3D-printed titanium ossicular chain reconstruction – hype or reality?

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There’s been a great deal of excitement in recent months about what’s being hailed as a world-first South African innovation that is set to restore precious hearing to scores of people who have damaged the tiny bones in their middle ear. This damage could be the result of a congenital defect, growths, infection or trauma.

The unique procedure utilises advanced 3D-printing technology to produce titanium versions of the chain of three tiny middle ear bones or ossicles – the malleus, incus and stapes (commonly referred to as the hammer, anvil and stirrup) – which are then implanted in the middle ear cavity to replace the existing damaged or malformed/missing ossicles (Fig. 1). This procedure, “3D-printed titanium ossicular chain reconstruction”, is being positioned as a superior option to conventional reconstruction methods, such as ossiculoplasty and stapedotomy, which have been used to date.

Fig. 1. The three human ossicles namely the malleus (M), incus (I) and stapes (S).

One would have thought that the ability to use 3D-printing technology as a potentially more effective alternative would have had the international Otological community buzzing with excitement. Otologists and Otosurgeons should be flocking to our shores to learn more from the team that developed the innovative procedure. However, the silence from the world’s academic and clinical experts in all things ear-related has been deafening.

Why?

The simple answer is probably because the vast majority of Otologists do not believe that any ossicular chain reconstruction involving the precise replication of the three ossicles, regardless of how they are produced, will deliver a long-term hearing benefit.
The reason for this is threefold:

1. The anatomy of the middle ear and the complex mechanics involved in hearing.
2. The fact that all previous attempts at reconstruction and implantation of replica ossicles involving prostheses made of various materials, as well as transplants of human ossicles, have either failed or have not produced results that are noticeably superior to conventional columellar (solid strut) reconstruction.
3. Lack of clinical data relating to long-term hearing restoration following middle-ear 3D-printed titanium ossicular chain implants.

**The anatomy of the middle ear**

The middle ear is an air-filled cavity in which the three linked ossicles are located (*Fig. 2*). The sole purpose of the ossicles is to transmit the sound vibrations from the tympanic membrane (ear drum) to the inner ear. The ossicles are suspended or held in place in the middle ear cavity by several ligaments.

![Middle ear diagram](image)

*Fig. 2. The middle ear houses the three linked ossicles.*

**Middle ear sound transfer**

Sound energy – in the form of sound waves or vibrations – that reaches the tympanic membrane is transferred to the inner ear mainly by the following amplifying systems:

1. The difference in surface area of the tympanic membrane and the stapes footplate:
   
   The sound pressure which is transferred from the larger surface area of the tympanic membrane to the smaller surface area of the stapes footplate in the oval window (or fenestra vestibuli – the opening that leads from the middle ear to the inner ear) – results in an increase in energy transfer via the ossicles to the cochlea in the inner ear by a factor of about 21:1 (*Fig. 3*). As only 66% of the tympanic membrane surface is able to vibrate effectively, the net result is an increase in sound pressure of 14:1. This equates to over 20dB.
2. The mechanical lever action of the ossicles:
   The lever effect of the length of the malleus umbo (the tip of the handle or manubrium of the hammer) to
   the point of rotation in relation of that of the incus long process (the longest part of the anvil ossicle)
   increases energy transfer by 1.3:1 (Fig. 4). This equates to about 2dB.

3. The catenary lever effect:
   Due to the buckling effect of the tympanic membrane, the energy transfer is increased by a factor of 2:1
   (Fig. 5).

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**Fig. 3.** The effective surface area of the tympanic membrane (Ae) is 14 times larger than surface area of the stapes footplate in
the oval window (As).

**Fig. 4.** The mechanical lever effect of the effective length of the malleus (lm) in relation of the effective length of the incus (li) increases
energy transfer by a factor of 1,3.

