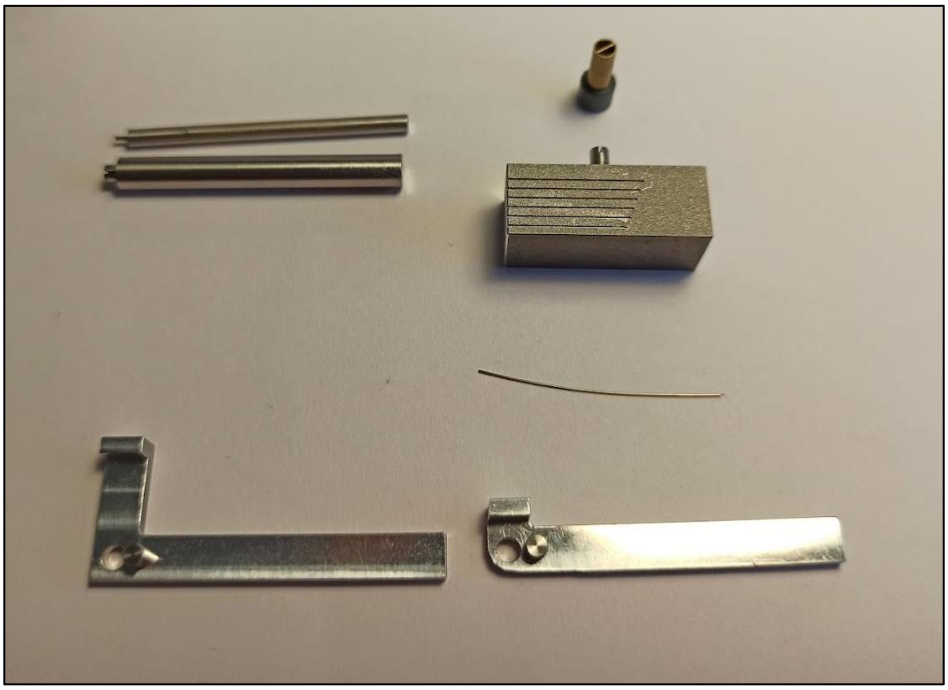
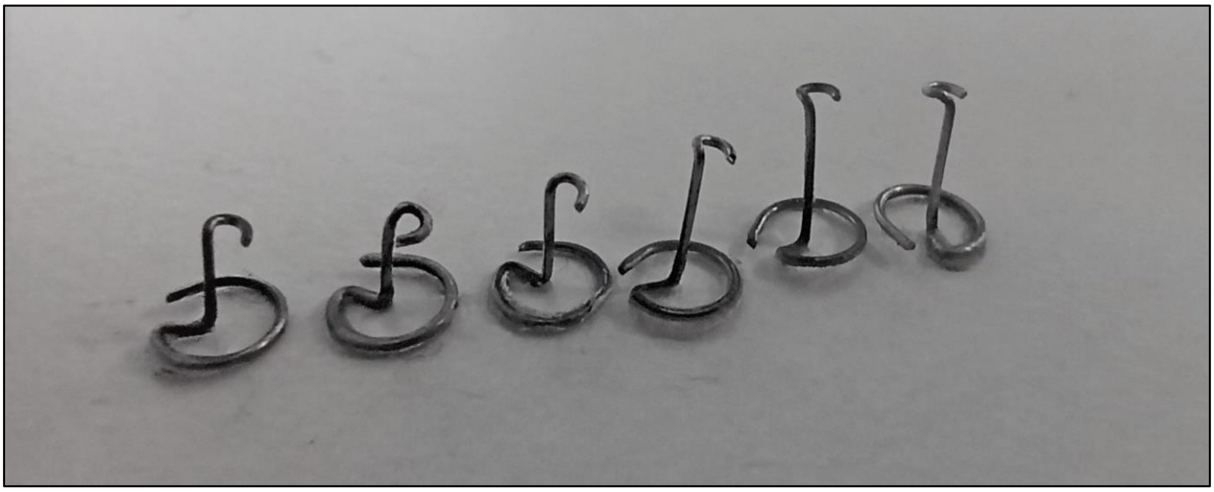
Design of an Affordable Total Ossicular Reconstruction Prosthesis(TORP)





Msc graduation project by Geert ten Have (4223055)

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ABSTRACT

The goal of this project is to design and create a low cost total ossicular reconstruction prosthesis (TORP) for use in low-middle income countries (LMIC). These middle ear prostheses are available on the market but are unaffordable for the general populace in LIMCs. A mould is designed with which a titanium wire TORP could be created . A multitude of wire TORPs are made and measured to test the performance of the mould. Transmission properties of the TORP are measured by using a Mechanical Middle ear Model(MMM), a synthetic recreation of the middle ear. This model is used to make a comparison of transfer functions between the wire TORP and a commercial model. The comparison showed slightly worse transmission properties for the wire TORP compared to its commercial counterpart. The result is a production method suitable for LIMCs that can create affordable TORPs that can fit in every middle ear.

TABLE OF CONTENTS

1 INTRODUCTION

1.1 PROJECT BACKGROUND

Total ossicular reconstruction prostheses (TORP) and partial ossicular reconstruction prostheses (PORP) are used to reconstruct the ossicles in the middle ear. Reconstruction can be needed when the degradation or fixation of the ossicles cause the patient to have conductive hearing loss.

TORPs and PORPs are made commercially available by many medical device companies. However, the cost of such a device is considered to be extremely high for people who live in low- and middle-income countries (LIMCs). This results in the absence of middle ear prostheses that are affordable for the general populace in LIMCs. Currently, a UK ear surgeon (Dr. Smith) based in Nepal builds his own prostheses out of titanium wire. However, the production of the prostheses is crude and limited. The aim of this project is to make a design of an affordable TORP or/and PORP that can be either produced in Nepal or shipped to Nepal.

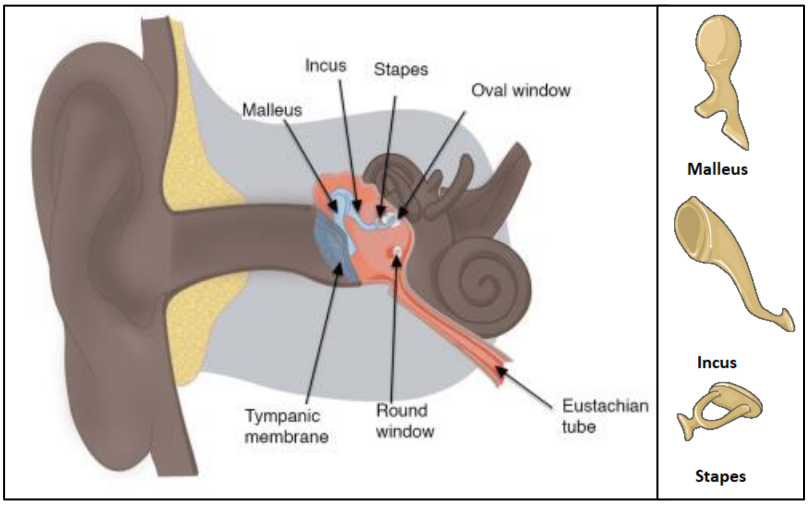

Figure 1. The middle ear and the separate ossicles *[15]. Left: an overview of the middle ear. Right: the 3 ossicles [generated using Servier Medical Art].*

1.2 ANATOMY AND PHYSIOLOGY

The ossicles are 3 bones situated in the middle ear and are called the malleus, incus and stapes. These 3 bones connect the tympanic membrane (TM) to the oval window. Connection between the ossicles and oval window is made with a part of the stapes called the footplate (see **Figure 4**). A figure of the middle ear and each separate ossicle is shown in **Figure 1**.

During sound transmission, the TM vibrates because of incoming soundwaves and the ossicles transfer these vibrations to the cochlea. Without the ossicles the vibrations won't be transferred.

1.3 TOTAL AND PARTIAL OSSICULAR RECONSTRUCTION PROSTHESIS

For decades, banked homograft (donated) ossicles or autograft (from same individual, with reshaping of the ossicle to fit in position) remained the gold standard for ossicular reconstruction. However the use of homograft ossicles has become unacceptable because of the potential of transferring diseases [1]. Autograft ossicle are still widely used, but are not always suitable, and take skill and time to shape correctly. Instead of human homograft or autograft ossicles, synthetic prosthesis are now more often used to reconstruct the ossicular chain, especially in more developed countries. There are different middle ear prostheses depending on what part of the ossicles is degraded. In the case of a TORP, the prosthesis replaces the function of all 3 ossicles (malleus, incus and stapes) while a partial ossicular reconstruction prosthesis(PORP) uses the intact stapes(see **Figure 2**).

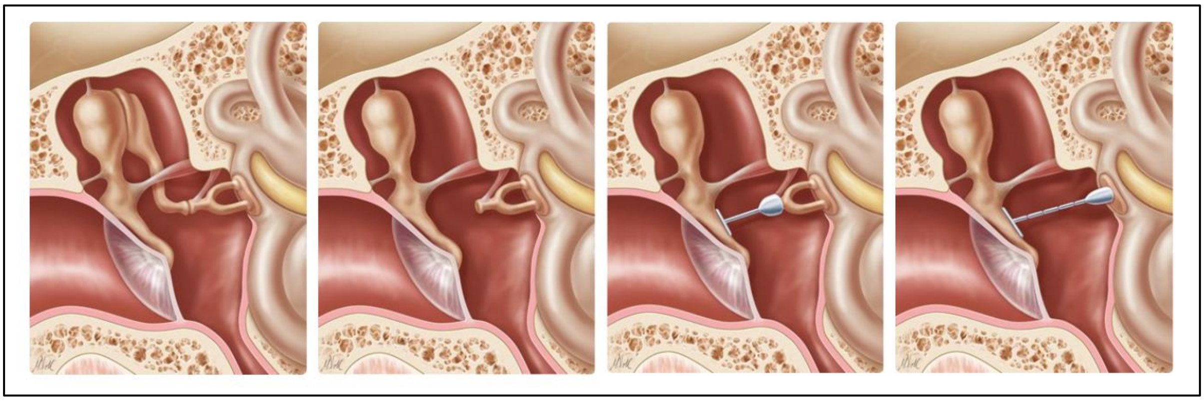

Figure 2. Middle ear. *From left to right : intact ossicles; without incus; with a PORP from malleus to stapes; with a TORP from malleus to stapes footplate [2].*

1.3.1 Overview state of the art

Most of the middle ear prostheses currently available have a similar design. This design makes a straight connection (a columella) between the TM or malleus handle, and the stapes footplate (TORP), or head of stapes (PORP). An example of such a prosthesis design is shown in **Figure 2**. Variety in the design is shown in the parts that make contact with the tympanic membrane(head of prosthesis) and stapes (foot of prosthesis). In this report, the shaft between the head and foot of the prosthesis is called a stem.

Common biomaterials used in middle ear prostheses are: Titanium, stainless steel, Hydroxyapatite (HA) and a variety of polymers [3] [4] [5] [6]. Titanium is the most common biomaterial used in middle ear prostheses. This is because of titanium's good biocompatibility, adjustability and mechanical properties [7].

The length of most available middle ear prostheses is adjustable. These prostheses have either a system to adjust the length of a prosthesis or uses a trimmable material (see HA PORP in **Figure 3**).

Various systems exist like the Kurz's TTP-VARIAC System [4] and Grace Medical's ALTO adjuster [3]. A variety of different TORP designs is shown in **Figure 3**.

Figure 3. TORP and PORP designs. *From left to right: titanium TORP with open head and foot with flexible connection [4], titanium TORP with a HA head [3], HA PORP with notched head [5] and a titanium PORP with a slitted bell-shaped foot [2].*

2 DESIGN REQUIREMENTS

There are multiple requirements for the design of an affordable prosthesis.

Material requirements are:

- *Low mass and high stiffness.* A low prothesis mass (below 40 mg) and high stiffness ensures optimal sound transmission [8] [1].
- *Intraoperative adjustability.* Differences in middle ear anatomy requires precise adjustments of the prosthesis [9].
- *Durable and biocompatible.* A durable and biocompatible material lowers the chance for the need of multiple revision surgeries because of possible complications. A biocompatible material has no bone deposition, resistance against degradation and infection.
- *No imaging artifacts during medical scans.*

General requirements are:

- *Good visibility.* Meaning that the prosthesis leaves enough room for the surgeon during its placement.
- *Good handling.* Meaning that the surgeon can easily move the prosthesis during placement.

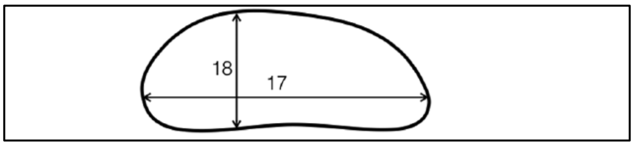

Figure 4. Stapes Footplate *[9]**.** The numbers 18 and 17 describes the width and length of the footplate respectively*

- *Prosthesis can either be made in different lengths or is adjustable.* In general, TORPs have a length of 3 to 7 mm and PORPs have a length of 1.5 to 5 mm [3] [2] [5] [4]. This is done to make sure it fits every middle ear.
- *Foot of TORP fits on stapes footplate.* The foot of a TORP must be small enough to fit the width(1.4 mm, varying from 1.1 to 1.7 mm) of the stapes footplate (see **Figure 4**) and the distance between the crura (see **Figure 5**) (1.7 mm, varying from 1.3 and 2.2) [9].
- *Head of TORP fits on tympanic membrane.* Size of prosthesis head is limited to a circle with a 3 mm diameter to ensure placement on tympanic membrane.
- *No sharp edges.* Sharp edges can lead to complications which require revision surgeries.

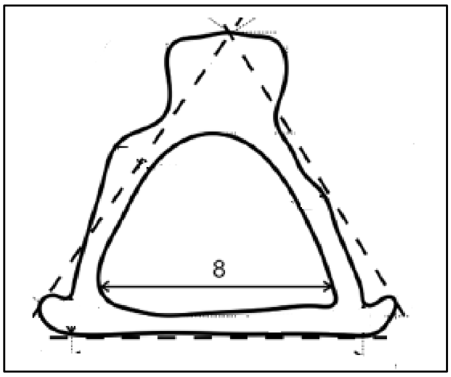

Figure 5. Sideview of stapes *[9]. 8 describes the length between the crura.*

Project specific requirements:

- *Low cost.* Costs for each prosthesis must be attainable for general populace in LIMC. The proposed costs for one implant is $5.
- *Production method is available in LIMC.* This is required because of the limited means of production (machines, expertise, etc.) in LIMCs. An alternative is shipping the finished prosthesis to LIMCs.

3 CONCEPT EVALUATION

3.1 3D PRINTING PLASTIC PROSTHESIS

In this concept, prostheses can be 3D printed in LIMCs using affordable FDM printers. This would result in locally printing plastic prostheses. 3D printing brings multiple advantages like the low amount of training needed to produce a prosthesis and the ability to adjust the design without changing the production method.

However, testing this concept resulted in the conclusion that the method is unattainable (see **Figure 37** in **Appendix B: Photos**). An insufficient resolution of affordable 3D printers resulted in failure to print the concept model (see **Figure 6**). This test was done on an Ender 5 printer (Creality, Shenzhen, China).

