	1	0
Dissatisfaction with hearing aid (amplification)	2	7
Dissatisfaction with hearing aid (feedback)	1	2
Dissatisfaction with hearing aid (physical appearance)	1	0

Quality of Life and Usage of Device

QoL was assessed once using the ''Nijmegen cochlear implant questionnaire'' (NCIQ) questionnaire (19), which is a validated, self-administered questionnaire with optimized psychometric properties. A total of 60 items have to be rated by the patients from 0 (''never'') to 5 (''always'') resulting in total-scores from 0 (''extremely poor'') to 100 (''excellent''). Three principal domains (''physical functioning,'' ''psychological functioning,'' ''social functioning'') and six subdomains (''basic sound perception,'' ''advanced sound perception,'' ''speech production,'' ''self-esteem,'' ''activity,'' ''social interaction'') were covered by the questionnaire. The questionnaire is available in different languages. In this study, the German version of the NCIQ was applied. The usage of device was estimated by patients on a 10-point Likert scale from 0 (''no usage at all'') to 10 (''usage for all waking hours'').

Statistical Analysis

For case-matching, a larger sample of patients undergoing SDT was compared to the study-cohort undergoing mPP via propensity score matching plug-in for SPSS24 (IBM, Armonk), as previously described (6). In short, the case-matched-cohort was matched to the study-cohort with respect to preoperative values, such as AC-PTA, bone-conductive (BC)-PTA, and ABG-PTA. A maximum difference of $\geq \pm 10$ dB-HL for each matching criterion was allowed. Since all patients of this previous study were included in the present follow-up study this step was not reproduced. Regarding preoperative values no significant differences in any of the audiologic findings were observed (all $p > 0.078$) (6). The interval between surgery and follow-up performed in this study was calculated. The preoperative AC-PTA, BC-PTA and ABG for the contralateral ear was also provided.

The main outcome parameters of the analysis were aided AC-PTA, aided WRS at 80 dB speech level and their respective functional gains, defined as difference between aided- and unaided AC-PTA and aided and unaided WRS at 80 dB speech level, respectively. Outcome parameters were compared within and between cohorts for patients undergoing either mPP or SDT. In addition, QoL and usage of device was compared between cohorts.

For continuous data means, medians and standard deviations (SD) as well as minimums and maximums were calculated. Mann–Whitney U and Wilcoxon tests were used to test for statistical significance defined as $p < 0.05$. Additionally, repeated measure ANOVA analysis were performed. In case of multiple comparisons Bonferroni correction was applied. All calculations were performed with SPSS24 and its corresponding plug-ins.

RESULTS

Study Population

A total of 160 otosclerotic patients with moderate to profound MHL (18) treated at either of the two institutions were identified as previously described (6). Of these, 14 patients underwent mPP surgery, whereas 5 were operated at *blinded* and 9 at *blinded*. Mean age was 54 ($\pm$9) years ranging from 40 to 69 years for all patients undergoing mPP surgery. Distribution of sex was comparable, that is, 7 patients were female. The reason of the 14 patients to opt for mPP are detailed in Table 2.

The remaining 146 patients with MHL, in total 146, received conventional SDT followed by postoperative fitting of HA. A subgroup of 14 of these patients were selected regarding predefined preoperative criteria to match the study-cohort of patients treated with mPP surgery (6). Predefined preoperative matching criteria ensured no significant differences between the study-cohort and the case-matched-cohort a priori ($p > 0.777$, (6)). The mean age was 56 ($\pm$11) years, ranging from 37 to 78 years for all matched patients undergoing conventional STD. Distribution of sex of the matched cohort was 8 females and 6 males. The mean follow-up time for patients undergoing mPP was 30.7 months compared to 55.4 months for patients undergoing SDT followed by fitting of HA. This difference was not significant ($p = 0.603$). Detailed data of all 28 patients included in the statistical analysis was presented in Table 3 (6).