**Fig. 5.** The catenary (buckling) effect of the tympanic membrane. The displacement (d1) due to the buckling of the tympanic
membrane is greater than the displacement (d2) near the centre where the tympanic membrane is fixed to the malleus. This input
sound pressure (p) is consequently amplified by a factor of 2(P).
The total mechanical energy transfer of the ossicles thus equates to 20-25 dB. However, the ossicles, via their mechanical lever action, play only a small part in the sound energy transfer process when compared to the combined effect of the surface area difference between the tympanic membrane and the stapes footplate in the oval window, and to a lesser extent, the catenary effect of the tympanic membrane. In other words, the role played by the ossicles in sound transmission is minuscule when compared to the surface area ratio of the tympanic membrane and stapes footplate in the oval window.

This raises two questions: how can the implantation of new prosthetic ossicles – regardless of how they are obtained – result in long-term restoration of a recipient’s hearing? What quality of hearing will result?

The tympanic membrane in sound transmission

At lower frequencies, up to 2000Hz, the intact tympanic membrane vibrates as a stiff plate (Fig. 6). It is hinged at the axis of rotation that coincides with the axial ligaments of the middle ear. At this point, stimulation is at its highest at the umbo of the malleus, causing a piston-like vibration of the stapes footplate (Fig. 7).

Fig. 6. At lower frequencies of up to 2000Hz the intact tympanic membrane vibrates as a stiff plate (light grey area).

Fig. 7. At lower frequencies of up to 2000 Hz, the axis of rotation that coincides with the axial ligaments causes a piston-like vibration of the stapes footplate. Stimulation is at its highest at the umbo of the malleus.

The tympanic membrane shape is asymmetrical along the malleus axis as the posterior part of the tympanic membrane is larger than the anterior part. This asymmetrical shape plays an important role in the way in which the membrane vibrates at higher frequencies.

At higher frequencies, above 2000Hz, the tympanic membrane pattern of vibration becomes complex, changing with different frequencies. The tympanic membrane vibration then consists of several rotational movements and incorporates more of the manubrium of the malleus (Fig. 8a and 8b).
In order to enable maximum sound transfer, prosthetic ossicles have to be fixed to the tympanic membrane because all components involved in the reconstruction of the ossicular chain must have contact with each other. However, when middle ear implants are connected to the tympanic membrane, there are always two potential problems. Research has shown that the material of which the prosthesis is made may either be absorbed by the body; or – in the case of titanium or metal prostheses – extruded through the tympanic membrane.

In order to prevent extrusion, it is therefore essential to use cartilage (usually taken from elsewhere in the body) to separate the titanium or metal implants from the tympanic membrane.

Even if the cartilage used is thin, it will still have to be wedged between the tympanic membrane and the titanium or metal implant, thus impacting the functioning of the tympanic membrane. This means that the tympanic membrane will no longer be able to function as it normally would at the higher frequencies (above 2000Hz).

Interestingly, there is a dearth of reported reconstructive Ossiculoplasty surgery results for the range above 3000Hz. This is because the reconstructed tympanic membrane and ossicles are not able to reproduce these high frequencies. If necessary, however, this short-coming can be improved with the use of hearing-aids.

**The functions of the ossicles.**

- Sound transmission

  The ossicles transmit sound energy from the tympanic membrane to the cochlea in the inner ear. The lever action of the ossicles leads to a slight amplification factor of 1.3:1. The movement that occurs in the ossicles during sound transmission is very small, attaining molecular dimensions of considerably less than 1mm. In fact, this movement is not visible to the naked eye (see section on the middle ear as a pressure receptor below).
During sound transmission, the joints between the ossicles are functionally fixed. This means that sound transmission through the ossicular chain is the same as it would be through a fixed columella or strut of the kind currently used in the conventional reconstruction methods, such as ossiculoplasty and stapedotomy.

In summary: At frequencies below 2000Hz, the in-and-out piston-like movement of the stapes can be duplicated with any type of columella, including a fixed strut or a 3D-printed reconstructed ossicular chain. A total ossicular replacement prosthesis (TORP) consisting of a titanium strut is used by numerous Otosurgeons (Fig 9). At higher frequencies, the movement of the stapes is complex and incorporates tilting. It is thus a major challenge to replicate, regardless of the prosthetic used. In fact, it has never been successfully achieved, even when using human ossicle transplants.

