Otology & Neurotology
40:292–300 Copyright © 2019 The Author(s). Published by Wolters Kluwer Health, Inc. on behalf of Otology & Neurotology, Inc.

OPEN

Modified-Power-Piston: Short-Incudial-Process-Vibroplasty and Simultaneous Stapedotomy in Otosclerosis

*Daniel Dejaco, †David Riedl, *Timo Gottfried, ‡Thomas Rasse, *Natalie Fischer, *David Prejban, §Viktor Koci, *Herbert Riechelmann, *Joachim Schmutzhard, and ‡Thomas Keintzel

**Department of Otorhinolaryngology–Head and Neck Surgery; †Department of Medical Psychology, Medical University of Innsbruck; ‡Department of Otorhinolaryngology–Klinikum Wels-Grieskirchen, Wels; and §Department for Hearing, Speech and Voice Disorders, Medical University of Innsbruck, Innsbruck, Austria*

Objective: If mixed-hearing-loss (MHL) occurs in otosclerosis, hearing-aids (HA) in addition to conventional-stapedotomy (SDT) may be necessary. If otosclerosis progresses or technical or medical problems prevent use of HA, combining active-middle-ear-implants (AMEI) with SDT (''power-piston'') may be considered. Previously, AMEI-coupling to the long-incudial-process was suggested. Here, a ''modified-power-piston'' surgery (mPP) coupling to the short-incudial-process was proposed, so no coupling over the positioned stapes-piston is required. We questioned whether mPP is as safe and effective as SDT.

Methods: Otosclerotic patients with MHL and limited satisfaction with previously worn HA receiving mPP were retrospectively reviewed at two Austrian tertiary otologic referral centers. Patients, receiving stapedotomy, were case-matched for preoperative pure-tone averages (PTA), bone-conduction (BC-PTA), air-conduction (AC-PTA), and air-bone gap (ABG-PTA). Postoperative changes in BC-PTA and in AC-PTA and ABG-PTA were defined as safety- and as efficacy outcome parameter.

Results: Of 160 patients, 14 received mPP and 14 stapedotomy. Preoperative findings were comparable (all $p = 1.000$). BC-PTA improved from 38.0 to 36.7 and from 37.1 to 36.9 dB-HL for mPP and SDT, respectively (Δ –1.3 versus –0.2 dB-HL; $p = 0.077$). AC-PTA improved from 66.8 to 47.1 and from 66.3 to 46.5 dB-HL for mPP and SDT, respectively (Δ –19.6 versus –19.7 dB-HL; $p = 0.991$). ABG-PTA improved from 28.8 to 10.4 and from 29.1 to 9.6 dB-HL for mPP and SDT, respectively (Δ –18.3 versus –19.5 dB-HL; $p = 0.771$).

Conclusion: In otosclerosis with MHL and limited satisfaction with HA, mPP appeared as safe and effective as SDT and may be considered a treatment alternative in these patients. **Key Words:** Otology—Otosclerosis—Outcome—Power-piston—Stapedotomy—Vibroplasty.

Otol Neurotol **40:**292–300, 2019.

Otosclerosis frequently presents with conductive-hearing-loss (CHL) (1). Hearing-aids (HA) are considered the reference treatment in otosclerosis (2). If technical (i.e., auditory-feedback) or medical problems (i.e., chronic-external-otitis [COE] prevent HA, conventional-stapedotomy [SDT] may be considered instead (2)). SDT may allow closure of the air-bone gap (ABG) in pure CHL. However, also mixed-hearing-loss (MHL) occurs in otosclerosis (1). To address the sensorineural part of the MHL, additional HA after SDT are required (3). If otosclerosis progresses further, or technical or medical problems prevent HA, even this combined treatment may be insufficient for audiologic rehabilitation (4).

For these cases, active-middle-ear-implants (AMEI) have been developed (5–11). Amongst other available AMEIs, the Vibrant Soundbridge® (VSB, MedEl; Innsbruck, Austria) is considered valuable, since various couplers for the floating-mass-transducer (FMT) are available. It was introduced in the 1990s (6) and obtained the indication for sensorineural-hearing-loss (SNHL) in 2002 (8). Originally, the FMT was coupled to the long-incudial-process (LP) (8). Recently, alternative (10), coupling sites were proposed (5,7,9–11). Thus, the indication for VSB expanded to MHL (5). Available coupling sites include the round-window (RW) (5), the oval-window (OW) (7,11), and the short-incudial-process (SP) (9). The

Address correspondence and reprint requests to Joachim Schmutzhard, M.D., Department of Otorhinolaryngology–Head and Neck Surgery, Medical University of Innsbruck, Anichstr. 35, 6020 Innsbruck, Austria; E-mail: joachim.schmutzhard@i-med.ac.at

Source of Funding: No financial support for any of the work presented in the present manuscript was obtained.

None of the authors named in the submitted work have any conflict of interest including financial or personal relationships that inappropriately bias his or her actions within 3 years of the work beginning.

DOI: 10.1097/MAO.0000000000002146

latter limits the extent of surgery from a wide posterior-tympanotomy to an extended-antrotomy (9).

Although VSB is considered safe and effective in patients with MHL caused by chronic-otitis-media (COM) (10,12,13), less data are available about its application in MHL caused by otosclerosis (4,14–16). Dumon first describe a VSB implantation together with SDT in one otosclerotic patient. A combined endaural and retroauricular approach was required. A LP-vibroplasty was performed followed by SDT. The FMT clip was fitted over the positioned stapes-piston. A complete closure of the ABG and additional gain via the VSB was achieved. The authors concluded that the gains of both procedures add up (4). Kontorinis performed a similar procedure in two patients with MHL caused by Osteogenesis imperfecta. The mean postoperative air-conductive (AC) pure-tone average (PTA) was 52.5 and 85.0 dB-HL, respectively. The authors referred to this operation as ''power-stapes''-surgery (15). Venail implanted two otosclerotic patients using VSB after SDT. The mean postoperative AC-PTA was 27.5 and 38.8 dB-HL, respectively (16). Recently, Coordes et al. (14) VSB-implanted one otosclerotic patient, who underwent bilateral conventional-stapedotomy (SDT) 20 years before. Here, a RW-vibroplasty was performed instead. A postoperative gain of 25 dB-HL was observed.

