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Ossiculoplasty on isolated malleus fractures: A human temporal bone study using laser Doppler vibrometry

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Key words

Bone cement - human temporal bone - laser Doppler vibrometry (LDV) - malleus fracture - ossiculoplasty

Abstract

Hypothesis: In the literature several surgical methods have been reported that aim to improve hearing in patients with isolated malleus fractures; however, it is still not clear which method gives the best results.

Background: In this study, laser Doppler vibrometry (LDV) was used to compare the outcome of different surgical methods on malleus fractures in fresh frozen human temporal bones.

Methods: Fractured malleus shafts of defrosted human temporal bones were repaired with bone cement, with a malleus prosthesis from cortical bone, or with a partial ossicular replacement prosthesis (PORP) from cortical bone, and LDV measurements were obtained for analysis.

Results: The best result was achieved with the bone cement only, applied directly at the site of the fracture. The malleus prosthesis and the PORP gave similar results.

Conclusion: All three surgical methods gave good results, but when the distal end of the fractured malleus can be attached close to the proximal end, the technique using only cement tends to be the best option. If the parts are too far apart, a malleus prosthesis or a PORP would be good options.

Introduction

According to the literature, isolated malleus fractures are not very common. In articles published during the latest 30 years only about 40 such fractures are described [1]. The main cause of this type of fracture is the withdrawal of a wet finger from the ear canal after taking a bath. Since isolated malleus fractures are not easy to find, if not specifically looked for, we believe that these fractures are often missed since the symptoms are rather diffuse. In the county of Norrbotten, Sweden, with a population of 250,000, we have identified approximately one case of isolated malleus fractures every year for the past 8 years. This gives an incidence of about four in a million every year. The symptoms of an isolated malleus fracture are as follows. After pulling out a wet finger from the ear canal, the patient usually suffers from a short painful sensation and a permanent mild hearing loss or dullness in the ear. Occasionally, there is a tinnitus, usually of high frequency, that sometimes becomes permanent. Objective findings are a conductive hearing loss as seen in an audiogram that is usually in the mid and high frequencies, and hypermobility observed with tympanometry. If otomicroscopy is performed, a fracture-line is sometimes seen, and with pneumatic otoscopy a hypermobile malleus shaft/umbo is often evident. Gentle palpation on the malleus shaft can also be useful in revealing this hypermobility. Watchful waiting, a hearing aid or an ossiculoplasty are options available for these patients.

The ossiculoplasty methods that have been used to treat isolated malleus fractures are, for example, fixation of the broken shaft with bone cement [2,3], or ossiculoplasty with either a partial ossicular replacement prosthesis (PORP) [4,5] or a total ossicular replacement prosthesis (TORP) [6]. Different methods of ossiculoplasty have also been tried to spare the ossicular chain, as for example stabilization of the fracture with bone chips [7,8] or with cartilage [9]. Because of the infrequent cases of isolated malleus fractures, it is nearly impossible to design a prospective study for comparing different ossiculoplasty methods to evaluate which methods give the best hearing results.

Laser Doppler vibrometry (LDV) is a method that has been previously used in numerous studies in both patients with middle ear pathology and also in temporal bone studies [10]. The LDV method detects the velocity of the movements of the ossicular chain, which makes it possible to estimate the loss/gain of sound transmission. It is a non-contact method that allows repeated measurements without disturbing the sound transmission. Furthermore, the velocity of tiny vibrating structures such as the stapes footplate can be measured by determining the Doppler frequency shift of a low intensity laser beam (21mW) [11].

In regard to the use of thawed temporal bones that had been fresh frozen, it was shown that the freezing process has minimal influence on acoustic behavior [12].

The aim of the present study was to examine three different ossiculoplasty methods with LDV to evaluate, which one of these methods would be best for restoring the sound transmission after an isolated malleus fracture.

Materials and methods

Fifteen fresh frozen human temporal bones, donated for research purposes, were used in the present study. The bones were prepared while still frozen by cutting away the cochlea, thus exposing the stapes footplate from the medial side. Furthermore, an access into the middle ear cavity from the middle fossa was drilled to visualize the eardrum and the ossicular chain (Fig. 1). After this preparation, the bones were stored at _20 8C. Before the measurements the bones were thawed and a closed cavity containing an earphone speaker and a microphone was attached with screws to the bony ear canal. The manipulations of the ossicular chain were made under an operating microscope (Zeiss OPMI Sensera, Jena, Germany).