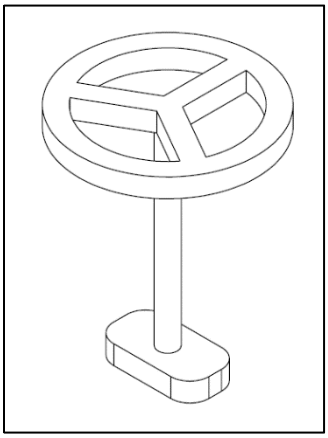

Figure 6. Concept model FDM 3D printer.

3.2 3D PRINTING TITANIUM PROSTHESIS

The following concept is printing the prosthesis in titanium using a laser powder bed fusion (LPBF) printer. In contrast to using a FDM printer, a titanium printer is precise enough to realize the required dimensions. Another advantage over the previous concept is the use of titanium, which is an excellent biomaterial [7].

However, costs of such a printer and its use is too high for this project. Absence of such printers in LIMCs also results in added shipping costs. Thus, the resulting cost of a titanium printed prosthesis is too high.

3.3 Injection moulding

Producing a prosthesis using injection moulding means producing a prosthesis by injecting the material into a mould. Using injection moulding would result in making polymer prostheses. The main advantage of injection moulding is the low cost per unit. A major downside is the high cost of producing an injection mould. In this concept shipping costs could also be added because of the absence of a local production plant.

3.4 Titanium wire prosthesis using a mould

In this concept a wire is formed by using a mould. Designs using a wire prosthesis are proven because of its use in early years of middle ear prosthesis development [1]. It is also the method doctor Smith currently uses in Nepal. Examples of the current production method and TORP are shown in **Figure 38** and **Figure 39**.

Advantages of wire moulding are: ease of production, low cost per unit and its use of titanium. A disadvantage is the creation of sharp edges during production, which could damage surrounding tissue.

4 Design

4.1 Concept choice

The titanium wire TORP with wire moulding as production method is the chosen concept. Titanium is the chosen material based on this projects preliminary literature review [10]. The project is limited to only the design of a TORP model. This is done to simplify the design and because of time limitations. Wire moulding is chosen because it can attain the cost requirement mentioned in **Chapter 2: Design requirements** while having a proven prototype(**Figure 38**).

4.2 Previous design

A previous design has been made and tested. The design was made for a preliminary course. The final design of that course is shown in **Figure 7**. The wire folds around the mould using your finger. This mould has the advantage of being able to form TORPs of 5 different sizes while using only 1 part. Disadvantages of the design were the inconsistent and poor quality of the TORPs formed by the mould. An example is shown in **Figure 8**.

Figure 8. TORP formed by previous design

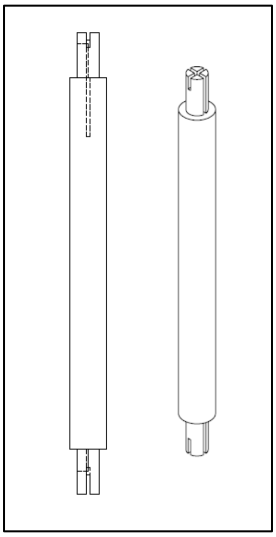

Figure 7. Final design wire mould medical device prototyping

4.3 Mould

The final design and corresponding part names of the mould are shown in **Figure 9**. This mould functions by isolating titanium wire into grooves and consequently forming the wire by turning it into these grooves. The isolated grooves are shown in **Figure 11**.

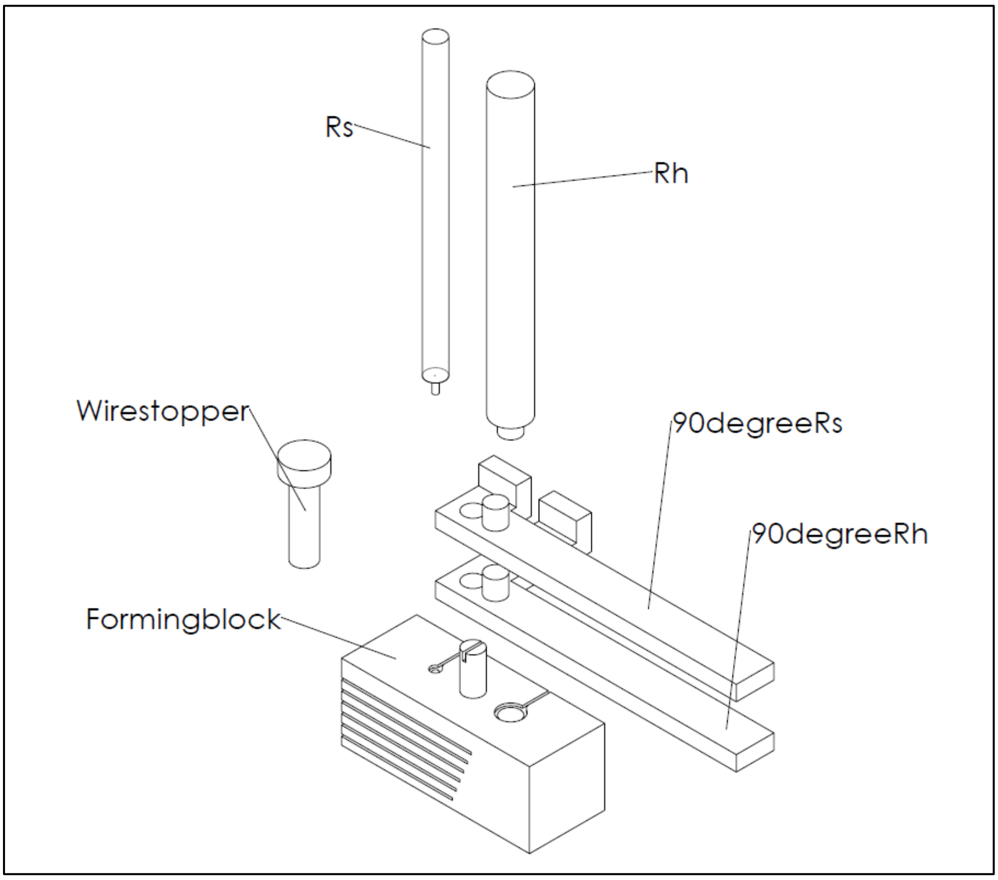

Figure 9. Final design wire mould.

An earlier version of this groove design was made and tested (see **Figure 40**). This version proved the concept of forming by turning the wire into the grooves. The final design improved on version 1 by adding the wirestopper, 90degreeRh and 90degreeRh parts. The wirestopper is made to hold down the wire during the forming procedure (see **Figure 10**). 90degreeRh and 90degreeRs are used to bend the wire at the point where enough wire is left to form the TORPs head and foot (see **Figure 12**). This length is determined by blocking the wire (see step 2 and 4 in **Figure 10**).

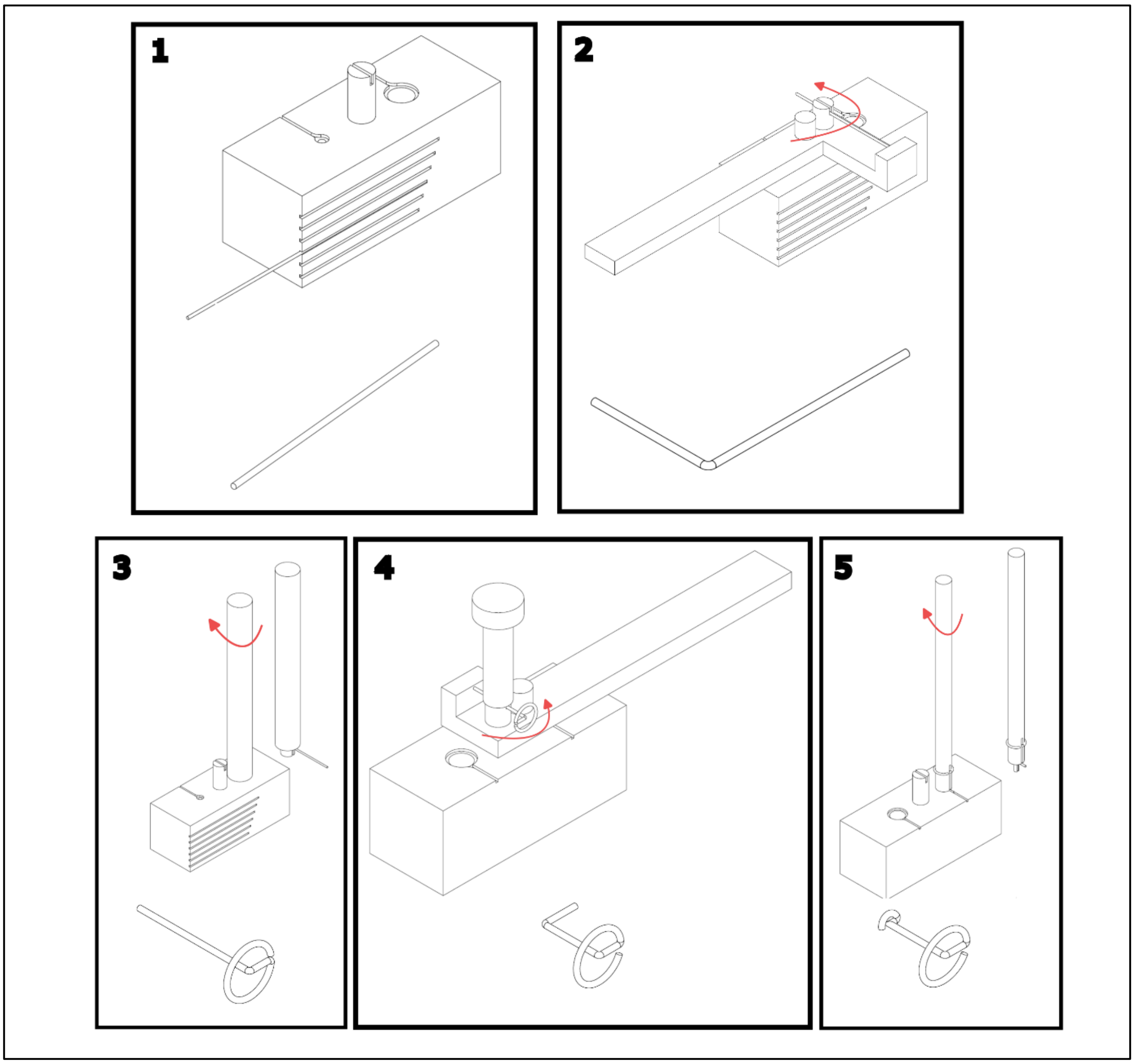

Figure 10. Designed forming procedure. *Step 1 : Cutting of the wire at the desired length. Step 2 : Bending the wire used to form the head by turning 90degreeRh anti-clockwise. Step 3 : inserting the formed wire into Rh and forming the head by turning Rh clockwise while Rh is inserted into the forming block. Step 4 : Bending the wire used to form the foot by turning 90degreeRs anti-clockwise. Step 5: clicking the formed wire into Rs and forming the foot by turning Rs clockwise.*

The mould is designed to make TORPs of 6 different lengths (2.5 mm, 3.0 mm, 3.5mm, 4.0 mm, 4.5 mm and 5.0 mm). Slots of 6 different sizes function as a holder for the wire while it can be cut at the desired length (see step 1 in **Figure 10**). Only a wire with a diameter equal or less than 0.3mm can be used in this mould.

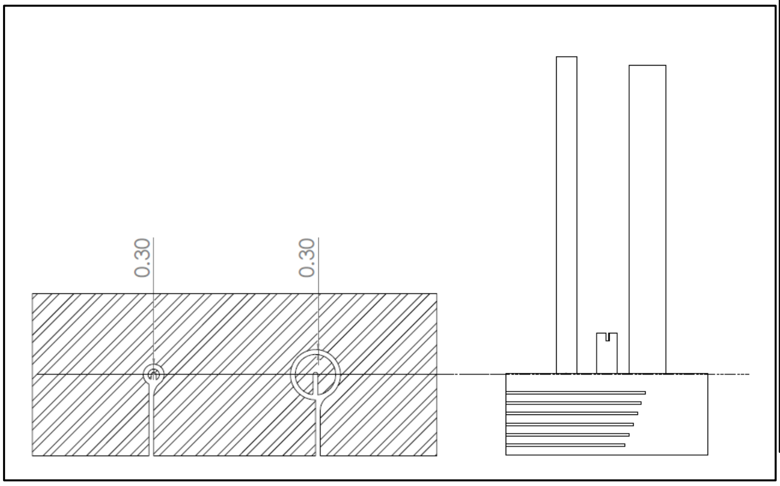

Figure 11. Grooves formed while Rh and Rs are inserted into forming block.

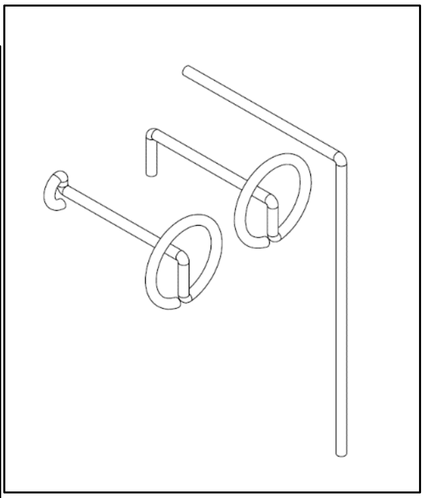

Figure 12. Progression titanium wire during forming.

Materials and machines

The forming block, 90degreeRh and 90degreeRs are aluminium parts made using a CNC (Fehlmann picomax 55, Seon, Switserland) milling machine. Aluminium is chosen because of its low price and ease to machine. The wirestopper is made from brass with a rubber top. Rh and Rs are made from stainless steel using the same CNC milling machine. The outer end of Rs (where the TORP slots in) is made using a wire electrical discharge machine (Fanuc, Oshino, Japan) because of the limitations of the CNC machine. This outer end is cut out in a single plane and is press fit into the handle. Rs and Rh are made from stainless steel because of the high stresses on these parts during forming. In version 1, where these parts were made from aluminium, Rh and Rs were damaged after single use.

Detailed drawings with dimensions (all in mm) of all parts are available in **Appendix A: Drawings**.

4.4 TORP

The final design of the TORP is shown in **Figure 13**. Compared to previous designs, this design adds a half circle instead of a straight wire (see **Figure 8**). This is done to improve the stability of the TORP. It is made using grade 1 pure titanium wire with a 0.3 mm diameter (AEM metal, Changsa, China). Grade 1 has the lowest stiffness and highest purity of all the pure titanium grades (compare to other pure titanium grades) [11]. This grade is chosen because it is the most malleable grade. The 0.3 mm diameter is chosen based on testing done by Dr. Smith (see **Figure 39**). A wire with this diameter is stiff enough to provide good handling while still having good visibility.

