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The Floating Mass Transducer on the Round Window Versus Attachment to an Ossicular Replacement Prosthesis

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Abstract

Hypothesis—The Vibrant Soundbridge Floating Mass Transducer® (FMT) is part of a commercially available implantable hearing device in which the FMT can be placed in the round window niche (RW) or attached to a partial (V-PORP) or total ossicular replacement prosthesis (V-TORP) contacting the stapes head or footplate. The goal is to provide efficient transfer of sound vibration into the cochlea. The hypothesis is that the FMT location on the prosthesis is superior to the RW location.

Background—No direct comparisons of the three FMT sites have been performed using the same measurement location.

Methods—A new measurement method called the “Third Window” method (TW) was used in eleven fresh human temporal bones to compare the sites. A small hole was made into the scala tympani of the temporal bones preserving the endosteum. A reflective target was placed on the TW endosteum and displacement of the cochlear fluid was measured using a Polytec HLV-1000 laser Doppler vibrometer. The input to the FMT at all locations was a constant 316 millivolts (mV); the frequency range was 0.5 to 0.8 kHz.

Results—The V-PORP and V-TORP FMT locations both provided statistically significant better performance above 1.0 kHz than the RW site, but not below that frequency. The V-PORP and V-TORP responses were similar at all test frequencies.

Conclusion—In this temporal bone model, the FMT provided better higher frequency performance when attached to a PORP or TORP than in the RW niche.

INTRODUCTION

Partial Ossicular Replacement Prostheses (PORP) and Total Ossicular Replacement Prostheses (TORP) have been used for many years in middle ear ossicular reconstruction. In the majority of cases, these implants achieve successful post-surgical closure of the air-bone gap. In many cases, a passive implant is not sufficient, particularly in cases of mixed hearing loss with a sensorineural component. The current solution for patients with a mixed hearing loss who require a reconstructive procedure with a PORP or TORP is to implant the PORP or TORP and offer a hearing aid to provide adequate post-surgical hearing, if needed.

Newer approaches for the correction of mixed hearing loss have recently been described using the Vibrant Soundbridge implantable hearing device (MED-EL Hearing Technology GmbH, Innsbruck, Austria). In this device, the transducer, called the Floating Mass Transducer (FMT), is normally placed on the long process of the incus in patients with a sensorineural hearing loss and intact ossicular chain (1-3). It is energized by an external amplifier with an acoustic microphone and battery that transmits the signal to the implant FMT using a trans-cutaneous radio-frequency (RF) system similar to that used in cochlear implants.

Colletti et al. (4) in 2006 published an approach utilizing the round window (RW) as the site for FMT placement (FMT-RW) in 6 cases of conductive or mixed hearing loss where ossicular reconstruction had not been successful and a conventional hearing aid was unsatisfactory. Recently, they presented additional data on 19 patients with mixed or conductive hearing losses using the technique compared with 19 patients who had conventional TORP reconstruction. (5) They found it produced significantly improved hearing results compared to the TORP treated cases; no complications were observed. Others have described similar successful results in cases of severe mixed or conductive loss using the FMT in the RW niche (6-8). Kiefer *et al.* (9) also evaluated the FMT contacting the RW in a patient with a malformed ossicular chain. The hearing results indicated that the aided thresholds were 15 to 30 dB better in the frequency range of 750–6000 Hz. Frenzel et al (10) found the procedure safe and effective in seven osseous atresia cases.

Huber et al. (11) described experiments in a human temporal bone model with the FMT attached to a PORP (V-PORP). They measured footplate displacement and found a relatively flat frequency response from 1.0 kHz to 8.0 kHz with a lower frequency roll-off. The maximum output was equivalent to a 125 dB SPL acoustic input at the tympanic membrane (TM). The lower frequency roll-off below 1.0 kHz is due to the mechanics of the FMT; it is designed to produce maximal gain at the higher frequencies where the majority of sensorineural hearing loss patients need the most amplification. RW placement of the FMT is indicated in ears with a conductive or mixed hearing loss where ossicular reconstruction is not possible or unsuccessful and a conventional hearing aid cannot be used (4-10). The PORP and TORP with attached FMT is indicated in ears where ossicular reconstruction is possible and needed but there is also a sensorineural hearing loss so that additional amplification will likely be needed following surgery. The RW location of the FMT could also be used in mixed hearing loss ears undergoing standard ossicular reconstruction where additional amplification after successful surgery is thought to be necessary.