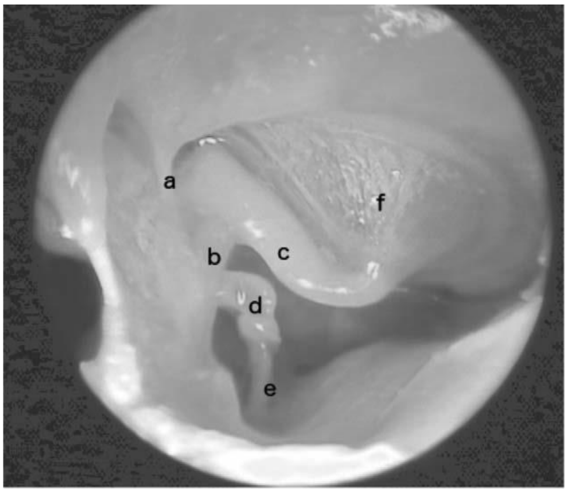

Figure 1. Picture of the drilled opening in the temporal bone and the access to the middle ear. The eardrum and the ossicular chain are intact. a = anterior ligament, b = tensor tympani tendon, c = malleus shaft, d = long process of incus, e = stapes, f = eardrum.

During the whole procedure the eardrum was kept intact. The temporal bones were kept moistened with article towels soaked with saline. The LDV measurements were made within hours after thawing of the temporal bones, and care was taken that the stapes footplate was moistened repeatedly during the measurements. Each measurement was repeated two or three times to make sure stable results were obtained. Differences between repeated recordings were minimal, so in order not to unnecessary overload the figures the repeat measurements are not shown. Since repeated measurements did not differ, they will not be displayed in the figures.

To determine the effect on the LDV measurements after several hours one temporal bone was intentionally left without hydration and was remoistened during the experiments.

Description of the LDV method

A semi-closed cavity containing an earphone speaker and a condenser microphone was placed with its open end over the ear canal. The cavity was screwed to the temporal bone and the space between the temporal bone and the cavity was then sealed with elastic paste (Otoform AKX, Dreve Otoplastic, Unna, Germany), so that the earphone speaker was able to comfortably produce the desired sound pressure level. Each temporal bone was equipped with its own sound generating cavity. Microphones were calibrated against a probe microphone with flat frequency response and traceable calibration certificate (Bruel&Kjaer 4182). For each measured frequency, sound pressure was adjusted to 90 dB SPL with an accuracy better than 1 dB. Vibration of the stapes was measured with a LDV (Polytec model 534 and controller OFV-5000). The head of the vibrometer was mounted on an operation microscope, and the beam could be positioned and focused within the field of view by a motorized mirror and focusing lens (a detailed drawing of the setup can be found in Peacock et al. [11]). A patch of reflective material was put on the medial side of the footplate to obtain sufficient optical reflection for the vibrometer. Patches were about 0.4mm × 0.4mmin size, and had a mass of less than 0.04 mg, which is less than 1.5% of the stapes mass (2.73 ± 0.28 mg, De Greef et al. [13]). Vibration response of the stapes footplate was measured in a frequency range of 0.5 to 4 kHz at eight frequency lines per octave.

Three different types of simulated ossiculoplasty were performed on the temporal bones and measured with LDV:

1. Ossiculoplasty using only bone cement to stabilize the fractured malleus shaft. The bone cement, Otomimix (Olympus, Jacksonville, Florida, U.S.A.) is a two-component bone cement that has been used clinically in otosurgery. A temporal bone was prepared as described above. With a backbiting forceps the malleus shaft was cut just distal to the tensor tendon (Fig. 2A). The fractured parts of the malleus were positioned near each other with a small piece of foam rubber that was put on the lateral surface of the eardrum via the ear canal. The eardrum was left intact and adherent to the malleus shaft and was not perforated. Bone cement was put on the medial surface of the malleus shaft and over the fracture. The foam rubber was removed after 10 minutes, after which the bone cement had hardened before the measurements. LDV measurements were performed before and after surgery. Figure 2B shows the fixation of the broken malleus shaft with bone cement.
2. Ossiculoplasty using a malleus shaft prosthesis. A temporal bone was prepared as described above and a similar malleus fracture was made as above. The distal end of the fractured malleus shaft was carefully removed, avoiding any perforation of the eardrum. After cutting the anterior ligament of the malleus, a malleus prosthesis was put in place on the malleus neck and on the proximal part of the