''Power-stapes''-surgery performed as SDT in conjunction with simultaneous or consecutive LP- or RW-vibroplasty for otosclerotic patients were previously reported in several case reports (4,14–17). All authors concluded the intervention to be safe (4,14–17). However, no case series exploring the significance of ''power-stapes''-surgery in otosclerotic patients are available (4,14–16). Moreover, certain limitations apply to the surgical technique previously proposed: all reports share a wide posterior-tympanotomy for FMT coupling. This bears the risk of injury to the Chorda-tympani, the facial-nerve, and the horizontal-semicircular-canal. Moreover, the FMT Clip has to be fitted over the positioned stapes-piston, additionally endangering the open inner-ear.

We propose a ''modified-power-stapes'' surgery (mPP) in otosclerotic patients, in which disease progressed or technical or medical problems prevent HA. We performed SP-vibroplasties in combination with simultaneous SDT in a larger series. Since the stapes is replaced by a piston and then mechanically driven by an AMEI, the surgery proposed here is referred to as mPP. Patients undergoing mPP were case-matched to patients undergoing SDT. We questioned whether mPP is equally safe and effective as SDT in a matched cohort. Clinical histories, surgical technique, and outcome performance tests are reported.

MATERIALS AND METHODS

Study-Population

This retrospective, matched case-control series exploring whether mPP is equally safe and effective as SDT was conducted at the Departments of Otorhinolaryngology, Medical University of Innsbruck and Klinikum Wels-Grieskirchen. Charts of adult otosclerotic patients with moderate to profound MHL (18) and limited satisfaction with previously worn HA which underwent mPP at either department, were retrospectively reviewed. Inclusion criteria are detailed in Table 1.

After chart review of the study-cohort was completed, a case-matched-cohort was generated from a larger sample of patients undergoing SDT at the Department of Otorhinolaryngology, Medical University of Innsbruck. Inclusion criteria for the case-matched-cohort were the same as for the study-cohort (Table 1) except for availability of postoperative aided pure-tone audiogram and speech-intelligibility test since these tests were not routinely performed in these patients.

Audiologic Performance Testing

Preoperative pure-tone audiograms were performed at the day before surgery with an Interacoustics AC40 audiometer (Electrotech Corporation, Chandigarh, India) in sound treated room. Thresholds were measured between 0.125 and 8 kHz, while the contralateral ear was masked with a small-band signal. For postoperative pure-tone audiograms, the latest audiogram performed was used. For postoperative aided pure-tone audiograms, the VSB was active and used. Preoperative word-recognition-scores (WSR) were only routinely measured in patients undergoing mPP at the

TABLE 1. *Detailed inclusion criteria for this retrospective, case control study exploring the safety and efficacy of modified-power-piston-surgery in comparison to conventional-stapedotomy*

Modified-Power-Piston	Conventional-Stapedotomy
Age ≥18 years	Age ≥18 years
history of otosclerosis	history of otosclerosis
moderate to profound mixed hearing loss limited satisfaction with previously worn hearing aids	moderate to profound mixed hearing loss
Modified Power Stapes surgery between 2010 and 2018	Conventional stapedotomy between 2010 and 2018
Air-conductive pure-tone-average of ≥40 dB hearing level	Air-conductive pure-tone-average of ≥40 dB hearing level
Bone-conductive pure-tone average of ≥20 dB hearing level	Bone-conductive pure-tone average of ≥20 dB hearing level
Available preoperative pure-tone audiogram	Available preoperative pure-tone audiogram
Available postoperative pure-tone audiogram	Available postoperative pure-tone audiogram
Available postoperative aided pure-tone audiogram[a]	
Available preoperative speech-intelligibility test[a]	
Available postoperative speech-intelligibility test[a]	

[a]Postoperative aided pure-tone averages and pre- and postoperative word recognition scores were available for patients undergoing modified stapes surgery only, since these findings were not routinely measured in patients undergoing conventional stapedotomy in the two departments.

day before surgery with an Interacoustics AC40 audiometer. WRS was measured using the German ''Freiburger'' speech-intelligibility test, using 50-word lists of monosyllabic nouns at supratreshold presentation levels between 60 and 110 dB SPL under free-field conditions without masking of the contralateral ear with small-band signal. Also postoperative WRS were only routinely measured in patients undergoing mPP with the VSB active and used.

Surgical Technique

Surgery was performed by three different surgeons with comparable surgical experience (19). After obtaining written informed consent, a facial-nerve monitoring (Neurosign 100, Neurosign surgical, UK) was installed and checked for functionality. A tympanomeatal-flap was created and the tympanic-membrane was mobilized, via a retroauricular-incision. The Chorda-tympani was spared. The posterior-superior bony auricular canal was drilled out using a 1.8 mm diamond-burr until full visualization of the LP, the incudostapedial-joint, the stapedial-superstructure, the RW, and the OW. The stapes was checked for fixation, confirming the diagnosis of otosclerosis (Fig. 1A). The incudostapedial-joint and the stapedial-tendon were severed, before the stapes-superstructure was removed.

A basic-mastoidectomy and extended-antrotomy were performed over the same retroauricular-incision, widely exposing the SP (Fig. 1B). After preparation of the periosteum pocket and the implant bed, the VSB's FMT (VORP 503, Med-El) was attached to the SP-coupler (Med-El), and implanted in the prepared bed. The SP-coupler was fixed to the SP and checked for sufficient freedom of movement (Fig. 1C). The coupling of the FMT was performed after the removal of the stapes-superstructure and before the stapes-piston implantation, giving maximum safety to the inner-ear.

