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## Forces Required for Isolated Malleus Shaft Fractures

\*Anton Rönnblom, \*Anders Niklasson, †Mimmi Werner, ‡Per Stål, and \*Krister Tano

*\*Department of Clinical Science, Otorhinolaryngology/Sunderby Research Unit; †Department of Clinical Science, Otorhinolaryngology; and ‡Department of Integrative Medical Biology, Laboratory of Muscle Biology, Umeå University, Umeå, Sweden*

**Background and Hypothesis:** Isolated malleus shaft fractures are rare cases. A commonly reported cause is a finger pulled out from a wet outer ear canal after a shower or bath. The objective was to investigate experimentally the mechanism and forces needed to establish an isolated malleus shaft fracture.

**Methods:** Ten fresh-frozen human temporal bones were adapted to allow visual inspection of the structures involved while negative pressure trauma was applied. Thirty malleus bones were broken and the required forces were measured. Measurements from 60 adult test subjects were used to create mathematical and physical models to calculate and measure the forces necessary for generating trauma. To calculate the maximum muscle force developed by the tensor tympani muscle, the muscle area and fiber type composition were determined.

**Results:** The temporal bone experiments showed that applied negative pressure in a wet ear canal could not fracture the

malleus shaft with only passive counterforce from supporting structures, although the forces exceeded what was required for a malleus shaft fracture. When adding calculated counteracting forces from the tensor tympani muscles, which consisted of 87% type II fibers, we estimate that a sufficient force is generated to cause a malleus fracture.

**Conclusion:** The combination of a negative pressure created by a finger pulling outward in a wet ear canal and a simultaneous counteracting reflexive force by the tensor tympani muscle were found to be sufficient to cause an isolated malleus fracture with an intact tympanic membrane. **Key Words:** Conductive hearing loss—Human temporal bone—Malleus fracture—Middle ear—Ossicular prosthesis.

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Traumatic middle ear lesions are relatively frequent but are seldom reported in scientific publications (1). The most common is injury to the tympanic membrane followed by incus luxation (1). The typical form of self-inflicted injury is due to attempts to clean the ear with a cotton swab or similar device (2). Injury including the malleus is rare and occurs in only 2% of the cases (1). Isolated malleus shaft fractures are exceedingly rare in the clinic as well as in the literature with less than 100 published cases (1–11). However, several authors underline that this condition

is easily missed since the tympanic membrane is intact (2–7,9–11), thus leading to its underdiagnosis (3,4,7). In most recently published cases, the symptomatology of an isolated malleus fracture is similar, i.e., a short, sharp pain with a small to intermediate residual conductive hearing loss that occurs after the patient had used a finger to evacuate the wet ear canal after a shower or bath (3). A typical finding is pneumatic otomicroscopy showing an increased movement of the malleus shaft distal to the fracture; this contrasts to the normal condition where the movement of an intact malleus during pneumatic otoscopy is minimal. Audiometry typically reveals a mild conductive hearing loss, usually in the mid to high frequencies. With high-resolution computer tomography a malleus fracture can sometimes be identified, but in most cases it is not (3).

Our clinic in Norrbotten county Sweden has a capture area of approximately 250,000 individuals. Since becoming aware of how isolated malleus fractures present, we have found 15 fractures during the last 15 years; this indicates that this fracture is probably more common than previously reported (4). Conservative treatment of these

Address correspondence and reprint requests to Anton Rönnblom, M.D., Ear Nose Throat clinic, Sunderby Hospital, 97180 Luleå, Sweden; E-mail: anton.ronnbloom@umu.se

