An Optimal Partial Ossicular Prosthesis Should Connect Both to
the Tympanic Membrane and Malleus: A Temporal Bone Study
Using Laser Doppler Vibrometry

Anders Niklasson, Kilian Gladine, Anton Rönnerblom, Magnus von Unge,
Joris Dirckx, and Krister Tano

Department of Clinical Science, Otorhinolaryngology, Umeå University, Umeå, Sweden;
Department of Physics, University of

Antwerp, Antwerp, Belgium; Department of Otorhinolaryngology, Akershus University Hospital,
Lørenskog, Norway;

University of Oslo, Oslo, Norway; and Centre for Clinical Research, Hospital of Västmanland
Västeraås,

Region Västmanland—Uppsala University, Västeraås, Sweden

Objective: To compare stapes vibrations in different partial
ossicular replacement prosthesis (PORP) applications.

Methods: Stapedial vibrations were measured on fresh frozen
human temporal bones with laser Doppler vibrometry. Eight
different types of common ossiculoplasty methods were
compared regarding recovery of stapes vibrations in relation
with the normal ossicular chain. The PORPs were divided into
three groups: 1) PORPs with the lateral contact only with the
tympanic membrane, 2) PORPs with lateral contact only to
the malleus handle, and 3) PORPs with lateral contact with
both the malleus handle and the tympanic membrane.

Results: The PORPs with lateral contact only to the malleus
handle performed better than the PORPs with lateral contact
to the tympanic membrane only at 2 kHz, but the best
recovery was found in the group with contact both to the
malleus handle and the tympanic membrane.

Conclusion: The best sound transmission might be achieved
by placing a PORP in contact with both the tympanic
membrane and the handle of the malleus. Key Words:

Laser Doppler vibrometry—Middle ear—Ossiculoplasty.

Ossiculoplasty is one of the most common otosurgical procedures that aim to restore hearing. Partial ossicular replacement prostheses (PORP) are often used when there is an intact and mobile stapes. In this procedure the stapes head is connected to the tympanic membrane and/or to the handle of the malleus. Total ossicular replacement prostheses are sometimes used, especially when the superstructures of stapes are missing. In this procedure, the stapes footplate is connected directly to the tympanic membrane and/or to the malleus.

There are many different types of PORPs available and otosurgeons tend to have his or her favourite. Common types of PORPs are columellas sculptured from the incus or prefabricated titanium prostheses.

It is very difficult to conduct controlled and randomized clinical studies that assess which types of PORP that best restore hearing. The reasons for this are due to variations that are difficult to control such as the skill of the surgeon and the course of the individual healing processes (1,2).

Laser Doppler vibrometry (LDV) has been used for many years in studies that assess vibration amplitude and velocity in human temporal bones to make analogies to hearing losses due to mechanical reasons in the middle ear (3–6). In a previous article, we described a LDV method in which it was possible to measure the vibrations of the stapes footplate from the inner ear side without any need of disturbing the tympanic membrane by elevating it (7). It was also possible to access the middle ear and make

various ossiculoplasties with minimal interference with the tympanic membrane or the stapes.

The aim of the present study was to use the LDV assessment method to compare the velocity of stapes vibrations after the placement of different types of PORPs that are commonly used in ossiculoplasty.

METHODS

The procedures applied in the LDV assessment method were described in previous articles (7,8). Six fresh frozen human temporal bones that were donated for research purposes were used in the present study. Before measurements the bones were stored at -20°C. While the specimen was still frozen the cochlea was cut away exposing the medial side of the stapes footplate. An access to the middle ear was created by drilling a hole through the tympanic tegmen in a middle fossa-like approach. The temporal bones were thawed, and before measurements a semiclosed cavity was made involving the external ear canal. The cavity contained an earphone speaker and a microphone that was screwed onto the planum mastoideum and sealed with elastic paste (Otoform AKX) over the ear canal (Fig. 1). Manipulations of the ossicular chain were made under an operating microscope (Zeiss OPMI Sensera, Jena, Germany). The velocity of the vibrations was measured perpendicular to the stapes footplate with LDV (Polytec model 534 and controller OFV-5000).

A reflective patch was placed on the medial side of the stapes footplate. During all the manipulations of the ossicular chain with the different PORPs, the tympanic membrane was kept intact. During the LDV measurements the stapes footplate was kept moistened by flushing the temporal bone with saline every 5 minutes; any overflow of saline was removed with suction.