The stapes-footplate was perforated with a Sharplan C40 carbon dioxide laser (Lumenis Ltd., Yokneam, Israel) resulting in a 0.6 mm perforation. A 0.6 mm Titanium stapes-piston (Heinz-Kurz GmbH, Dusslingen, Germany) was inserted into the stapes'-footplate perforation and cramped to the LP (Fig. 1D). The stapes-footplate and the piston's cramping site were covered with connective tissue. Since the stapes is replaced by a piston and then mechanically driven by and AMEI, the surgery proposed here is referred to as mPP instead

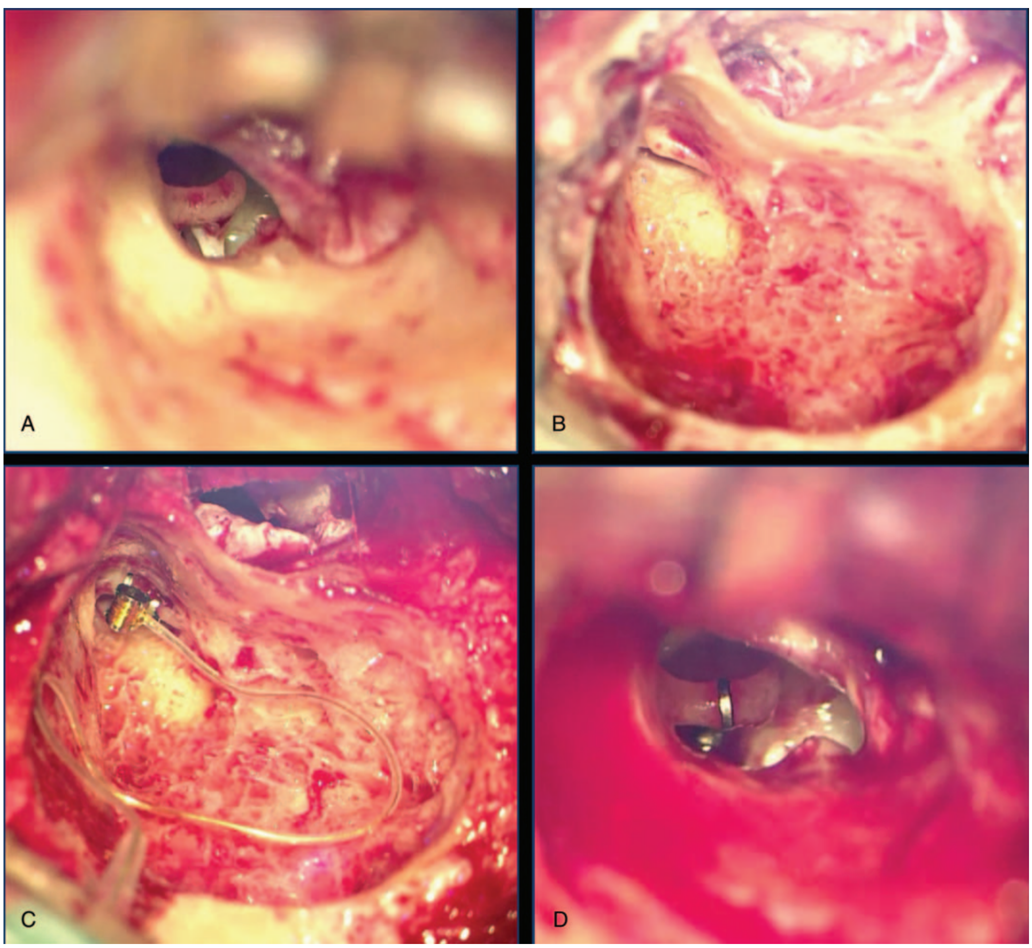

FIG. 1. ''Intraoperative microscopic images of selected key steps in modified-power-piston-surgery of the right ear.'' The stapes were checked for fixation, confirming the diagnosis of otosclerosis, after full visualization of the stapedial-superstructure was granted by drilling out the posterior-superior bony auricular canal (*A*). The short-incudial-process was widely exposed via basic-mastoidectomy and extended-antrotomy (*B*). A periosteum pocket for the Vibrant Soundbridge® (VORP 503, Med-El, Innsbruck, Austria) was created and the floating-mass-transducer (FMT) attached to the short-incudial-process-coupler on top of the short-incudial-process and checked for sufficient freedom of movement (*C*). The coupling of the FMT was performed after the removal of the stapes-superstructure, giving maximum safety to the inner-ear (*D*). For additional detail, please also refer to the main text.

of the previously frequently used term ‘‘power-stapes’’ (15), which should be reserved for AMEI-coupling to an intact, complete stapes.

For the SDT, the surgical technique was the similar as for the mPP previously described except for the SP-vibroplasty steps. In contrast to mPP, the SDT was performed over an endaural approach.

Statistical Analysis

Calculation of Outcome Parameters

As recommended by the Committee on Hearing of the American Academy of Otolaryngology–Head and Neck Surgery (20), both, AC-PTA and BC-PTA were calculated by dividing the added thresholds at 0.5-, 1-, 2-, and 3-kHZ by four pre- and postoperatively. ABG-PTA was calculated by subtracting BC-PTA from AC-PTA pre- and postoperatively. WRS were calculated as percentage value at 80 dB SPL pre- and postoperative for patients undergoing mPP only.

Moreover, scattergrams relating pre- and postoperative AC-PTA and WRS for patients undergoing mPP were provided. Since WRS was not routinely measured pre- and postoperatively in patients undergoing SDT, data were not available. Therefore, improvement in WRS between mPP and SDT could not be compared and was not considered as outcome parameter.

Propensity-Score-Matching

A larger sample of patients undergoing SDT at the Department of Otorhinolaryngology, Medical University of Innsbruck, was compared to the study-cohort undergoing mPP via propensity-score-matching plug-in for SPSS24 (IBM, Armonk, NY). The case-matched-cohort was matched to the study-cohort for preoperative 1) AC-PTA, 2) bone-conductive (BC)-PTA, and 3) ABG-PTA. A maximum difference of $\geq \pm 10$ dB-HL for each matching criterion was defined as acceptable tolerance margin for possible matches.

