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Affordable Design of Total Ossicular Replacement Prostheses in Low- and Middle-Income Countries

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Thesis Report

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Abstract

The objective of this thesis project is to develop an economically viable design for a titanium total ossicular replacement prosthesis (TORP) that caters to the needs of low- and middle-income countries (LMICs). The author focused on addressing the problem from the manufacturing aspect and two primary approaches, additive manufacturing (AM or 3DP) and metal forming, were selected in the literature review attached in Appendix A. One concept was generated for 3DP, utilizing selective laser melting (SLM) to fabricate a straightforward structure using Ti6Al4V. Additionally, two similar concepts, 2A and 2B, were proposed for metal forming, involving precise metal laser cutting of a two-dimensional piece and subsequent bending to achieve a three-dimensional TORP shape. Concept 2A features a fixed-length shaft, whereas Concept 2B incorporates an adjustable zigzagged shaft, aiming to obviate the need for storing multiple sizes of TORPs. These concepts were manufactured into prototypes and systematically evaluated based on predetermined assessment criteria including affordability, manufacturing process, precision, sound transmission property, and simplicity. After assessment, Concept 1 was omitted from the final solutions due to its high cost and demanding post processing steps. And Concept 2A and 2B were deemed as potential TORP designs for the costs of 3.5 and 0.9 euros, dimensional errors of 2.22 % and 2.33 %, preparation duration of 0 and 5 minutes, and the comparable performances in manufacturing process and sound transmission with the commercial products. In conclusion, the TORP designs produced by precision laser cutting were considered the more cost-effective and accessible solutions for LMICs in need of ossiculoplasty.

Contents

1 Introduction

1.1 Background

A total ossicular replacement prosthesis (TORP) is a medical device used in otologic surgery to treat hearing loss caused by ossicular chain dysfunction. The ossicular chain consists of the tiny bones (malleus, incus and stapes) in the middle ear responsible for transmitting sound vibrations to the inner ear (See Fig. 1). The TORP is designed to replace the entire chain when damaged or absent. It is typically made of biocompatible materials like titanium or ceramics and is customized to fit the patient's anatomy. It consists of three components: a flat surface positioned beneath the undersurface of the tympanic membrane or beneath the handle of the malleus bone, which is part of the tympanic membrane; a smaller planar surface situated atop the stapes' footplate, adjacent to the oval window of the cochlea; and a connecting rod linking these two surfaces. The TORP helps restore sound conduction by bridging the gap between the eardrum and the inner ear, allowing for improved hearing function and potentially enhancing the patient's quality of life.

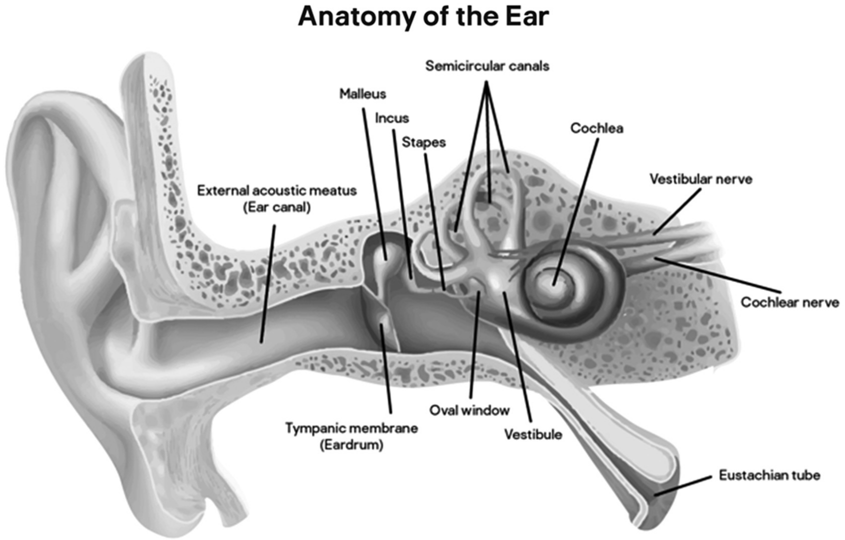


Figure 1: Human middle ear anatomy [1]

In low- and middle-income countries (LMICs) today, the utilization of TORP faces several challenges. Limited financial resources, inadequate healthcare infrastructure and a shortage of skilled otologic surgeons contribute to the limited availability and accessibility of TORP surgeries. High costs associated with the prosthesis itself further restrict its widespread use. This is mainly due to the precise design, manufacturing, and customization to meet individual patient needs. This involves sophisticated engineering, advanced materials, and specialized manufacturing processes, all of which contribute to the overall cost. Moreover, limited market competition, research and development costs, and regulatory requirements also impact the pricing of TORPs.

To improve the situation, reducing costs and improving affordability are necessary to make TORP and other hearing restoration treatments more accessible to those in LMICs. For example, the material and manufacturing technology for the designed TORP need to be locally available or can be ordered and shipped with a low cost. Additionally, the design should be straightforward to allow for ease of operation, enabling local surgeons to learn the procedures easily.

1.2 State of the Art

TORPs have been rapidly developed in recent times, and numerous shapes and materials have been investigated to improve the technology. In terms of design, TORPs are now available in a variety of shapes and sizes to match the patient's specific anatomical requirements. Customization allows for better fit and optimal sound transmission. Moreover, newer designs aim to minimize extrusion rates and enhance long-term stability. Regarding materials, biocompatible options like titanium, ceramic, and medical-grade plastics are commonly used for TORP manufacturing. These materials offer durability, biocompatibility, and improved sound transmission properties. Ongoing research and development efforts aim to explore novel materials that can further improve performance and reduce complications.

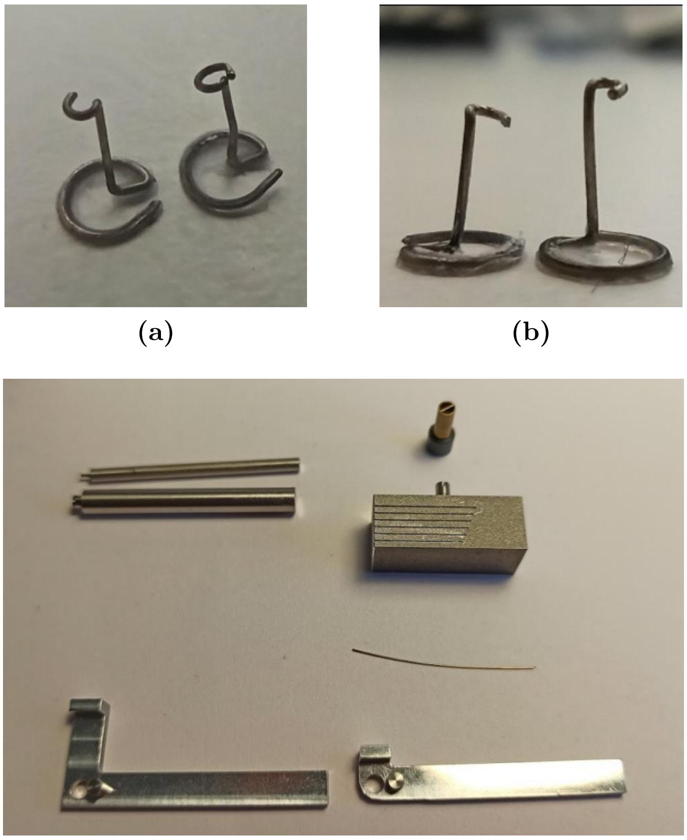
The market offers a variety of commercial products with a wide range of options for TORPs. These products come in different designs, materials, and attachment mechanisms to cater to patients' diverse requirements. One notable example is the ALTO system developed by Grace Medical; see Fig. 33 (a) [2], which has been successfully used in clinical settings. The ALTO adjuster allows surgeons to make quick size adjustments during surgery, providing flexibility and reducing inventory and costs. SPIGGLE & THEIS also provides similar concepts, where the shaft can be trimmed, and the shortened end is covered by the shoe or the head to prevent sharp edges, as shown in Fig. 33 (b) [3]. Moreover, Kurz has introduced additional sizers that facilitate precise measurements between the malleus and the oval window, ensuring accurate and desired installation (see Fig. 33 (c)) [4].

(a) Grace Medical **(b)** SPIGGLE & THEIS **(c)** Kurz

Figure 2: Existing commercial TORP products from different companies [2, 3, 4]

1.3 Previous Studies

Previous studies have been done on a thesis project of affordable TORP design by Geert ten Have [5] and a literature review on possible TORP manufacturing methods. A cheap TORP was proposed by bending a thin wire into a three-dimensional (3D) shape using a self-designed mold (see Fig. 3). According to the previous studies, titanium is considered more suitable as a material for its higher stiffness, lighter mass, lower risks of failure, good biocompatibility, easy handling and adjustment by the surgeons, etc., and thus the scope is narrowed down. Based on it, the literature study done by the author collected the current manufacturing methods of small-sized titanium parts in general instead of the limited publications regarding TORP production.



(a) (b)

(c)

Figure 3: The wire TORPs proposed in a previous thesis project. (a) and (b) show the TORPs in different views and (c) displays the designed bending mold set [5]

1.4 Aim of the Project

The objective of this thesis project is to formulate a cost-effective TORP design tailored for LMICs, while taking into account various manufacturing techniques. Following an extensive review of existing literature, the selection of manufacturing methods has been narrowed down to additive manufacturing (commonly known as 3D printing) and precision laser cutting. The major tasks in this project are the selection of production methods, designing of structural elements, planning of post-processing procedures, and related factors, each of which significantly influences the project's success. By proposing various methodologies, the primary goal is to significantly reduce TORP production costs, allowing it accessible to LMICs, with a particular focus on facilitating affordability for a collaborative hospital in Nepal.

This design report is structured as follows. Section 1 provides an overview of the background and usage of TORP in LMICs. It establishes the objectives of the study and presents a review of relevant prior research in this field. Section 2 defines the research problem and presents a comprehensive list and explanation of the criteria employed to address the problem. The literature review adopted to generate potential solutions and the subsequent process of narrowing down the options are elucidated in Section 3. Section 4 takes the conclusion from the previous literature study and introduces possible design ideas based on morphological overview. The ideas are then narrowed down into the concept solutions in Section 5. It introduces and explains the concept solutions, which are subsequently evaluated in Section 6, along with a commercial TORP products, based on the predetermined assessment criteria. Section 7 presents a thorough review of the assessment, including a comparison with existing commercial products, and provides suggestions for future development. Finally, the conclusion is drawn in Section 8.

2 Problem Definition

2.1 Problem Scope

Today, the commonly-used commercial TORPs are often unaffordable for LMICs. The aim of this thesis study is to develop an affordable and novel TORP design for health facilities in developing countries from the perspective of production method. And the study is based on the background of the Ear Department in Green Pastures Hospital, Pokhara, Nepal. The annual usage of TORPs in this context ranges from 50 to 100 pieces, so the cost is calculated based on 400 pieces per series. The products or prototypes are expected to be cheap enough but still possess sufficient functionality for LMICs to benefit patients suffering from ossicular chain dysfunction.

2.2 General Design Criteria for TORP

The general guidelines apply to overall TORP designs and require careful consideration of several criteria to ensure optimal functionality and patient outcomes.