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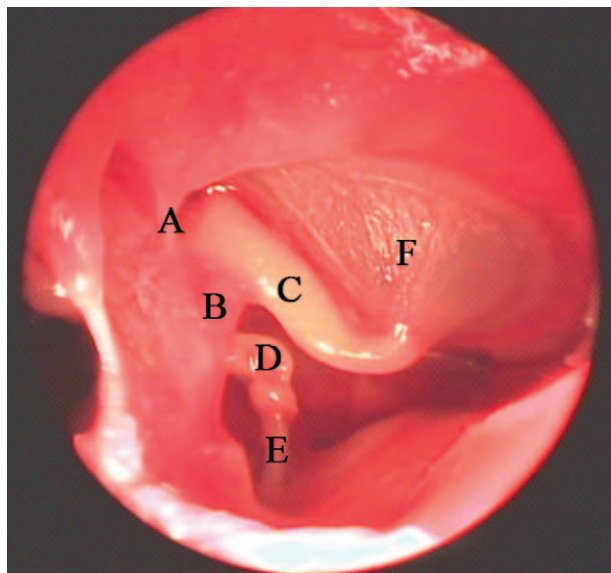
patients is recommended in mild cases. However, different surgical treatment options have been presented for patients with substantial conductive hearing loss, and in the literature, the frequency of surgery varies from 20 to 100% (2,5–7,11–14). At our clinic, approximately 47% have been treated with surgery.

It is puzzling that such a modest trauma as pulling a finger out of a wet ear canal could fracture one of the human body's hardest bones, which otherwise is rarely affected by more severe trauma. To our knowledge, the forces involved in this trauma have not been studied, although it was proposed that the relative fixation of the malleus head in the epitympanum (6) and a negative pressure created by a rapid outward withdrawal of a finger from a wet ear canal (3) might be a cause of trauma. The aim of the present study was to investigate the mechanism and the forces needed to fracture a human malleus shaft, and if the described trauma could present a risk to a normal ear.

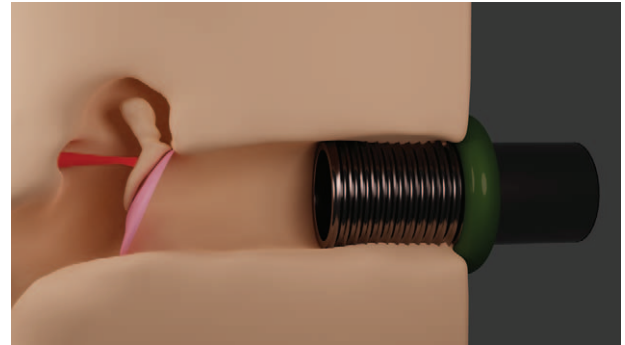
## METHODS

In a pilot experiment, 10 fresh-frozen human temporal bones donated for research purposes were used. To get visible access to the middle ear from the medial side and thus keeping the tympanic membrane and the ossicular chain intact during the experiment, an opening was drilled into the middle ear from the skull base at the point where the tensor tympani muscle enters the middle ear. In this opening, an endonasal Karl Storz Hopkins II 30 degree rigid endoscope was fitted and connected to a camera for documentation of middle ear structures (Fig. 1).

To create a repeatable controlled negative pressure distal to the tympanic membrane, an outwardly sealed cylinder was adapted to fit the temporal bones (Fig. 2). With this setup, the application of negative pressure of different magnitudes could be made while simultaneously observing and recording



**FIG. 1.** Photo taken via a rigid endoscope through a drilled opening in the middle fossa. This viewing is the middle ear from its medial side. *A*, Anterior ligament. *B*, Tensor tympani tendon. *C*, Malleus shaft. *D*, Long process of incus. *E*, stapes. *F*, Tympanic membrane. Photo: A Rönnblom.



**FIG. 2.** Ear canal vacuum adaptor setup: The soft tissue was removed from the cartilage part of the ear canal. The bony part of the ear canal was widened in its distal part to get a circular fitting in which a threaded stainless-steel cylinder was screwed. The fitting was externally sealed with elastic paste (Otoform Ak X) (green).