Audiologic Outcome Measures

Sound Perception

Pure tone audiograms in unaided condition measured postoperatively were available for all the 28 patients. Regarding pure tone audiograms in aided condition 23 of 28 were available. The study group of patients receiving

TABLE 3. *Clinical data of all included 28 otosclerotic patients with mixed hearing loss*

	Modified Power Piston[b]	Conventional Stapedotomy	Chi square
Sex			
Male	7	6	$p = 1.0$
Female	7	8	
Age (years)[a]	54 ($\pm$9; 40–69)	56 ($\pm$11; 37–78)	
Number of previous ear surgeries[a]	1 ($\pm$1.3; 0–3)	0 (0.4; 0–1)	$p = 1.0$
Site of surgery[a]			
Right ear	9	9	$p = 1.0$
Left ear	5	5	
Department at which surgery was performed			
Innsbruck	5	14	$p = 0.003$
Wels-Grieskirchen	9	0	

[a]For continuous data means, standard deviations (SD), minimums and maximums were provided.
[b]Numbers of patients were provided.

mPP reached an AC-PTA of 47.1 dB-HL (±14.9 dB-HL; range 27.5–77.5 dB-HL) in unaided condition postoperatively measured compared to 34.3 dB-HL (±7.8 dB-HL; range 23.8–48.8 dB-HL) with activated AMEI. The difference was significant (Wilcoxon test; $p < 0.001$; *Z*-value 3.31; Fig. 1). For the matched cohort group treated with the conventional STD an AC-PTA of 46.5 dB-HL (±13.2 dB-HL; range 28.8–67.5 dB-HL) in unaided condition measured postoperatively compared to 31.9 dB-HL (±11.1 dB-HL; range 27.5–52.5 dB-HL) in aided condition with HA, was observed. Differences between unaided and aided were significant (Wilcoxon test; $p < 0.008$; *Z*-value 2.67; Fig. 1). The AC-PTA in unaided condition measured postoperatively did not differ significantly between mPP- and SDT patients (Mann–Whitney *U* test; $p = 0.232$; *U*-value 72.0). An improvement of hearing thresholds was observed for mPP- and SDT-patients when using either the audio-processor of the AMEI or the HA (−12.8 dB-HL vs. −14.8 dB-HL), however, the difference was not significant between groups (repeated measures ANOVA; $p = 0.114$; *f*-value 2.726; Fig. 1). Moreover, no significant difference between groups of the mean postoperative AC-PTA in aided condition was observed (Mann–Whitney *U* test; $p = 0.439$; *U*-value 50.0; Fig. 1).

The hearing of the contralateral ear did not significantly differ between patients undergoing mPP and patients undergoing SDT followed by fitting of hearing aids, respectively with 44 dB-HL vs. 41 dB HL for AC-PTA, 33 dB-HL vs. 32 dB-HL for BC-PTA, and 10 dB-HL vs. 9 dB-HL for ABG (all $p > 0.435$).

Speech Perception

Postoperative WRS in unaided condition of the Freiburg Monosyllabic word test in quiet were available for 23 of 28 patients. Postoperative WRS in aided condition were available for 23 of 28 patients. Patients having received mPP obtained a mean postoperative WRS of 75% at 80 dB speech level (±19.7%; range 25.0–100.0%) in unaided condition compared to 93.2% (±7.2%; range 75.0–100.0%) with activated AMEI. This difference was significant (Wilcoxon test; $p < 0.002$; *Z*-value 3.08; Fig. 2). The matched cohort group of patients treated with conventional STD reached a mean postoperative WRS of 67.8% (±19.2%; range 35.0–95.0%) at 80 dB speech level compared to 82.8% (±17.2%; range 50.0–100.0%) when using a HA. This difference was significant (Wilcoxon test; $p < 0.007$; *Z*-value 2.70; Fig. 2). Postoperative WRS in unaided condition measured at 80 dB speech level between both groups did not significantly differ (Mann–Whitney *U* test; $p = 0.358$; *U*-value 48.5). An improvement in WRS was observed in both groups after activation of the audio-processor of the AMEI as well as after receiving the HA (+18.2% vs. +15.0%). The difference was not significant (repeated measures ANOVA; $p = 0.597$; *f*-value 0.288; Fig. 2). Moreover, no significant difference between mean postoperative aided WRS at 80 dB speech level, defined as primary outcome parameter for speech perception, was observed (Mann–Whitney *U* test; $p = 0.179$; *U*-value 41.0).