Firstly, the prosthesis should be custom-designed to match the patient's specific anatomical requirements, taking into account factors such as the size and shape of the ossicular chain and the surrounding middle ear structures. The dimensions of the TORP, including the length and diameter, play a critical role in achieving proper sound transmission and mechanical stability. Based on existing products, TORPs with a length ranging from 3.0 mm to 4.5 mm have shown successful outcomes in most patients. The head attaching to the tympanic membrane should be around a diameter of 3.6 mm, and the foot on the oval window side should have a diameter smaller than 1.0 mm. The head and foot should be concentric for stability reasons. Furthermore, visibility during surgeries is also important to facilitate the process. Clear visibility enables precise placement of the prosthesis, ensuring optimal contact and alignment with the remaining ossicular chain, and thus enhancing the chances of successful hearing restoration.

Moreover, the material is crucial for biocompatibility, durability, acoustic performance, etc. Titanium is a preferred material for making TORPs due to its exceptional properties. Firstly, titanium is biocompatible, meaning it is well-tolerated by the human body and minimizes the risk of adverse reactions or complications. Secondly, titanium is lightweight yet strong, allowing for creating durable and mechanical stress resistant TORPs. Ductility is also a valued attribute in a TORP because it allows for shaping the prosthesis for optimal fit. In some cases, the orientation of the head plate may need to be adjusted to align with the angle of the tympanic membrane. Additionally, titanium exhibits excellent corrosion resistance, ensuring long-term stability within the middle ear environment.

Lastly, titanium has favorable acoustic properties, enabling efficient sound transmission and optimal hearing restoration. Hence, it is a common material in dental and medical implant applications.

Overall, the design of TORP should consider patient-specific factors, optimal dimensions, suitable materials, etc. to achieve successful hearing restoration and long-term stability in patients with middle ear ossicular damage.

2.3 Assessing Criteria

Apart from the above general design criteria, customized assessment criteria are also required to apply contexts for this specific project. The objective is to develop a cost-effective TORP design for use in LMICs. Thus, the assessment criteria should adhere to the below guidelines, which were consulted with Dr. Michael Smith, the consultant ear surgeon and head of services at Green Pastures Hospital.

2.3.1 Affordability

The TORP design should be affordable in terms of cost in LMICs. The expenses consist of the manufacturing costs of TORP itself and add-on features, such as additional connector or adjustment devices.

Affordability was evaluated based on the expenses associated with materials, manufacturing, and delivery in the production of the designed TORP. At Green Pastures Hospital, the annual utilization rate of TORPs ranges from 50 to 100 units. Consequently, the hospital possesses the financial capacity to place an order of 100 pieces for each of the four different lengths, totaling 400 pieces, thereby reducing the average cost per unit for some specific manufacturing methods. According to Dr. Smith, an approximate marginal cost of 10 euros was applied for Green Pastures Hospital.

2.3.2 Manufacturing Process

The manufacturing method of the design should be easily accessed and conducted. The local facilities should have the capability to produce the products independently, or alternatively, the option to order and receive the products at an affordable cost.

The evaluation of the manufacturing process considered its accessibility and conduciveness. A grading system was employed to assess the level of accessibility. If the TORP could be manufactured within the health facility itself, the highest grade of 5 was assigned. In cases where local manufacturers were present in the LMICs, and there was no additional post-processing required from buyers, a grade of 4 was assigned; where the buyers were required to do post-processing themselves, a grade of 3 was given. However, if the only available manufacturers were located overseas, the lowest grades of 2 or 1 were attributed depending on whether post-processing was needed. A marginal value of grade 1 was assigned for comparative purposes, as this criterion was not deemed crucial.

2.3.3 Precision

The manufacturing method selected for the TORP design should maintain high dimensional accuracy, even when producing tiny parts.

Precision was assessed by measuring the dimensions of the critical features and comparing them with the computer-aided design (CAD) models to ensure that the deviation fell within a predetermined threshold. The critical features included the diameters of the head and footplates and the overall length. The marginal value of the mean absolute error (MAE) was set to be 5 %.

2.3.4 Sound Transmission Property

The design should be able to successfully and stably transmit sound vibrations. As the material is constant, i.e., titanium, the other mechanical and physical properties are considered satisfactory and will not be discussed in this project despite of their importance.

Sound transmission could be tested by obtaining the transfer functions of a mechanical middle ear model (MMM), which will be explained in further section. The evaluation method primarily began by confirming the presence of frequency peaks that corresponded to those observed in the commercial TORPs. Visual examination of the overlaid graphs was conducted with a focus on resemblances in the overall curve shapes, particularly the crests and troughs. Then, the root mean square error (RMSE) was calculated to provide an overall measure of how much the curves deviated from that of the empty setup across different frequency ranges. In this context, a higher RMSE value denoted a better sound transmission rate. The RMSE of ALTO Dornhoffer was used as the reference value for calculating percentage errors. The designated frequency intervals included 0.1 to 1 kHz, 0.1 to 4 kHz and 0.1 to 10 kHz, representing the ranges with the most steady magnitudes, the spectrum relevant to human vocal frequencies, and the complete frequency spectrum, respectively. However, in the assessing process, only the frequency range from 0.1 to 4 kHz would be considered, since this particular interval is of primary interest in the context of TORP design. No specific marginal or ideal values are defined for this criterion, given the absence of a universally accepted standard. The process of identifying these characteristics is explained in Section 6.

2.3.5 Simplicity

The number of processing steps and the processing time during ossicular reconstruction surgery should be minimal or optimal. It should also be considered if the part after manufacturing is in near-net-shape. The evaluation method can be simplified by testing the preoperative preparation time for a TORP.

The simplicity of TORPs could be evaluated based on the complexity of its preparation and the requirement for additional machinery or tools. This aspect could be assessed by analyzing the duration of the pr-op preparation undertaken by surgeons, which involves customizing each prosthesis to meet the specific needs of individual patients. It excludes the iterative adjustment phases. According to Dr. Smith, most cases of tympanoplasty and ossiculoplasty take approximately 1.5 hours. And the preparation time takes around 10 minutes, which was considered the marginal value.

3 Literature Studies

A literature study was conducted to gather preliminary ideas of possible design concepts. The research question was formulated broadly as: *"What are the more cost-effective methods to produce precision titanium products in LMIC?"* The researching direction should also be aimed to answer the sub-questions: *"By what manufacturing methods? In what shape/design? Does it fulfill the requirements for TORP materials?"*

The manufacturing methods investigated in the literature research included powder metallurgy (PM), metal injection molding (MIM), additive manufacturing (AM or 3DP), and metal forming. PM is a manufacturing technique that involves compacting fine metal powders into a desired shape and then sintering them at high temperatures to create a solid metal component. MIM combines plastic injection molding and powder metallurgy to produce complex metal parts with high precision. 3DP, on the other hand, constructs metal objects layer by layer from digital designs, allowing intricate geometries. Finally, metal forming consists of various processes like forging and rolling, where metals are shaped through mechanical deformation, enhancing their strength and durability. Additionally, secondary processes such as machining, surface finishing, and coating were also explored, as they are often necessary for ensuring prosthesis safety.

Based on the information gathered from the articles, the four manufacturing methods, PM, MIM, 3DP and metal forming, were assessed by the following criteria including affordability, simplicity, physical/mechanical properties and precision. And weights were assigned to each criterion according to their priority, which was determined based on literature review. Thus, the final scores were shown in Table 9 with 3DP and metal forming emerged as the most suitable approaches. The detailed report is attached in Appendix A.

Method / Criterion	PM	MIM	3DP	Forming
Affordability (weight 4)	++	+	++	+++
Precision (weight 3)	+	++	+++	+
Physical/Mechanical properties (weight 2)	+	++	+	+++
Simplicity (weight 1)	++	++	+++	+
Total score	6	7	9	8
Weighted score	15	16	22	22

Table 1: Evaluation table of the manufacturing methods for TORP. The rating scales are +++ (good, score 3), ++ (moderate, score 2) and + (acceptable, score 1).

Among all metal 3DP methods, laser directed energy deposition (LDED) seems promising for near-net and intricate designs. Moreover, LDED provides a better modulus of toughness and a more freeform generation than the common selective laser melting (SLM) [6]. However, if 3DP is adopted, it is recommended to order parts from external providers rather than setting up the system locally since it can be very expensive.

As for metal forming, it presents a potentially more cost-effective approach for obtaining products with favorable physical and mechanical properties if post-machining is permitted. Titanium can be initially cast or forged into wires or plates. At Green Pastures Hospital, the surgeons currently employ a molding production method using titanium wire of various thicknesses (with a preference for 0.3 - 0.4 mm) for its simplicity and cost efficiency. However, this method often leaves sharp edges that can pose a risk of damaging the surrounding tissues. A viable solution is to maintain the current system and incorporate surface finishing techniques like sandblasting, grinding, or polishing to address the issue of sharp edges. Another suggestion involves producing pure titanium plates and using abrasive water jet cutting, wire electrical discharge machining (WEDM), or laser cutting to achieve the desired intermediate shape. Subsequently, due to the ductility of pure titanium, the wire or plate can be trimmed and/or bent to achieve the final structure.

4 Concept Phase

Drawing upon the findings of the literature review, it has been determined that 3DP and metal forming are the most appropriate manufacturing methods for the current context. Since each method consists of different processing solutions, a morphological overview was performed to find the most suitable ones. Consequently, a series of ideas were developed and assigned to one of these production techniques based on the distinctive attributes. Furthermore, in order to assess the feasibility of the generated designs, thorough discussions were conducted with Dr. Smith to narrow down the concept solutions.

4.1 Morphological Overview

A systematic designing process for TORPs used in LMICs was carried out following the morphological overview. Since the material was already determined to be titanium based on the previous studies, the parameters such as biocompatibility and general physical properties were fixed correspondingly. Therefore, the overview was conducted for the possible geometrical structures of 3DP and metal forming.

The initial step involves identifying the crucial geometric parameters or functions that significantly impact the TORP design. These functions include the connection with tympanic membrane, connection with stapes and the connection in between. Given that the major dimensions are determined, they are excluded from the scope of consideration.

For each function, a range of design variations was defined based on the characteristics of 3DP and metal forming. These variations were brainstormed to include options that could be relevant and effective for LMICs. For the connection with tympanic membrane and stapes (head and footplate shapes), there are five variations: circular, annular, c-shape, s-shape and rectangular. Regarding interconnection, or the shaft shape, five variations exist: straight, zigzagged, oblique, bifurcated and tapered. Table 2 is generated for clearer inspection.

By systematically combining the design variations from each parameter in the below Table 3, a matrix of potential TORP geometry configurations was generated with suggested manufacturing method. Each combination represented a unique arrangement of geometric features and was preliminarily evaluated against the specific assessment criteria and the suggestions from Dr. Smith. The initial assessment focused on parameters such as ease of surgical implantation, compatibility with local medical practices, attachment stability, etc. Based on the evaluation, a subset of TORP geometry combinations that align well with LMIC needs was selected. These design options proceeded to further analysis and validation stages based on the assessing criteria.