![Fig 9. A total ossicular replacement prosthesis (TORP) made of titanium. Courtesy: Spiggle & Theis.](image)

- Frequency modulation through the functioning ligaments

  The ossicles vibrate in a complex manner which changes at different frequencies. This requires the presence of functioning ligaments in order to change the axis of movement (Fig. 10).

![Fig. 10. Middle ear ligaments. Anterior malleolar ligament (a), lateral malleolar ligament (b), superior malleolar ligament (c), posterior incudal ligament (d) and annular ligament (e).](image)

At a low frequency of around 1000Hz, the rotation axis is between the anterior malleolar ligament and the posterior incudal ligament which causes the umbo and the stapes head to perform a piston-like movement (Fig. 11a).

At a higher frequencies of around 2000Hz, the rotational axis moves to the malleus head. The axis of rotation whirls. As a result, the umbo at the tip of the malleus and the stapes head vibrate elliptically (Fig. 11b).
At even higher frequencies of around 4000Hz, the rotational axis on the incus also moves to its upper part, and the tip of the manubrium and the stapes display a piston like movement yet again (Fig. 11c).

Therefore, if the ligament and joint function is not precisely replicated, the only response to sound that one could get would be the piston-like movement for the frequencies below 2000Hz.

At low frequencies, the ossicles effectively act as a strut rather than the moving/vibrating parts required for sound transmission at higher frequencies. However, the use of three individual prosthetic ossicles would be less stable than a single prosthetic strut. For higher frequencies, there would be a need to precisely replicate not only the ossicles, but also the ligaments, muscles and joints that enable the middle ear’s main sound transmission structures to function as they should.

Fig. 11a. At a low frequency of around 1000Hz the umbo and stapes head perform a piston-like movement.

Fig. 11b. At a higher frequency of around 2000Hz the rotation axis moves to the malleus head and the umbo and stapes head vibrate elliptically.

Fig. 11c. At a high frequency of around 4000Hz the rotational axis on the incus also moves to its upper part and the umbo and stapes head display a piston-like movement yet again.

- The middle ear as a pressure receptor

Research indicates that pressure regulation by the ossicles is probably more important than sound conduction for long-term hearing. During pressure variations of non-acoustic loads such as that experienced during tests to examine the ear, for example pneumatic otoscopy, tympanometry and forced valsalva manoeuvres, the tympanic membrane produces slow, unidirectional displacements of up to 1 mm. These are visible to the naked eye (see section on Sound Transmission above). During these movements, the joint between the malleus and incus has to disarticulate and glide so that the incus can move up and down, buffering the pressure on the stapes and uncoupling it from the extensive displacements of the tympanic membrane and malleus.
Fig. 12. Middle ear synovial joints. Malleo-incudal joint (a) and incudo-stapedial joint (b).

The piston-like in-and outward movement of the stapes never exceeds 10-30 um, regardless of the pressure in the external ear canal. The malleo-incudal and incudo-stapedial joints are functional hyaline synovial joints with highly differentiated anatomy, able to mediate very small frictional resistance (Fig. 12).

When there is large movement at the tympanic membrane (as a result of a very loud sound or acoustic load) the ossicles move in such a way at the ligaments that the stapes movement is very small, thus providing protection against the loud sound blasting the inner ear, and potentially damaging it and causing irreversible deafness. This clearly indicates that unless the action of the joints is mimicked when implanting prosthetic ossicles, the ability to reproduce the protective function of these ossicles will be lost.

- Attachment for the functional middle ear muscles

Any joint in the human body needs movement, intermittent pressure and friction to be physiologically active. The delicate joints of the ossicles in the middle ear are no different. In a functional middle ear, these movement, pressure and friction functions are mediated by the middle ear muscles – the tensor tympani and stapedius muscles (Fig. 13).

The acoustical function of the middle ear muscles for the attenuation of, and protection against sound is still uncertain. The two muscles are aligned perpendicularly, yet act as antagonists when moving the ossicles. This movement is essential to ensure that the delicate joints remain lubricated and functional, and that circulation is maintained.