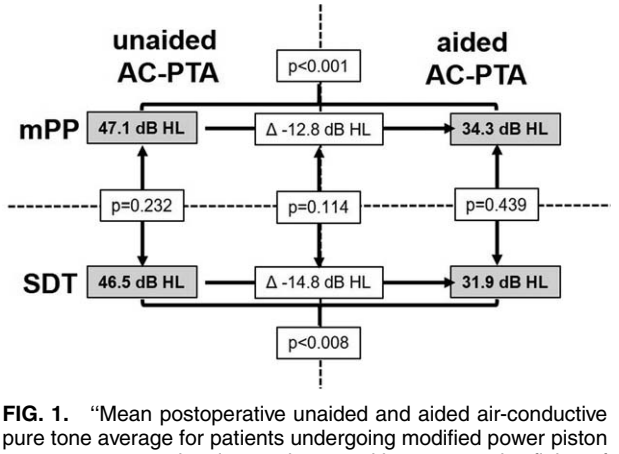

FIG. 1. "Mean postoperative unaided and aided air-conductive pure tone average for patients undergoing modified power piston surgery or conventional stapedotomy with postoperative fitting of hearing aids." Mean postoperative unaided (left side of the diagram) and aided (right side of the diagram) pure tone averages (PTA) measured via air-conduction (AC). Patients undergoing modified power piston surgery (mPP) are depicted in the upper part of the diagram, patients undergoing conventional stapedotomy with postoperative fitting of hearing aids (SDT) are depicted in the lower half of the diagram. For standard deviations, ranges, *f*- and *Z*-values refer to main text. In terms of sound perception, a benefit for mPP- and SDT-patients was observed after activation of VSB/HA (−12.8 vs. −14.8 dB-HL). However, neither the difference between the change nor between the mean postoperative aided AC-PTA significantly differed ($p = 0.114$ and $p = 0.439$, respectively).

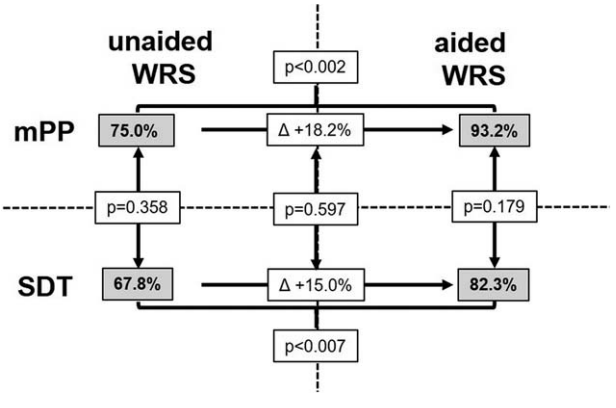

FIG. 2. "Mean postoperative unaided and aided word recognition score at 80 decibel sound pressure level for patients undergoing modified power piston surgery or conventional stapedotomy with postoperative fitting of hearing aids." Mean postoperative unaided (left side of the diagram) and aided (right side of the diagram) word recognition score (WRS) measured at 80 decibel (dB) sound pressure level (SPL). Patients undergoing modified power piston surgery (mPP) are depicted in the upper part of the diagram, patients undergoing conventional stapedotomy with postoperative fitting of hearing aids (SDT) are depicted in the lower half of the diagram. For standard deviations, ranges, *f*- and *Z*-values refer to main text. In terms of speech perception, an improvement for mPP- and SDT-patients was observed after activation of the AMEI audio processor or the HA (+18.2 vs. +15.0%). Neither the difference between the change nor between the mean postoperative aided WRS at 80 dB speech level significantly differed ($p = 0.059$ and $p = 0.179$, respectively).

Quality of Life and Usage of Device

In total 23 of 28 patients returned a complete NCIQ questionnaire on QoL. The total score of the patient group having received a mPP was 70.4 (±13.3; range 30.8–83.8). In the three principal domains ''physical functioning,'' ''psychological functioning,'' and ''social functioning'' scores of 75.2, 66.3, and 70.5 were reached. In the subdomains ''basic sound perception,'' ''advanced sound perception,'' ''speech production,'' ''self-esteem,'' ''activity'' and ''social interaction'' scores of 37.1, 43.9, 39.3, 36.5, 36.6, and 35.7 were obtained.

Patients treated with conventional STD showed a total score of 69.9 (±19.2; range 40.0–93.8). In the three principal domains ''physical functioning,'' ''psychological functioning,'' and ''social functioning'' scores of 74.6, 66.6, and 65.4, were reached. In the subdomains, ''basic sound perception,'' ''advanced sound perception,'' ''speech production,'' ''self-esteem,'' ''activity,'' and ''social interaction'' scores of 37.4, 42.1, 39.1, 36.8, 37.6, and 34.8 were achieved.