4.2 Additive Manufacturing

4.2.1 Selection of Printing Method

According to the conclusion of the literature review, LDED was considered the most suitable printing method for titanium precision production. It involves the use of a high-

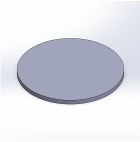
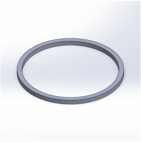
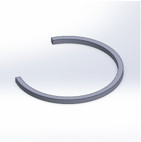
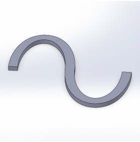
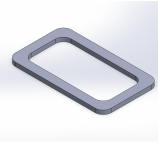
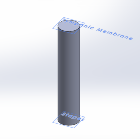
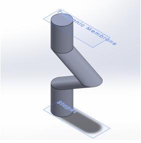
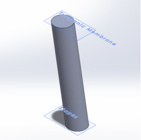
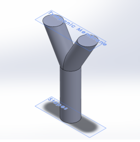
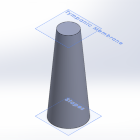
Function	**Design variation**				
	Variation 1	Variation 2	Variation 3	Variation 4	Variation 5
Connection with tympanic membrane	Circular 	Annular 	C-shape 	S-shape 	Rectangular 
Connection with stapes	Circular	Annular	C-shape	S-shape	Rectangular
Interconnection	Straight 	Zigzagged 	Oblique 	Bifurcated 	Tapered 

Table 2: The morphological table for generating the concept solutions along with the schematics. For the interconnection, the upper plane represents the tympanic membrane, while the lower one stands for the stapes side.

Function	**Combination 1**	**Combination 2**	**Combination 3**	**Combination 4**	**Combination 5**
Connection with tympanic membrane	Annular	Annular	Annular	C-shape	S-shape
Connection with stapes	Circular	Annular	Annular	C-shape	S-shape
Interconnection	Bifurcated/Straight	tapered	Straight	Straight/Zigzagged	Straight
Suitable method	3DP	3DP	Metal forming	Metal forming	Metal forming

Table 3: The matrix of potential concept solutions and the corresponding suitable method

powered laser to melt and deposit metal powder layer by layer, creating a solid object. It allows for the addition of materials to existing structures, making it suitable for repair or modification tasks. However, the process may have limitations in achieving fine detail and intricate geometries due to the size of the deposited particles [7].

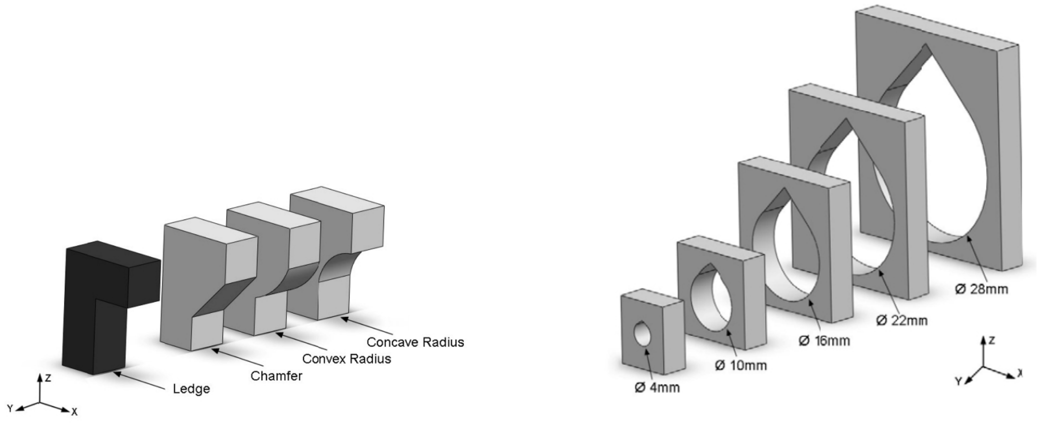
After consulting 3DP experts and extra information gathering, LDED was determined to be too coarse for TORP production, and SLM was the more appropriate solution. It utilizes a laser to selectively melt and fuse fine metal powder, creating fully dense complex parts [8, 9]. It offers higher precision and can produce intricate designs with excellent surface finish. SLM is ideal for producing small, intricate components with tight tolerances and high accuracy, making it suitable for applications requiring fine detail and complex geometries like TORPs.

Overall, while both LDED and SLM can achieve precision production, SLM is often favored for applications requiring intricate and highly precise components, while LDED is advantageous for repair and modification tasks. Therefore, in this project, SLM was selected for TORP 3DP eventually.

4.2.2 Important Design Rules for SLM

Apart from the general design rules for TORP, there are other guidelines especially for SLM. Following the design rules organized by Thomas (2009) [10], the preferable structures, size limitation, geometric compensation, etc. were taken into consideration before printing.

For example, adequate part-support structures should be included to prevent warping and maintain stability during printing. But due to the small dimension of TORP, self-supporting structures are preferred. Overhanging features should be avoided or minimized to prevent drooping or excessive support requirements. Chamfers and radius with suitable angles can replace the vertical corner of overhangs and omit supports, as shown in Fig. 4 (a). Upright circular holes can be built within a minimum and maximum diameter (Ø1-7 mm) or be adjusted into water-drop shape (see Fig. 4 (b)). Additionally, suitable wall thicknesses is crucial to ensure structural integrity and minimize thermal stresses. The smallest possible wall thickness is 0.4 mm, and the minimum size between features is 0.3 mm. Incorporating proper drainage holes or channels facilitates the removal of trapped powder after printing. Finally, additional thickness might be required for up-facing, down-facing surfaces and side walls to achieve high accuracy, tight tolerance and specific surface finish. For instance, 0.3 mm thickness should be added to the up-facing sides for flat surfaces, while 0.7 mm is necessary for fully dense metal surfaces. Following these design rules maximizes the success rate and quality of components produced using SLM technology.



(a) **(b)**

Figure 4: Examples of self-supporting structures: (a) alternative geometries for overhang ledges, such as chamfers and radius (b) alternative geometries for circular holes in water-drop shape in different dimensions [10]

4.2.3 Possible Concept Development based on the Morphological Table

To adhere to the design rules of SLM and meet the specific requirements of TORP, three initial conceptual designs were generated, drawing inspiration from existing products and Table 3. Fig. 5 illustrates the designs and shows the characteristics. The first concept entailed the utilization of an annular headplate and a circular footplate, connected by a primarily straight shaft that bifurcates into conical shapes at both ends, as Combination 1 in Table 3. The head features triangular holes to enhance visualization. The slope angles of the conical ends were carefully selected at 45 degrees to ensure the creation of self-supporting structures. Based on Combination 2, the second concept include annular head and footplates with a tapered shaft, transforming into a frustum shape while incorporating similar holes on the sides. The third concept also adheres to the principles of Configuration 1 but adopts a simpler configuration, featuring a straight shaft throughout the whole structure. The head in the form of a circular ring with a straight stem serves as both support and the base of the shaft.

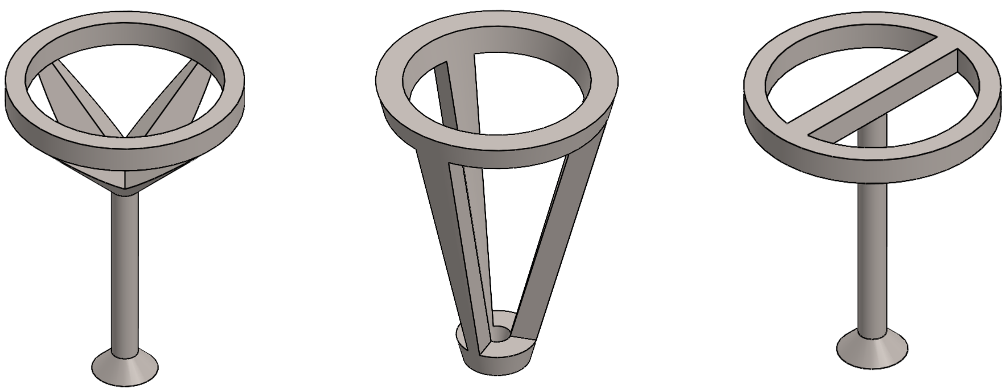

(a) Design 1 **(b)** Design 2 **(c)** Design 3

Figure 5: The three initial TORP designs for SLM manufacturing method. Design 1 consists of an annular head and a circular foot with a bifurcated shaft; Design 2 has annular head and foot with a tapered shaft; Design 3 contains an annular head and a circular foot with a straight shaft.

After consultation with Dr. Smith, it was determined that the first design featuring conical ends was deemed acceptable. However, it posed challenges in terms of visibility and assessing the position of the foot on the stapes footplate due to its obstructive nature. The second design, characterized by a frustum structure, had been discarded as it might come into contact with the horizontal canal of the facial nerve, impeding proper placement of the foot component at the center of the stapes footplate. In contrast, the third design, incorporating a ring-shaped headplate, was regarded as the most suitable option, although minor adjustments were required to optimize its structure. For instance, modifying the circular ends to oval shapes allowed better adaptation to the central region of the tympanic membrane. Furthermore, fillets should be introduced to reinforce stability at the connection between the shaft and the headplate, while chamfers could be added to certain edges to mitigate sharpness. Consequently, Design 3 had undergone further refinement and was considered one of the concept solutions.

4.3 Metal Forming

4.3.1 Selection of Cutting Method

An alternative concept involved the utilization of sheet titanium instead of wire titanium in the fabrication of TORP, as previously designed. The current wire TORPs in use are crafted manually, lack constant dimensions, and may feature sharp edges, hence the desire to develop more consistent and controlled devices. Various metal cutting methods, including water jet cutting, WEDM, and laser cutting, were available for implementation. However, careful assessment was necessary before employing these methods, considering the specific requirements of the TORP structure and the contextual circumstances of this project.

First of all, water jet cutting utilizes a high-pressure jet of water mixed with abrasive particles to precisely cut through materials. It is a versatile and non-thermal cutting process, making it suitable for a wide range of materials, including metals like titanium. Water jet cutting provides high accuracy and does not produce heat-affected zones, preserving the integrity of the material. However, it may result in tapering and surface roughness due to the excessive forces, especially for smaller-sized parts.

WEDM involves the use of a thin wire electrode that passes electrical discharges to erode the material and create precise cuts. WEDM is known for its ability to cut complex shapes and hard materials. It offers excellent precision, but the process can be relatively slow and may leave a recast layer that requires additional post-processing. Moreover, WEDM machines are typically specialized equipment that requires a significant upfront investment. The wire electrodes used in the WEDM process can be relatively expensive and need to be regularly replaced as they erode during machining. The process itself can also be time-consuming, which can lead to increased labor costs compared to other cutting methods.

Laser cutting employs a focused laser beam to melt and vaporize the material, resulting in precise and clean cuts. It is a fast and highly accurate method, well-suited for intricate designs and thin materials. Laser cutting offers versatility in terms of material compatibility but may introduce heat-related issues, such as thermal distortion or recast layers.

The selection of a cutting method for TORP production was contingent upon various factors, including the properties of the materials involved, the desired level of precision, surface finish requirements, and production limitations. Considering the requirement for exceptionally precise manufacturing of small TORP components, water jet cutting was initially disregarded as a less suitable method. Furthermore, the utilization of WEDM was deemed impractical for this particular project due to its associated high costs. Consequently, precision laser cutting was chosen as the preferred method for production. Heat-related concerns, such as local-hardening and embrittlement, were considered insignificant due to the relatively thinness of the titanium sheets, estimated to be approximately 0.3 mm, based on the dimensions of the titanium wire employed in the previous prototype. This thinner material profile resulted in reduced heat generation during the cutting process, ensuring optimal manufacturing outcomes.