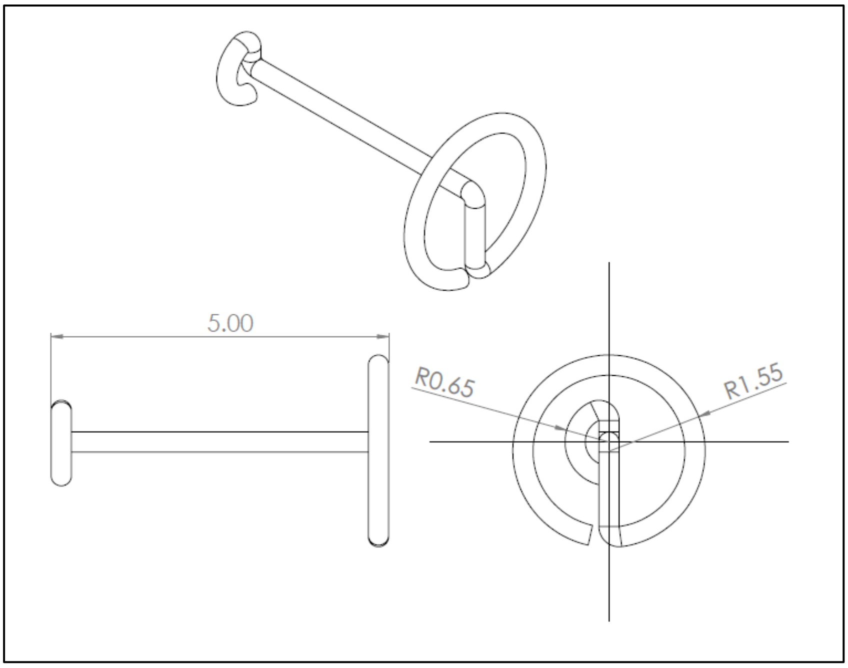

Figure 13. Final TORP design

The head and foot part have a theoretical radius of 1.55 mm and 0.65 mm respectively. This is based on the size of the groove in the forming block. The TORP model in version 1 (see **Figure 32**) has a stapes design which used a full circle with a 0.82 mm radius. This design is based on the average dimensions of the stapes footplate [9]. In contrast to version 1, the foot of the final design is a half-circle with a 0.65 mm. The designed length and width of the foot is 1.3 and 0.8 mm respectively. Theoretically, this design can fit every patient based on the dimension requirements in **Chapter 2: Design requirements**.

5 VALIDATION METHOD

5.1 MOULD

Performance of the mould is validated by looking at the following variables: TORP weight (M_T), stem length (L_s) , head diameter (D_h), foot length (L_f) and foot width (W_f). The dimensions are shown in **Figure 14**

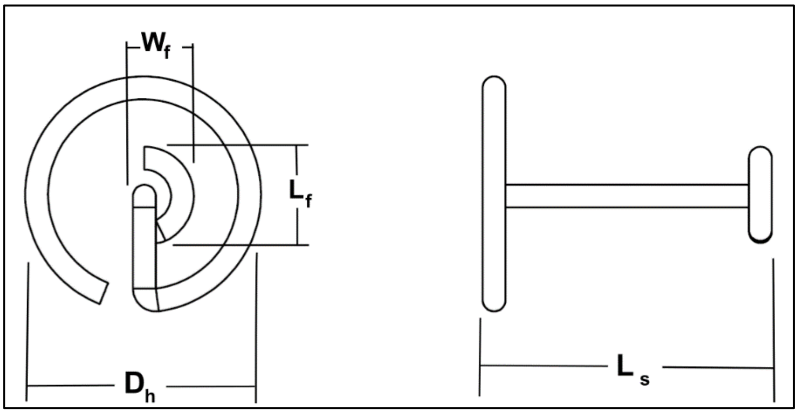

Figure 14. TORP with its dimensions.

Stem length and TORP weight are used to gain insight into the consistency of the cutting method. This is because the initial length of the wire should be the only influence on the stem length and weight.

Head and foot dimensions are used to see if the TORP is made according to the design requirements set in **Chapter 2: Design requirements**.

5.2 TORP

Conventionally, determining transmission properties of TORPs is done by using temporal bones. In the temporal bone, structures of the middle ear are intact and can be used to test TORPs. For this project, using donated material was not possible. That is why a synthetic alternative is used to determine transmission properties.

The validation method of the TORPs transmission properties is called a mechanical middle ear model (MMM) [12]. A MMM is a recreation of the middle ear using synthetic materials. It allows for comparison of transmission properties of middle ear implants [12]. Comparison is done by measuring the transfer function of the MMM while replacing only the TORP. An example is shown in **Figure 15**.

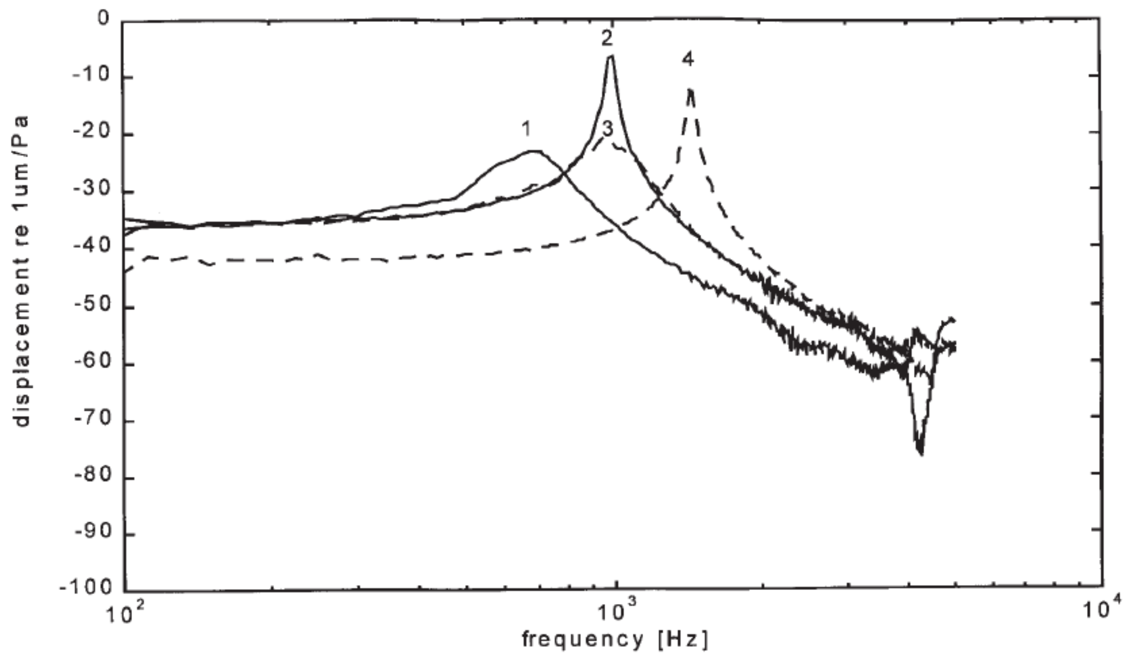

Figure 15. Transfer functions of a MMM with different prostheses. *Each transfer function corresponds with a TORP which has either an increased mass (1), damping (3), stiffness (4) or is a normal TORP (2) [12].*

The transfer function of the MMM is expected to be a 2nd order mechanical system (see **Figure 15**). This results in a stable level of displacement in the frequency range below the resonance peak and a resonance peak around 1000 Hz. At frequencies above the resonance peak, a negative slope of around 20 dB per octave is expected. The main region of interest in the transfer function of the MMM is the resonance peak around 1000 Hz. Variations between mass, stiffness and damping of a TORP can shift the resonance frequency or change the peak displacement at this frequency [12].

In this project the MMM is designed to achieve the following :

- Compare transmission properties of wire TORP with a commercially available model
- Compare transmission properties between wire TORPs of different sizes

The goals of the test are to:

- Determine if the transmission properties of the wire TORP is comparable with currently available models
- Determine consistency in transmission properties wire TORP
- Gain insight into influence of stem length on transmission properties of wire TORP

5.3 EXPERIMENTAL SET-UP

The test setup measures the transfer function of the MMM. A diagram of this test setup is shown in **Figure 16**. The final design of the test setup with all components and their names is shown in **Figure 18**.

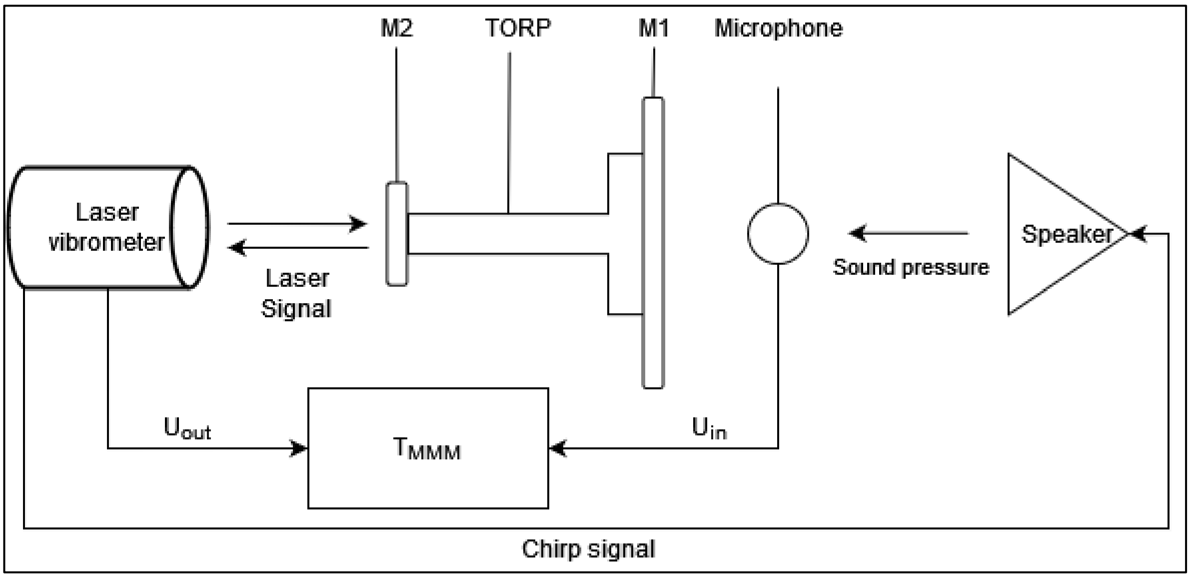

Figure 16. Diagram of the set-up. The microphone measures the sound pressure coming from the speaker controlled by the laser vibrometer. M1 and M2 represent membrane 1 and 2 respectively. The laser vibrometer measures the displacement of M2. Transfer function T_{MMM} is calculated as a quotient of the spectra U_{out} and U_{in}.

The realized test setup is shown in **Figure 17**. The TORP is fit between two silicone (shore 8a, Polyestershoppen BV, Moordrecht, Netherlands) membranes that mimic the tympanic membrane (glued on membrane holder) and stapes footplate (glued on movable tube). The membrane that mimics the tympanic membrane and stapes footplate are called Membrane 1 and 2 respectively.

A speaker gives a input signal, which is measured by a microphone, while a laser vibrometer (PSV-400, Polytec GmbH, Baden-Württemberg, Germany) measures the output of the system on the surface of membrane 2, where the TORPs foot is placed.

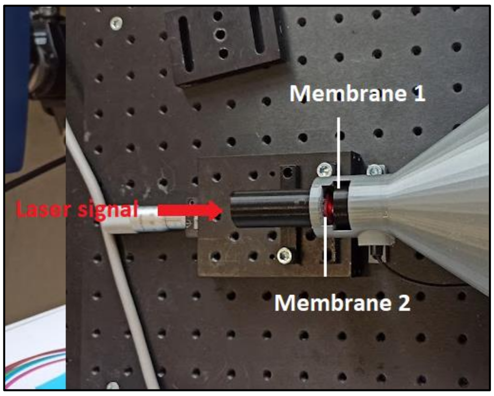

Figure 17. Realized MMM.

The linear actuator (PT1-M, Thorlabs, Newton, USA) displaces Membrane 2 and displays the membranes location on the axis of movement. All other parts are 3D printed (Prusa MK3s, Prusa Research, Prague, Czech republic) in PLA and are made so it can all be bolted down on a breadboard(MB2503-M, Thorlabs, Newton, USA). During testing it is important to keep all variables constant. Comparing transmission properties with a MMM is only possible if every variable, except the fitted prosthesis, is close to equal.

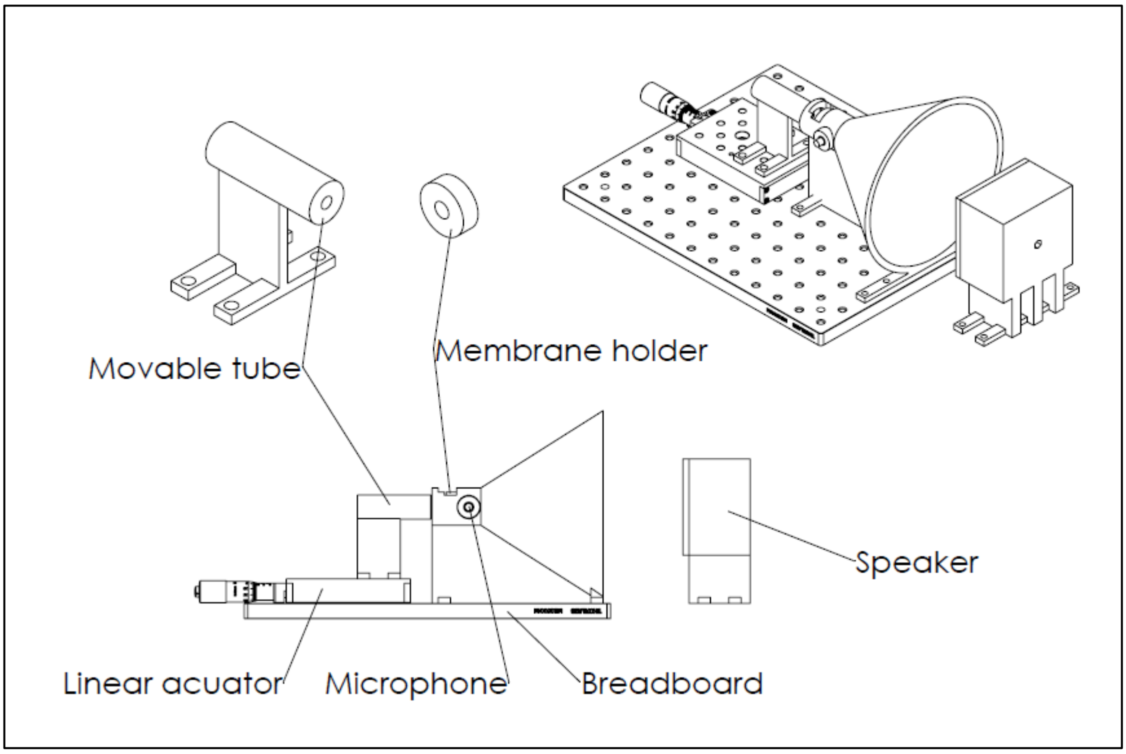

Figure 18. Test setup. *Test setup with all components and their respective names*

Four prostheses for every designed stem length (2.5 mm, 3.0 mm, 3.5 mm, 4.0 mm, 4.5 mm and 5.0 mm) are formed. Production is done in cycles of a single prosthesis for each stem length from 2.5 mm up to 5.0 mm until all prostheses are formed. A TORP is named by its model (designed stem length) and version (production cycle). There is one commercial model (mXACT Total offcenter WS, MED-EL Medical Electronics, Innsbruck, Austria) available for testing. The material of this model is grade 2 titanium.

They are weighed and measured using a calliper(Mitutoyo, Japan) and a precision scale(AX105 DeltaRange, Mettler Toledo, Columbus, USA).

The movable tube and membrane holders for every prosthesis(n=25) are 3D printed. 15 x 15 x 2 mm silicone membranes(n=1 for membrane 2 and n=25 for Membrane 1) are made. The membranes have a compliance of 35000 µm/N. Glue (cyanoacrylate, Henkel AG, Düsseldorf, Germany) is used to attach all membranes to the membrane holders and movable tube. An example of 2 fully prepared membrane holders is shown in **Figure 19**.