Eight different types of PORPs were tested on six temporal bones (Table 1), and the order in which the different prostheses were tested was randomly chosen. The intention was to achieve the best fit. In a few PORP placements it was difficult to decide if the PORP had the optimal shape and length. Therefore, repeated measurements were made after minor adjustments of the PORP (Table 1). LDV was performed with an intact ossicular chain and after ossicular reconstruction.

In four patients (Table 1), a small amount of glue (Loctite) was applied at the connection between the stapes head and the PORP and between the handle of malleus and the PORP. This was done to mimic the clinical situation with the PORP stabilized by fibrous healing tissues. After gluing the bones were not reused for testing.

Furthermore, care was taken to insert columellas of adequate lengths to avoid causing increased tension to the tympanic membrane. The PORPs were made from different incuses and always adjusted for the best fit in each temporal bone and the titanium PORPs were adjusted with a cartilage graft for the best fit. In one temporal bone, too long PORPs were tested to increase the tension (Fig. 2).

The prostheses were divided into three groups according to their relation to the tympanic membrane and the handle of the malleus:

Group one prostheses (n=4) had lateral contact to the tympanic membrane only (TMO). These were a Kurtz Bell Titanium 2.5mm prosthesis, herein called “Tuebingen” (Fig. 3A), a malleus head sculptured into a columella, patients “malleus head” (Fig. 3B), an incus sculptured to fit the contour of the tympanic membrane and positioned with the tip pointing toward the umbo, “PORP umbo” (Fig. 3C), and an incus

sculptured into a columella with the lateral tip pointing posteriorly toward the posterior portion of the annulus, “PORP posterior” (Fig. 3D). For the titanium PORP a cartilage graft was always used in between the PORP and the tympanic membrane according to the standard procedure in middle ear surgery.

Group two prostheses (n¼2) had lateral contact to the handle of the malleus only, called Malleo-stapedial assembly (MSA). These were an MSA positioned toward the umbo, “MSA umbo” (Fig. 4A), and a MSA positioned perpendicularly to the handle of malleus, “MSA” (Fig. 4B).

Group three prostheses (n¼2) had lateral contact with both the tympanic membrane and the handle of the malleus. These were a Kurtz Bell Titanium 2.5mm prosthesis with hook, “Tuebingen Hook” (Fig. 5A), and a novel PORP designed sculptured from an incus (NiTa¼Niklasson-Tano) with the same properties as the Tuebingen with hook (Fig. 5B). A cartilage graft for the titanium prosthesis was used as above.

RESULTS

The results are presented as graphs showing the ratio (expressed in dB) of the stapes velocity amplitudes from the different prosthesis applications, compared with the stapes velocity amplitudes in the intact middle ear.

Repeated measurements of the same prosthesis in the same temporal bone did not alter the velocity curve. The mean loss of velocity of the stapes footplate (in relation to the normal ossicular chain) when the incus was removed was 35 dB in the low, 40 dB in the mid, and 20 dB in the high-frequency ranges (data not shown).

Group One

PORPs in lateral contact with the tympanic membrane only (Tuebingen, Malleus head, PORP posterior, PORP umbo) produced relatively high velocity response recovery in the lower frequencies but not in the higher frequency range (Fig. 6A).

Group Two

PORPs in lateral contact with the handle of the malleus only (MSA) without touching the tympanic membrane performed better than group one at 2 kHz (Fig. 6B).

Group Three

The Tuebingen prosthesis with hook combining lateral contact with both the handle of malleus and the tympanic membrane mostly produced high velocities, except for at the highest frequencies. As a result of these findings we modeled a new type of PORP, NiTa, from an autologous incus. The NiTa prosthesis produced similar results as those of the Tuebingen prosthesis (Fig. 6C). The concept of the NiTa prosthesis is also to make contact with both the tympanic membrane and the handle of malleus.

In Figure 7 the means of the LDV results from each of the three main groups of PORPs are compared.

The standard error was calculated for frequencies at 200, 2000, and 4000 Hz (low, mid, and high frequencies).

At 2000 Hz the worst prostheses were in the TMO group.

The MSA group performed worst at 200 Hz, but performed better than the TMO group at 2000 Hz. The third group however, connecting both with the tympanic

membrane and the malleus handle, showed better velocities than the two other groups at all three frequencies.