No significant differences between the mPP and the SDT group was observed regarding the total score of the NCIQ or the principal- or subdomains of this questionnaire (in all pair comparisons $p > 0.39$; see Table 4). In addition, neither the NCIQ's total score nor the three principal domain score or any of the NCIQ's subdomains significantly correlated with the postoperative AC-PTA or WRS in aided or unaided conditions (in all cases pair comparisons showed $p > 0.05$; Mann–Whitney U test).

Data on usage of device as rated subjectively on a 10-point Likert scale by the patients was available in all the included patients. Patients with mPP reported a mean usage of the device (i.e., audio-processor of the AMEI) of 6.1 on the Likert scale (±3.9; range 0.0–10.0) compared to 3.0 (±2.7; range 0.0–8.0) for SDT-patients with HA. This difference was significant ($p < 0.001$). No significant correlation between the mean usage of device and any of the NCIQ subdomains ''basic sound perception,'' ''advanced sound perception,'' ''speech production,'' ''self-esteem,'' ''activity,'' and ''social interaction,'' were observed (all $p > 0.05$; Mann–Whitney U test).

Postoperative Complications

Data on postoperative complications were available for 28 of 28 patients (Table 5). Of 14 patients having received mPP, 3 reported postoperative complication, which were pain and paresthesia of the operated ear (2 patients), vertigo (3 patients), and autophony (1 patient). Of these complications in the mPP-group, vertigo persisted for more than 4 weeks in one patient and autophony in another patient. Of 14 patients treated with conventional STD, 4 reported postoperative complications, which were pain (1 patient) and vertigo (4 patients). Of these complications in the mPP-group, vertigo persisted for more than 4 weeks in one patient.

DISCUSSION

In patients with otosclerosis and MHL, conventional SDT aims on closing the ABG. Additional supply of a HA is necessary to address the sensorineural part of the MHL (3). In some patients, medical or technical problems prevent wearing of HAs. In these patients, combination of AMEI with simultaneous SDT might be considered as treatment option (4–9).

Notably, chronic external otitis (4) and dissatisfaction with HA due to feedback are considered relatively uncommon in otosclerotic patients. Consequently, these conditions were rarely observed in the present study population (Table 2). Only 1 of 14 patients reported chronic external otitis and only 3 of 14 patients reported dissatisfaction with HA due to feedback. These patients were employed as carpenters (1 patient) and/or musicians (2 patients) and therefore especially challenged during working hours (e.g., working with circular saw, playing concerts). The majority of the patients in this study opted for mPP due to dissatisfaction with HA due to a lack of amplification (Table 2). Based on these observations,

TABLE 4. *Quality of life raised via ''Nijmegen cochlear implant questionnaire'' for all included 24 otosclerotic patients with mixed hearing loss*

	Modified Power Piston		Conventional Stapedotomy			
	Mean	SD[a]	Mean	SD[a]	U	p
Total score	70.4	± 13.3	69.9	± 19.2	76.0	0.68
Physical functioning	75.2	± 15.5	73.8	18.7	82.0	0.92
Psychological functioning	66.3	± 11.0	67.1	16.7	81.0	0.88
Social functioning	70.5	15.9	65.4	23.5	77.5	0.74
Basic sound perception	67.9	± 19.5	68.5	± 23.6	84.0	>0.99
Advanced sound perception	84.6	± 14.0	80.2	± 11.4	62.5	0.27
Speech production	73.2	± 19.3	72.7	± 22.4	82.0	0.92
Self-esteem	66.3	± 11.0	67.1	± 16.7	81.0	0.88
Activity	66.4	± 22.1	68.9	± 26.3	84.0	>0.99
Social interaction	64.3	± 11.3	61.9	± 21.4	70.5	0.49

[a]Standard deviations.

TABLE 5. *Treatment complications of all included 28 otosclerotic patients with mixed hearing loss*

Type of Complications	Modified Power Piston	Conventional Stapedotomy
Pain	1/14	1/14
Paresthesia	1/14	0/14
Vertigo	3/14[a]	4/14[c]
Autophony	1/14[b]	0/14

[a]In one of three patients vertigo persisted for more than 4 weeks.
[b]Autophony persisted for more than 4 weeks.
[c]In one of four patients vertigo persisted for more than 4 weeks; it is to note that one patient might report more than one complication.

thorough recording of workplace history besides sole audiologic performance testing appeared important in selecting treatment options.