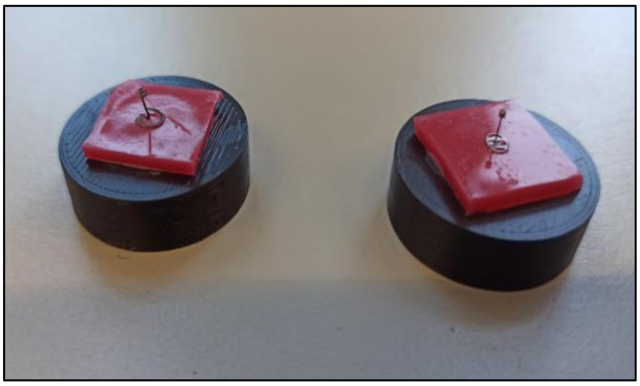

Figure 19. Prepared membrane holders. L*eft: prepared wire TORP, Right: prepared commercial TORP*

Tension in the test setup is kept constant by placing membrane 2 always on the same location relative to the TORPs foot. This is done by finding the first point(between membrane 2 and foot) of contact using the linear actuator. Membrane 2 is placed an additional 0.5 mm beyond point of contact.

The output is expressed as a spectrum (U_{out}) of the displacement of the mimicked stapes footplate(membrane 2) using the FFT procedure.

The input signal is a periodic chirp with a frequency range of 100 to 4000 Hz with an amplitude of 5 V. At membrane 1, this input signal is measured and is expressed as a spectrum of the amplitude (U_{in}). A single input spectrum is determined beforehand, using the average of a few measurements (see **Figure 41**).

The transfer function is determined as a quotient of the output and input spectra (**Equation 1**).

Equation 1. Transfer function of MMM

$$T_{MMM} = \frac{U_{Out}}{U_{in}}$$

6 RESULTS

6.1 DIMENSIONS AND WEIGHT

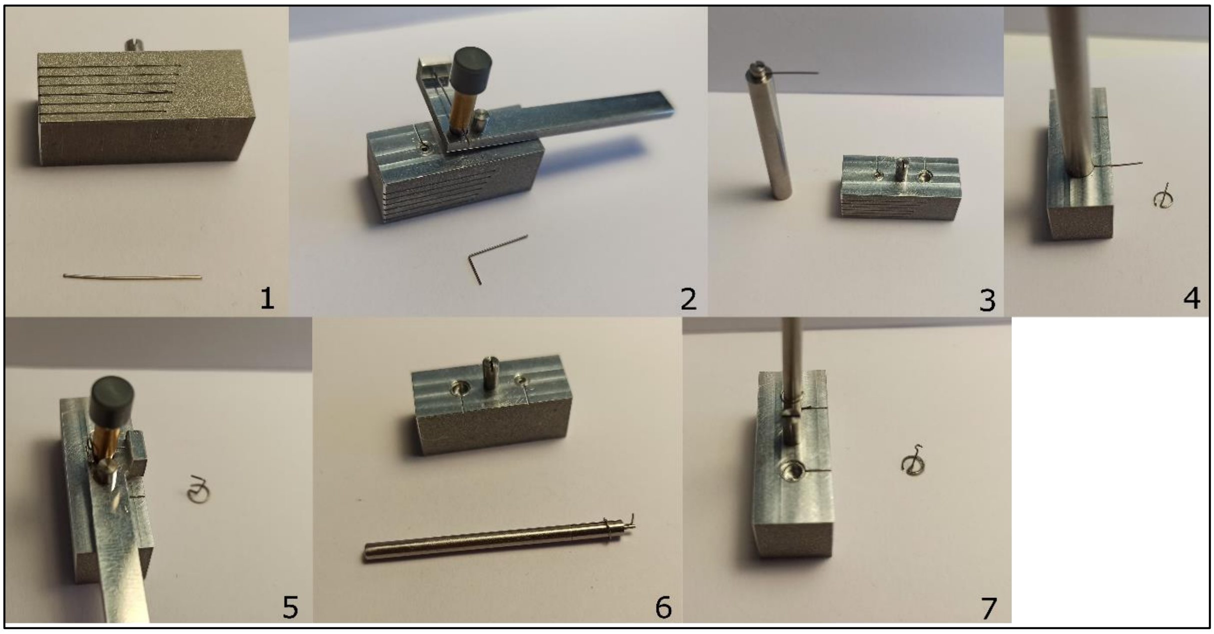

Figure 20. Resulting procedure. *Step 1 : Cutting of the wire at the desired length. Step 2 : Bending the wire used to form the head by turning 90degreeRh anti-clockwise . Step 3 : inserting the formed wire into Rh. Step 4 : forming the head by turning Rh clockwise while Rh is inserted into the forming block. Step 5 : Bending the wire used to form the foot by turning 90degreeRs anti-clockwise. Step 6: clicking the formed wire into Rs. Step 7 : forming the foot by turning Rs clockwise.*

All dimensions and weight are measured of the formed prostheses (see **Figure 20**). The production time for each procedure was around 5 minutes. Four versions are made for each designed L_S (called model in **Table 1** and **Table 2**). The version of a prosthesis corresponds with its production cycle (1 to 4). The standard deviation from the mean L_S for all prosthesis models (n=24) is 0.16 mm. A large outlier is version 3 of the 3.5 mm model with a deviation of 0.38 mm (see **Figure 22**).

Table 1. Average stem length and weight

Prosthesis model	Average L_S (min - max)	Average M_T (min - max)
2.5 mm(n=4)	3.11 mm (2.85 - 3.40 mm)	4.42 mg (4.36 - 4.47 mg)
3.0 mm(n=4)	3.58 mm (3.30 - 3.90 mm)	4.56 mg (4.45 - 4.62 mg)
3.5 mm(n=4)	4.27 mm (4.05 - 4.65 mm)	4.77 mg (4.69 - 4.89 mg)
4.0 mm(n=4)	4.46 mm (4.20 - 4.65 mm)	4.82 mg (4.78 - 4.88 mg)
4.5 mm(n=4)	4.85 mm (4.75 - 5.10 mm)	5.04 mg (5.03 - 5.08 mg)
5.0 mm(n=4)	4.92 mm (4.80 - 5.10 mm)	5.15 mg (5.09 - 5.24 mg)
Commercial(n=1)	4.19 mm	4.26 mg

Average D_h, L_f and W_f, organized by prosthesis model, is shown in **Table 2**. This is used to gain insight into the moulds consistency. Total (n=24) average D_h is 3.45 mm with a standard deviation of 0.10 mm. A large outlier is version 2 of the 3.5 mm model with a D_h of 3.10 mm (see **Figure 23**). Total average L_f is 1.26 mm with a standard deviation of 0.05 mm. Total average W_f is 0.99 mm with a standard deviation of 0.11 mm. A large outlier is version 2 of the 5.0 mm model with a W_f of 1.35 mm (see **Figure 21**). Average W_f is larger for larger (4.0, 4.5 and 5.0 mm) models compared to the smaller (2.5, 3.0 and 3.5 mm) models (see **Table 2**).

Table 2. Average head diameter, foot length and width.

Prosthesis model	Average D_h (min - max)	Average L_f (min - max)	Average W_f (min - max)
2.5 mm(n=4)	3.47 mm (3.40 - 3.50 mm)	1.25 mm (1.20 - 1.35 mm)	0.89 mm (0.80 - 0.95 mm)
3.0 mm(n=4)	3.44 mm (3.35 - 3.50 mm)	1.26 mm (1.20 - 1.30 mm)	0.92 mm (0.80 - 1.00 mm)
3.5 mm(n=4)	3.33 mm (3.10 - 3.55 mm)	1.26 mm (1.20 - 1.35 mm)	0.92 mm (0.90 - 1.00 mm)
4.0 mm(n=4)	3.55 mm (3.50 - 3.60 mm)	1.29 mm (1.25 - 1.30 mm)	1.00 mm (1.00 - 1.00 mm
4.5 mm(n=4)	3.45 mm (3.40 - 3.50 mm)	1.21 mm (1.20 - 1.25 mm)	1.04 mm (1.00 - 1.10 mm)
5.0 mm(n=4)	3.46 mm (3.40 - 3.50 mm)	1.27 mm (1.25 - 1.35 mm)	1.13 mm (1.00 - 1.35 mm)

Figure 21. Version 4 and 2 of 5.0 mm model. *Left : version 4 (W_f = 1.00 mm) , Right : version 4 (W_f = 1.35 mm).*

Figure 22. Version 1 and 3 of 3.5 mm model. *Left: version 1 (L_S = 4.10 mm), Right: version 2 (L_S = 4.65 mm) .*

Figure 23. Version 2 and 4 of 3.5 mm. *Left: version 2 (D_h = 3.10 mm), Right: version 4 (D_h = 3.40 mm).*

Table 3 shows the average W_f, L_f and D_h based on its production cycle (1 to 4). This is used to see the influence of the wear on Rs and Rh, the most vulnerable parts of the mould.

Table 3. Average foot width, foot length and head diameter.

	Average W_f (standard deviation)	Average L_f (standard deviation)	Average D_h (standard deviation)
Version 1	0.96 mm (0.07 mm)	1.26 mm (0.01 mm)	3.45 mm (0.04 mm)
Version 2	1.04 mm (0.13 mm)	1.26 mm (0.02 mm)	3.41 mm (0.14 mm)

Version 3	0.98 mm (0.03 mm)	1.25 mm (0.01 mm)	3.48 mm (0.02 mm)
Version 4	0.96 mm (0.03 mm)	1.27 mm (0.03 mm)	3.47 mm (0.02 mm)

6.2 TRANSFER PROPERTIES

For every prosthesis, 4 scans are done and after every scan the membrane holder is removed and fitted again. The average of these 4 scans form a single measurement of 1 prosthesis. Deviation between these scans was on the scale of femtometres (10^{-15}). For the comparisons, the average of 4 versions (16 scans) of every model is used. The value of the transfer function is transformed from magnitude to decibel and is expressed as dB(µm/amplitude).

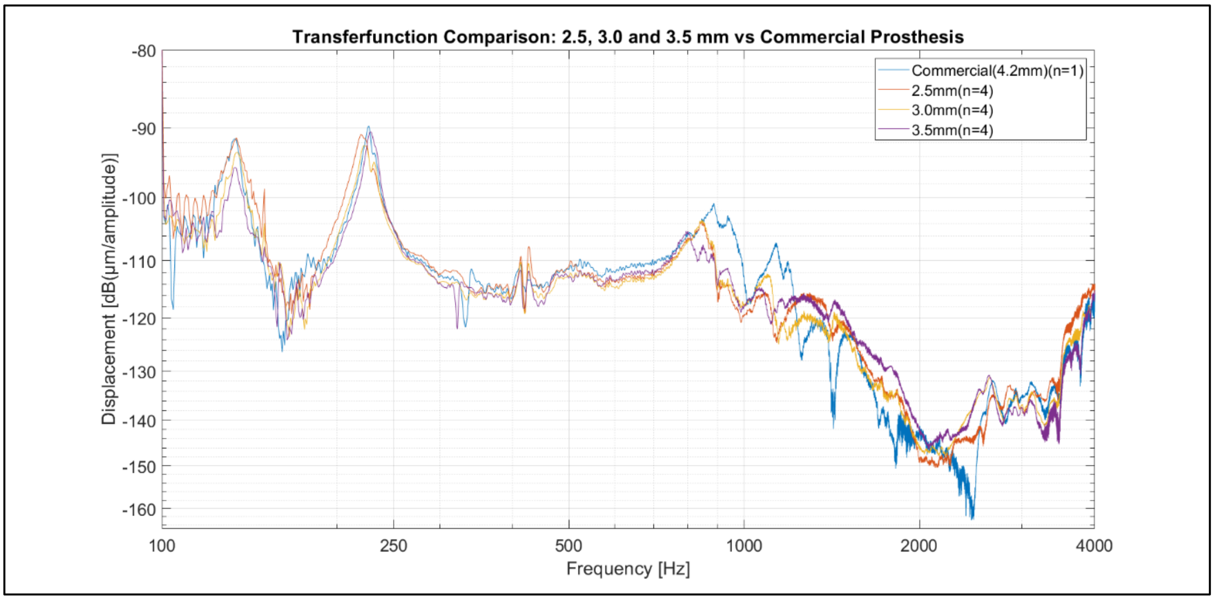

Figure 24. Transfer functions of the 2.5, 3.0 and 2.5 mm model vs commercial model.

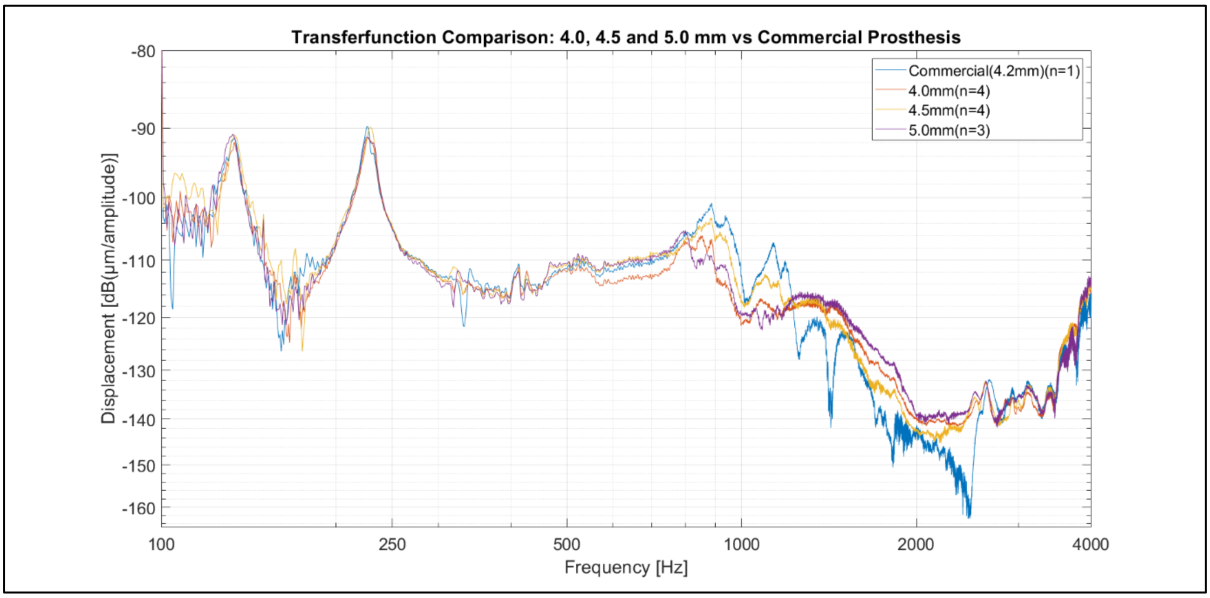

Figure 25. Transfer functions of the 4.0, 4.5 and 5.0 mm model vs commercial model.

The comparison of transfer functions between models is split into **Figure 24** (2.5, 3.0 and 3.5 mm models) and **Figure 25** (4.0, 4.5 and 5.0 mm models) to prevent cluttering. Averages are used for the transfer function comparisons. These averages use the transfer functions determined by using the measurement of all versions for each model. Separate transfer function for each version with their models average are available in **Appendix C: Graphs**. The transfer function of version 4 of the 5.0 mm model is not taken into account because of a failed scan. A combined transfer function using the average of all versions is used to compare the transmission properties of the Wire TORP with the commercial TORP (see **Figure 26**).