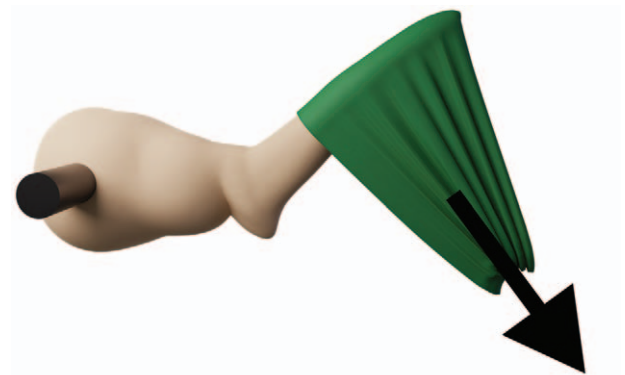
the reactions of the tympanic membrane and the malleus. It was also possible to stabilize or pull the tensor tympani tendon to visualize structural movements with a fictive muscle reaction.

Negative pressure was applied via a reinforced air pressure hose generated with both a surgical pump (Ardo Master) and a 100 cl stainless syringe. The surgical pump builds up a vacuum that was then shortly released into the hose. The syringe was connected to the hose and the plunger withdrawn; this was done with air, water, and a mixture of these in the system. This model allowed us to create a force similar to and greater than that for the described trauma.

## Force Causing a Malleus Fracture

For measurements of the force needed to fracture a malleus, 10 malleus ossicles from fresh frozen temporal bones and 20 dry stored ossicles were used. It was previously shown that different preservation methods have no effect on the structure or the mechanical strength of the ossicles (15). All mallei were stripped of any soft tissue and examined under a microscope to ascertain that there were no visible flaws.

The malleus head was then fixated and force applied by pulling a dynamometer that was connected to the ossicle via an artificial tympanic membrane laid along the malleus shaft (Fig. 3). Upon fracture, the maximum force was recorded from the dynamometer.



**FIG. 3.** The head of the malleus was fixated at the point marked with a dark cylinder. An artificial membrane (green) was attached along the shaft simulating the tympanic membrane. The membrane was then pulled with a dynamometer in the direction that the force was applied and measured (*arrow*).

**Ear Canal Measurements**

To establish the possible force developed by the extraction of a finger from a wet ear canal, both a mathematical and an experimental approach were made. In 60 randomly chosen adults, equally divided by sex and without previous or present ear pathology, the length of the ear canal and the length that a finger could be inserted into the ear canal without discomfort or pain were measured. All measurements were done by one of the authors (A.R.). The examination included a visual inspection via an ear microscope to exclude pathology, and when necessary, to remove wax. The control person was then instructed to insert a finger in a verified dry ear canal. With a felt-tip pen, the point where the finger and the entrance of the ear canal meet was marked on both the finger and ear canal at two sites of contact. The shortest distance from a mark to the fingertip and the shortest distance from the entrance of the ear canal to the tympanic membrane were measured. The latter was measured in an ear microscope examination using an ear suction device that was turned off and modified with a measurement scale.

**Calculation of Negative Pressure Force**

Using the ideal gas law  $PV = nRT$  and assuming that the external auditory meatus is completely sealed during the event makes  $PV$  a constant.

We can further derive to the formula:  $F = PA \times \frac{L_1 + X}{L_1}$

$P$  = standard normal air pressure defined as 101,000 Pascal  
 $A$  = area of the tympanic membrane, average at  $64.3 \text{ mm}^2$  according to Pannu et al. (16)