4.3.2 Possible Concept Development based on the Morphological Table

Similarly, three initial conceptual designs were formulated for the laser cutting method based on Table 3. These designs were executed by cutting a titanium sheet in a two-dimensional (2D) manner and subsequently bending the head and footplates vertically, into the form of a TORP. Fig. 6 showcases the designs and provides an overview of their distinctive features. The initial concept was generated from Combination 3 in Table 3, incorporated two annular feet, each bent in an opposing direction to achieve equilibrium. Similarly, Designs 2 and 3 modified the shape of the feet into C-shape and S-shape according to Combination 4 and 5, respectively, with the aim of enhancing balance. All shafts were initially designed as straight, but a zigzagged structure was also possible for the bending operation.

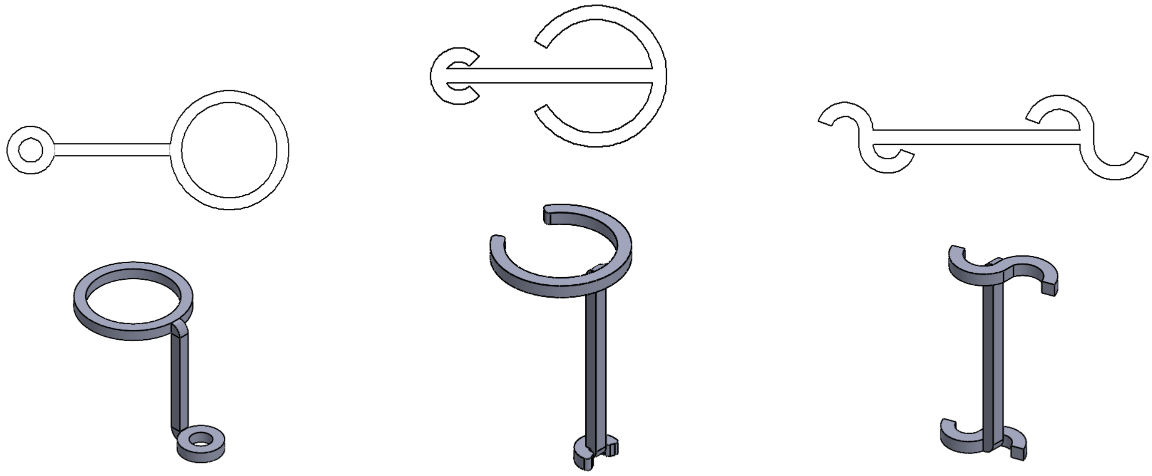

(a) Design 1 **(b)** Design 2 **(c)** Design 3

Figure 6: The three initial designs for laser cutting manufacturing method before and after bending. Design 1 has annular head and foot with a straight shaft; Design 2 consists of C-shaped head and foot with a straight shaft; Design 3 includes S-shaped head and foot with a straight shaft.

After careful deliberation with Dr. Smith, it was evident that all the proposed ideas were viable. With slight further modifications, the second design exhibited the advantage of facilitating easier alignment owing to its rounded feet. By locating the bending positions at the centers, it became feasible to achieve the desired concentricity between the head and footplates unlike the first design. Additionally, the cutting pattern employed in this design exhibited greater density as the openings of the plates were directed towards the central region, which led to less waste of the materials. Thus, design 2 had subsequently undergone additional refinement, considering it a viable candidate among the concept solutions.

5 Concept Solutions

The structure of a TORP is designed to restore the functionality of the middle ear and improve hearing. A TORP typically comprises three main parts: a long rod, a head and a foot. The long rod, also known as the shaft or body, serves as a replacement for the damaged or missing incus bone. It is custom-designed to match the patient's anatomical requirements. The length and diameter of the rod are critical to ensure proper sound transmission and mechanical stability within the middle ear. The head and foot are the other important components of a TORP. They are designed to connect and transmit sound vibrations to the footplate part of the residual stapes bone and the oval window of the cochlea from the tympanic membrane. The plates are placed securely using surgical techniques.

During TORP surgical procedures, the damaged or diseased middle ear ossicles are removed, making way for the placement of the prosthesis. The surgeon carefully positions the TORP, aligning the long rod with the remaining structures of the middle ear and placing the plates to ensure proper sound transmission. The surgeon may use an additional piece of cartilage to discourage extrusion and infection on the side of the tympanic membrane.

5.1 Concept 1: Additive Manufacturing

5.1.1 Design Explanation

After considering multiple design proposals as mentioned in the previous section, the prototype depicted in Fig. 7 was developed. Leveraging the inherent flexibility offered by 3DP, the shaft of the prototype can be erected from the center of the headplate. In order to enhance visualization during surgical procedures, the headplate was designed with a predominantly open structure, incorporating a central beam for support, which also served as the foundation for the shaft. The oval shape of the headplate facilitated improved adaptation and alignment when attaching it to the tympanic membrane. The headplate had the maximum width of 3.8 mm, while the smaller one had a diameter of 1.0 mm. To mitigate the risk of sharp edges and minimize susceptibility to fatigue failures, the right-angle connections should be modified to incorporate 45-degree chamfers on both the headplate and cone-shaped features on the footplate. However, since cartilage is often attached to the headplate during surgery, chamfer was only required on the foot side. Similarly, 45-degree chamfers were implemented on the upward-facing surfaces for the same reasons.

For a more stable printing process, the printing orientation was from the head to the foot as illustrated in Fig. 7. This avoided imbalance of the structure. The prototype could be printed into different lengths from 3.0 to 4.5 mm.

5.1.2 Manufacturing Details

The printing process was performed by an SLM machine in the lab of BioMechanical Design, Delft University of Technology. The printing setting was arranged by the lab's 3D

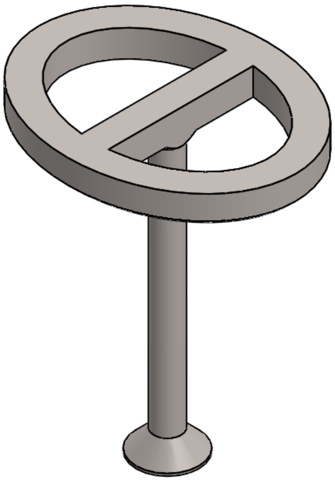
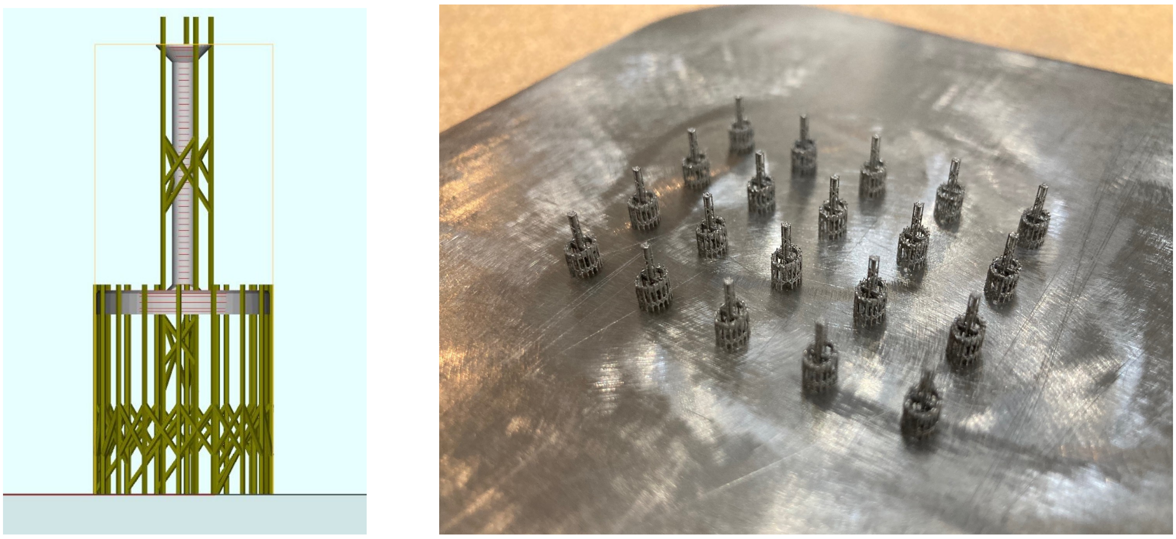


Figure 7: Schematic of the designed TORP by SLM

printing expert. The SLM printing procedure involved several key steps. To begin, a layer of fine Ti6Al4V (grade 5) powder, which is a common material used for medical implants, was evenly spread on the build platform. A high-powered laser beam selectively scanned and melted the powder particles based on the desired 3D model. The melted material solidified, creating a solid layer. The build platform was then lowered, and the process was repeated for subsequent layers until the entire object was formed. After printing, excess powder was removed by a wiper.

To improve the printing process, the technician incorporated certain support structures, despite the intended design being support-free. As illustrated in Fig. 8 (a), the TORP was elevated by multiple beams. This eliminated the necessity for additional thickness to achieve smoother layers. As stated in the design rules, additional thickness is typically necessary in specific orientations to ensure a smooth or fully dense part following the WEDM cutting process. By substituting the additional thickness with beams, the removal process became more straightforward, negating the need for a WEDM machine. Furthermore, additional support was introduced to the straight shaft, which ordinarily did not require any. This precautionary measure was taken to prevent potential breakage due to the wiping force exerted, considering the shaft's inherent thinness. Twenty pieces were printed at once as shown in Fig. 8 (b).



(a)

(b)

Figure 8: (a) The CAD model with supporting structures for SLM (b) The actual situation and arrangement during SLM printing

5.2 Concept 2: Metal Forming

5.2.1 Design Explanation

Fig. 9 illustrates a 2D model obtained through laser cutting, which was refined from the C-shaped design mentioned in Section 4. Following the established design guidelines, the head and foot possessed diameters of 3.6 mm and 1.0 mm, respectively. A titanium sheet thickness of 0.3 mm is employed. Notches, positioned at the centers of the circular feet, were incorporated on both sides of the shaft to indicate the bending locations. These notches were oriented in the same direction to maintain a consistent cross-sectional area, aiming to prevent any weakening of the shaft. Furthermore, all corners were rounded to facilitate smooth motion of the laser beam, consequently minimizing the risk of fracture. Lastly, both the upper and lower sides necessitated deburring to eliminate any sharp edges.

Upon the completion of the 2D titanium piece preparation, it underwent a bending process to transform it into a TORP, employing two distinct shaft designs. In the first design approach, only the head and footplates were bent, while the middle shaft remained in a straight configuration. In contrast, the second design incorporated a longer shaft that engaged in bending at various angles, allowing different total lengths for the TORP. The shaft designs are separated into Concept 2A and 2B in the following sub-sections.

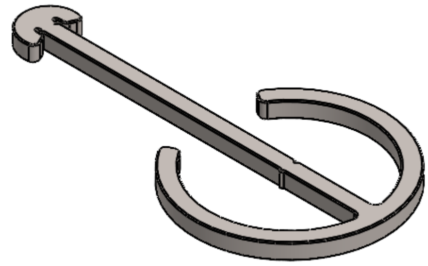


Figure 9: Schematic of the designed TORP by laser cutting before bending

5.2.2 Concept 2A: Fixed-Length Shaft

The first design involved a straight fixed-length shaft configuration. By following the notches on the shaft, the head and footplates could be bent at a 90-degree angle with the shaft, aligning with the centers of the plates. The straight shaft design provided increased stiffness and strength but lacked length adjustability. Consequently, during the laser cutting process, various models were designed with shaft lengths ranging from 3.0 to 4.5 mm. The resulting TORPs of different lengths after the bending procedure are illustrated in Fig. 10.