At lower frequencies, the displacement of Membrane 2 is nearly equal between the 2 types of TORPs until around 800 Hz. Between a frequency range of around 800 to 1200 Hz the displacement of the commercial model is higher compared to the average of all TORP models (see **Figure 24** and **Figure 25**). Between a frequency range of 1200 to 2600 Hz the displacement of the wire TORP is on average higher but the smaller models (2.5 and 3.0 mm) have an equal or lower displacement between a range of 2000 to 2200 Hz. At the highest frequencies the displacement of all models (wire and commercial) is similar.

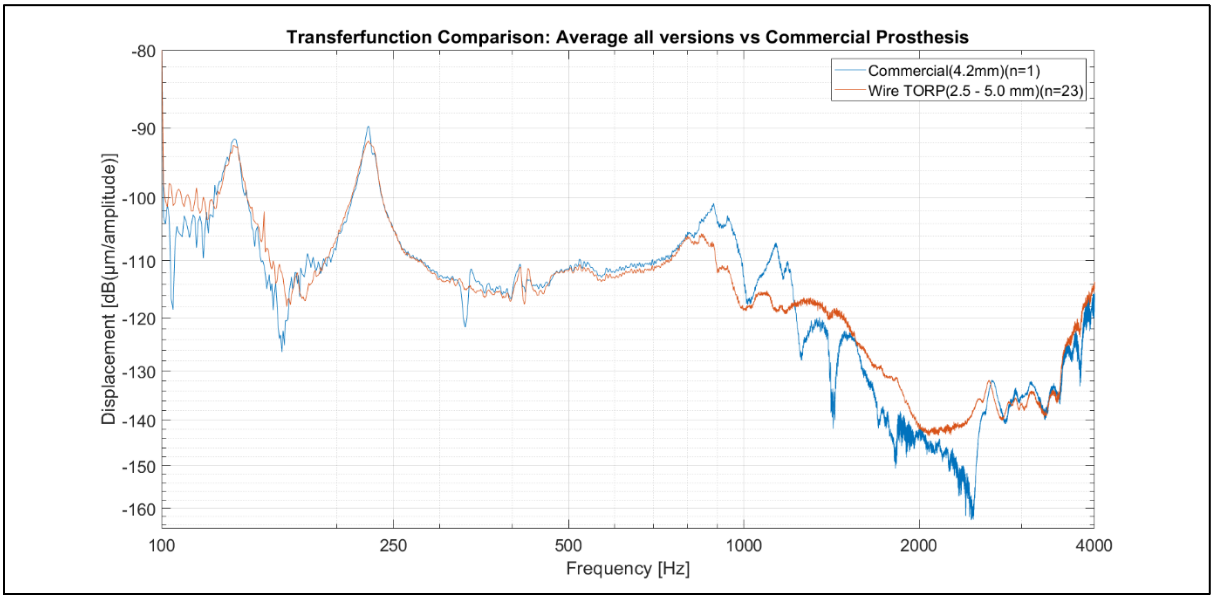

Figure 26. Average of the transfer functions of all versions and transfer function of commercial model.

Measurements of the test setup without adding a TORP result in similar transfer functions compared to measurements with an added TORP (see **Figure 27**). Transfer functions of the empty test setup are based on a single measurement before testing. Noise in the measurements of the setup with both membrane 1 and 2 fitted in is because of the limited amount of measurements.

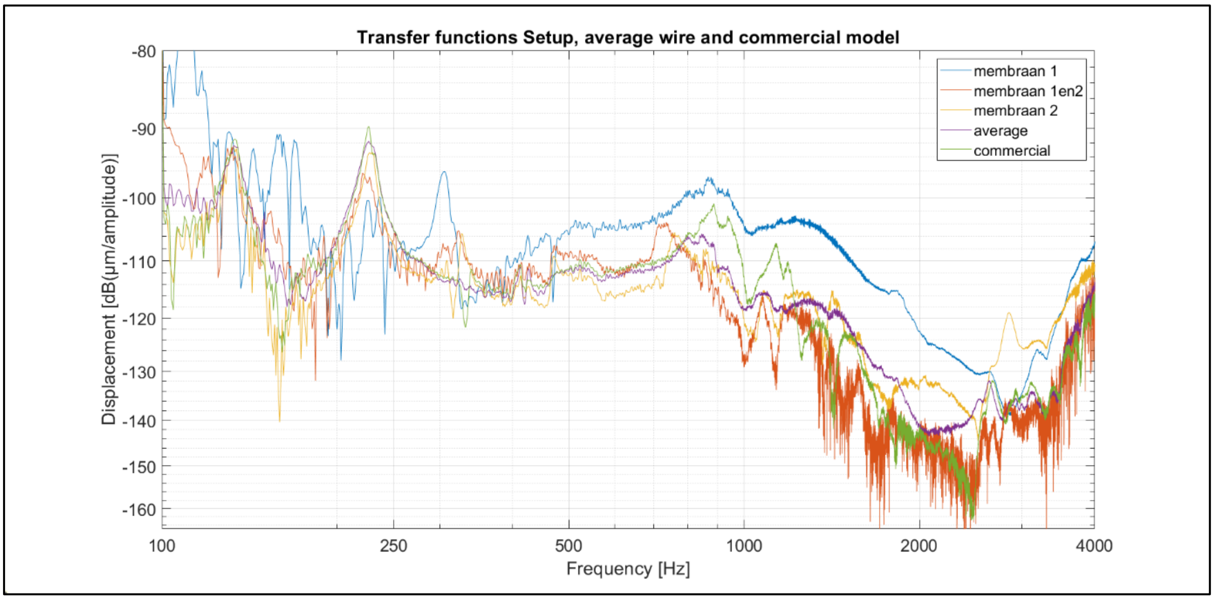

Figure 27. Transfer functions of the test setup, wire and commercial TORP. *The setup is measured while using only membrane 1, membrane 2 and while both membranes are in the setup.*

6.3 Wear

After using the mould to form multiple TORPs (around 40) the parts can be worn down. The wirestopper, 90degreeRh, 90degreeRs and Rh parts are completely intact based on visual inspection. Forming block is worn down on the edge where the titanium wire enters the isolated grooves. The tip of Rs is deformed at multiple spots. Because of this, clicking the formed wire into Rs became considerably more difficult.

Figure 28. Tip of Rs after multiple uses

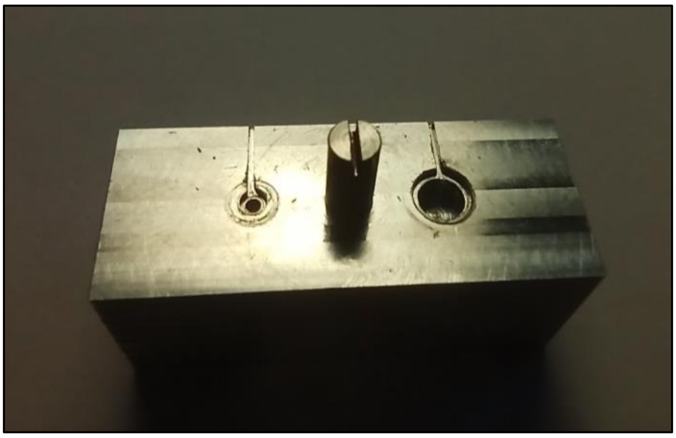

Figure 29. Forming block after multiple uses

6.4 Estimated costs

Cost single TORP

A single TORP uses 20 mm titanium wire (cut-off length is 14.75 to 17.25 mm) assuming a small bit of waste wire. Grade 1 titanium wire with a 0.3 mm diameter costs $60 / meter (AEM Metals, China). Using these assumptions, the material costs per TORP is $1.20 (0.02 * 60).

Mould

The costs for producing 1 mould is calculated using a standard rate for instrument makers. This rate is set at €45/hour (according to Nationale Beroepengids - 2022). Material costs are not include because of their negligible cost.

The instrument maker who made the prototype, took around 20 hours to make the parts. Specifically, 1 workday (8 hours) on the Rs part. This leads to an amount of €900 (20 * 45).

7 DISCUSSION

7.1 MOULD

The wire mould forms the TORPs at an acceptable consistency for most of the process. Consistency is good when looking at the forming of the head and foot of the TORP. This is based on the small deviation in head diameter, foot width and foot length (0.10, 0.11 and 0.05 mm). These deviations are small enough that the head and foot will fit on the tympanic membrane and stapes footplate (based on averages in **Table 2**). The cutting step of the forming process shows inconsistency . This inconsistency is visible in **Table 1** (look at min – max L_S). The actual stem length does not correspond with the designed lengths. This discrepancy between designed and intended stem length can be corrected as long as the stem length is consistent.

The diameter of the middle pin of the forming block (2.5 mm) is too large. Which leads to a lack of wire to form the TORPs foot. This resulted in smaller foot widths at the smallest cut-off lengths (see **Table 2**). Incidentally, this revealed that the 90degreeRs part bended too much wire. This resulted in a relatively high foot width (see for example **Figure 21**).

Because the wire gets blocked after a single turn of Rh the TORPs head is not round (example **Figure 23**). This can result in negative effects to the middle ear because of it sticking out. This could be solved by adjusting the shape of the isolated groove so the wire gets pushed inward at the end of the turn.

Multiple use of the mould resulted in wear on Rs (see **Figure 28**). The wear did not hinder performance of the part, based on its consistency over the production cycles (see **Table 3**). A replacement of Rs can be necessary after multiple uses because the formed wire cannot fit into the part anymore due to deformation.

This means that the cost per wire can get considerably higher. Producing Rs takes about 8 hours which, using the same rate at **Paragraph 6.4: Estimated costs** adds(€45/hour), adds 9 euros ($9.00) on the existing costs per TORP ($1.20). Assuming the part needs replacement after 40 uses(current number of use).

The created TORP fits the dimensions necessary to fit in a middle ear. Its affordability is good ($10.20) and excellent when an instrument maker can help with the project ($1.20).

7.2 TORP

In the following part the transmission properties of the TORPs is discussed.

The transfer function of the MMM with a TORP fitted in is not as expected. Resonance peaks in the lower frequencies, besides the resonance peak at 1000 Hz, are not expected. These resonance peaks are also not as pronounced compared to the previous research [12]. Resonance at the natural frequencies of the 3D printed PLA structures might cause the peaks at 130 and 230 Hz.

A large difference in compliance of the membranes can also change the transfer function. The membranes all had a compliance of 35000 µm/N while the compliance levels found in the research is much lower(2000 µm/N and 1500 µm/N). Compared to the MMM in [12], the tension between the membranes was probably much lower because of this high compliance. Lower tension leads to a shift of the resonance peak to lower frequencies [13].

The transfer function of the test setup is similar to the transfer function of the setup with a prosthesis fitted in (see **Figure 27**). This can explain the similarities between the measured transmission properties of the wire TORPs and the commercial model. However, these results are also expected because of the similar weight, dimensions and material properties of the commercial and wire TORP [12].

The biggest difference found between the test setup, wire models and commercial models is in the frequency range of 800 to 1200 Hz. Which is also the main region of interest because in this range a resonance peak is expected, as said in **Chapter 5: Validation method**. Thus, the focus in this discussion will be on this frequency range.

In the 800 to 1200 Hz range two main differences are visible between transfer functions of the wire and commercial TORP. The commercial TORP has a higher magnitude of resonance and the resonance frequency is slightly higher. An increased resonance frequency can be explained by the higher grade of titanium used for the commercial model (grade 2), which has a higher stiffness [11]. This higher stiffness can result in a shift in resonance frequency (see **Figure 15**) [12].

A lower magnitude of resonance can be caused by added damping. Extra damping limits the magnitude of resonance at the natural frequency but it also increases the transmissibility at frequencies above the natural frequency [14]. Both these effects are visible in the transfer functions of all wire TORPs.

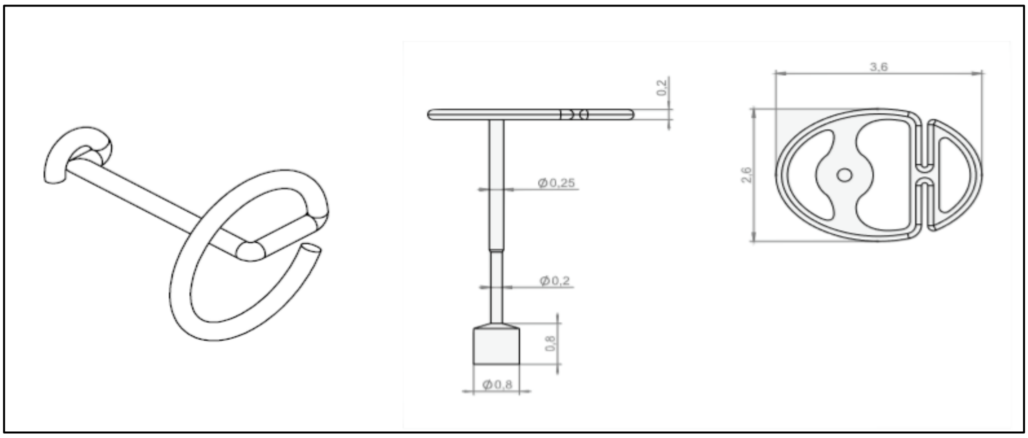

Figure 30. Design of wire (left) and commercial TORP (right) [17].

The added damping can be caused by the higher moments in the head and foot of the wire TORP compared to the commercial TORP. This is because of the single point of attachment of the foot and head (see **Figure 30**).

7.3 Recommendations

Recommendations for future research on this topic are given in the following part.

Making the wire TORP with a stiffer grade of titanium could limit the added damping in the wire TORP. A downside of this change can be an increase in costs because of added wear on the Rs part.

Cutting of the wire can be improved by having straight wire and deeper grooves. The titanium wire used in this project was coiled up which complicated the cutting and forming process. Deeper grooves adds stability during cutting.

Costs per TORP can be lowered by improving the lifetime of the Rs part. Using a stiffer grade of steel could improve the lifetime but might complicate the production of the mould.

The MMM used in this project did not behave according to expectations as said in the previous paragraph. There are 2 peaks at lower frequencies which might be resonance peaks of the lightweight 3D printed PLA structures. An increase in mass of these structures lowers the natural frequency of these parts. This increase in mass can shift these peaks outside of the 100 to 4000 Hz frequency range.

In future research the compliance of the membranes should be closer to the compliance of the tympanic membrane and oval window like in previous research [12].

In the current design there is no way to directly measure the tension at which the TORPs were fitted between the membranes. Measuring this directly improves the reliability of the results.

The input signal that is sent to the speaker can also be improved. The frequency range should be extended at both the lower and higher end. This is done to prevent dips in sound pressure around 100 and 4000 Hz (see **Figure 41**) and to enable possible research at higher frequencies.

The mould should get in the hands of medical professionals to see how fast the production method can be learned and how consistent the process is.

Properties like handling and stability of the TORP are still untested. Using these TORPs during training of medical professionals can help gaining insight into these properties.

8 Conclusion

At the start of the project the goal was to design an affordable middle ear prosthesis that can be produced in LIMCs. A titanium wire TORP and a steel mould are designed to achieve this goal.

The mould makes TORPs with consistent head and foot parts but with inconsistent stem lengths. Improvements to the cutting process and small changes to the design can improve the moulds consistency and affordability.

The MMM is a promising model to determine the transmission properties of a TORP without using donated material. However, transfer functions of the model did differ from expectations.

Adjustments to the weight of the setup and the compliance of the membranes can help to achieve the expected results.

Measured transmission properties of the wire TORP are slightly worse compared to the commercial model. Added damping is expected to be the reason for this worse performance. Increasing the stiffness of the titanium wire could limit this added damping.