$X$  = the length of the external auditory meatus filled with a finger

$L_1$  = the distance from tympanic membrane to the fingertip

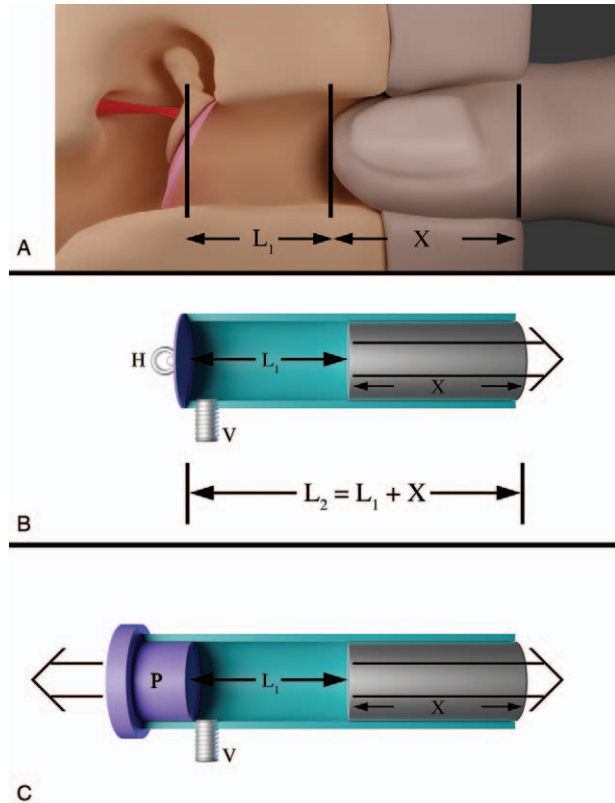
$L_2$  = the total length of the ear canal, measured on our test persons to calculate  $L_1$  by subtracting  $X$ . (Fig. 4B).

With this formula, the force applied via the tympanic membrane due to air expansion can be calculated. It is also possible to account for several variabilities such as the likely scenario that the ear canal is not sealed during the entire extraction of the finger (by subtraction from  $X$ ). Moreover, the amount of air between the finger and the tympanic membrane could be lessened due to the presence of water (by subtraction from  $L_1$ ). Since water expansion can be considered negligible, it was not accounted for in the equation. Hydraulic mechanisms work on the effectiveness of energy transfer in liquid.

**Negative Pressure Force Measurements in Models**

As for the experimental approach, one of the authors (A.R.) constructed a cylinder resembling the size of an ear canal with a silicon rubber membrane that mimicked the size of a tympanic membrane. In this artificial membrane, an elongated fixing point made of a steel wire that mimicked the malleus shaft in placement and size was fitted, but with a hook outwardly. This device was fixated via the hook to a dynamometer. To minimize the risk of calibration error, the same dynamometer was used as in the fracture measurements. Excess air was evacuated via a screw valve. A piston was drawn out from the cylinder at the same distance as the mean length that our test subjects could insert their fingers in the ear canals ( $X$  in Fig. 4), and the force was measured (Fig. 4B). This model allowed movement of the artificial tympanic membrane, simulating a scenario without tensor tympani muscle activation.

To simulate a nonmoving tympanic membrane that includes counteracting forces from the tensor tympani muscle, another model was constructed by AR. This model used the same type



**FIG. 4.** A, A schematic illustration of the force generating trauma when a finger is withdrawn the length of  $X$  out of the ear canal.  $L_1$  marks the distance between the tympanic membrane and the fingertip. The tensor tympani muscle and its tendon are in red. B, Schematic illustration of our scale model of the trauma with an artificial tympanic membrane (blue) with a cast in metallic malleus replica that attaches to the force measuring dynamometer via a hook marked H. V marks a screw valve for normalization of pressure before the piston that acts as the withdrawn finger is extracted the length  $X$  (drawn here as a hollow arrow to the right). C, A similar construct as in (B), but when the first piston is drawn the length of  $X$  (marked by the hollow arrow to the right), the dynamometer attached to the second piston marked P measures the force required to withdraw P. The friction force needed to withdraw P is separately measured and then subtracted from the result to give the force applied by the negative pressure of withdrawing the first piston.

of cylinder, but instead of a flexible membrane, the distal end was filled by a piston with a small sealant lip made of elastic paste (Otoform Ak X). The force required to overcome the friction while extracting the piston without negative pressure in the model was measured 10 times with consistent results. Then negative pressure was established by pulling the first piston to a length representing the measurements from our test persons. The second piston was then withdrawn, the force required was measured, and the previously measured friction was subtracted. This was repeated 40 times. Thus, the force generated by the negative pressure from the piston represented the force from the finger in the ear (Fig. 4C).