No direct comparison of the three locations of the FMT (V-PORP, V-TORP, and FMT-RW) has been performed in regard to the acoustic gain produced by each. Spindel and Ball (12) described experiments in 10 human temporal bones comparing the FMT–RW with the standard FMT incus placement, using stapes footplate displacement as the measurement of output for the incus located FMT and RW displacement for measurement of the output of the FMT – RW. The same voltage inputs to the FMT were used in each case. The FMT – RW showed superior performance at all test frequencies. A criticism of the results obtained is the use of two different measuring sites for the comparison, as well as the difficulty in accurately measuring RW displacement with a FMT-RW device in the RW niche. The purpose of this study is to compare the function of the FMT on the RW to the FMT used as part of a PORP and TORP in a human temporal bone model, using the same measurement site.

MATERIALS AND METHODS

Specimens

Eleven fresh human temporal bones were extracted from human cadavers within 48 hours of death using a Schuknecht bone saw at the time of autopsy. The cored specimens were wrapped in gauze, placed in a 1:10,000 solution of Merthiolate in normal saline, and stored at 5°C. All measurements were performed within 6 days of death. For each temporal bone, the tympanic membrane (TM) and middle ear were inspected under an operating microscope to ensure that the ear appeared normal. Bones with an abnormal TM or middle ear were not used.

Temporal bone preparation

Following the removal of any attached connective tissue, the anterior bony wall of the external auditory canal was drilled down to a 2-mm rim, leaving the annulus intact. A plastic tube (internal diameter, 8.5 mm; length, 25 mm) was fixed around the bony ear canal using clay so that the axis of the tube was perpendicular to the TM. The tube contained an earphone adapter on the side near the lateral end with a probe tube opening 2 mm from the medial end. An opening was made in the mastoid cortex for insertion of the prostheses. The remainder of the temporal bone was embedded in dental cement (Kerr, Romulus, MI) to produce a solid specimen block.

Preparation for “Third Window” Measurement Method

Simple mastoidectomy and posterior hypotympanotomy were performed, and the mastoid and tympanic segment of the facial nerve was removed to reveal the oval window and RW. The basal turn of the cochlea was skeletonized using a diamond burr (diameter, 1.5 mm), and the bony wall of the scala tympani removed creating a “Third Window” (TW) into the cochlea. The area of the TW was gradually extended to an area of approximately 1.5×1.5 mm. Care was taken to leave the endosteum intact with no loss of cochlear fluid. A 0.5 mm square piece of reflective tape (3M, St. Paul, MN) was placed on the TW. The opening in the mastoid cavity was then sealed by building up the sides with modeling clay and placing a glass coverslip on top. The bone was then secured in a temporal bone holder.

Measurement systems

Measurements were taken using the SYSid 6.5 audio band measurement and analysis system (SYSid Labs, Berkeley, CA). With a DSP-16+ processing board (Ariel, Cranbury, NJ), this software produces an output signal to drive the sound source and synchronously measures and averages the magnitude and phase angle of two input signals at each frequency using a fast Fourier transform. The sound stimulus consisted of stepped tones swept at 100 logarithmically spaced frequency points from 0.5 to 8 kHz. The results are presented in graphic form using the SYSid software. Phase data was also obtained but is not included in this report.

Sound was presented at the side of the lateral end of the plastic tube using a #2955 Knowles hearing aid earphone (Knowles Electronic, Itasca, IL). The open end was closed with a thin glass coverslip held in place with petroleum jelly. The sound pressure in the plastic tube was measured within 3 mm of the TM using an ER-7C microphone (Etymotic Research, Elk Grove Village, IL) attached to a probe tube inserted through an opening in the plastic tube. The sound signal was amplified by a D-75 power amplifier (Crown, Elkhart, IN) and fed into the earphone, giving each tone an intensity ranging from 80 to 120 dB SPL. The results were calculated relative to an input of 80 dB SPL at the TM.

Test FMT devices

Three FMT test devices were provided by the manufacturer (MED-EL Hearing Technology GmbH, Innsbruck, Austria). The first (FMT-RW) was designed to drive the RW and is similar to that used by Colletti et al (4,5). The clip normally present to attach onto the incus was removed and a 1.5×1.5 mm square of silicone rubber, 1.5 mm thick, was glued to the end of the FMT contacting the RW membrane. Colletti et al (4,5) used a piece of fascia as a pad between the RW and FMT.

The second (V-PORP) was a FMT attached by a clip to the side of a commercially available Bell Tübingen titanium prosthesis (Heinz Kurz GmbH, Medizintechnik, Dusslingen, Germany). Two lengths were available: 3.75 mm and 4.25 mm; the shorter had a mass of 33.8 mg and the longer a mass of 33.9 mg, including the FMT.