The combination of AMEI with simultaneous SDT was, firstly referred to as ''power piston'' surgery by Kontorinis and colleagues (7), SDT is performed to close the ABG, while simultaneously an AMEI is implanted to address the sensorineural part of the MHL (4–7,9). Recently, a modification of this surgical approach (''mPP'') was proposed, which minimizes the risk of damaging anatomical structures in the middle ear by limiting the extent of surgery to an extended antrotomy (6). In a case series including a total of 28 patients, the mPP approach was found to be equally safe and effective as SDT alone in a matched cohort (6). However, this previous study only compared the two surgical techniques (6). The additional benefit for MHL-otosclerotic patients with activated audio-processer of an AMEI or wearing HA after surgery in terms of sound- and word recognition was insufficiently explored. In the present study, mPP-patients were compared to case-matched SDT patients with postoperative HA. The benefit between these two groups of patients in terms of audiologic performance, QoL and usage of device was explored.

For both groups, an improvement in sound- and speech perception was observed when using the audio-processor of the AMEI or the HA. The patients of the mPP group reached a mean functional gain of 13 dB-HL and a mean gain in speech perception of 18% compared to 15 dB-HL and 15% for patients with conventional SDT and HA. The difference between the unaided and the aided condition was highly significant and clinically relevant in both groups ($p < 0.008$). Neither the mean functional gain ($p = 0.11$) nor the mean gain in speech perception ($p = 0.60$) between the groups significantly differed (Figs. 1 and 2).

Few data is available on the mean functional gain and mean gain in speech perception comparing the power piston surgery to conventional SDT and subsequent fitting of a HA. Regarding AMEI, Buchhager and colleagues reported a mean functional gain of 12.5 to 33.0 dB-HL and a mean gain in speech perception of 30% to 60% in a recent review (20). In case of HA, Kwak and co-workers reported a mean functional gain of 21.3 dB-HL and a mean gain in speech perception of 36% (21). Comparison of the mPP approach to SDT and postoperative fitting of a HA with respect to audiologic performance was not reported so far. One study by Lee and colleagues was found, which compared the audiologic outcome of AMEI with passive middle ear implants followed by fitting of HA in 24 patients with MHL due to COM. Therein a functional gain of 35.8 dB-HL and a mean gain in speech perception of 5.3% was reported for the AMEI compared to 18 dB-HL and 10.9% for passive middle ear implants followed by fitting of HA ($p = 0.16$; $p > 0.05$) were reported (17). Similar results were found in the present study. In particular, the mean functional gain in patients having received mPP was slightly below the values of the study of Lee and colleagues, whereas the gain for speech perception was slightly above (17).

Regarding QoL, the mPP resulted in a mean total score of 70 compared to 70 for SDT-patients and postoperative fitting of a HA. This data suggests that patient's satisfaction is equally high for both treatment options. More precisely, the mean scores for the three principal domains ranged from 66 to 75 for the mPP-group and from 67 to 75 for the SDT-group. For the 6 subdomains of the NCIQ questionnaire the scores range from 36 to 44 for the mPP-group and from 35 to 44 for the SDT-group (Table 3). No significant difference between both groups for any of the QoL scores were (in all cases $p > 0.4$; Table 3). No correlation between QoL scores and the audiologic outcome parameters was observed (in all cases $p > 0.05$). Regarding the usage of device, patients having received the mPP reported a mean score of 6 compared to 3 in the SDT-group. The difference was significant ($p < 0.001$). The reason for this deviation in device usage between the two groups is not known. The difference observed might just indicate a selection bias: all patients having received mPP were previously fitted with HA but reluctant to use them for medical or technical reasons (Table 2). In the majority of the patients, dissatisfaction with hearing aids was the reason to opt for mPP. Thus, their choice might suggest that they were naturally invested in their new technology and were therefore more likely to use the device.

In addition, other factors including duration between surgery and follow-up (i.e., the novelty wears off over time) and hearing of the contralateral ear (i.e., good hearing obviate the need to use a device for the weaker ear) might affect device usage. In the present study no significant difference between patients undergoing mPP or SDT followed by fitting of HA was observed for the interval between surgery and follow-up (30.7 vs. 55.4 months; $p = 0.603$) or hearing of the contralateral ear (44 vs. 41 dB-HL AC-PTA, 33 vs. 32 BC-PTA, 10 vs. 9 ABG, all $p > 0.435$). However, this might be due to limited number of patients enrolled in the study. Typically wearing comfort of a HA is comparable to wearing comfort of an audio-processer of an AMEI. Correlations between the usage of device and the QoL scores were not observed (all $p > 0.05$).