Outcome Parameters

Clinical data of patients including sex, age, type of surgery, number of previous ear surgeries, site of surgery, and department at which surgery was performed was recorded (Table 2). Outcome parameters were mean postoperative 1) AC-PTA, 2) BC-PTA, 3) ABG-PTA and the corresponding pre- to postoperative changes within cohorts and between cohorts for patients undergoing either a) mPP or b) SDT. We questioned whether mPP is equally safe and effective as SDT in a case-matched-cohort. The change between mean pre- and postoperative BC-PTA served as safety outcome parameter. No change or a change towards a lower mean postoperative BC-PTA (negative values) was considered as positive outcome. The change between mean pre- and postoperative AC-PTA, the ABG-PTA and the percentage rate of complete ABG-closures achieved, served as effectiveness outcome parameter. A change towards a lower mean postoperative AC-PTA and/or a lower mean postoperative ABG-PTA (negative values) was considered as positive outcome. Additionally, 4) postoperative aided pure tone PTAs and 5) postoperative WRS only for a) mPP were provided.

Frequency data were presented in tabular form. For patients undergoing mPP only, pre- and postoperative AC-PTA in relation to WRS presented as scattergram as recommended was provided (20). For continuous data means and standard deviations (SD) as well as minimums and maximums were provided. Chi-square and Fisher’s exact tests were used to test for statistical significance defined as $p < 0.05$. Additionally repeated measure analysis of variance analysis and Cohen effect size calculations were performed. All calculations were performed with SPSS24 and its corresponding plug-ins.

RESULTS

Patient’s Characteristics

A total of 160 otosclerotic patients with moderate to profound MHL (18) were included in this retrospective study. Of these, 14 patients underwent mPP for limited satisfaction with previously worn HA. Reasons for limited satisfaction with previously worn HA include auditory-feedback and COE (eight and six patients, respectively). Of the 14 patients, which underwent mPP, five were operated at the Department of Otorhinolaryngology, Medical University of Innsbruck and nine at the Department of Otorhinolaryngology, Klinikum Wels-Grieskirchen. Of these, seven patients were women. The mean (±SD) age was 54 (±9) years, ranging from 40 to 69 years (Table 2).

The remaining 146 patients underwent SDT followed by HA fitting, if required. Of these, 14 patients were matched to the study-cohort undergoing mPP for preoperative AC-PTA, BC-PTA, and ABG-PTA. Of these,

TABLE 2. *Clinical data of 24 otosclerotic patients with moderate to profound mixed hearing loss (18) undergoing either modified-power-piston-surgery or conventional-stapedotomy*

	Modified-Power-Piston[b]	Conventional-Stapedotomy	χ^2
sex			
Male	7	6	$p = 1.0$
Female	7	8	
Age (yr)[a]	54 (±9; 40–69)	56 (±11; 37–78)	
Number of previous ear surgeries[a]	1 (±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.

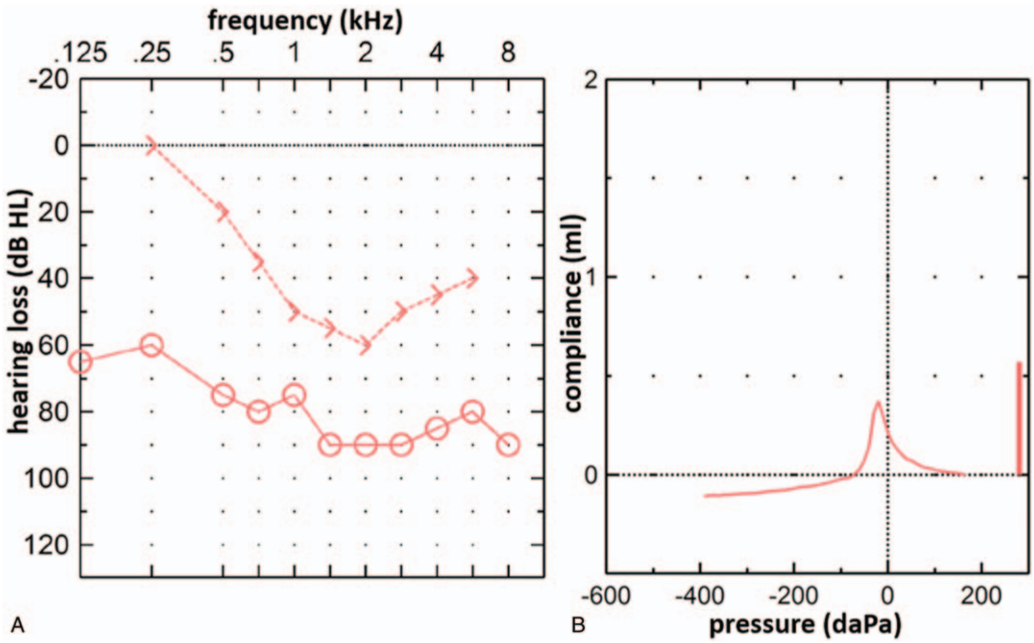

FIG. 2. "Representative preoperative pure-tone audiogram and tympanometry selected from the study-population undergoing modified-power-piston-surgery of the right ear." Preoperative air-conductive threshold for warble tones for the right ear ranged from 60 to 90 dB-HL with an air-conductive pure-tone average of 82.50 dB-HL (*red circles* and *red continues line*, *A*). Bone-conductive threshold ranged from 0 to 60 dB-HL with a bone-conductive pure-tone average of 43.75 dB-HL (*red clips* and *red dashed line*, *A*). Tympanometry was regular with a compliance of 0.37 mL at 0 daPa and a tone of 226 Hz (*B*). Ipsilateral stapedial reflexes were not detectable at 80 and 100 dB between 0.5 and 4 kHz (not depicted).

eight patients were women. The mean (±SD) age was 56 (±11) years, ranging from 37 to 78 years (Table 2). Detailed data of all 28 patients included in the statistical analysis is presented in Table 2.