5.2.3 Concept 2B: Adjustable-Length Shaft

The second design incorporated an adjustable shaft as a modification. The initial design featured a straight shaft measuring 6.0 mm, which exceeded the intended lengths of the

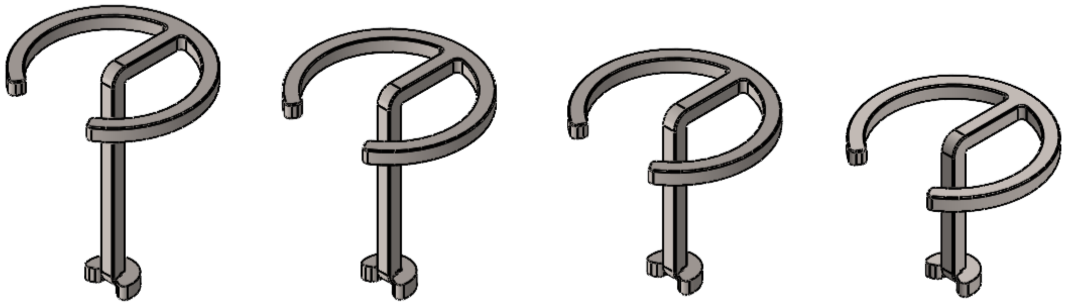


Figure 10: Comparison between Concept 2A (laser cut TORP) with different lengths of fixed shaft. From left to right: length 4.5, 4.0, 3.5 and 3.0 mm)

TORPs. This design strategy enabled the reduction of the shaft length by introducing an additional bend, facilitating coverage across the complete range of target lengths. Consequently, only one type of TORP required to be prepared for different patients, eliminating the need for multiple sizes. As illustrated in Fig. 11, the bent section was positioned closer to the headplate, not only avoiding the surrounding tissues but also enhancing visibility during surgical procedures. Aside from the bent segment, the straight shafts closer to both the head and footplates were arranged collinearly to ensure stability and balance.

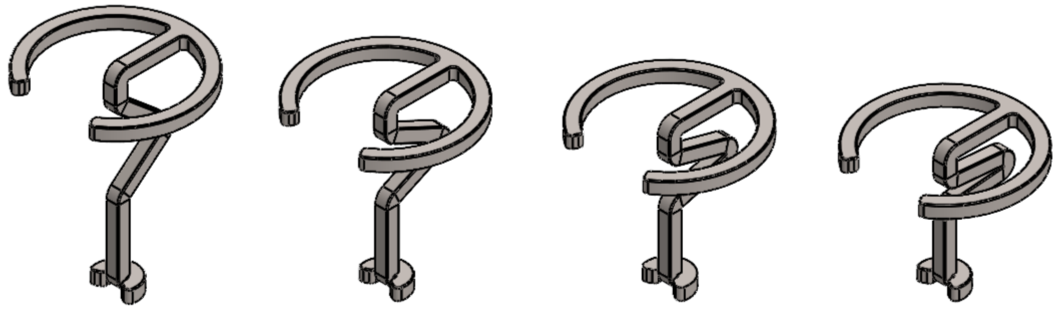


Figure 11: Comparison between Concept 2B (laser cut TORP) with different lengths of adjustable shaft. From left to right: length 4.5, 4.0, 3.5 and 3.0 mm)

Bent shafts are not observed commonly in the majority of current TORP products and research. Consequently, a thorough review of the literature was conducted to gain deeper insights into this specific design aspect. Diab et al. (2018) [11] also adopted TORPs with adjustable stems, as shown in Fig. 12. A total of 723 patients (comprising 921 operations) diagnosed with chronic suppurative otitis media and congenital ear malformations underwent tympanoplasty with ossiculoplasty. Among these cases, the utilization of titanium TORPs was observed in 309 instances. The design of the TORPs incorporated an extensible and compressible stem, enabling precise adjustment of the prosthesis length. Subsequent oscillometric tests demonstrated that the TORPs exhibited favorable sound wave conductivity, with consistent conductivity observed across all stem configurations. Thus, the properties of bent TORPs are considered acceptable. Additionally, considering the elastic nature of the tympanic membrane, the potential decrease in stiffness resulting from the inclusion of a bent shaft is not expected to significantly impact surgical outcomes.

Figure 12: Existing TORP designs with adjustable shafts [11]

5.2.4 Manufacturing Details

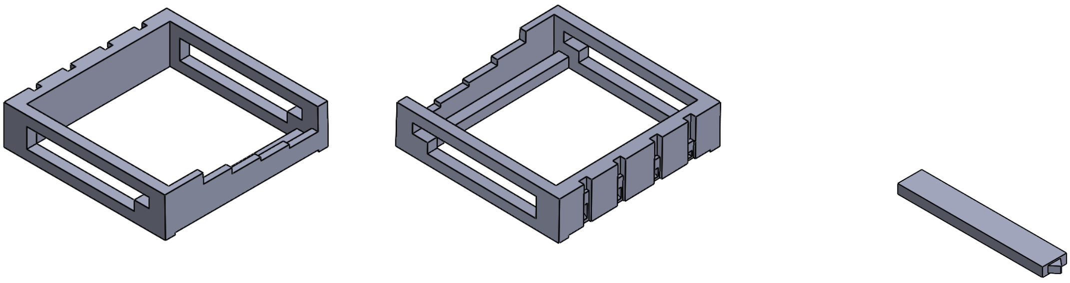
Since titanium is more expensive, stainless steel was used as an alternative for titanium since it was often used as the material of TORPs previously. The stainless steel prototypes were exclusively used for the sound transmission experiments, while the titanium ones were utilized to assess data comparability.

The TORPs were manufactured by Laser Technology Janssen, the Netherlands. The titanium components were precision-cut from titanium grade 2 sheets with a thickness of 0.25 mm, as a result of the unavailability of 0.3 mm sheets. Additionally, the 301 stainless steel sheet utilized had a thickness of 0.3 mm.

5.2.5 Bending Tools

Initially, manual bending was employed for Concept 2; however, achieving consistent outcomes in terms of length and concentricity proved challenging. To address this issue, a simple bending tool set was devised to enhance uniformity, as depicted in Fig. 13. The bending tool consists of two distinct sides, each tasked with specific bending functions. One side manages the perpendicular bending of the head and footplates, while the other facilitates the zigzagged bending of the adjustable shafts. The dimensions can be seen in Fig. 45, Appendix B.

The stepped wall for bending the head and footplates features five different heights: 6.0, 4.5, 4.0, 3.5, and 3.0 mm. Users can conveniently select their desired length by sliding along the edge. The process involves positioning the headplate beneath the groove located at the wall's base. Viewing from above, the headplate can be positioned in alignment with a reference beam on the bottom surface, indicating the center of the plate which is the exact bending location. Subsequently, a pair of tweezers can be utilized to bend the shaft upward along the stepped wall. Finally, the footplate is bent downward to align with the upper edge of the wall, ensuring accurate length adjustment. The wall is inclined at an angle of 1 degree from the vertical to offset the elastic tendency of rebounding. On the opposing side, four vertical grooves are presented, each featuring a distinct socket with varying depths near the base. These sockets accommodate the shaft, which can be pressed into them using the corresponding pressing tool, resulting in the desired zigzagged shape. The pressing tool mirrors the shape of the socket counterpart, guaranteeing precise alignment of the shaft within the socket. Similarly, the headplate is placed within the bottom groove during pressing. As the pressing occurs, the footplate moves downward along the vertical groove. Finally, minor adjustments to the shaft's alignment with the head and footplates can be made using tweezers. The procedures are visually outlined in Fig. 47 and 48 of Appendix C.



(a) **(b)**

Figure 13: The bending tool set. (a) On the left, the stepped wall is used for bending the head and footplates of TORPs with different lengths. The five different grooves are used for TORP with length of 6.0, 4.5, 4.0, 3.5 and 3.0, respectively. On the right, the grooves from left to right are adopted to created zigzagged shafts for TORPs with adjustable lengths of 4.5, 4.0, 3.5 and 3.0 mm from a 6.0 mm straight shaft. (b) The pressor for a 4.5 mm long zigzagged TORP for example.

6 Concept Results and Evaluation

In order to determine the most appropriate TORP concept(s) for LMICs, a comprehensive evaluation was conducted, considering the assessment criteria outlined in Section 2. These criteria include affordability, manufacturing process, precision, sound transmission properties, and simplicity. Additionally, prototypes were manufactured to validate the feasibility of the processes and to facilitate further experiments. Commercial TORPs were obtained for comparison.

6.1 Evaluation Methods

Among all the evaluation methods, affordability, manufacturing process and simplicity can be directly examined through accessible information and straightforward testing. However, precision and sound transmission property necessitate the procurement of specialized experimental equipment and the conduct of corresponding experiments.

Firstly, the precision measurement was conducted in the DEMO lab, Delft University of Technology. A measuring microscope (MF-U, Mitutoyo, Japan) was used to measure the critical dimensions four decimal places, allowing for accurate determination of measurements to the nearest 0.0001 mm. Each concept solution was assessed using a single prototype of varying lengths, as the marginal value of 5 % was considered achieved as long as one prototype demonstrated conformity.

As for sound transmission, it could be tested by a MMM system mimicking the structure of a human middle ear. The schematic can be seen in Fig. 15 [5]. It involved connecting a TORP to the middle ear model and subjecting it to a controlled sound input with different frequencies. The acoustic signal, emitted by a speaker, served as the input and was captured by a microphone for measurement purpose. Subsequently, the sound pressure traversed the external auditory canal, middle ear, and reached the inner ear sequentially through the membranous structures denoted as M1 (membrane 1, representing tympanic membrane), the TORP, and M2 (membrane 2, representing oval window). Then, a laser Doppler vibrometer (LDV) was used to quantify the vibrations at M2 as the output signal.

By comparing the input and output signals, the TORP's effectiveness in transmitting sound could be evaluated by the resulting transfer functions. The input signal (U_{in}) was a periodic chirp signal with a frequency range from 0.1 to 10 kHz at 5V amplitude. The output signal (U_{out}) was measured as a spectrum of the vibration velocity of M2. After the time domain signals were converted by the fast Fourier transform (FFT) procedure into frequency domain signals, the transfer function of the entire system could be calculated by $H_{total} = \frac{U_{out}}{U_{in}}$. Similarly, the transfer function of an empty setup was obtained only with M1 and M2 without a TORP in between. By the equation $H_{TORP} = \frac{H_{total}}{H_{empty}}$, the transfer functions solely for the TORP was calculated. For every category, three different prototypes were measured three times each to obtain the average outcomes. There were three types of comparison groups:

1. Comparison between a concept solution and the commercial TORPs

2. Comparison between different lengths, including 3.0, 3.5, 4.0 and 4.5 mm, for Concept 2A and 2B

3. Comparison between materials, titanium and stainless steel, for Concept 2A and 2B

The figures of comparison were demonstrated in the subsections below for each concept solution. Only the section from 0.1 to 10 kHz was cropped for comparison because it represents the normal range of human hearing in daily situations. The curves containing all TORPs are shown in Fig. 14, giving the examples of legends used in further figures. And the flowchart of obtaining the results is shown in Fig. 16. Figure examples generated each step are displayed in Appendix E.