The third (V-TORP) was a FMT attached by a clip to a titanium Bell Tübingen TORP made by the same manufacturer; two lengths were available: 4.75 mm and 5.00 mm. The mass was 33.9 mg for the shorter prosthesis and 34.0 mg for the longer. The input to the FMT devices was provided by the SYSid software with a constant input of 316 mV at all test frequencies between 0.5 and 8.0 kHz. This voltage was chosen to provide an optimal output within the linear capability of the FMT.

Surgical approach

FMT on the RW—The baseline velocity of the target on the TW was first measured in response to a 80 dB SPL sound pressure input at the tympanic membrane in eight intact human temporal bones using a laser Doppler vibrometer (LDV: HLV-1000; Polytec, PI, Costa Mesa, CA). The measurement of TW velocity was mathematically converted to displacement over the frequency range 0.5–8.0 kHz. The bony lip of the RW was drilled down until the RW membrane could be seen clearly for fitting the FMT. The FMT was then placed in contact with the RW membrane, and care was taken to ensure that the axis of the FMT was perpendicular to the RW (Fig. 1A). The displacement of the TW in response to an FMT input of 316 mV over the same frequency range as the baseline testing was measured in 8 ears.

FMT Attached to PORP or TORP—After the FMT-RW response was measured, the incudostapedial joint was cut, and the incus removed *via* the facial recess. An FMT attached to a PORP (V-PORP) was inserted through the facial recess and placed between the malleus handle and stapes head (Figure 1B). The measurement was then repeated using the same FMT input of 316 mV. Next, the V-PORP was removed and the FMT attached to a TORP (V-TORP) placed between the same location on the malleus handle and the center of the stapes footplate; the stapes superstructure remained intact (Figure 1C). Measurement of TW displacement was again performed in the same way. Seven temporal bones were used for these measurements. The choice of prosthesis length was based on producing “optimal” tension between the malleus and stapes head or footplate; the longer prostheses were typically used.

RESULTS

Comparison of the three types of FMT stimulation

Figure 2 shows the results for TW displacement of the three forms of FMT stimulation. The curve of the baseline ear response to 80 dB SPL acoustic stimulation at the TM is also shown. In Fig. 3, these displacement results were converted to an equivalent acoustic input at the TM in SPL. With FMT-RW stimulation, the mean TW response was equivalent to a 98–108 dB SPL input at the tympanic membrane at 1.0 to 8.0 kHz. The V-PORP produced a

response of 112-118 dB SPL at the same frequencies. The V-TORP produced similar displacement as the V-PORP above 1.0 kHz with a decreased response at higher frequencies above 5.0 kHz. All had a lower frequency roll-off below 1.0 kHz with both the V-PORP and V-TORP having a slope of about 18dB/oct while the FMT-RW was nearly flat below 0.8 kHz.

The V-PORP and V-TORP produced statistically greater TW displacement than the FMT-RW at several frequencies between 1.0 and 4.0 kHz; this is shown in Table I.

Stapes footplate displacement after TW preparation

TW preparation can potentially damage the cochlea and affect the transfer function by changing cochlear impedance. The TW was made into the scala tympani of the cochlea so the acoustic effect should be minimal compared to a TW connected to the scala vestibuli. Therefore, stapes footplate (FP) displacement was measured with the V-PORP before and after the TW was made to evaluate the effect of the TW preparation in 3 ears. Input was 316 mV over the frequency range 0.5 to 8.0 kHz. The stapes target was a 0.5×0.5 mm piece of 3M reflective tape attached to the center of the stapes footplate. Figure 4 shows that the displacement curves were almost identical below 2 kHz and the maximal difference was within 5 dB at 5 kHz.

Linearity of TW displacement

Displacement at the TW to an increasing stimulation level of the V-PORP was linear between 10 mV and 1000 mV inputs measured at 10 dB intervals in one ear (Fig. 5).