Preoperative Findings

For mPP patients, mean preoperative AC-PTA, BC-PTA, and ABG-PTA was 66.8, 38.0, and 28.8 dB-HL, respectively. A representative preoperative pure-tone audiogram and tympanometry of the right ear of a 55-year-old female patient undergoing mPP for moderate to profound MHL and limited satisfaction with previously worn HA for 5 years because of COE is depicted in Figure 2.

For SDT patients, mean AC-PTA, BC-PTA, and ABG-PTA was 67.1, 37.5, and 29.6 dB-HL, respectively. Neither of this preoperative audiologic findings significantly differed between the study-cohort and the case-matched-cohort ($p = 0.939$, $p = 0.849$, and $p = 0.777$, respectively). Additional SD, minimums and maximums are provided in Table 3.

For mPP patients only, WRS was available for 13 of 14 patients. Mean preoperative WRS at 80 dB SPL was 32.0%. Preoperative scattergrams for patients undergoing mPP as recommended (20) are depicted in Figure 3A.

Postoperative Findings

Safety

For mPP patients, mean preoperative BC-PTA was 38.0 compared with 36.7 dB-HL postoperatively, which was not significant ($p = 0.450$; Table 3). A representative postoperative pure-tone audiogram and additional aided threshold using VSB® (MedEl, Innsbruck, Austria) of the right ear of the same 55-year-old female patient as presented in Figure 2 after mPP is depicted in Figure 4.

For SDT patients, mean preoperative BC-PTA was 37.1 compared with 36.9 dB-HL postoperatively, which was not significant ($p = 0.540$; Table 3). Postoperative change in mean BC-PTA for mPP patients was better with −1.3 compared with −0.2 dB HL for SDT, but this difference was not significant ($p = 0.077$). No significant difference in mean postoperative BC-PTA between mPP and SDT was observed ($p = 0.450$; Table 3)

Efficacy

For mPP patients, mean preoperative AC-PTA was 66.8 compared with 47.1 dB-HL postoperatively, which was significant ($p < 0.001$; Table 3). For SDT patients, mean preoperative AC-PTA was 66.3 compared with 46.5 dB-HL postoperatively, which was significant ($p < 0.001$; Table 3). Postoperative change in mean AC-PTA for mPP was −19.6 compared with −19.7 dB-HL for SDT, which was not significant ($p = 0.991$). No significant difference in mean postoperative AC-PTA between mPP and SDT was observed ($p = 0.550$; Table 3).

For mPP patients, mean preoperative ABG-PTA was 28.8 compared with 10.4 dB-HL postoperatively, which was significant ($p < 0.001$; Table 3). For SDT patients, mean preoperative ABG-PTA was 29.1 compared with

TABLE 3. *Preoperative and postoperative audiologic findings for a total of 24 otosclerotic patients with moderate to profound mixed hearing loss (18) undergoing modified-power-piston-surgery (n = 14) or conventional-stapedotomy (n = 14)*

	Cohort	Preoperative[b]	Postoperative[b]	Change[b]	
Bone-conductive PTA[a]	Modified-power-piston	38.0 (6.7; 22.5–46.3)	36.7 (7.8; 25.0–47.5)	−1.3 (6.7; −6.3–12.5)	$p = 0.450$
	Conventional-stapedotomy	37.1 (8.2; 20.0–46.3)	36.9 (11.8; 17.5–58.57)	−0.2 (10.4; −27.5–15.0)	$p = 0.540$
		$p = 0.849$	$p = 0.450$	$p = 0.077$	
Air-conductive PTA[a]	Modified-power-piston	66.8 (11.5; 48.8–81.3)	47.1 (14.9; 27.5–77.5)	−19.6 (16.9; 0.0–53.8)	$p = 0.001$
	Conventional-stapedotomy	66.3 (13.0; 48.8–88.8)	46.5 (13.2; 28.8–67.5)	−19.7 (14.1; −12.5–41.3)	$p = 0.001$
		$p = 0.939$	$p = 0.550$	$p = 0.991$	
Air-bone-gap PTA[a]	Modified-power-piston	28.8 (8.2; 20.0–45.0)	10.4 (9.9; 0.0–31.3)	−18.3 (12.7; 0.0–45.0)	$p = 0.001$
	Conventional-stapedotomy	29.1 (8.4; 15.0–42.5)	9.6 (6.9; 1.3–21.3)	−19.5 (8.1; 3.8–31.3)	$p = 0.001$
		$p = 0.777$	$p = 0.450$	$p = 0.771$	

[a]Pure tone average.
[b]Mean decibel hearing level (dB-HL). Standard deviations (SD), minimums and maximums were provided.

9.6 dB-HL, which was significant ($p < 0.001$; Table 3). Postoperative change in mean ABG-PTA for mPP was –18.3 compared with −19.5 dB-HL for SDT, which was not significant ($p = 0.771$). No significant difference in mean postoperative ABG-PTA between mPP and SDT was observed ($p = 0.450$; Table 3).

In mPP patients, complete closure of the ABG was achieved in 43% (6/14), compared with 30% (4/14) in SDT patients. Although the rate of postoperative complete closures for mPP was higher than for SDT, this difference was not significant ($p = 0.695$).

Postoperative aided PTA were available for mPP patients only, since aided pure-tone audiograms were not routinely measured in patients undergoing SDT in the two departments.