To demonstrate the repeatability of the experiments, Fig. 17 (a) displays the filtered transfer functions for three tests of the same prototype and (b) shows the averaged ones for three prototypes of the same concept design. Concept 1 (3DP TORP) is taken as an example in this section, while the rest are shown in Appendix E. For the three repetitions of the same prototype, overlapping is evident. However, when comparing different prototypes, greater dissimilarity emerges, possibly due to differences among the prototypes or changes in ambient conditions. The RMSEs throughout the whole frequency range, i.e., 0.1 - 10 kHz, between Prototype 1 and Prototype 3, and between Prototype 2 and Prototype 3 are 37.3 and 24.8 mm/s/V, respectively. And the RMSE values between a designed TORP and the empty setup in the same frequency range are around 570 mm/s/V (see Table 13, Appendix E). Therefore, the disparities in the magnitudes of the transfer functions are deemed relatively minor, and they are unlikely to exert a substantial influence on the final results.

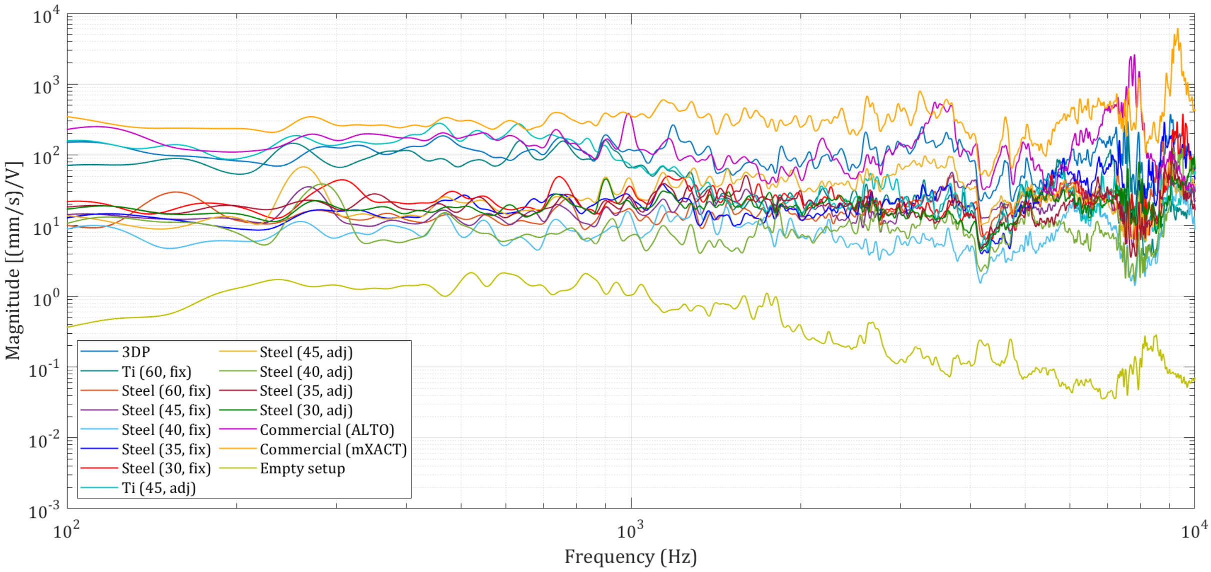


Figure 14: All transfer functions obtained by the sound transmission property experiments. The legends were consistent in the further figures. "3DP" stands for Concept 1. "Ti (60, fix)" means the TORP is laser cut from titanium sheet with a fixed shaft in the length of 6.0 mm. Similarly, "steel (45, adj)" indicates the laser cut TORP is made of stainless steel with an adjustable shaft in the length of 4.5 mm. "Commercial (ALTO)" and "Commercial (mXACT)" are the two types of commercial TORPs used in this project. Finally, "Empty setup" is the transfer function measured from an empty MMM setup.

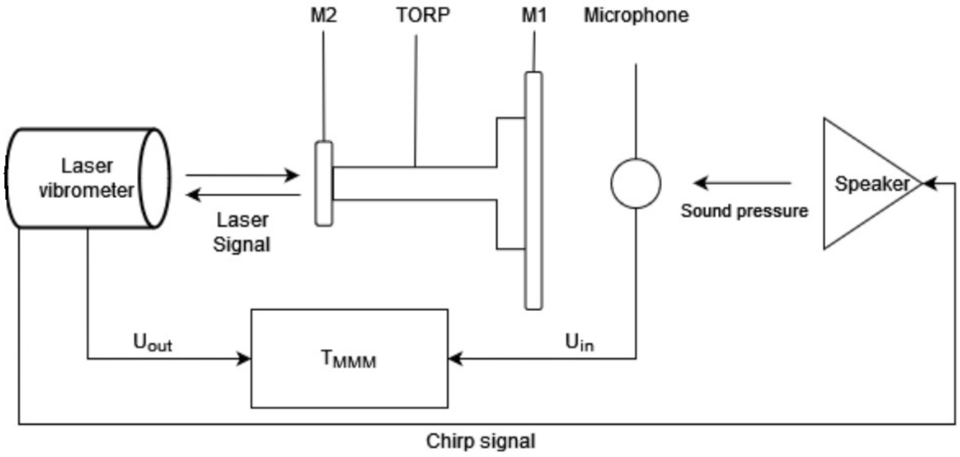


Figure 15: Schematic of the designed MMM [5]. M1 and M2 stand for membrane 1 and 2. The transfer function T_{MMM} is calculated by the input (U_{in}) and output signal (U_{out}).

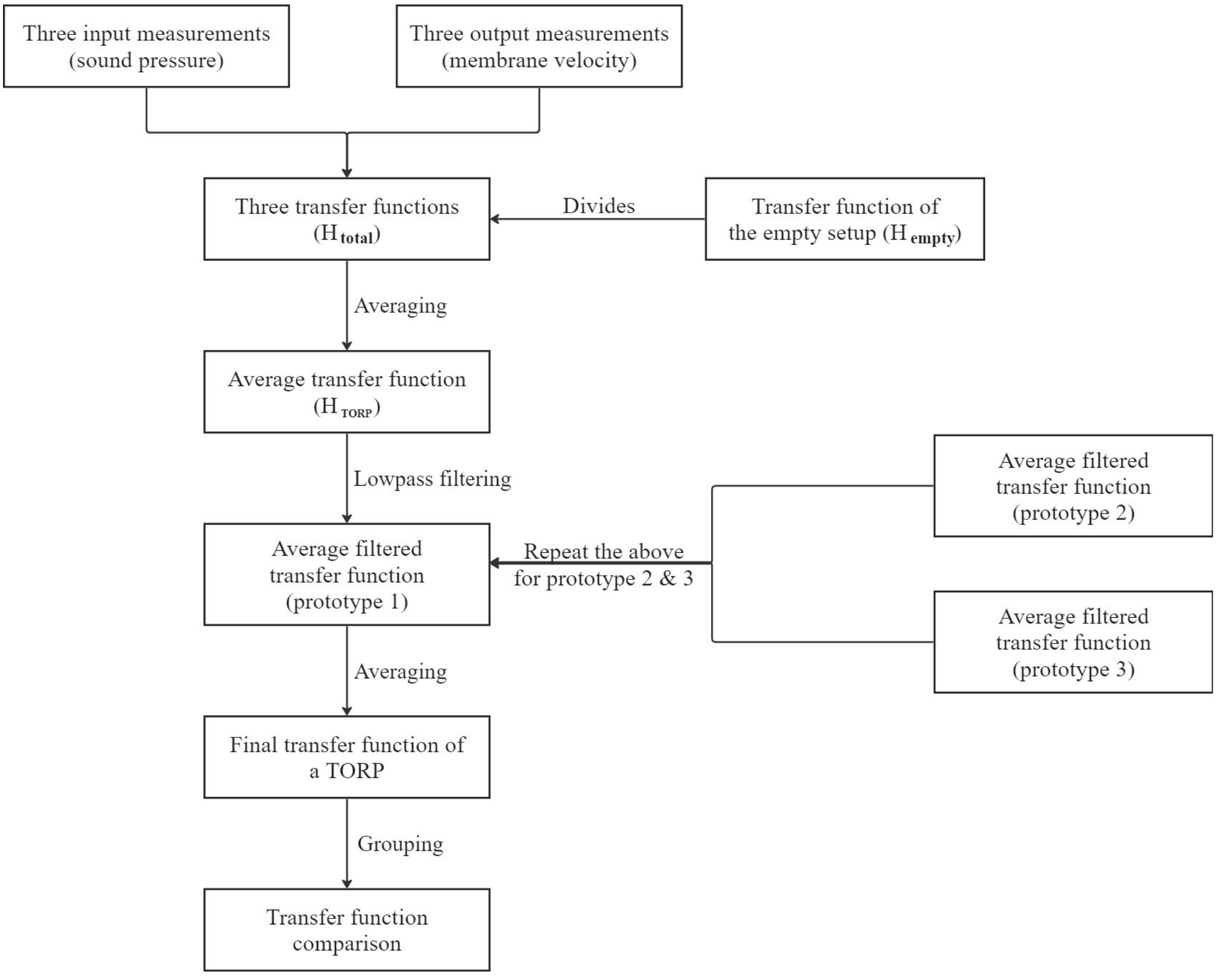
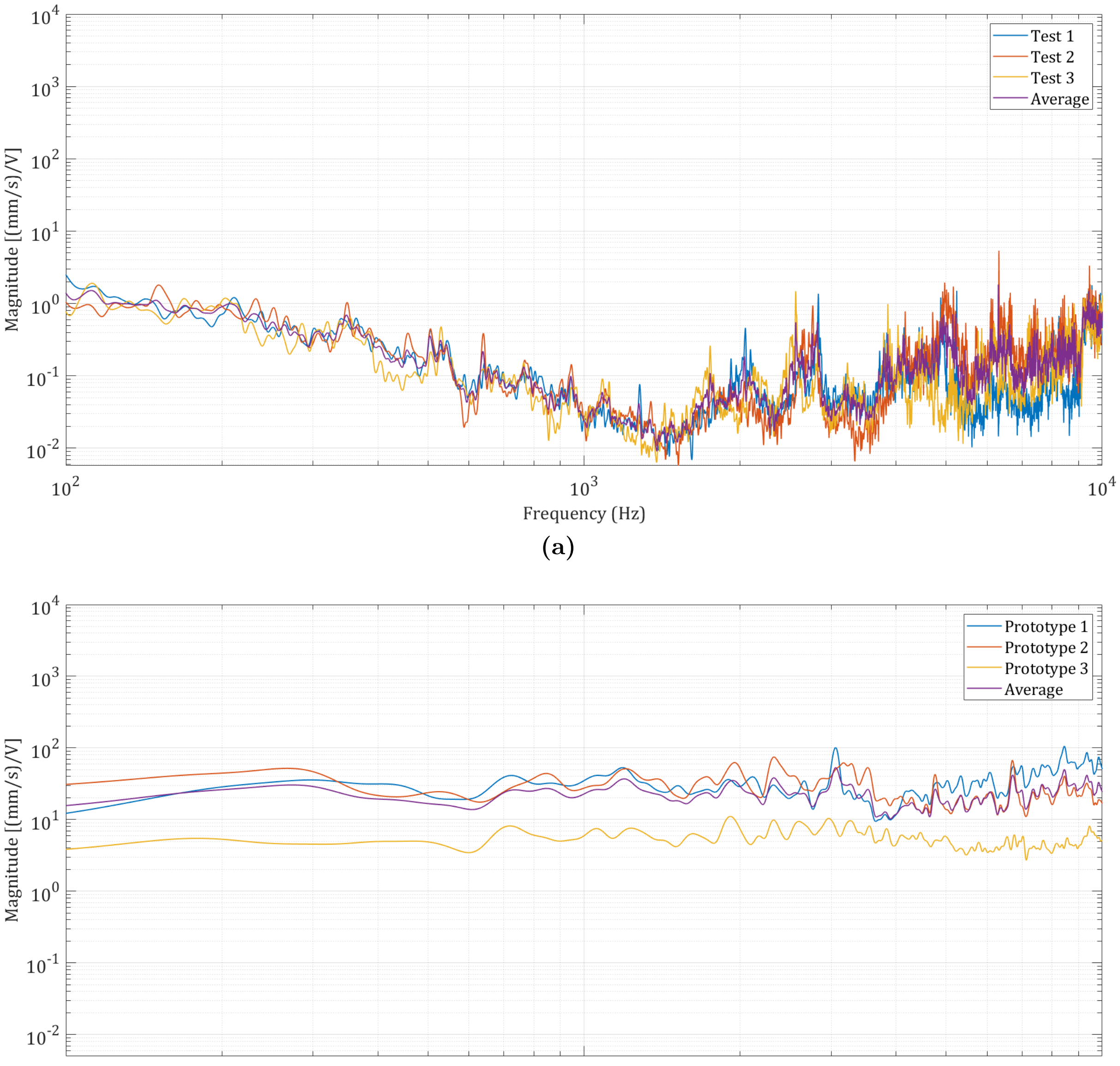