fractured malleus shaft to elongate the broken malleus shaft (Fig. 3A). The prosthesis was cut from cortical bone in the shape of a needle with a hole to fit around the short process of the malleus, and a groove to fit on the malleus (Fig. 3B). The prosthesis was fixed onto the malleus with bone cement and measurements were performed after at least 10 minutes of hardening. The eardrum was fixed to the malleus prosthesis with fibrin tissue glue (Tisseel®) or commercial superglue. LDV measurements were performed before and after surgery. The removal of the anterior ligament of the malleus did not affect the velocity measurements (data not shown).

3. Ossiculoplasty with a PORP. A temporal bone was prepared as described above and a similar malleus fracture was made as above. The fractured distal end was carefully removed from the medial attachment to the eardrum, without damaging the eardrum. A PORP of cortical bone, about 3.5mm in height, was placed from the stapes head to the eardrum (Fig. 3C). The PORP did not have any contact with the malleus shaft. The eardrum was attached to the PORP with tissue glue or with superglue (Loctite) to get a good contact between the PORP and the eardrum. LDV measurements were performed before and after surgery.

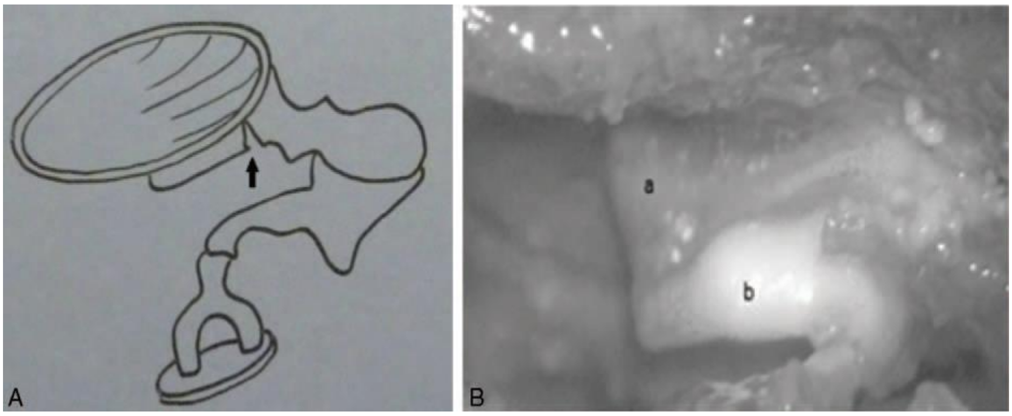

Figure 2. *A*, *Arrow* shows the site of a proximal malleus fracture. *B*, a = medial side of the eardrum. b = the repaired malleus shaft with bone cement.

To investigate the influence of the site of the malleus fracture on the sound transmission, the malleus shaft was cut at three different distances from the umbo – a distal (1 mm), a medial (2 mm), and a proximal (3 mm) fracture just distal to the tensor tympani tendon. LDV measurements were performed after each fracture. The stapes velocity was also measured within a 24 hours time span, keeping the temporal bone at room temperature and after remoistening the stapes footplate.

All procedures involving the temporal bones used in the study were approved by the ethical committee of Umeå University, dnr 2014–352-31.