When longer prostheses were tested, the velocity decreased mostly in the lower frequencies, even though the higher frequencies did somewhat better due to the better contact with the stapes head, due to the increased tension (Fig. 2).

After gluing four of the PORPs, to mimic the more fixed situation after the scar formation, the LDV results improved with an average of 4.9 dB as calculated at 0.5, 1, 2, and 3 kHz, mostly in the frequencies above 1 kHz. Two examples are shown in Figure 8.

DISCUSSION

The aim of the present study was to use a LDV assessment model on thawed fresh-frozen human temporal bones, as described by Niklasson et al. (7), to investigate which type of PORP would give the best hearing results. Since stapes velocity amplitude is directly proportional to hearing sensation, the dB values can be interpreted in the same way as dB hearing loss (or gain) on an audiogram. Clinical LDV settings described in the literature that aim to measure the sound vibrations of the ossicular chain use the posterior tympanostomy as the route (5,9–11). It was shown that thawed fresh-frozen human temporal bones give similar results as that of fresh temporal bones (11,12). In the present model it was, however, possible to measure velocities in the “normal” situation with an intact ossicular chain as a reference. It was also possible to keep both the stapes and the tympanic membrane intact while testing eight different types

of PORP.

An advantage of evaluating different PORP types with LDV is that it is possible to assess the velocity results under the same conditions in the same middle ear and without any interference due to individual healing conditions.

The measurements were always related to the “normal” situation of each temporal bone. One weakness of the study was that the normal tympanic membrane is funnel shaped and thus has a steep angle from the annulus toward the umbo, which may be a disadvantage for some of the PORPs we used. With a postoperatively healed tympanic membrane, the membrane often becomes less funnel shaped due to its adaptation to the shape of the PORP.

In the present study it was found that the PORPs most commonly used (Fig. 6A) produced good sound transmission in the lower frequencies (<1 kHz) but poorer transmission in the mid and high frequencies. Gluing the contact between the stapes head and the prosthesis, however, increased the velocity in the higher frequencies (Fig. 8), as a crude simulation of fibrous tissue stabilizing the contact between the PORP and the stapes. The loss of velocity in the high-frequency range could mostly be explained by the rather loose connection between the PORP and the stapes head in the present temporal bone model. Probably, this velocity drop in the high frequencies would not be observed in the clinical situation due to scar tissue formation between the stapes head and the prosthesis.

Furthermore, the PORPs with lateral contact only to the malleus (MSA) produced better results at 2 kHz than

PORPs with lateral contact only to the tympanic membrane (Tuebingen, Malleus head, PORP posterior, PORP umbo). This indicates some benefit of “adding” the vibrational energy of the malleus to that of the tympanic membrane. Thus, the best velocity was found when combining contact with both the tympanic membrane and the malleus handle (NiTa and Tuebingen Hook, Fig. 6C). Also, in an acoustic temporal bone model Elbrond and Elpern (13) described that the low-frequency transmission is aided if the PORP is in contact with both the handle of the malleus and the tympanic membrane. Such a position might also increase the stability of the PORP in the postoperative healing phase with less risk of luxation of the PORP. Here, we present a novel design of a PORP (NiTa), which can be readily sculptured from an autologous incus.

However, it seems that if the malleus handle is preserved in the ossiculoplasty situation, a PORP that connects to both the tympanic membrane and the malleus handle would be preferable to optimize the hearing results. The reason for this was not studied further in the present study, but it is not unlikely that a PORP with a close contact with the handle of the malleus could mediate sound vibration energy, collected by the malleus handle at the umbo region as well as directly from the tympanic membrane vibrations.

In the present LDV model, the best low and medium frequencies velocity results were found with loose fitting prostheses. Similar findings have also been described in other studies (5,14–18). The reason may be that a loose fit would avoid over-stretching of the annular ligament of

the stapes. The drawback of the loose fit, however, was the drop of velocity in the high-frequency range. Gluing the prostheses gave a better contact between the stapes head and the PORP and between the PORP and the malleus which probably gives a better mechanical sound transmission, and therefore might be in a better clinical analogy where the PORP is fixed due to postoperative fibrosis between the stapes and the prosthesis.

The method used in the present study is reproducible and stable, which makes it useful for evaluating different ossiculoplasty methods in the future. A weakness of this model, however, is that the cochlea is removed, which is done to get LDV access to the medial side of the stapes plate. The cochlear removal probably increases the velocity in certain frequencies, but since the same situation was present when the normal ear with an intact ossicular chain was measured, it was possible to relate the results to the normal ear as a control.