DISCUSSION

1. Validity of measurement of TW displacement

For many years, measurements of stapes footplate and RW displacement in human temporal bones have been used to determine the function of the middle ear (13,14). These methods are also suitable for use in comparisons of the effects of ossicular prostheses and implantable hearing devices (14-16). Measurements of cochlear pressure have also been used (17,18), however, that method requires a significant amount of preparation. When comparing middle ear prostheses, whether active or passive, the same site for measurement should be used. The usual site for the measurement of middle ear acoustic function using a laser Doppler technique is at the center of the stapes footplate (13). We have also used RW displacement to determine relative differences in transmission in the same temporal bone (14). We felt neither of these sites would be satisfactory to compare the three FMT conditions using a single site. The RW site was not possible for accurate measurement of the RW FMT due to the presence of the FMT. While the footplate site could be used to compare the V-PORP and V-TORP, using it to compare the FMT-RW would measure reverse stimulation through the cochlea, something that could produce an artifact. Vestibular sound pressure measurement has been used in previous experiments by our group (18,19). As mentioned previously, it is much more technically challenging and takes longer time to perform. A new method, measurement of TW displacement, was developed so that RW and stapes stimulation with the FMT could be compared using the same measurement site. As previously noted, removal of the cochlear wall in the process of TW preparation may produce a change in the transfer function by affecting cochlear impedance. Therefore, we measured stapes center displacement with the V-PORP before and after the TW preparation in three ears. The difference in stapes displacement before and after the TW was within 5 dB at all frequencies so measurement of TW displacement appears to be a valid method for this study. (Fig 4)

The method allows for relative comparisons in the same ear using the same target location on the TW, similar to the use of RW displacement, described in a previous study (14).

2. FMT-RW

There have been previous reports regarding the suitability of RW stimulation using an implant device either before or at the time of the Colletti et al. (4,5) papers. Spindel *et al.* (20) demonstrated that a small magnet surgically implanted on the RW in guinea pigs could be used to drive the cochlea via an external coil. The system produced responses similar to the effects of sound waves as shown by the auditory brainstem response. Kiefer *et al.* (9) applied the FMT to the RW in a patient with a malformed ossicular chain. The hearing results indicated that the aided thresholds were between 15 and 30 dB better in the frequency range of 750–6000 Hz. Colletti *et al.* (4) reported the hearing outcome of a FMT-RW in seven patients with hearing impairment caused by ossicular chain defects not suitable for middle ear reconstruction; some had a sensorineural component as well. According to their results, postoperative aided thresholds of 20–30 dB HL were achieved for all patients, as compared with unaided thresholds ranging from 60–80 dB HL. A later paper (5) reported similar results in an additional 19 patients.

In the current study, the maximal TW vibration produced by the FMT-RW was equivalent to a 98–108 dB SPL input at the tympanic membrane at 1.0 to 8.0 kHz with a lower frequency roll-off below 1.0 kHz (Fig. 3). Increased gain could be achieved by increasing the input voltage to the FMT, however 316 mV was chosen since it was similar to the maximum voltage used in the usual Vibrant Soundbridge placement; increased voltage produces greater output but a shorter battery life. The acoustic gain of the FMT-RW was less than the V-PORP and V-TORP at all test frequencies (Fig 2 and 3) and we suggest it is due primarily to sub-optimal coupling between the RW membrane and the RW-FMT. Dumon *et al.* (21) reported on the performance of a piezo-electric vibrator placed on the RW compared to placement on the stapes in guinea pigs. The results indicated that the most effective stimulation site was the stapes, and they speculated that dispersion of the energy transmitted by the vibrator to the flexible membrane of the RW may be greater than when the bony stapes footplate is stimulated. The significant differences found in this temporal bone study would suggest clinically that if a V-PORP or V-TORP could be used, all else being equal, either would be expected to give better post-operative aided hearing results than a RW-FMT placement. Obviously, unaided post-operative hearing thresholds should be better with a V-PORP or V-TORP.

Another factor is that the middle ear was intact in these experiments while in the usual clinical case, the footplate is disconnected from the ossicles and TM. This could increase the impedance produced by the middle ear so that RW-FMT gain would be improved by removal of the incus, all else being equal. We did a comparison in one ear of FMT-RW function before and after incus removal. No significant difference was seen in the TW measurements.

3. V-PORP and V-TORP

In 1994, Tos *et al.* (22) reported a series of 6 cases where a PORP or TORP with a magnet in the head was implanted and energized by a coil deep in the ear canal connected to a post-auricular hearing aid. They reported functional gains of 40 to 70 dB HL across the 125 to 8 kHz frequency range. McGee *et al.* (23) also studied this system but it never became commercially available.

Huber *et al.* (11) used a 100 mV input into the V-PORP and found a response equivalent to 108 to 125 dB SPL at the TM from 1.0 to 8.0 kHz. Despite the 10 dB lower input stimulus,

they obtained about 10 dB higher V-PORP results at frequencies below 3 kHz and 10 dB lower results at frequencies above about 6 kHz. The reasons for this are not clear but one possibility is differences in the multitone signal used by Huber et al versus the single tone method used by SYSid.