Figure 16: The flowchart of obtaining the final transfer functions of different types of TORPs for comparison



(a)

(b)

Figure 17: (a) The three transfer functions obtained for the same 3DP prototype in three repetitions and the average transfer function based on them (b) The three average transfer functions obtained for three 3DP prototypes and the total average transfer function calculate from them

Adopting MMM, the sound transmission properties could be compared among different designs and the commercial products. Based on the experimental design of Meister et al. (1999) [12], a revised MMM was developed by ten Have (2022) [5] as shown in Fig. 18. The model consisted of a breadboard to fix the relative distance between each component. The breadboard accommodated a speaker, a cone responsible for amplifying and isolating the sound input, a microphone inserted into the side of the cone, a movable tube with M2 attached at the end, and a linear actuator employed to regulate the distance between M2 and the TORP.

The breadboard, movable tube and membrane holders were 3D printed using PLA and PETG (Prusa MK3s, Prusa Research, Prague, Czech Republic). The TORP was positioned between two silicone rubber membranes (Rubbermagazijn B.V., the Netherlands) representing the tympanic membrane (M1) and oval window (stapes footplate, M2). These membranes had dimension of 15 x 15 x 0.3 mm were affixed to the membrane holder by cyanoacrylate glue and possessed a tensile strength of 6.5 MPa. The input signal was generated by a speaker and measured by a microphone, while a single point LDV (OFV 505, Polytec GmbH, Baden-Württemberg, Germany), a vibrometer controller (OFV 2200, Polytec GmbH, Baden-Württemberg, Germany) and an oscilloscope (Smart Oscilloscope STO1102E, Micsig Technology, Shenzhen, China) recorded the system's output on the surface of M2, where the TORP's foot was located.

To facilitate displacement, a linear actuator (PT1-M, Thorlabs, Newton, USA) displaced M2 and provided the fixed distances of the membranes along the axis of movement. Maintaining constant variables during testing was crucial for meaningful comparison of transmission properties. To maintain identical tension in the test setup, M2 was consistently placed at the same location relative to the TORP's foot. This was achieved by determining the initial point of contact (between M2 and the foot) using the linear actuator.

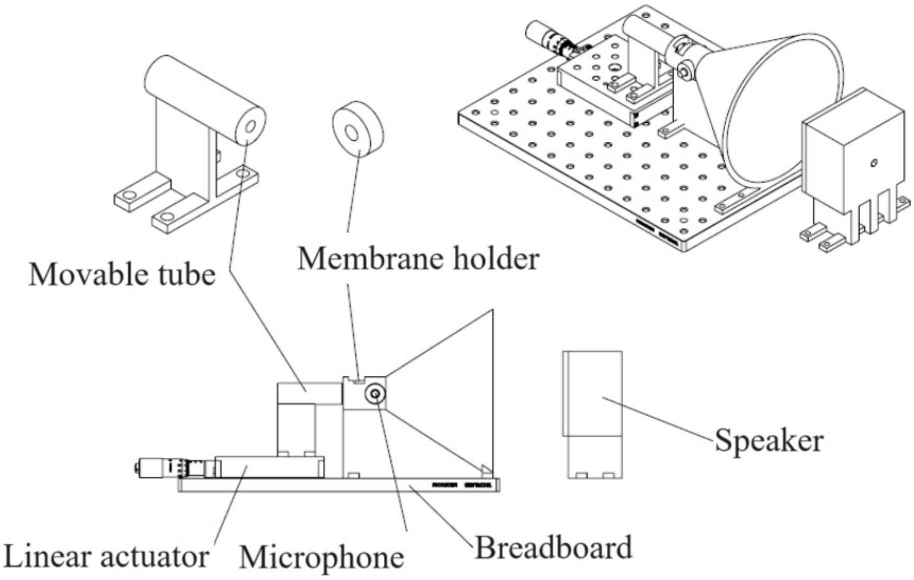


Figure 18: Test setup of the designed MMM [5]

Table 4 presents the evaluation methods for the five criteria. The determination of marginal values was informed by prior research findings, expert recommendations from Dr. Smith, and literature research. An optimal value of 20 % improvement is envisioned for each criterion.

Criteria	**Evaluation Method**	**Marginal Value**	**Ideal Value**
Affordability	The average cost of a single TORP under a 400-piece series.	€10	€8
Manufacturing Process	How easily the manufacturing process can be accessed and conducted.	Grade 1	Grade 2
Precision	The dimension differences between the designed and manufactured TORPs.	5 %	4 %
Sound Transmission Property	The curve resemblance and the RMSE of the transfer function between the commercial (ALTO Dornhoffer) and the designed TORPs in the frequency range of 0.1 to 4 kHz.	-	-
Simplicity	The preparation time from the manufactured piece to a customized TORP during surgeries.	$\leq$ 10 min.	$\leq$ 8 min.

Table 4: Evaluation methods for the five assessment criteria and the corresponding marginal and ideal values.

6.2 Commercial Product: ALTO Dornhoffer

The commercial TORP, ALTO system developed by Grace Medical Inc. [2], was provided by Erasmus MC, Rotterdam. The Dornhoffer implant offers a range of notable features as the following. The TORP showcases a contoured head made of hydroxyapatite (HA) with a window, effectively enhancing visualization during surgical procedures. Furthermore, an additional groove is incorporated to accommodate the presence of the malleus if applicable (see Fig. 19 (a)). The inclusion of a footplate shoe significantly enhances implant stability and allows for adjustments to ensure proper attachment within the remnants of the stapes crus. The ALTO Dornhoffer system is packaged with disposable sizers and preloaded into the patented ALTO adjuster, facilitating the implant sizing process (see Fig. 19 (b)). Its reliable performance, compatibility with various anatomies, and positive clinical outcomes have contributed to its widespread adoption in hospitals, making it a preferred choice for many middle ear reconstruction surgeries.

(a) **(b)**

Figure 19: (a) ALTO Dornhoffer partial and total implant with footplate shoe (b) ALTO adjuster [2]

The comparison between ALTO Dornhoffer and the evaluated concepts was conducted using available data and tests. For example, the first two criteria could be evaluated based on collected information. Regarding affordability, the precise price of the TORP was not accessible due to confidentiality reasons; however, it was confirmed to considerably exceed the marginal value. In terms of accessibility, it was assigned a grade of 2 since its acquisition is limited to ordering from the company, which is not situated in any LMIC. Additionally, no preliminary procedure was required before surgeries.

As for the other criteria, tests are required. Precision measurement, in particular, could not be performed due to significant structural differences between ALTO Dornhoffer and the concept solutions. However, as the TORP has been a certified medical implant for a long time, the precision is, therefore, regarded as compliant with the assessment criterion and will not be subject to further evaluation.

As shown in Fig. 20, ALTO Dornhoffer is compared with the empty setup. Within the frequency range of 100 to around 3100 Hz, the magnitude maintains a relatively consistent trend at approximately 112.2 mm/s/V. Beyond 3100 Hz, a more erratic pattern in magnitude is shown. Evident peaks are discernible at frequencies of 3584 and 7810 Hz. For the same reason as precision, the sound transmission property was not evaluated due to its certified status.

As for the transfer function of the empty setup, most of the magnitudes are below zero, which means there is no successful sound transmission. Between 180 to 1070 Hz, there is a maximum vibration of 2.0 mm/s/V, but it is relatively small compared to the magnitude of ALTO Dornhoffer.

Besides the ALTO Dornhoffer TORP, the commercial product used in the previous study, mXACT Total Prosthesis Offcenter (MED-EL Medical Electronics, Innsbruck, Austria) [13] was also adopted in this project as another reference for more thorough comparison. According to the data measured previously [5], this prosthesis exhibits a length of 4.19 mm and a mass of 4.26 mg. In Fig. 20, the magnitude of transfer function observed in mXACT Offcenter surpasses that of ALTO Dornhoffer, with a difference of approximately 232.2 mm/s/V before 4000 Hz. The reason might be the much lighter mass, which is nearly one-fourth that of ALTO Dornhoffer. Also, a peak is shown at 9306 Hz. Nevertheless, both commercial products demonstrate satisfactory sound transmission properties.

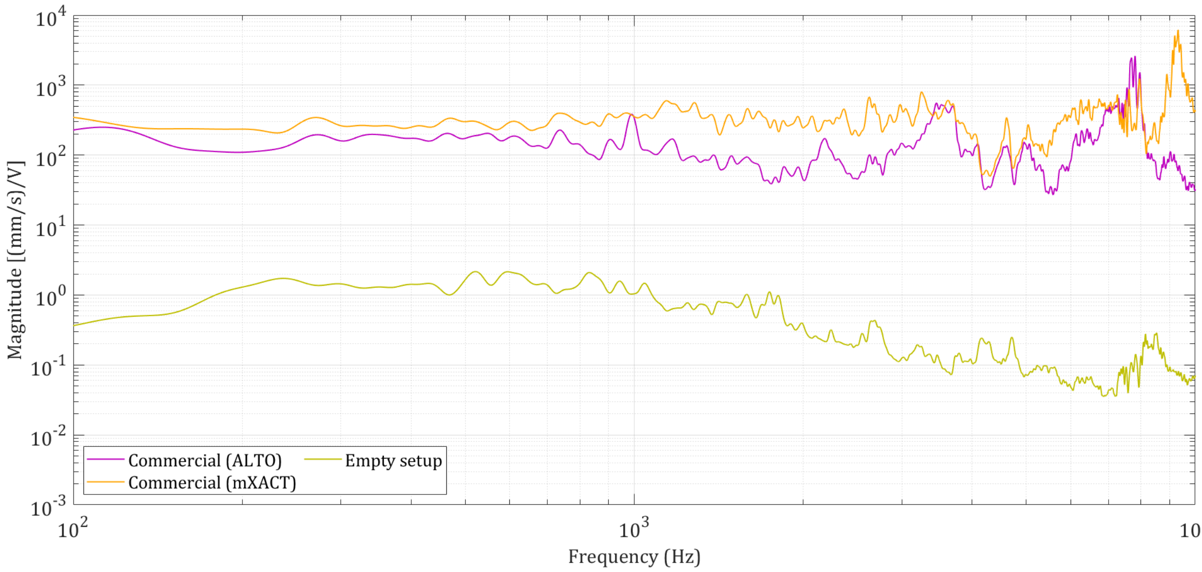


Figure 20: The transfer functions of the two commercial TORPs (ALTO Dornhoffer and mXACT Offcenter) and empty setup

Lastly, for simplicity, the surgeons have the option to trim the TORP using the adjuster according to each patient, a process that takes about 5 minutes. An ideal performance has been established.