For mPP patients, the mean postoperative aided PTA was 35.5 compared with 47.1 dB-HL postoperatively, which was significant ($p < 0.001$). The additional

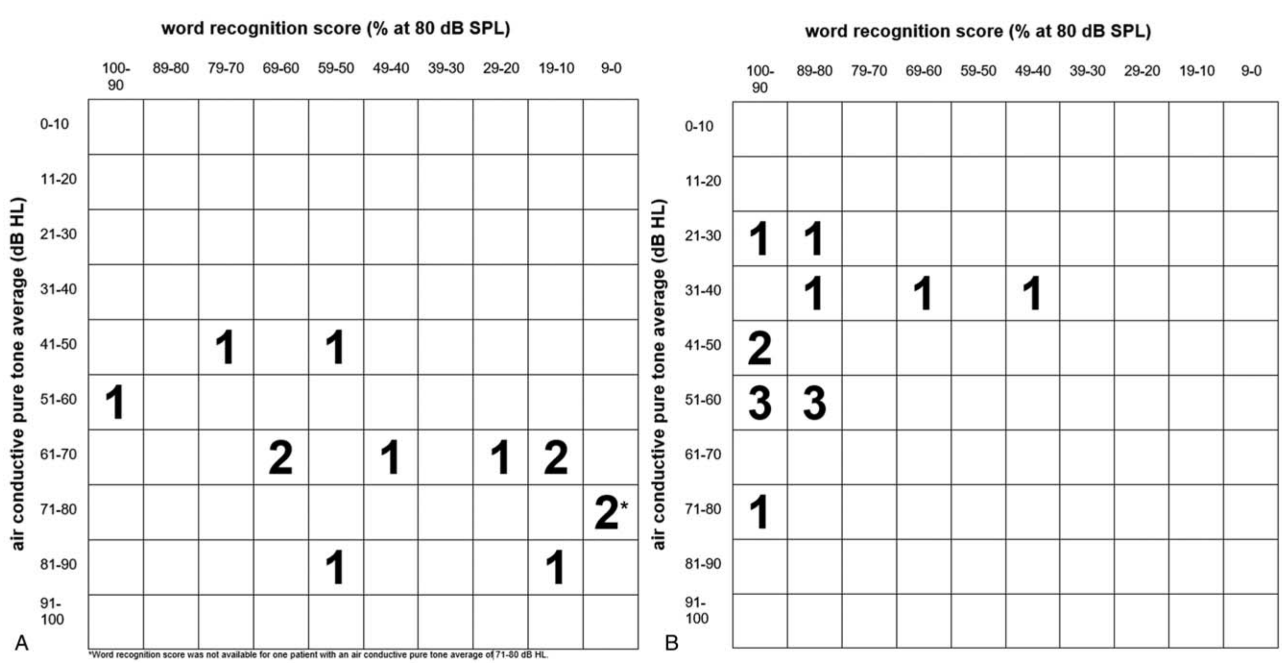

FIG. 3. "Pre- and postoperative scattergrams relating air-conductive pure-tone average to word recognition score for modified-power-piston surgery." Scattergram relating pre- (*A*) and postoperative (*B*) air-conductive pure-tone average (AC-PTA) to word recognition score (WRS) as recommended by the Hearing Committee of the American Academy of Otolaryngology–Head and Neck Surgery for patients undergoing modified-power-piston-surgery (mPP). AC_PTA was calculated as recommended plotted on the *y*-axis in increasing 10 dB-intervals from 0 to 91 dB from top to bottom. WRS was measured using the German "Freiburger" speech-intelligibility test, using 50-word lists of monosyllabic nouns at 80 dB SPL under free-field conditions and plotted on the *x*-axis in increasing 10% in descending order from left to right.

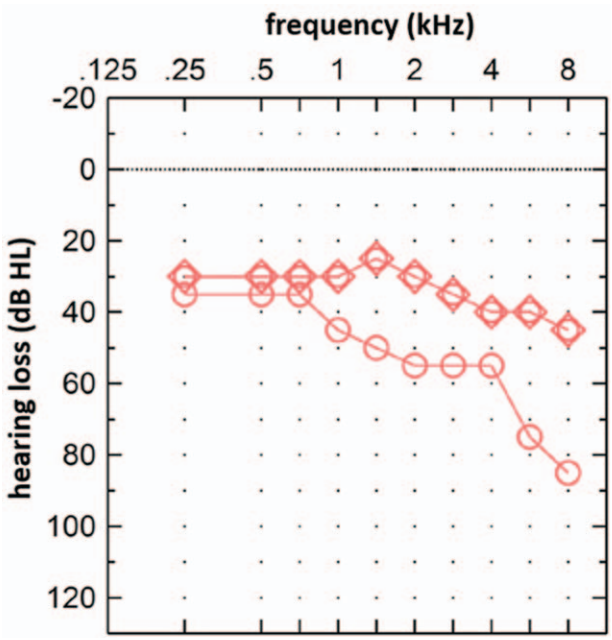

FIG. 4. "Representative postoperative pure-tone audiogram with additional aided threshold selected from the study-population undergoing modified-power-piston-surgery of the right ear." Postoperative air-conductive threshold for warble tones for the right ear ranged from 35 to 85 dB-HL with an air-conductive pure-tone average of 47.5 dB HL, which translates to a gain of 35.0 dB-HL (*red circles* and *lower red continues line*). Aided threshold using the Vibrant Soundbridge® under free field conditions in a sound treated room via a loudspeaker located 1 m in front of the patient ranged from 30 to 45 dB-HL with a pure tone average of 32.5 dB-HL, which translates to an additional gain of 12 dB HL (*red diamonds* and *upper red continues line*). This aided pure-tone average almost reaches the 30 dB-HL margin, where additional hearing aids for adequate audiologic rehabilitation may be considered unnecessary.

improvement between mean postoperative aided PTA and mean postoperative AC-PTA for mPP patients was 11.6 dB-HL, which was significant ($p < 0.001$). Also the aided postoperative PTA for mPP patients was significantly better than the postoperative AC-PTA for patients SDT (35.5 versus 46.5 dB-HL; $p < 0.001$).

For mPP patients only, WRS was available for 14 of 14 patients. Mean preoperative WRS at 80 dB SPL was 85.0%. Postoperative scattergrams for patients undergoing mPP as recommended (20) are depicted in Figure 3B.