**Calculating the Strength of the Tensor Tympani Muscle**

The relationship between the maximum force that a muscle can perform is related to its cross-sectional area and to the

composition of fiber types that build the muscle. Based on this, the force interval that the tensor tympani muscle theoretically develops was calculated by measuring the diameter of the muscle belly and analyzing the fiber type composition of the muscle. If the fiber type composition is not taken into account, the force span in a human muscle has been suggested between 35 and 137 N/cm<sup>2</sup> for whole muscles (17).

### **Muscle Samples and Immunohistochemical Methods**

Five samples from the middle part of tensor tympani muscle were taken postmortem from previously healthy adult subjects. The specimens were immediately frozen in liquid propane chilled with liquid nitrogen. Five  $\mu\text{m}$  thick serial muscle cross-sections were cut in a cryostat at  $-20^{\circ}\text{C}$ , and immunostained with monoclonal antibodies against contractile slow myosin heavy chain protein I (MyHCI, mAb A4.840, Developmental Studies Hybridoma Bank, IA) for fiber typing, and basement membrane laminin  $\alpha$ -2 (mAb 5H2, Novacastra Laboratories, Newcastle Upon Tyne, UK) for the identification of muscle cell border. For details of the immunohistochemical multistaining technique see Shah et al. (18).

### **Muscle Fiber Type Classification and Fiber Area Measurement**

Muscle cross-sections double-stained with mAbs against A4.840 and 5H2 were scanned at  $\times 40$  magnification with a fluorescence microscope (Leica DM6000B, Leica Microsystems CMS GmbH, Wetzlar, GER) equipped with digital high-speed fluorescence CCD camera (Leica DFC360 FX). Muscle fibers showing immune-reactivity for the slow MyHCI mAb were classified as type I, whereas fibers lacking staining were classified as type II. The cross-sectional area of muscle fibers was calculated by tracing the membrane of each muscle fiber stained for laminin on each photo using customized morphometric software (Leica QWin software, Leica Microsystems Ltd. Heerbrugg, Switzerland). The relative cross-sectional areas formed by type I and type II fibers were calculated.

### **Ethics Approval**

The regional Medical Ethical Committee in Umeå, Sweden (dnr 2014-352-31) and the Swedish Ethical Review Authority (No. 2020-03240) approved this study. Autopsy specimens were collected in agreement with Swedish laws and regulations on autopsy and transplantation.

### **RESULTS**

During application of negative pressures equal to or exceeding the force that experimentally fractured the malleus, no fracture occurred in the temporal bone pilot. A review of the video-recordings showed that with force applied only from the external ear canal, the malleus moved relatively freely with the tympanic membrane, and the malleus shaft did not appear to be put under significant stress. With increased force applied, and particularly with a larger proportion of water in the ear canal, the risk for a rupture of the tympanic membrane increased without affecting the malleus. Fixation of the tensor tympani tendon resulted in a reduced movement of both the malleus and tympanic membrane. Repeating the test with fixated tensor tympani tendon did not cause fractures, but the force applied did cause tension via the tympanic membrane that visually appeared to be centered toward the point of the malleus shaft just distal to the fixation of the tensor tympani tendon. However, by pulling the tensor tympani muscle, i.e., mirroring a stretch reflex, the bone was broken. Our experimental model did not allow us to apply and measure simultaneous forces in both directions.

### **Force Causing a Malleus Fracture**

The mean force required to cause a malleus fracture was  $2.27 \pm 0.81$  N. Detailed measurements are presented in Table 1.

**TABLE 1.** *The force measured in Newtons for the respective experiments*

Forces in Newtons	Mean	Standard Deviation	Minimum	Maximum
Force required for malleus fracture				
A. All mallei: (30)	2.27	0.81	1.0 (3)	4.0 (2)
B. Fresh malleus: (10)	2.15	0.67	1.0 (1)	3.0 (2)
C. Old/dry malleus: (20)	2.33	0.88	1.0 (2)	4.0 (2)
Calculated negative pressure force				
D. All air and full pull				13.3
E. One-third water filled and one-third seal held				9.9
Measured negative pressure force				
F. Free moving tympanic membrane (40)	1.00	0.23	0.5 (4)	1.5 (4)
G. Fixed tympanic membrane (40)	5.03	0.85	3.0 (1)	7.0 (2)