Fig. 13. Middle ear muscles with tendons. Tensor tympani muscle (a) and stapedius muscle (b).
• The shape of the stapes

In most people, the shape of the stapes supra-structure is asymmetric. The posterior crus is longer, more curved and usually thicker than the anterior crus. This shape has no benefit for sound conduction over a symmetric shape. However, the asymmetry of the stapes indicates that there is a force on the bone by the stapedius muscle, as is the case with muscles, tendons and bones throughout the body.

When the stapedius muscle retracts, the net effect on the inner ear fluid is zero, as the point of rotation of the stapes causes a correlating increase in pressure in the posterior and decrease in the anterior parts of the stapes. It is still open to question whether the stapedius muscle really attenuates and protects against loud sound. A symmetric stapes would cause a force load vector running outside the bone. Due to the asymmetry however, the pull of the stapedius muscle runs within the bony arch, resulting in a more favourable bending force (Fig. 14a and Fig. 14b). Therefore, the action of the stapedius tendon and muscle point rather towards maintaining joint function in the ossicles.

![Fig. 14a. Symmetric stapes design.](image)

![Fig. 14b. The stapes is formed in such as a way (with a larger poster crus) that when the stapedius muscle contracts the net force of increase in the posterior aspect equals that of the reduction in the anterior aspect, raising the question: how it can attenuate sound? Therefore, it is likely that the contraction rather causes movement and thus functioning of the incudo-stapedial joint.](image)

**Titanium prosthesis**

Is titanium the best material for the construction of ossicle prosthesis?

Ossicles have a critical mass at which they function optimally. Increasing the mass with a replacement prosthesis would lead to reduced movement at the stapes footplate and a decrease in sound conduction in the high frequencies.

The total mass of the three human ossicles is 56 micrograms. A solid titanium TORP weighs about 37 micrograms (Fig.15a). Ideally, a TORP should not exceed 40 micrograms. Three titanium ossicles are likely to weigh considerably more, thus impairing sound conduction. A solid TORP in a stable position conducts sound very effectively (Fig. 15b).
Reporting results after ossicular reconstruction

The only way to ascertain the long-term value of any ossicular reconstruction procedure is through audiometric testing. As stated so elegantly by Karl-Bernd Hüttenbrink:

“Yet, all our efforts to improve acoustics, which might even result in a closed air-bone gap in the first audiogram directly postoperative, are only of academical value, if the prosthesis material slowly dissolves or is rejected and extruded. We must ask ourselves as otosurgeons, for how long the hearing result will remain stable in the following years.”

As far as can be ascertained, no short-, medium- or long-term audiometric testing results have yet been published following the implantation of 3D-printed titanium ossicles.

In summary

Concerns about the validity of the concept of 3D-printed titanium ossicular chain reconstruction of the middle ear to restore hearing function are based on the following facts:

- There is no published experimental data.
- While similar ossicular chain reconstructions made from other materials, as well as transplantation of human ossicles, have been tried these have never produced a better outcome for improved sound transmission than that provided via a standard columella.
- There will be no pressure stabilizing effect of the middle ear through the joints, muscles and ligaments as these cannot be replicated.
- The mass of the titanium ossicular prostheses appears to be too high.
- Whether 3D-printed titanium ossicular chain reconstruction can be functionally stabilized in the middle ear space over the medium- to long-term is highly questionable.
- There have been no published results of any audiometric tests following the procedure that would ultimately prove its efficacy.
To date, there does not appear to have been any acknowledgement of, support for, or interest in this procedure from the international Otological fraternity.

Conclusion

It is doubtful that any 3D-printed titanium ossicular chain reconstruction will show a long-term hearing benefit compared to a standard, columellar type reconstruction, yet the risk would be considerably higher. This would be true for any procedure that attempts to utilize exact replicas of the ossicles.

Acknowledgement

Marilyn de Villiers from Wordsmith for editing of the script.

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