In the present study, the V-PORP and V-TORP gave similar outputs based on TW measurements up to around 2.0 kHz. Above this frequency the V-PORP maintained a relatively flat frequency response up to 8.0 kHz while the V-TORP response rolled off more at higher frequencies, particularly above 5.0 kHz where the difference was near 9.0 dB SPL (Fig 3).

The differences seen between the V-PORP and V-TORP may simply be another example of the former having better coupling to the stapes than the latter. In most middle ear reconstructions, a PORP produces a superior post operative hearing result than a TORP, all else being equal. (24) The differences in relative mass were similar and not thought to be a factor. Differences in relative tension are a problem with these measurements and at this time there is no good way to quantify tension. The optimal length prosthesis was chosen individually in this study from two available lengths of V-PORP and V-TORP selecting the length that gave the best transmission for each prosthesis. It is possible that different lengths not available might have produced different results.

4. TW method

This new method, in our opinion, is similar to using the round window (RW) as a measurement site for comparison of middle ear devices or procedures. (14) However, it allows us to make comparisons of devices that stimulate the RW as well as the stapes footplate. The opening is made about 2 mm from the RW niche and measures the cochlear fluid pressure wave in the scala tympani. This pressure wave should mimic, except for phase, a pressure wave in the scala vestibuli, similar to measurements of RW vibration. It is essential that the endosteum remains intact and that cochlear fluid is present and not lost. The location of the opening in the cochlea is above the 10 kHz cochlear frequency map so its effect is thought not a factor since our highest measurement is 8.0 kHz. The effect on higher frequencies is not known. The fresh human temporal bone model used in these experiments has been found to maintain the cochlear fluids and provide reproducible measurements. (13,15,18,19) Additional information on the method is in preparation and preliminary findings have been presented. (25)

CONCLUSIONS

The V-PORP and V-TORP produce statistically significant greater TW displacements that are up to 18 dB higher than the FMT-RW at several frequencies between 1.0 and 4.0 kHz; the results are statistically significant. (Table I) Differences were present but not as great below 1.0 kHz. The TW approach appears to be a useful new method to compare devices that stimulate the RW with prostheses that stimulate the stapes.

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Figure 1.

A The Round Window FMT (RW-FMT) in place in the RW niche

B The PORP with attached FMT (V-PORP) in place between the malleus handle and stapes head.

C The TORP with attached FMT (V-TORP) in place between the malleus handle and stapes footplate. The stapes superstructure was left intact.

Figure 2.

Mean peak amplitude of TW displacement. The acoustic stimulation result is in response to an 80dB SPL acoustic input at the TM in 8 ears. A FMT was applied to the round window (FMT-RW) in 8 ears, attached to a PORP (V-PORP) in 7 ears and attached to a TORP (V-TORP) in 7 ears. The input to the FMT was the same for each location, 316 mV

Figure 3.

The mean amplitude of third window (TW) displacement for the three FMT conditions shown in Figure 2 has been converted to an equivalent SPL input at the TM based on the displacement curve produced by the 80 dB SPL acoustic at the TM in the eight baseline ears.

Figure 4. Footplate (FP) displacement with FMT attached to a PORP (V-PORP) before (solid line) and after (dotted line) TW preparation (n = 3). Input to the V-PORP is 316mV from 0.5 to 8.0 kHz

Figure 5.

Linearity of third window displacement with a FMT attached to a PORP (V-PORP) in one ear. Input voltage was increased from 10 mV to 1000 mV in 10 dB steps. The lowest curve was at 10 mV input; next curve at 31.6mV; next curve at 100mV; next curve at 316mV and the highest curve at 1000mV.

Table I

Frequency (kHz)	0.5	1.0	2.0	3.0	4.0	6.0	8.0
FMT-RW	90.3 (1.9)	102.8 (2.5)	97.7 (2.4) **	100.3 (2.7) **	102.7 (3.4) *	107.6 (5.5)	108 (3.7)
V-PORP	91.4 (5.6)	112.3 (3.6) **	116.6 (3.5) *	116.3 (3.2) *	116.3 (3.2)	117.6 (5.9)	116 (5.6)
V-TORP	97.9 (3.3)	117.1 (2.8)	112.8 (3.9)	112.5 (3.6)	112.1 (3.4)	110.5 (3.3)	107 (3.2)

** P<0.01, * P<0.05

The mean amplitude (relative dB SPL) and the standard error of the mean (SEM) at seven representative frequencies for the three conditions are compared using one-way analysis of variance (ANOVA) for statistical analysis. The Bonferroni correction was used for comparison between the three locations of the FMT. The solid lines connect results with differences that are statistically significant at the $p<.05$ or $p<.01$ levels.