In parentheses are the numbers of measurements the data are based upon. A: Force required for fracture on all bones tested, B: freshly sourced bones, and C: older stored bones. D–E: Calculations based on theoretical perfect conditions and therefore only showing possible maximum force. D: The in vivo unlikely scenario with an ear canal filled only with air and the finger extracted its full length before the seal between the finger and outer ear canal is lost. E: The more likely scenario with one-third of the distance between the fingertip and the tympanic membrane water filled and the seal lost after one-third of the withdrawal. F–G: From our cylinder model tests. F (Refer to Fig. 4B): simulate the forces transferred onto the malleus via a tympanic membrane without any restrictions on its movement. G (Refer to Fig. 4C): force developed with very little movement allowed, simulating a simultaneous tensor tympani muscle pull.



### Measurements of the Ear Canal

The mean age of the test subjects was 46 years (range 26–64 yrs). The length of the finger inserted into the ear canal (X) was  $12.6 \pm 2.2$  mm. There was no significant correlation between X and sex or age. The mean distance between the entrance of the ear canal and the tympanic membrane ( $L_2$ , Fig. 4) for men was  $25.2 \pm 0.6$  mm, and for women was  $24.1 \pm 0.8$  mm ( $p < 0.01$ ). The mean  $L_2$  for all test subjects was  $24.7 \pm 0.88$  mm. Calculation from the data set above using all test subjects gave a mean  $L_1 = 12.1 \pm 1.9$  mm.

### Calculated Negative Pressure Force

The theoretical maximum force generated under perfect conditions with only air present in the ear was 13.3 N. Assuming that half the volume between the fingertip and the tympanic membrane is filled with water, and that the seal between the finger and the ear canal was lost halfway out, the result was still 13.3 N. A more modest assumption of one-third of the volume filled with water and the seal lost after one-third of the pull resulted in a force of 9.9 N (Table 1).

### Negative Pressure Force Measured in Models

In the cylinder model simulating a free moving tympanic membrane, the mean force was  $1 \pm 0.23$  N. In the cylinder model simulating a fixed tympanic membrane, the mean force was  $5 \pm 0.9$  N (Table 1).

### Calculation of the Strength of Tensor Tympani Muscle

The mean diameter of the tensor tympani muscle was 2.0 mm, which would give a maximal force in the span of 1.1 to 4.3N (17). The mean cross-sectional area occupied by type II fibers predominated distinctly in the tensor tympani muscle,  $86.9 \pm 12.1\%$  (range 74.5–99.9%). Since a muscle composed primarily of type II fibers is more powerful than one with type I fibers, the maximum force exerted by the tensor tympani muscle might be closer to the upper span.

## DISCUSSION

In this study, we show that the forces simulating a finger being removed from a sealed wet ear canal are sufficient to break a malleus shaft if the tensor tympani muscle is simultaneously tensed through a stretch reflex.

It was previously suggested that the malleus is an uncommon site of ossicular injury due to its relatively broad support within the middle ear compared with the other ossicles (19). Of its six described ligaments, the malleo-cochleariform ligament enveloping the tensor tympani tendon is suggested to be the most important in that it retains the malleus against outward displacement (19). The malleus head's relative fixation in the epitympanum was suggested to be a sufficient stabilizer of the ossicle for the sudden lateral movement of the shaft to cause a fracture (6). However, our temporal bone pilot suggests that these anatomical structures do not cause

enough passive force to induce a malleus shaft fracture regardless of the amount of negative pressure force applied via the ear canal. Without resistance force applied via the tensor tympani muscle, the malleus moves too freely to be under enough tension to fracture.