DISCUSSION

If otosclerosis progresses or technical or medical problems prevent HA, SDT alone may be insufficient for audiologic rehabilitation (4). AMEIs may be considered instead in otosclerotic patients with moderate to profound MHL and limited satisfaction with previously worn HA (5). Currently, the VSB (6) is preferably implanted at our departments. While initially LP-vibroplasties (8) were performed, surgical technique evolved and different coupling sites (5,7,9–11) and new indications (5,8) were proposed. Available data regarding mPP in otosclerotic patients is case report based (4,14–16). Most previous reports performed a LP-vibroplasty via a wide posterior-tympanotomy coupling the FMT clip over the positioned stapes-piston (4,15,16). This may endangers vital anatomical structures and the open inner ear. We propose mPP as SP-vibroplasty in combination with simultaneous SDT (Fig. 1). This mPP was performed in a larger series. We explored this modified intervention for safety and efficacy compared with matched SDT patients.

Charts of otosclerotic patients with moderate to profound MHL (18) and limited satisfaction with previously worn HA, which underwent mPP at either of two tertiary otologic referral centers between were retrospectively reviewed (Table 1). Complete data sets for mPP patients, consisting of clinical data (Table 2), pre- and postoperative pure-tone audiograms, pre- and postoperative speech-intelligibility test and postoperative aided pure-tone audiograms, were available for 13 patients (Table 3). One preoperative speech-intelligibility test was missing in one patient. They were matched for preoperative bone-conduction (BC-PTA), air-conduction (AC-PTA), and air-bone gaps (ABG-PTAs) with SDT patients. Finally, complete data sets for 28 patients were available, of which clinical data (Table 2) and preoperative audiologic findings (Table 3) did not significantly differ (all $p < 0.777$; Table 3), which suggests successful matching. Since the limited satisfaction with previously worn HA and not acoustical indications were the reason for undergoing mPP rather than SDT for all patients included, a possible selection bias may be negligible.

The change between mean pre- and postoperative BC-PTA served as safety outcome parameter. We assumed the intervention as safe, if no change or a change towards the better occurred. For both interventions the pre- and postoperative mean BC-PTA changed towards slightly better values with 38.0 to 36.7 and 37.1 to 36.9 dB-HL for mPP and SDT, respectively. Although, the numeric change in postoperative mean BC-PTA for mPP was slightly better with –1.3 compared with –0.2 dB-HL, this difference did not reach significance ($p = 0.077$). However, a trend might be suggested. Since no deterioration of postoperative mean BC-PTA was observed in mPP patients, the present data suggest that both interventions might be comparably safe (Table 3).

The change between mean pre- and postoperative AC-PTA and ABG-PTA served as safety outcome parameter. Changes towards lower values were considered as positive outcome. For both interventions a significant change between pre- and postoperative mean AC-PTA was observed from 66.8 to 47.1 and from 66.3 to 46.5 dB-HL for mPP and SDT, respectively (both $p < 0.001$; Table 3). The postoperative change in mean AC-PTA was almost identical with –19.6 for mPP and –19.7 dB-HL for SDT. Consequently, no significant difference was observed ($p = 0.991$).

Similar observations were made for the change between mean pre- and postoperative ABG-PTA. For both interventions a significant improvement in mean postoperative ABG-PTA was observed with 28.8 to 10.4 and 29.1 to 9.6 dB-HL for mPP and SDT, respectively (both $p < 0.001$). Although the change in mean postoperative ABG-PTA for mPP with −18.3 was slightly less than for SDT with −19.5 dB-HL, this difference was not significant ($p = 0.771$). In contrast, the rate of postoperatively achieved complete closures was 13% higher for mPP. Although this difference was not significant, various levels of expertise of the surgeons involved may be discussed as reason. However, since all surgeons had comparable experience (19) the sample size is considered a more likely cause. Postoperative aided PTA were available for patients mPP only, since aided pure-tone audiograms were not routinely measured in patients undergoing SDT in the two departments. Due to the retrospective study design, this data could also not be reproduced. The VSB SP-vibroplasty in addition to the simultaneously performed SDT resulted in an additional mean postoperative gain of 11.6 dB-HL resulting in a postoperative aided PTA of 35.5 dB-HL, which was significant ($p < 0.001$). This aided PTA for mPP patients almost reaches the 30 dB-HL margin, where additional hearing aids for adequate audiologic rehabilitation may be considered unnecessary (21) (Fig. 4). The reasons for patients to choose mPP instead of SDT were limited satisfaction with previously worn HA due to auditory-feedback and COE. Since HA after mPP were not required, this lack of disadvantages of HA may be considered as benefit for patients choosing mPP.

The postoperative results observed in the present cohort were comparable to previous case reports (14–17). Kontorinis reported a postoperative mean AC-PTA for two patients of 52.5 and 85.0 dB-HL. However, these patients were suffering from otosclerosis caused by osteogenesis imperfecta and a LP-vibroplasty was performed instead of the SP-vibroplasty described here (15). Venail reported postoperative mean AC-PTA of 27.5 and 38.8 dB-HL in two patients. However, the SDT was not performed simultaneously in this study (16). Coordes reported a mean functional gain of 25 dB-HL after a RW-vibroplasty. Again, the SDT was performed approximately 20 years before the RW-vibroplasty (14). Most recently, Powell et al. (17) performed a comparable SP-vibroplasty as described in the present study, in one otosclerotic patient, who was no longer able to wear HA because of COE. SP-vibroplasty was followed by a SDT 6 weeks after. A postoperative ABG-PTA reduction from 55 to 20 dB-HL was reported.

Several limitations need to be addressed. Generally, the level of evidence of retrospective studies is limited, especially if the sample size is small (22). We aimed at improving the level of evidence by collecting data from two tertiary otologic referral centers and by creating a matched case-controlled series. Despite these efforts, the present study design remains inferior to any prospective, controlled, or even randomized-controlled trial (22) and therefore studies with superior design should be performed in future.