The result is a production method suitable for LIMCs that can create affordable TORPs that can fit in every middle ear.

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Appendices:

A. DRAWINGS

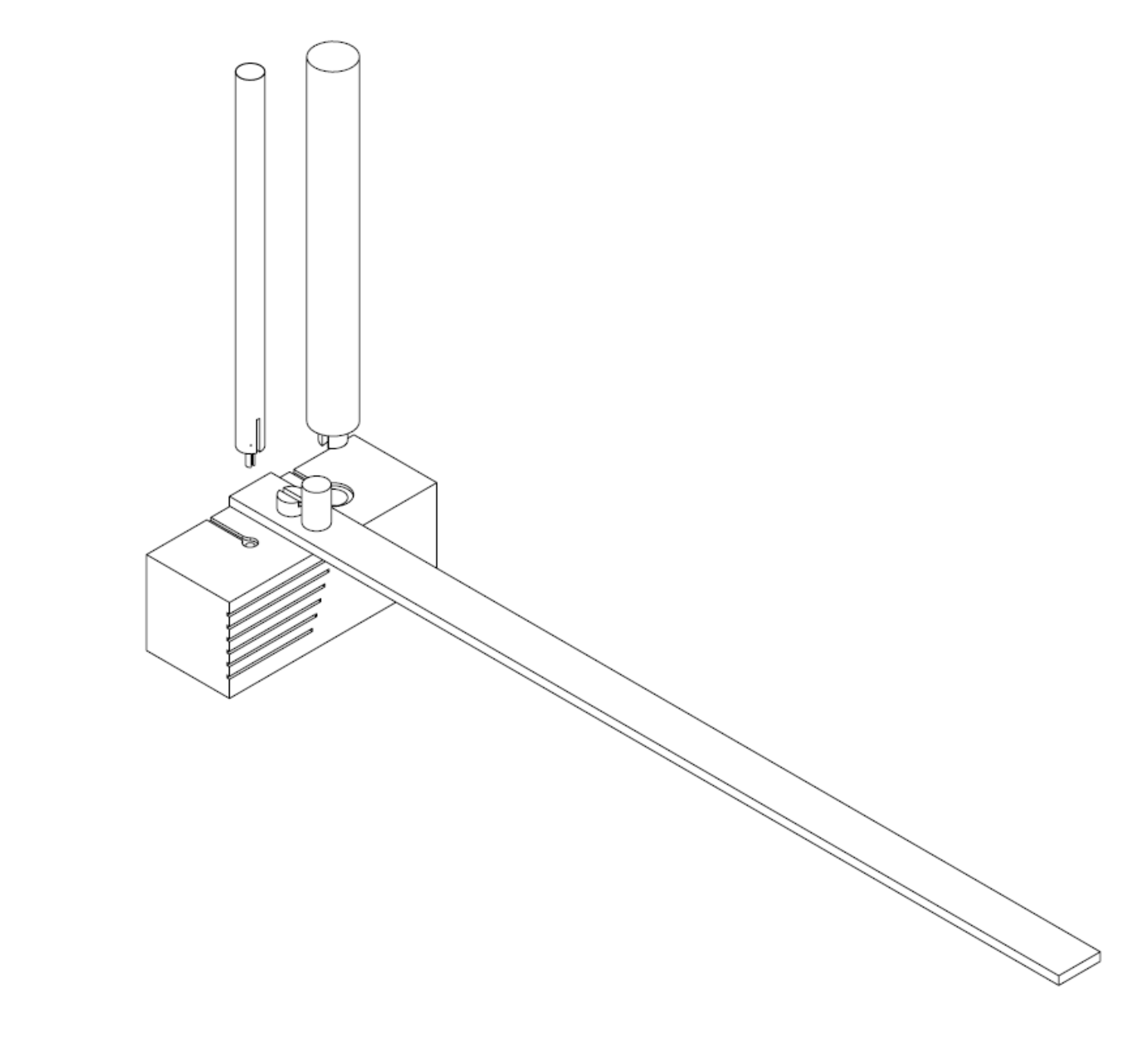


Figure 31. Groove design version 1

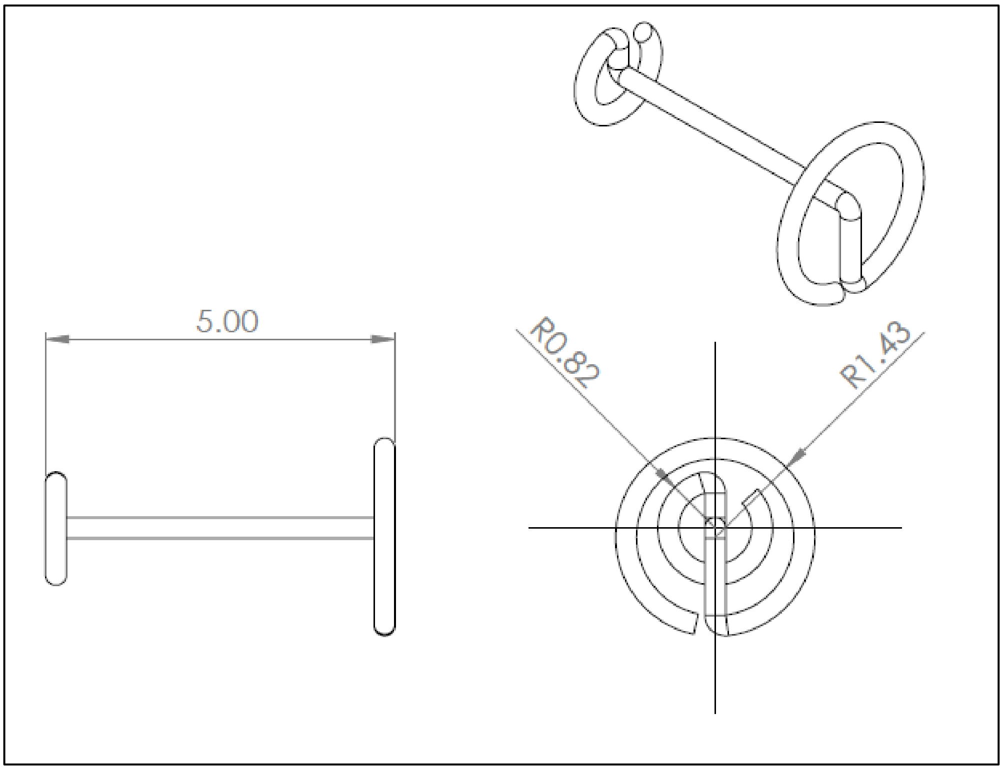


Figure 32. TORP Version 1

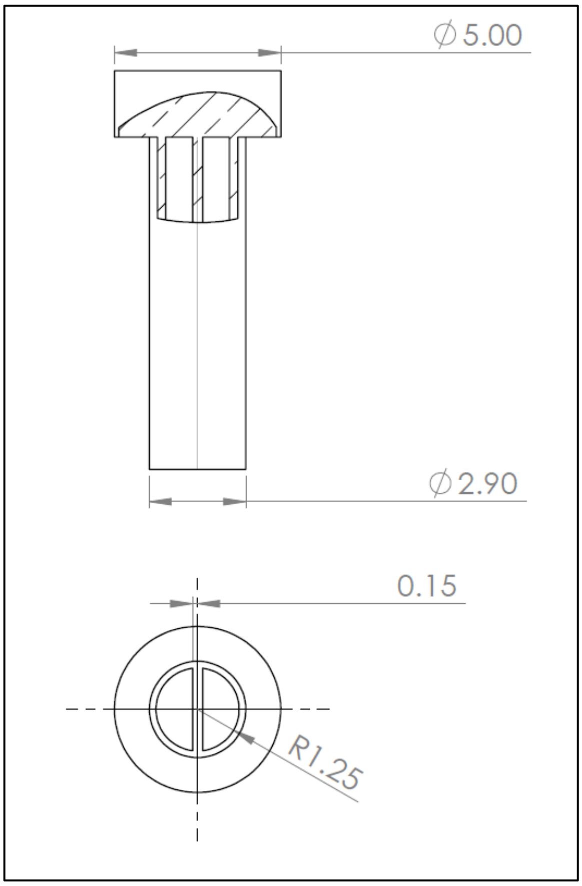


Figure 33. Wirestopper

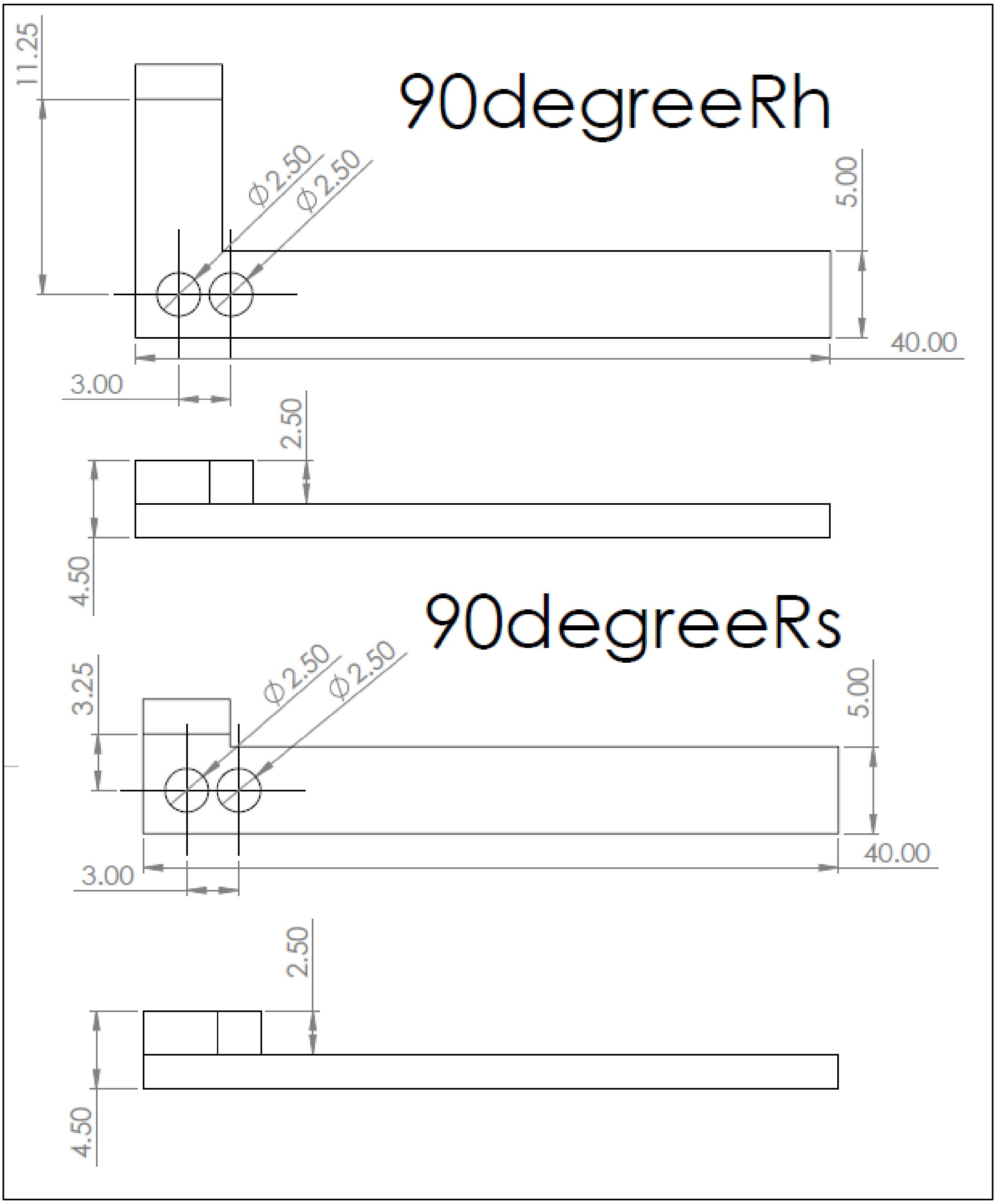


Figure 34. 90degreeRh and 90degreeRs

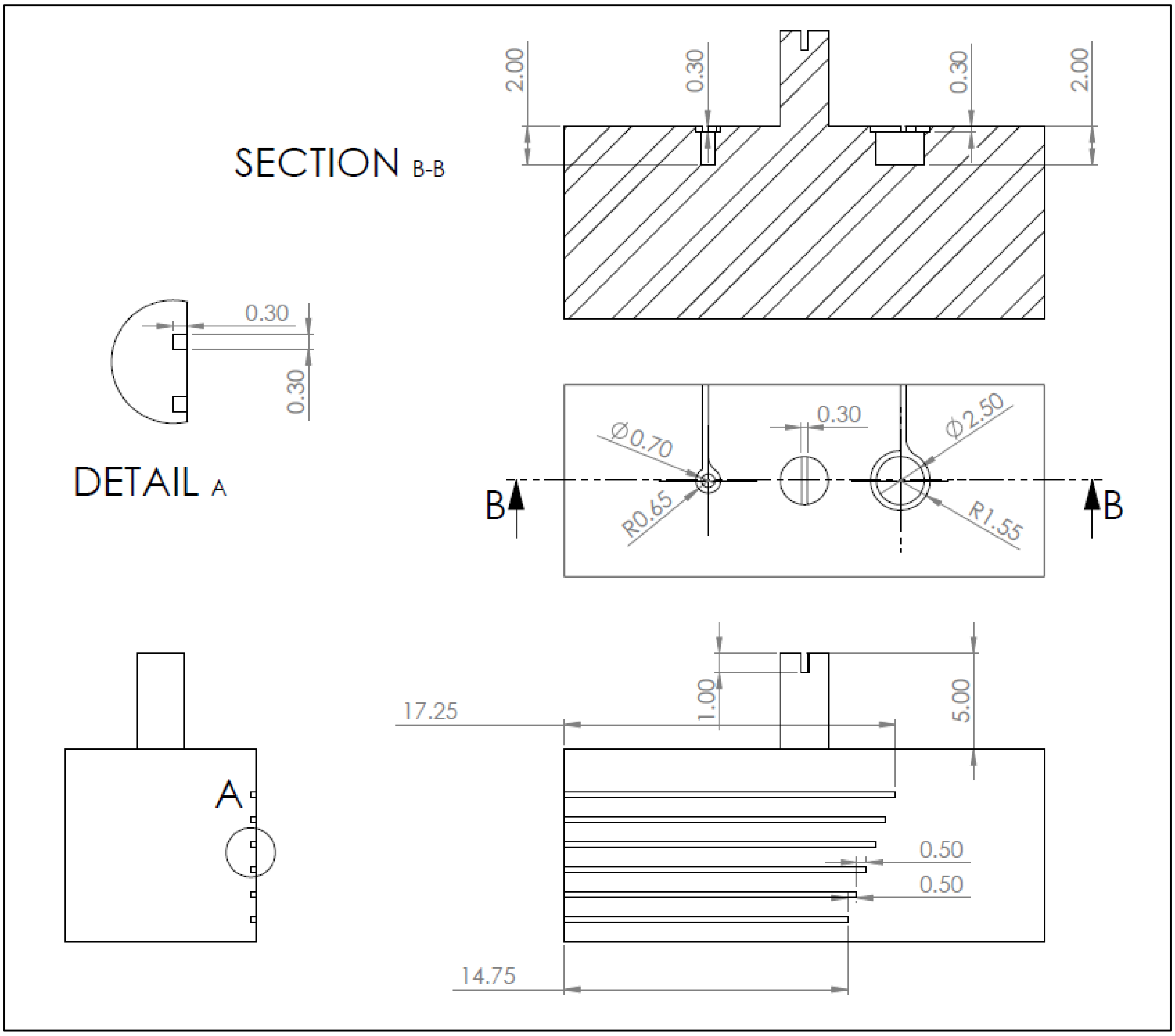


Figure 35. Forming block

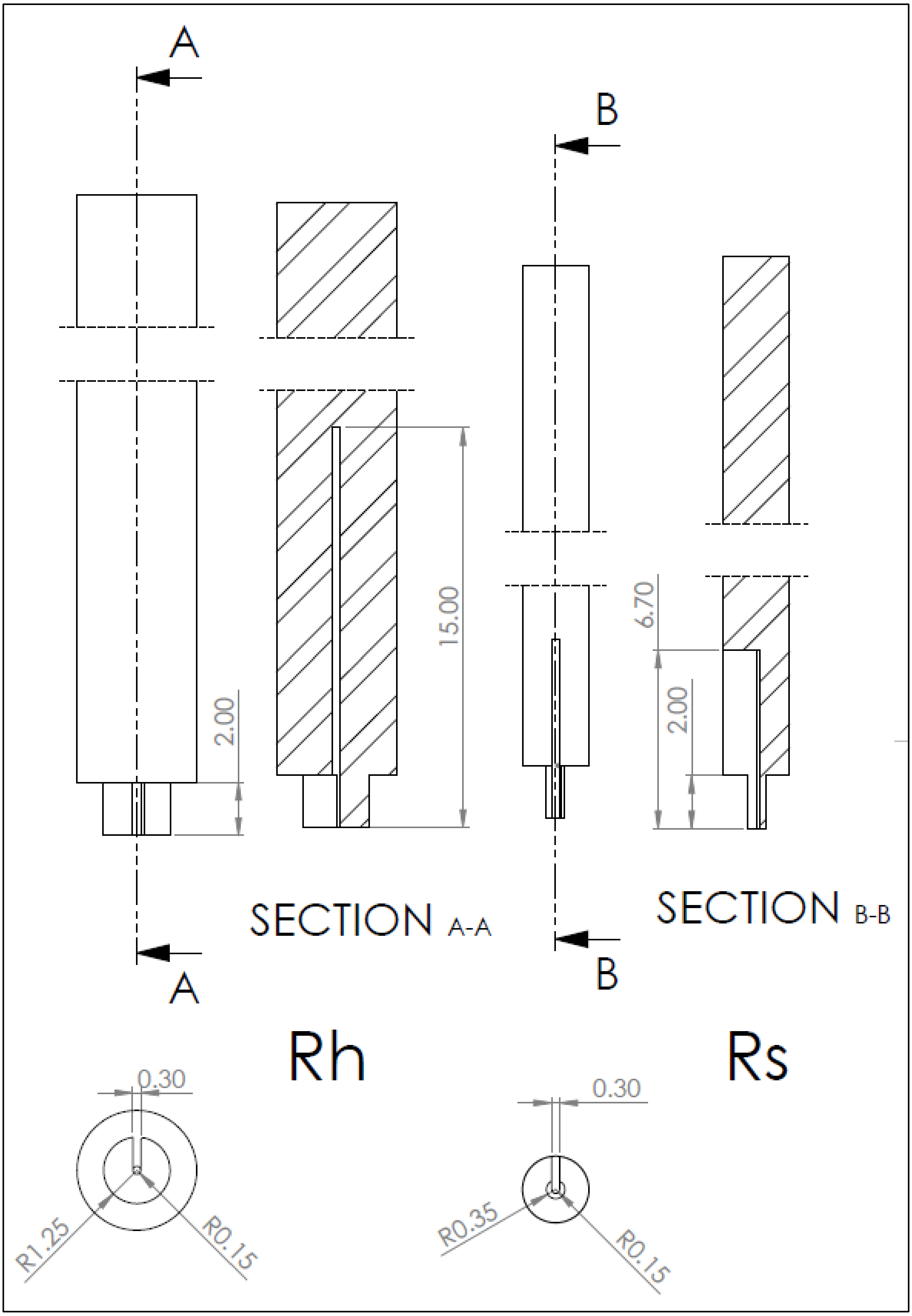


Figure 36. Rh and Rs

B. PHOTOS

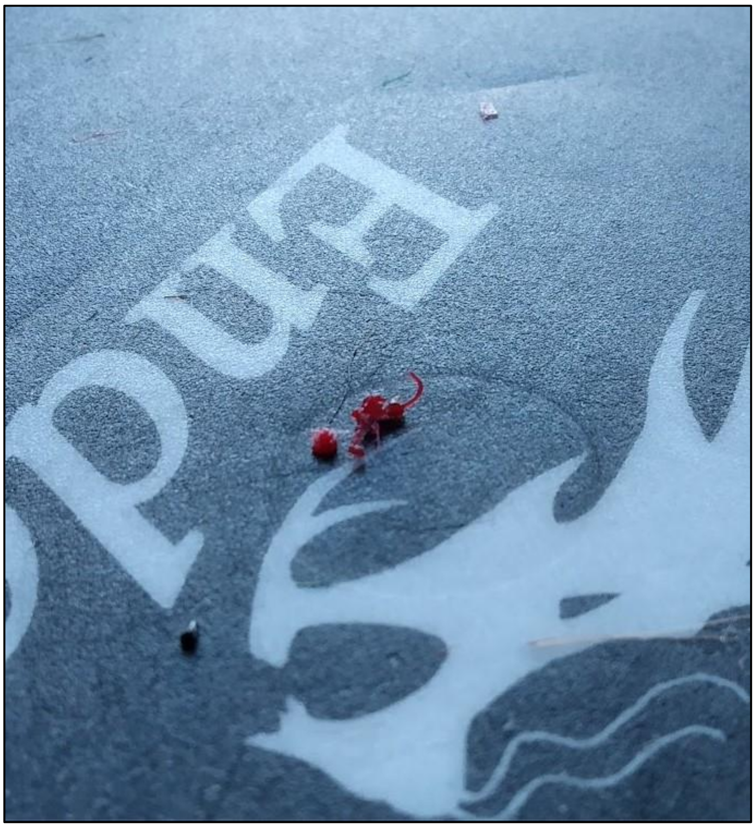


Figure 37. Result of test 3D printing concept

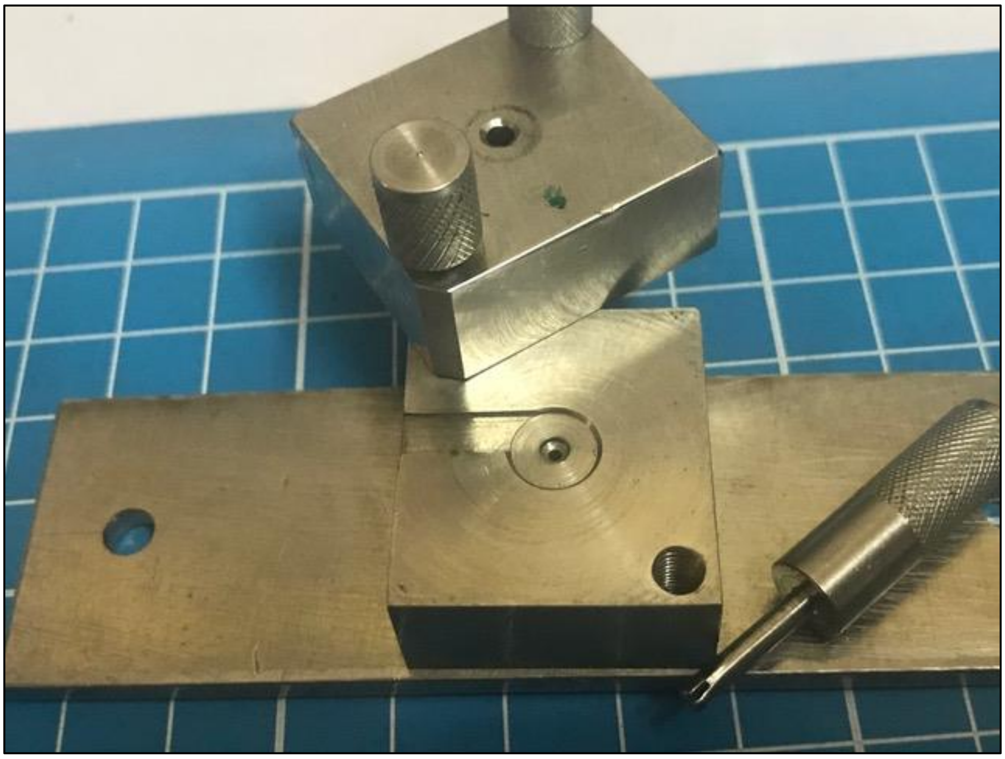


Figure 38. Current production method in Nepal

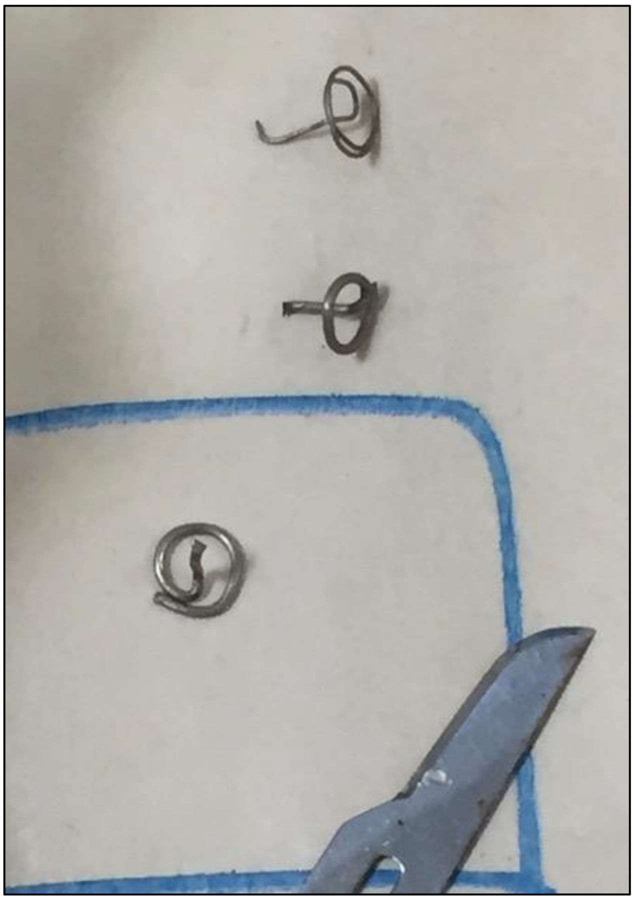


Figure 39. Examples of current TORP models with different wire diameters