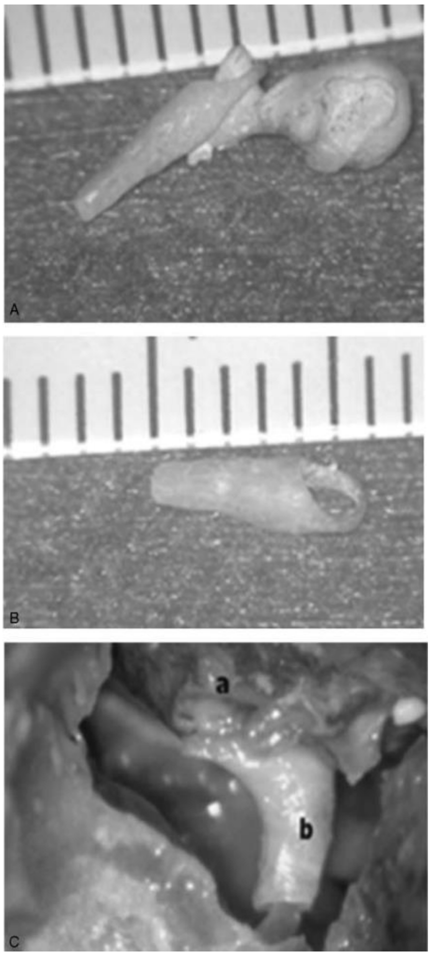

Figure 3. *A*, The malleus prosthesis in position. Vertical bars = 1mm. *B*, Photograph of the malleus prosthesis made from cortical bone. There is a groove on the side of the prosthesis that is placed alongside the broken shaft to stabilize the prosthesis against the proximal remnant of the malleus shaft. *C*, PORP sculptured from incus. a = medial side of the eardrum after removal of the distal end of the fractured malleus shaft. b = PORP in place on top of the stapes head.

Results

Figures 4-6 show changes in stapes velocity for a certain manipulation of the temporal bones, relative to the stapes velocity in the intact situation. Changes in velocity are depicted as velocity ratios that are considered relative to the line of zero velocity ratio, which represents the intact situation.

Figure 4 shows changes in stapes vibration response for different positions of the malleus fracture. An increasing loss of velocity is seen the more proximal the fracture is along the malleus shaft. The distal fracture shows a loss of velocity of about 5 dB in the higher frequencies (around 3 kHz) and in the medial fracture the loss of velocity is even more pronounced in the higher frequencies – about 10 to 20 dB loss of velocity. The proximal fracture showed a significant loss of velocity of about 35 dB, especially in the mid-frequency range (around 2 kHz) and about 15 dB loss in the higher frequencies.

The change of the stapes velocity within 21 hours was no more than 3 dB (Fig. 5A) when the specimen was rehydrated before the LDV measurements. However, there was a rapid deterioration of the velocity if the footplate was not rehydrated before the LDV measurements (Fig. 5B).

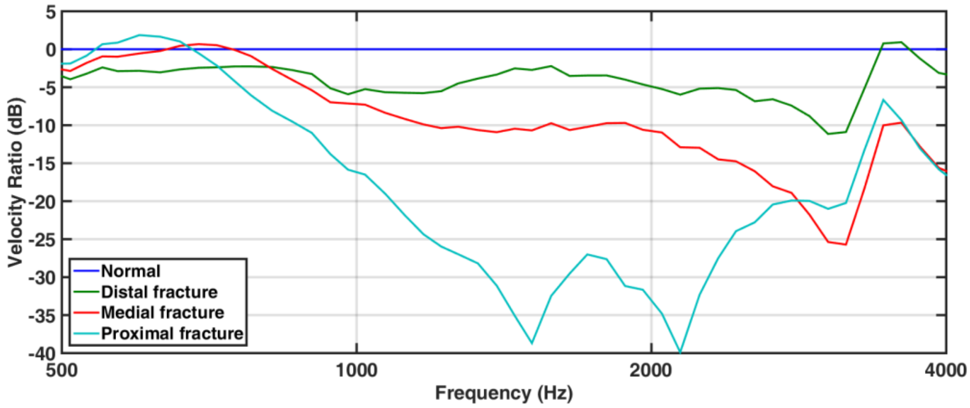

Figure 4. Change of stapes vibration response as a function of frequency for different positions of the malleus fractures. The zero line depicts the situation before the fractures were made. The loss of velocity in the medial and distal fractures is most pronounced in the higher frequencies, and in the proximal fracture there is a significant loss especially in the mid-frequencies. (See online version for color.)