Additionally, two major postoperative findings were missing for the present analysis due to its retrospective nature. Firstly, no aided postoperative PTA for patients undergoing SDT were available. Since, these patients were matched to the patients undergoing mPP mainly because of moderate to profound MHL, it appears likely that patients with comparable preoperative audiologic findings require additional HA after SDT for adequate rehabilitation. Secondly, both, the indication for SDT as well as the postoperative follow up at both our institution was based purely on pure-tone audiograms. No WRS were raised for these patients. Since retrospective chart reviews were performed, this data could not be reproduced. The change in WRS between the mPP and SDT could not be explored. Therefore it was excluded as outcome parameter. Thus, currently no conclusions can be drawn, whether mPP could be a possible standard procedure for patients with otosclerosis. Better-designed trials (22) should raise these two postoperative audiologic findings for patients undergoing SDT (20). To compensate for this lack of vital data, pre- and postoperative scattergrams for patients undergoing mPP were provided as recommended by the Committee on Hearing of the American Academy of Otolaryngology–Head and Neck Surgery (20) (Fig. 3). Since no WRS for patients undergoing SDT were available, no scattergrams could be provided.

mPP as combination of a short-incudial-process-vibroplasty with simultaneous conventional-stapedotomy limits surgery to an extended antrotomy, possibly sparing vital anatomical structures and coupling the FMT over the positioned stapes-piston (4,15,16). In otosclerotic patients with moderate to profound mixed-hearing-loss (18) or if technical or medical problems prevent hearing-aids, mPP may considered a treatment alternative to conventional-stapedotomy.

REFERENCES

1. Foster MF, Backous DD. Clinical evaluation of the patient with otosclerosis. *Otolaryngol Clin North Am* 2018;51:319–26.
2. Nazarian R, McElveen JT, Eshraghi AA. History of otosclerosis and stapes surgery. *Otolaryngol Clin North Am* 2018;51: 275–90.
3. Merkus P, van Loon MC, Smit CF, et al. Decision making in advanced otosclerosis: an evidence-based strategy. *Laryngoscope* 2011;121:1935–41.
4. Dumon T. Vibrant soundbridge middle ear implant in otosclerosis: technique - indication. *Adv Otorhinolaryngol* 2007;65:320–2.
5. Colletti V, Soli SD, Carner M, Colletti L. Treatment of mixed hearing losses via implantation of a vibratory transducer on the round window. *Int J Audiol* 2006;45:600–8.
6. Dazert S, Shehata-Dieler WE, Dieler R, Helms J. Vibrant Soundbridge middle ear implant for auditory rehabilitation in sensory hearing loss. I. Clinical aspects, indications and initial results. *Laryngorhinootologie* 2000;79:459–64.
7. Huttenbrink KB, Beutner D, Zahnert T. Clinical results with an active middle ear implant in the oval window. *Adv Otorhinolaryngol* 2010;69:27–31.
8. Luetje CM, Brackman D, Balkany TJ, et al. Phase III clinical trial results with the Vibrant Soundbridge implantable middle ear hearing device: a prospective controlled multicenter study. *Otolaryngol Head Neck Surg* 2002;126:97–107.

9. Schraven SP, Dalhoff E, Wildenstein D, et al. Alternative fixation of an active middle ear implant at the short incus process. *Audiol Neurootol* 2014;19:1–11.
10. Vyskocil E, Riss D, Honeder C, et al. Vibroplasty in mixed and conductive hearing loss: comparison of different coupling methods. *Laryngoscope* 2014;124:1436–43.
11. Zehlicke T, Dahl R, Just T, Pau HW. Vibroplasty involving direct coupling of the floating mass transducer to the oval window niche. *J Laryngol Otol* 2010;124:716–9.
12. Ernst A, Todt I, Wagner J. Safety and effectiveness of the Vibrant Soundbridge in treating conductive and mixed hearing loss: a systematic review. *Laryngoscope* 2016;126:1451–7.
13. Lee JM, Jung J, Moon IS, Kim SH, Choi JY. Benefits of active middle ear implants in mixed hearing loss: stapes versus round window. *Laryngoscope* 2017;127:1435–41.
14. Coordes A, Jahreiss L, Schonfeld U, Lenarz M. Active middle ear implant coupled bilaterally to the round window despite bilateral implanted stapes prostheses. *Laryngoscope* 2017;127:500–3.
15. Kontorinis G, Lenarz T, Mojallal H, Hinze AL, Schwab B. Power stapes: an alternative method for treating hearing loss in osteogenesis imperfecta? *Otol Neurotol* 2011;32:589–95.
16. Venail F, Lavieille JP, Meller R, et al. New perspectives for middle ear implants: first results in otosclerosis with mixed hearing loss. *Laryngoscope* 2007;117:552–5.
17. Powell HRF, Pai I, Ghulam H, Jiang D. An alternative approach to mixed hearing loss in otosclerosis: stapes surgery combined with an active middle-ear implant. *J Laryngol Otol* 2018;132:457–60.
18. World Health Organization. Hearing impairment grades; 2018. Available at: http://www.who.int/deafness/hearing_impairment_-grades/en/. Accessed August 29, 2018.
19. Watson GJ, Byth K, da Cruz M. Outcome in stapedotomy suryger: the learning curve redefined. *Otol Neurotol* 2015;36:1601–3.
20. Gurgel RK, Jackler RK, Dobie RA, Popelka GR. A new standardized format for reporting hearing outcome in clinical trials. *Otolarnygol Head Neck Surg* 2012;147:803–7.
21. Boeheim K, Pok SM, Schloegel M, Filzmoser P. Active middle ear implant compared with open-fit hearing aid in sloping high-frequency sensorineural hearing loss. *Otol Neurotol* 2010;31:424–9.
22. Anglemyer A, Horvath HT, Bero L. Healthcare outcomes assessed with observational study designs compared with those assessed in randomized trials. *Cochrane Database Syst Rev* 2014;Mr000034.