Currently, no other data comparing the QoL or usage of device of mPP with SDT and postoperative fitting of HA in the specific setting of otosclerosis with MHL is available. The closest comparable study to the present study by Zwartenkot and colleagues explored the long-term

outcome in patient satisfaction in 33 patients with SNHL and chronic external otitis, who received an AMEI (22). A mean NCIQ's total score of 61.1 ± 13.7 and mean scores for the three principal domains ''physical functioning,'' ''psychologic functioning,'' and ''social functioning'' 60, 59, and 64 score points, were reported, respectively (22). The mean NCIQ's total score observed for mPP-group in the present study was slightly higher than reported by Zwartenkot and co-authors (22). Hence, QoL of the mPP-group seems in line with QoL of typical AMEI users. In terms of usage of device, Atas and co-workers compared QoL and daily usage habits of an AMEI with conventional HAs in 19 patients with CHL or MHL undergoing round-window vibroplasty. The authors used a different QoL instrument than the NCIQ, which does not allow for direct comparison. Overall, some contrasting findings to the present study need to be addressed. The authors reported a significantly higher QoL scores in patients with AMEI than in patients with HA ($p < 0.05$). No significant difference was observed between the usage of device of the AMEI-group and the HA-group. However, it is noteworthy to mention that Atas and colleagues compared these satisfaction outcomes in patients who used HA preceding a VSB implantation. Thus, a selection bias might be suggested (23).

It should be acknowledged that bone-anchored HA are another treatment option for otosclerosis with MHL.

In terms of audiologic performance, Ricci and colleagues reported ABG closure with 10 dB-HL for 6 of 7 (85.7%) after implantation with the bone-anchored hearing aid Baha (Cochlear Limited, Sydney, Australia), which was comparable to conventional SDT (78.2–95.0%). In the present study, the rate was lower with 9 of 14 mPP-patients (64.3%). Unfortunately, the preoperative audiologic findings were not reported separately for the otosclerotic patients by Ricci (24). Thus, the comparability of the two studies is hampered. The authors concluded that BAHA represent a valid treatment option in all patients for whom stapedotomy bears too great of a risk. Notably, also mPP was previously observed to be safe: the short-incudial-process coupling limits the surgery to an extended antrotomy, sparing vital anatomical structures. Moreover, no coupling of the floating-mass-transducer of the positioned stapes-piston is required, thus providing additional safety for the inner ear (6). In addition, in contrast to bone-anchored HA, AMEI provided binaural hearing. A further advantage is that mPP provides a surgical closure of the ABG improving the patients hearing without amplification via the AMEI. This cannot be observed in patients treated with bone anchored hearing devices.

In terms of QoL, Mc Larnon and co-authors reported an increase in QoL of 27.7 score-points measured with the Glasgow Benefit Inventory in three patients with otosclerosis after implantation of bone-anchored hearing aids (Branemark, Oticon Medical, Smorum, Denmark). These three patients were enrolled in a larger retrospective questionnaire study including a total of 94 patients (25). Unfortunately, the comparison of the two studies is hampered, since in the present study a different questionnaire to assess QoL was used (19).

Studies comparing bone anchored devices with AMEI in otosclerosis are further needed in order to illuminate this question.

Several limitations need to be addressed. Generally, the level of evidence of cohort studies is limited, especially if the number of included patients is small (26). To increases this number, data from two tertiary otologic referral centers was collected (6). Thus, a bias might has been introduced since different surgeons and audiologists were involved in the treatment of the included patients. No data about the experience of the surgeons nor about fitting strategies and experience of the professionals involved in the fitting process was available for the present study. Since both, surgery and postoperative fitting of AMEI and HA is a complex process involving various steps (27), the observed functional- and speech perception gains observed in this study might vary. Finally, the chosen, study design remains inferior to prospective, controlled or randomized-controlled trials (26).

Both treatment options provided equal benefits in terms of sound- and speech perception. QoL and surgical complications were comparable in both groups, while patients after mPP seemed to use their device more frequently. Overall, the mPP can be considered as an alternative treatment option in patients with otosclerosis and MHL if medical or technical problems prevent using a HA.

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