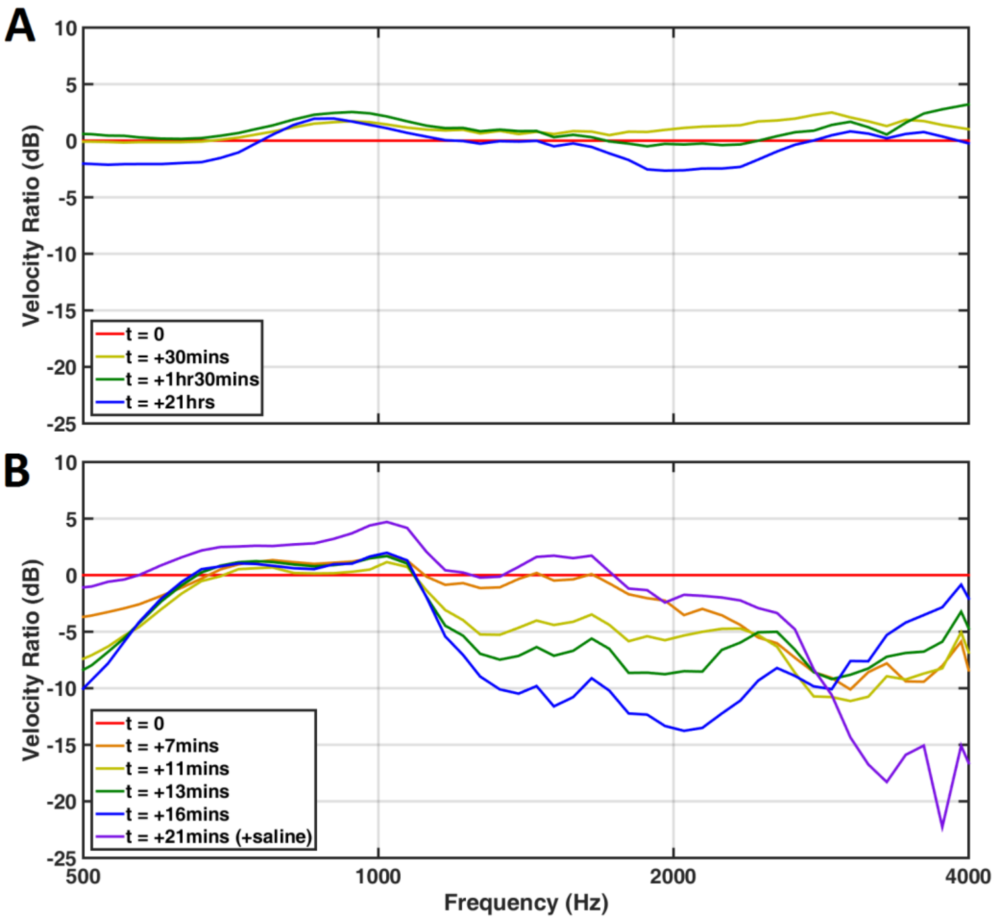

Figure 5. *A*, Change of stapes velocity over a 21-hour time span. The maximal loss of velocity of nearly 3 dB is found at 2 kHz after 21 hours. LDV measurements for the experiments were made within a few hours after thawing. *B*, Change of stapes velocity as a function of time, without rehydration of the specimen. This figure displays the importance of keeping the stapes footplate hydrated before each measurement, as a progressive loss of velocity is already observable after 10 to 15 minutes. When the footplate was rehydrated (+21 min + saline), the velocity recovered. (See online version for color.)

Detaching the malleus shaft from the eardrum, except at the umbo and short process, had a minimal effect on the stapes velocity (data not shown). Thus, it seemed that the most important attachment between the malleus and eardrum was at processus brevis and umbo.

Figure 6 shows the effect of different restoration procedures on stapes velocity. Figure 6A shows stapes velocity change because of malleus fracture, measured in eight temporal bones. When an isolated malleus fracture is created just distal to the tensor tympani tendon (= proximal fracture), a loss of velocity is seen which is more pronounced at the higher frequencies. The mean loss of velocity, compared with the normal situation, is 12 dB at 1 kHz, 14 dB at 2 kHz, and 23 dB at 4 kHz. Although the fracture was made in the same way in all of the eight temporal bones, there is a wide range regarding the loss of velocity, so the loss of velocity at 4 kHz varies between 10 and 35 dB. Repairing the fractured malleus shaft with bone cement only (Fig. 6B) shows nearly no loss of velocity up to about 2 kHz, although the mean value declines 10 dB at 4 kHz. The mean loss of velocity with the bone cement method is 3 dB at 1 kHz, 3 dB at 2 kHz, and 10 dB at 4 kHz. The malleus prosthesis method (Fig. 6C) already shows a loss of 10 dB from 1 kHz and onwards. The mean loss of velocity with the malleus prosthesis is 10 dB at 1 and 2 kHz and 13 dB at 4 kHz. The PORP method (Fig. 6D) shows a decline of 10 dB after 1.5 kHz and shows the worst results of the three methods in the higher frequency range. The mean loss of velocity with the PORPs is 5 dB at 1 kHz, 7 dB at 2 kHz, and 14 dB at 4 kHz. All three methods have good results in the lower frequency range, but the results of the PORP method have the largest spread, while the other two ossiculoplasty methods have more predictable results across the different temporal bones. Figure 6E shows the mean values of the results depicted in Figure 6, A-D. The bone cement method thus showed a slightly better result compared with the other two methods.