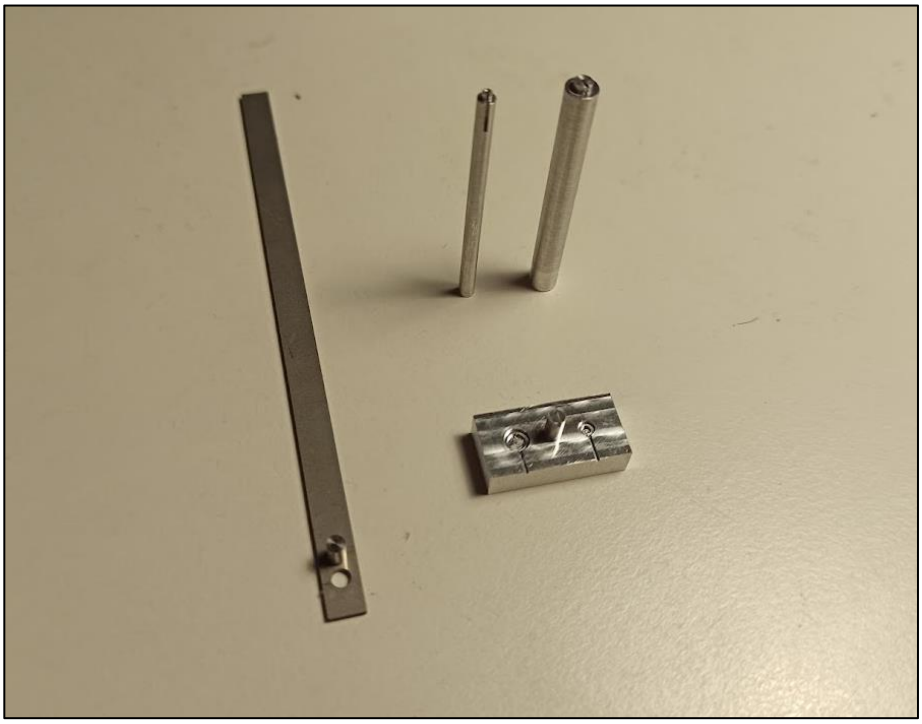


Figure 40. Groove design version 1

C. Graphs

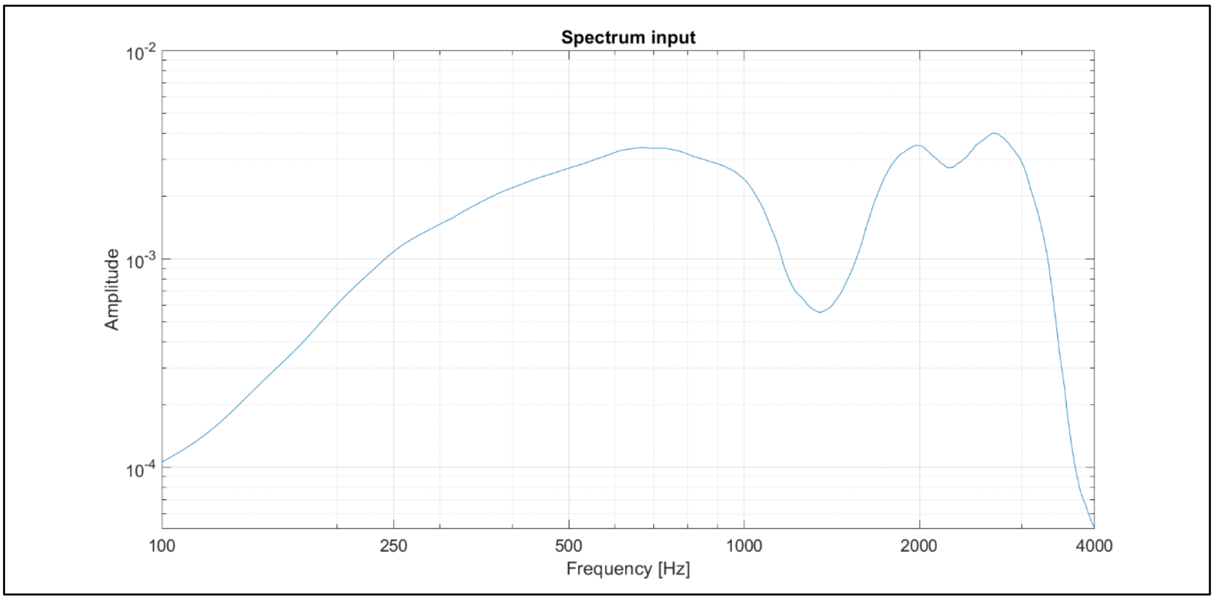
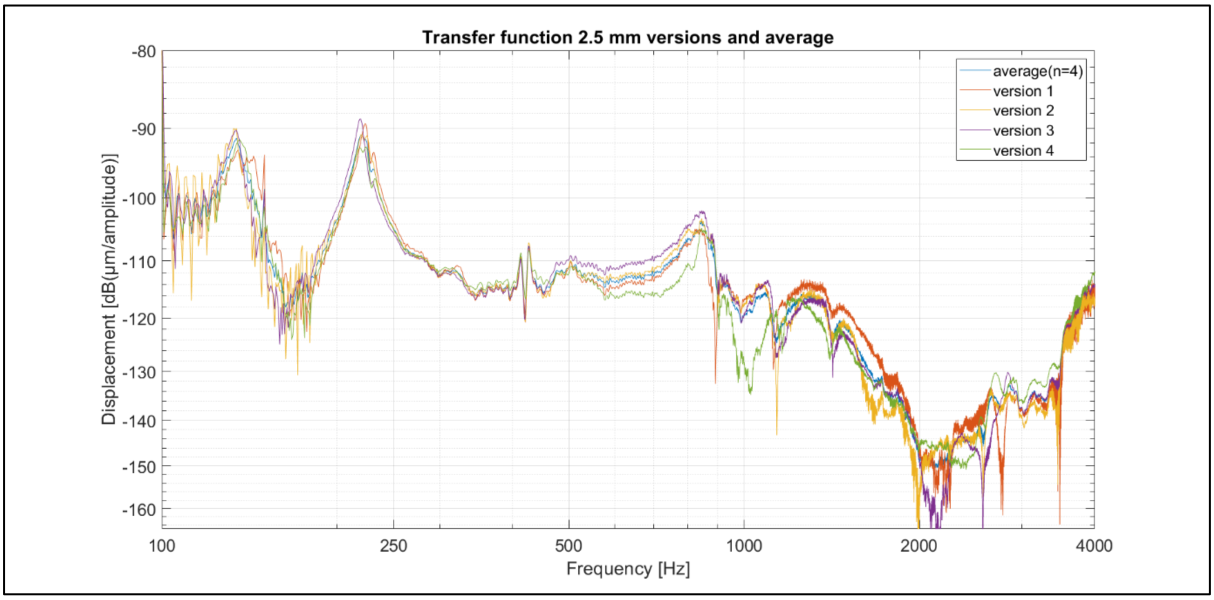
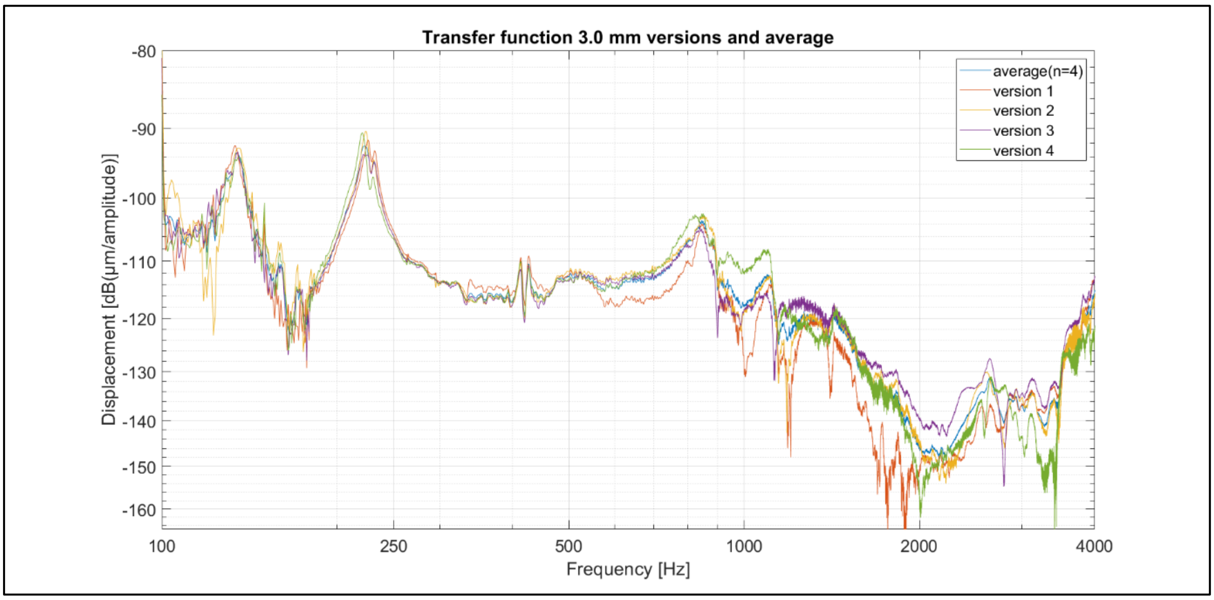


Figure 41. Spectrum of the input signal.



Transfer function 2.5 mm versions and average
average(n=4)
version 1
version 2
version 3
version 4
Displacement [dB(µm/amplitude)]
-80
-90
-100
-110
-120
-130
-140
-150
-160
100
250
500
1000
2000
4000
Frequency [Hz]



Transfer function 3.0 mm versions and average
average(n=4)
version 1
version 2
version 3
version 4
Displacement [dB(µm/amplitude)]
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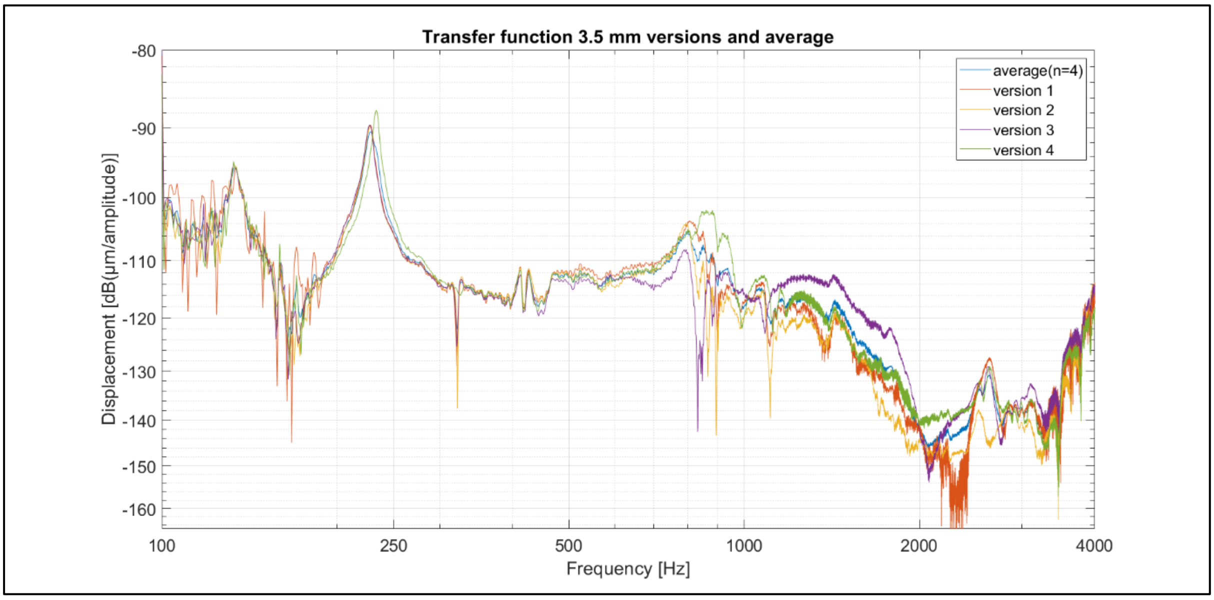
-100
-110
-120
-130
-140
-150
-160
100
250
500
1000
2000
4000
Frequency [Hz]



Transfer function 3.5 mm versions and average
average(n=4)
version 1
version 2
version 3
version 4
Displacement [dB(µm/amplitude)]
-80
-90