CONCLUSION

The LDV measurements showed best results from PORPs in lateral contact with both the tympanic membrane and the handle of malleus (NiTa and Tuebingen).

The velocity in the frequencies above 1 kHz improved when simulating the healed situation by gluing the PORP to the stapes head.

REFERENCES

1. Merchant SN, Rosowski JJ, McKenna MJ. Tympanoplasty. *Operative Tech Otolaryngol Head Neck Surg* 2003;14:224–36.
2. Brackmann DE, Sheehy JL, Luxford WM. TORPs and PORPs in

- tympanoplasty: A review of 1042 operations. *Otolaryngol Head Neck Surg* 1984;92:32–7.
3. Nakajima HH, Ravicz ME, Merchant SN, Peake WT, Rosowski JJ. Experimental ossicular fixations and the middle ear's response to sound: Evidence for a flexible ossicular chain. *Hear Res* 2005;204:60–77.
4. Alian WA, Majdalawieh OF, Van Wijhe RG, Eijnell H, Bance M. Prosthetic reconstruction from the tympanic membrane to the stapes head or to the stapes footplate? A laser Doppler study. *J Otolaryngol Head Neck Surg* 2012;41:84–93.
5. Goode RL, Killion M, Nakamura K, Nishihara S. New knowledge about the function of the human middle ear: Development of an improved analog model. *Am J Otol* 1994;15:145–54.
6. Goode RL, Ball G, Nishihara S, Nakamura K. Laser doppler vibrometer (LDV)—a new clinical tool for the otologist. *Am J Otol* 1996;17:813–22.
7. Niklasson A, Ronnblom A, Muyschondt P, Dirckx J, von Unge M, Tano K. Ossiculoplasty on isolated malleus fractures: A human temporal bone study using laser Doppler vibrometry. *Otol Neurotol* 2016;37:895–901.
8. Peacock J, Dirckx J, von Unge M. Magnetically driven middle ear ossicles with laser vibrometry as a new diagnostic tool to quantify ossicular fixation. *Acta Otolaryngol* 2014;134:352–7.
9. Neudert M, Zahnert T, Lasurashvili N, Bornitz M, Lavcheva Z, Offergeld C. Partial ossicular reconstruction: Comparison of three different prostheses in clinical and experimental studies. *Otol Neurotol* 2009;30:332–8.
10. Voss SE, Rosowski JJ, Merchant SN, Peake WT. Acoustic responses of the human middle ear. *Hear Res* 2000;150:43–69.
11. Rosowski JJ, Davis PJ, Merchant SN, Donahue KM, Coltrera MD. Cadaver middle ears as models for living ears: Comparisons of middle

ear input immittance. *Ann Otol Rhinol Laryngol* 1990;99 (5 pt 1): 403–12.

12. Goode RL, Ball G, Nishihara S. Measurement of umbo vibration in human subjects—method and possible clinical applications. *Am J Otol* 1993;14:247–51.

13. Elbrond O, Elpern BS. Reconstruction of ossicular chain in incus defects. An experimental study. *Arch Otolaryngol* 1965;82:603–8.

14. Vlaming MS, Feenstra L. Studies on the mechanics of the reconstructed human middle ear. *Clin Otolaryngol Allied Sci* 1986;11: 411–22.

15. Neudert M, Bornitz M, Lasurashvili N, Schmidt U, Beleites T, Zahnert T. Impact of prosthesis length on tympanic membrane's and annular ligament's stiffness and the resulting middle ear sound transmission. *Otol Neurotol* 2016;37:e369–76.

16. Morris DP, Bance M, van Wijhe RG, Kieft M, Smith R. Optimum tension for partial ossicular replacement prosthesis reconstruction in the human middle ear. *Laryngoscope* 2004;114:305–8.

17. Nishihara S, Goode RL. Experimental study of the acoustic properties of incus replacement prostheses in a human temporal bone model. *Am J Otol* 1994;15:485–94.

18. Bance M, Morris DP, Vanwijhe RG. Comparison of the mechanical performance of ossiculoplasty using a prosthetic malleus-to-stapes head with a tympanic membrane-to-stapes head assembly in a human cadaveric middle ear model. *Otol Neurotol* 2004;25: 903–9.