Discussion

Isolated fractures of the malleus are easily missed in the clinic. Since they are quite rare, it is difficult to gather enough clinical material for randomized clinical studies of treatment methods. The multitude of different suggested methods in the literature might be explained by this difficulty to perform clinical trials. The present study aimed to compare the acoustic outcome of three different ossiculoplasty methods in vitro – one that has recently been used clinically with good results, namely the bone cement method [3], a new method designed by one of the authors (AN) called the malleus prosthesis method, and finally the PORP method, which is the most commonly used ossiculoplasty method when the stapes superstructures are intact. One drawback of the PORP method, in contrast to the other two methods, is that it requires the removal of the incus and subsequently the further destruction of the ossicular chain.

By using fresh frozen human temporal bones and the LDV method, we were able to perform the ossiculoplasty operations under controlled conditions, to compare the efficacy of each of the methods for restoring the hearing. The LDV method has been used previously on temporal bones for such purposes [14, 15]. In the present study the velocity was measured at the medial side of the stapes footplate, which is a well accessible measurement site and relevant for assessing acoustic energy transmission to the inner ear. Moreover, thereby the highest measurement sensitivity is obtained. Manipulations on the ossicular chain can be done, and the laser beam can be easily repositioned to the same location and under the same angle between subsequent manipulations of the temporal bone. Furthermore, by measuring footplate motion from the medial side, there is no need for an additional opening to the middle ear cavity to access the footplate with the laser beam. This access to the middle and inner ear allowed us to keep both the tympanic membrane and the remnant of the ossicular chain intact. Removal of the cochlea evidently changes the acoustic impedance of the middle ear, but as all measurements are done under this same condition this can be accepted for the benefit of the advantages mentioned.