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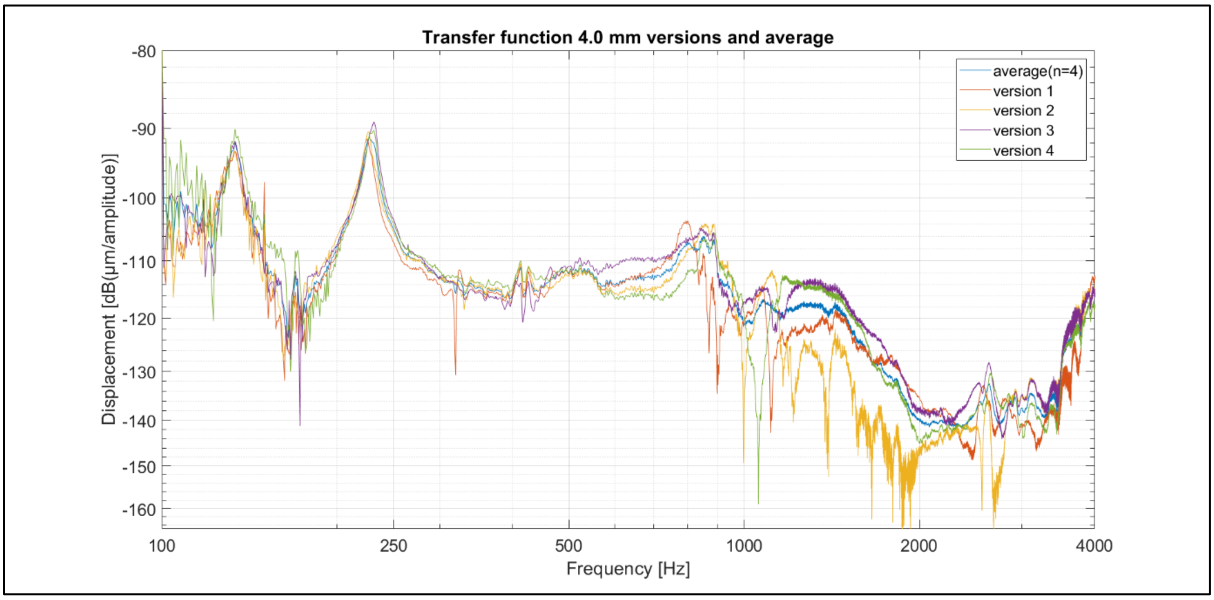
1000
2000
4000
Frequency [Hz]


Transfer function 4.0 mm versions and average
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version 2
version 3
version 4
Displacement [dB(μm/amplitude)]
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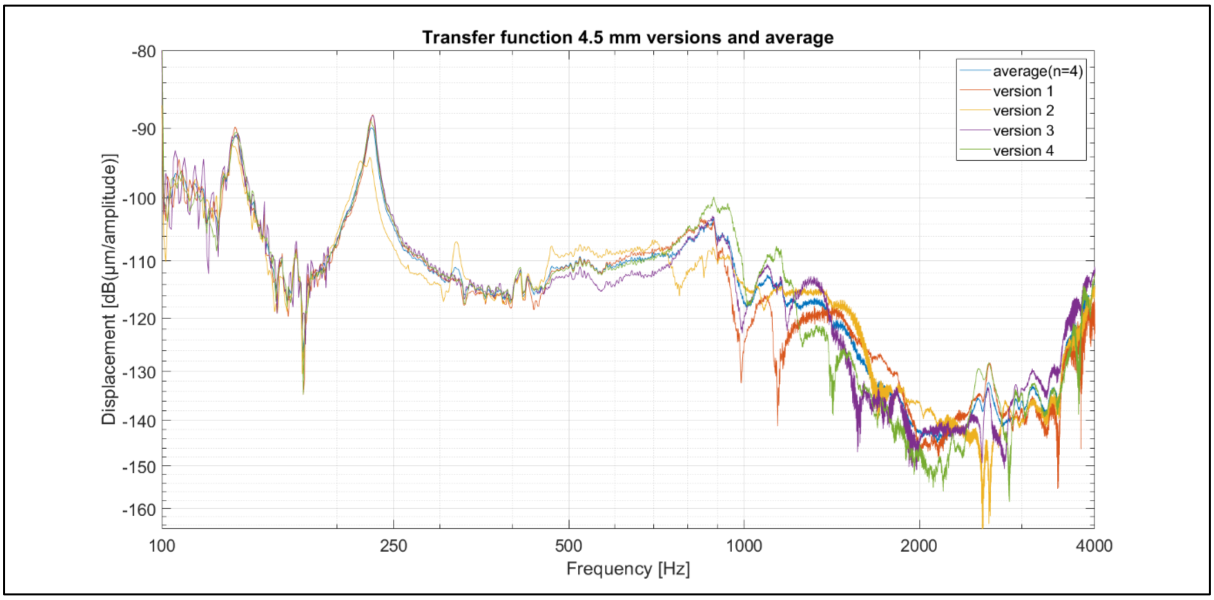
1000
2000
4000
Frequency [Hz]


Transfer function 4.5 mm versions and average
average(n=4)
version 1
version 2
version 3
version 4
Displacement [dB(μm/amplitude)]
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100
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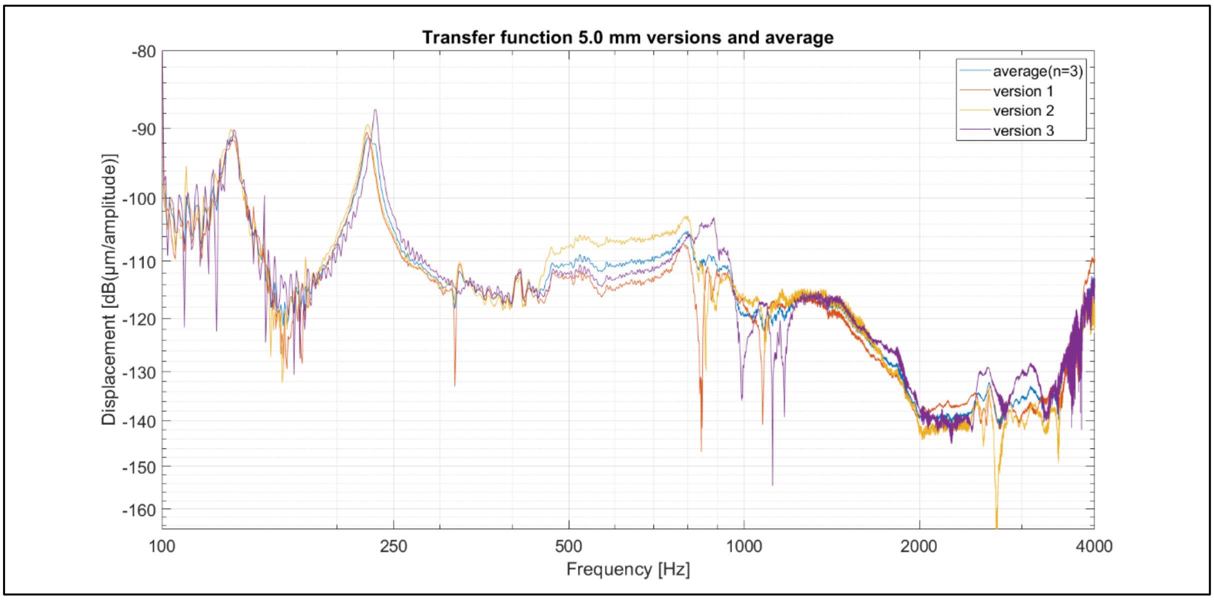
500
1000
2000
4000
Frequency [Hz]


Transfer function 5.0 mm versions and average
average(n=3)
version 1
version 2
version 3
Displacement [dB(μm/amplitude)]
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-90
-100
-110
-120
-130
-140
-150
-160
100
250
500
1000
2000
4000
Frequency [Hz]