The mathematical model in our study shows undoubtedly that enough force to break a malleus shaft can be achieved under theoretical conditions. This still applies when the seal around the finger holds only a part of the withdrawal. It is especially evident if accounting for water being present between the fingertip and the tympanic membrane, which supposedly is the reason for ear prodding after shower/bath in the first place. We think that water in the ear canal is crucial to this specific trauma for two reasons. First, it aids in the seal between the finger and ear canal thus allowing negative pressure build-up. Second, since a part of the ear canal is filled with water, less air is left to expand, and the force transferred to the tympanic membrane is larger. However, this model does not account for the flexibility of the soft tissues in the outer ear canal and the tympanic membrane. The results from the mathematical model are therefore likely higher than can be achieved in vivo.

Our cylinder models were built to complement the mathematical model and to demonstrate that the forces possible to achieve in "practice" were much lower than the theoretical models predicted. The measurements in the cylinder models were performed with only air in the system to give an estimate of the lower end of possible forces. This showed that the movement of the tympanic membrane has a significant effect on the negative pressure buildup. Simulating a completely free moving tympanic membrane without any support structures only allowed enough force buildup to account for the 10% frailest measured malleus fractured. The model simulating a tympanic membrane held firm in place allowed a buildup of negative pressure that was twice the required mean for a malleus fracture and 1N above the highest recorded measurements. Taken together, all experiments point toward the necessity for a tensor tympani activation at the same time as the outward movement of the tympanic membrane to create an isolated malleus shaft fracture.

The tensor tympani muscle was reported to be activated by tactile stimulation of facial areas, swallowing, phonation, and most commonly as part of the startle reaction, but not from external sound (20). However, the most plausible cause for a sudden contraction of the muscle might be related to a stretch reflex. This is based on the fact that the tensor tympani muscle contains muscle spindles, a stretch receptor that primarily detects changes in the length of the muscle (21). During the withdrawal of the finger in the ear canal, the negative pressure might cause muscle lengthening of the tensor tympani muscle, and thus stretching of the muscle spindles. This will immediately increase the alpha motor neuron activity resulting in a muscle contraction to resist the stretching.

To our knowledge, the morphology and strength of the human tensor tympani muscle have not been studied. Contractions of the tensor tympani muscles in cats and rabbits have been elicited at controlled lengths by electric stimulation of their motor nerves at varying stimulus frequencies. The measured forces on average were 0.53 N in cats and 0.32 N in rabbits (22).

Based on the muscle diameter and the force a muscle can produce per area, we estimated the maximum force in the span of 1.1 to 4.3 N (17). Our analysis of the muscle fiber composition showed that it was comprised of 87% type II fibers, which are known to be stronger and faster than type I fibers but less fatigue resistant (23). Since the mean cross-sectional area occupied by type II fibers predominated in the tensor tympani muscle, it is likely that the maximum force exerted by the muscle is closer to the upper span. The tensor tympani muscle might be strong enough to generate the 2.3 N mean force required for a fracture. We are convinced that a fracture in an ear with no pre-existing defects can occur if one adds this force to the existing passive support of the malleus and the synchronic forces that arise when pulling a finger outward in the ear canal. Further studies of the muscle would be required to ascertain this. It thus seems like the support structures and protective mechanisms that in most circumstances aid against trauma are turned against us when the trauma force is directed outward. This suggests that anyone without previous pathology could accidentally harm themselves in this way, and that isolated malleus fractures might be underdiagnosed.

A weakness of the present study was the failure to produce a simultaneous counteracting force from the tensor tympani muscle in our temporal bone model. Although both our mathematical model and our experimental cylinder models represent simplified versions of the trauma mechanisms, the differences between the model design and reality had no significant effect on energy transfer. However, the length of the seal may affect the result, as shown in the mathematical model. The flexibility of the tissues involved does affect negative pressure to a great deal, as revealed in the cylinder models. Regardless of the weaknesses in the models and methods, the present study relies on several methods complementing each other, which makes it a valuable addition to this uncharted field of knowledge.

## CONCLUSION

Negative pressure, created by a finger pulled out from a wet ear canal, is sufficient to cause an isolated malleus fracture with intact tympanic membrane, only if there is a simultaneous force in the opposite direction. The tensor tympani muscle has the capacity to generate this counteracting force.

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