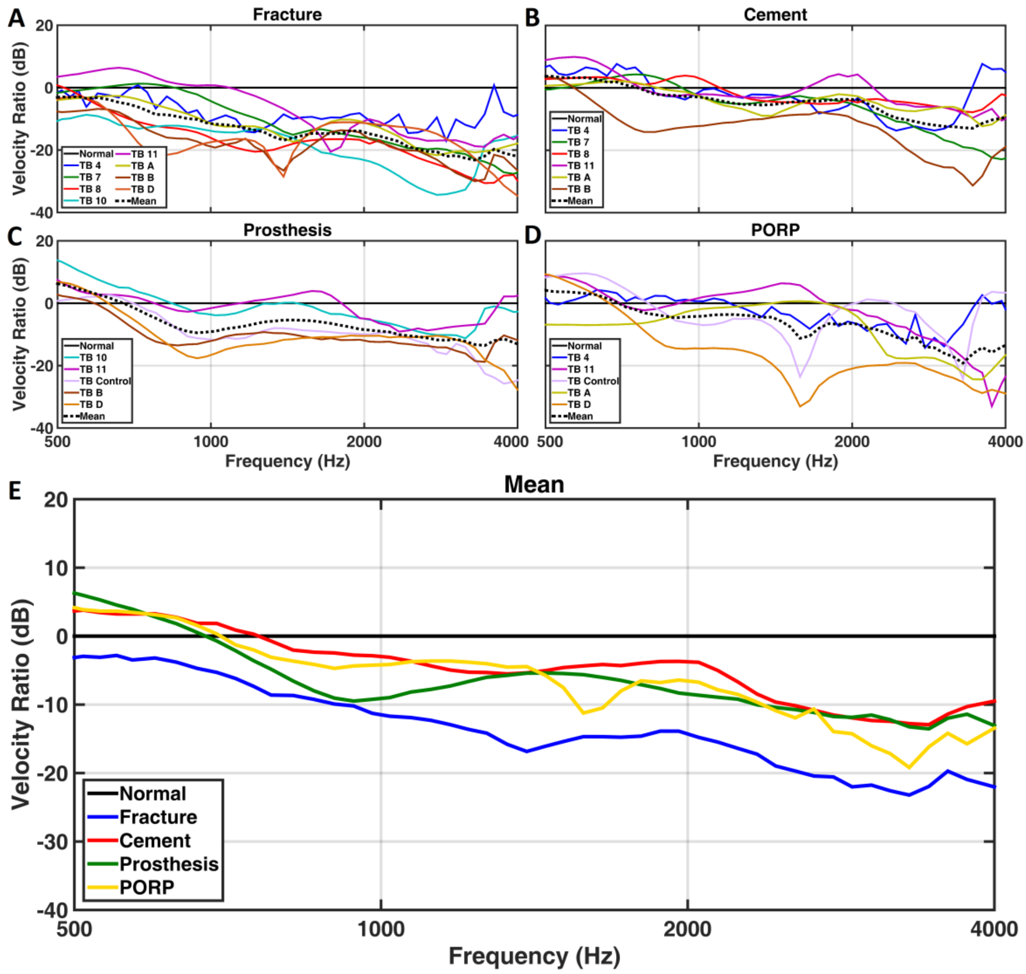

Figure 6. *A*, Effect of a proximal isolated malleus fracture on the loss of stapes velocity, measured in eight different temporal bones (TB). There is a clear increasing trend in the loss of velocity towards higher frequencies, which is also found in clinical cases with a similar fracture. The zero line depicts the situation before the fracture was made. *B*, Effect of treating the isolated malleus fractures with bone cement after attaching the fractured parts as close as possible to each other. The zero line depicts the situation before the fractures were made. The mean recovery at 1 and 2 kHz is about 10 dB, compared with the fractured situation. *C*, Effect of treating the isolated malleus fractures with a malleus prosthesis. The zero line depicts the situation before the fractures were made. The mean recovery at 1 and 2 kHz is only about 5 dB, compared with the fractured situation. The best result is seen in the mid frequency range. *D*, Effect of treating the isolated malleus fractures with a PORP made of cortical bone (see Fig. 3C). The zero line depicts the situation before the fractures were made. The mean recovery at 1 and 2 kHz is between 5 and 10 dB, compared with the fractured situation. The best result with the PORP is observed in the lower and mid frequencies. *E*, Graphical plot of mean values of the above procedures. (See online version for color.)

The created proximal malleus fractures caused a loss of velocity that is in concordance with the clinical situation of patients with isolated malleus fractures that carry a conductive hearing loss that increases towards the higher frequencies. Also, in the clinical situation, the degree of hearing loss varies, even when fractures have similar locations on the handle of malleus. The reason for this is unclear, but further studies possibly including the use of digital holography might shed light on this.

The present study showed that stabilization of the fractured handle of malleus with bone cement yielded the best velocity restoration, and could therefore be recommended as a method of choice in the clinic, although many imponderabilia still prevail in this issue. The results were in accordance with reports from Hato et al. [2] and of Delrue et al. [3] who also reported good results after ossiculoplasty with bone cement. PORP placement is a conventional ossiculoplasty method, but it involves further destruction of the ossicular chain and often leaves an airbone gap of about 10 dB [16]. The PORP method also showed the largest variation in velocity recordings, which corresponds well with clinical reports on a wide range of postoperative hearing outcomes [17]. In some of the patients with isolated malleus fractures that had been on watchful waiting for a longer time, our experience is that the distal part of the fractured malleus could be degenerated and atrophied. In such a situation, the bone cement method is probably not ideal, and the PORP or malleus prosthesis method could be an alternative.

Conclusion

Isolated malleus fractures in fresh frozen and thawed temporal bones lead to stapes velocity changes that resemble the changes in hearing sensitivity as observed in the clinical situation, namely a conductive hearing loss that increases towards the higher frequencies. The treatment when the fractured handle of malleus was stabilized with bone cement only showed a slightly better result than using a PORP or specially designed malleus prosthesis from cortical bone.

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