6.3 Concept 1: 3D Printing

Affordability
The estimated cost was obtained from online quotations provided by 3D printing manufacturers. As a result of the unique characteristics of 3DP, the average price of larger quantities did not undergo significant reductions comparable to batch production methods. And Ti6Al4V was more expensive than typical metal materials, such as stainless steel and aluminum. The pricing ranged from of 29 to 65 euros per TORP, surpassing the threshold of affordability based on the marginal value.

Manufacturing Process
In terms of accessibility, a grade of 1 was assigned due to the current limited availability of metal 3DP manufacturers in Nepal, as well as in other LMICs. SLM machines, employed for metal 3DP, are considered high-end, industrial-grade printers with prices typically ranging from tens of thousands to several hundred thousand dollars. The specific cost varies significantly based on the build volume size, laser power, build speed, and overall machine capabilities. Consequently, for LMIC healthcare facilities seeking to adopt such designs, procuring from overseas sources may present a more feasible solution. Furthermore, as shown in Fig. 21 (b), the TORP was very rough after printed and required surface finishing as post-processing step. The process for transforming newly-printed components into TORPs included two primary steps: support removal and surface finishing. Given the small dimension of the prototypes and the considerable hardness of the titanium alloy, only sanding was feasible but relatively labor-intensive. For experienced users, the total post-processing time for a single TORP piece was about 17 minutes, including 2 minutes of support removal and 15 minutes of surface finishing.

Precision
The prototypes with a length of 4.5 mm were printed for checking the feasibility and further experiments. In Fig. 21, the printed prototypes are displayed, and a more detailed 2D drawing is attached in Fig. 41, Appendix B. For this prototype, the major and minor axes of the headplate, diameter of the footplate and the total length were measured. As shown in Fig. 11, Appendix D, the MAE was calculated as 2.51 %, achieving the ideal value.


(a) **(b)**

Figure 21: (a) The physical prototype of Concept 1 in different views (b) The prototype before removing supporting structures after SLM

Sound Transmission Property

The average transfer function of Concept 1 (length 4.5 mm) is depicted in Fig. 22, based on three measurements of each three prototypes. In contrast to the commercial TORPs, notable peaks are not evident. Regarding the frequency trend, a consistent magnitude level is observed from 100 to around 4100 Hz. Subsequently, the signal experiences slight fluctuations until 10 kHz. Between the frequencies of 100 and 3200 Hz, the response curve closely aligns with that of the commercial TORPs, with a maximum deviation of 268.1 mm/s/V. Within the ranges of 3200 to 3900 Hz and 6500 to 8500 Hz, there are somewhat wider gaps in the target curves, approximately 397.2 and 2566.7 mm/s/V apart. A large difference can also be observed between the transfer functions of Concept 1 and that of the empty setup.

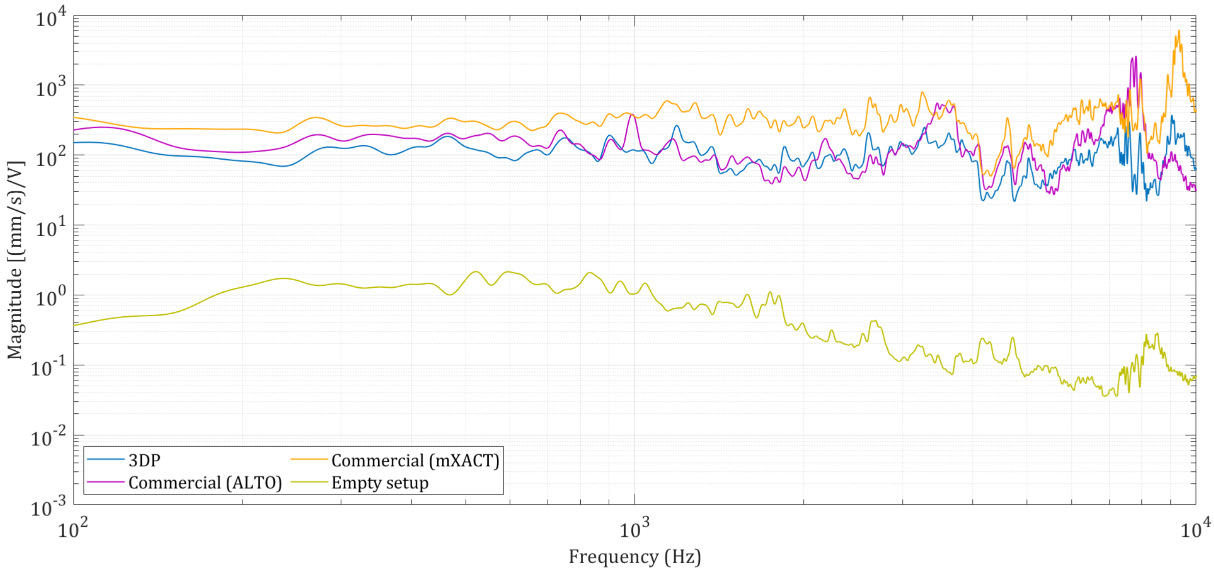


Figure 22: The transfer functions of Concept 1 (3DP TORP), commercial TORPs and empty setup

Simplicity

Despite the relatively extended post-processing time following printing, no modifications were required prior to surgery. Since TORPs were manufactured at their final lengths, the necessity for surgeons to perform any length alterations was eliminated. Consequently, the preparation time could be considered negligible.

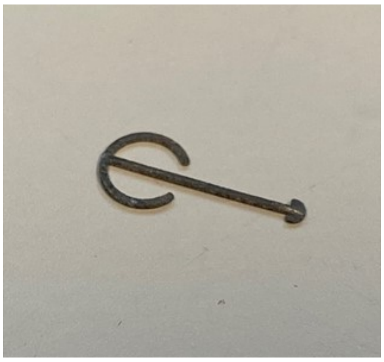
6.4 Concept 2A: Metal Forming (Fixed-Length Shaft)

Affordability
According to the laser cutting manufacturer, the production cost for fabricating 10 TORPs of the same length utilizing grade 2 pure titanium material was 350 euros. Notably, the cost remained relatively consistent when considering a larger production batch, such as 100 pieces, due to the characteristics of laser cutting. Consequently, the total price for ordering four distinct sizes of TORPs at 100 units per size would be around 1400 euros. Additional cost of the bending tool was also estimated from online quotations provided by 3D printing manufacturers, which was at a minimum of 10 euros. This resulted in an average cost of 3.525 euros, meeting the ideal value.

Manufacturing Process
As for the manufacturing process, a grade of 1 was assigned due to the current limited availability of precise metal laser cutting manufacturers in Nepal, or LMICs in general. The cost of a precise metal laser cutter can vary significantly depending on various factors such as the size, power, features, and the manufacturer. Laser cutters can range in price from a few thousand dollars for entry-level desktop models to several hundred thousand dollars for industrial-grade machines. Thus, for LMIC healthcare facilities seeking to adopt such designs, procuring from overseas sources may present a more feasible solution. Although there was no post-processing, such as surface finishing, needed for this prototype, bending was required to shape the head and footplates. Using the bending tool to indicate the bending locations, the plates could be easily bent without the need for additional measurements. Nonetheless, the compact dimensions and resilient properties of titanium increased the difficulty of achieving precise 90-degree bends. After repeated practices, the author achieved a processing time of approximately 5 minutes per TORP.

Precision
For Concept 2A, prototypes made of stainless steel were produced for the lengths of 3.0, 3.5, 4.0, 4.5 and 6.0 mm. And the material titanium grade 2 was only used for 6.0 mm long prototypes. Without following the initial design, the notches were not able to be performed due to the small distances between edges. Indication lines using a lower laser power setting were suggested as an alternative to notches, but this could potentially weaken the shaft structure. Additionally, the laser cutting machine was unable to generate such low energy. Thus, a relatively simpler structure was cut and can be seen in Fig. 23. Detailed dimensions can be found in Fig. 42 and 43, Appendix B.

Measurements were taken for the diameters of the head and footplates, as well as the total length. Moreover, a specific measurement was conducted to ensure the footplate met the criterion of maximum 1.0 mm in any direction, which includes the distance between the bending corner of the shaft to the other edge of the footplate. As shown in Fig. 24 (a), the intended bending location was planned precisely at the center of the footplate, but in reality, it often situated closer to the shaft as shown in Fig. 24 (b). The dimension did not contribute to the MAE but solely served as a criterion for pass or fail assessment. According to the DEMO lab, the average MAE of a titanium TORP (6.0 mm) is 3.37 %; for stainless steel TORP, the average MAE values are arranged in ascending order of length, with values of 0.74 %, 0.91 %, 2.70 %, 1.66 % and 3.94 %, respectively. Thus, the average MAE of all lengths of TORPs, 2.22 %, fulfills the ideal performance. Regarding the pass/fail evaluation, only the stainless steel TORPs of 6.0 and 4.5 mm failed the measurements, exceeding the threshold of 1.0 mm.



(a)

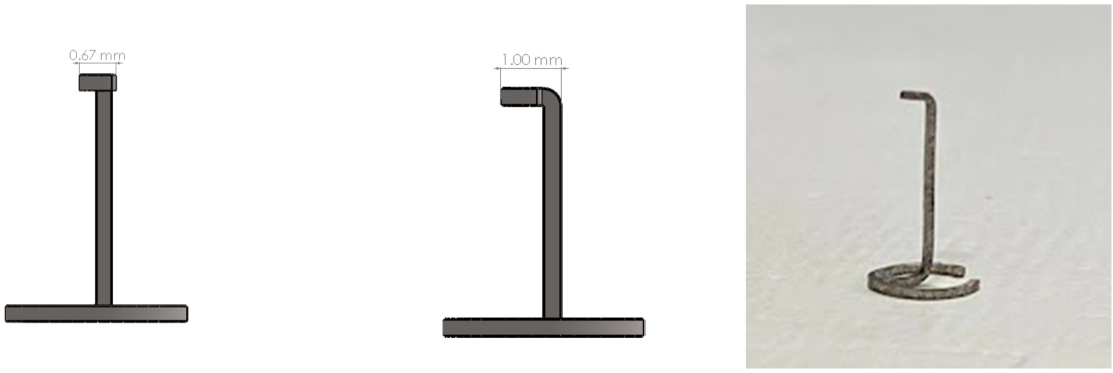
(b)

Figure 23: (a) The physical prototype of Concept 2A and 2B before bending (b) The Concept 2A prototype in different views after bending and forming the head and footplates. The TORP with length of 6.0 mm and titanium material is taken as an example.

Sound Transmission Property

For Concept 2A, the majority of tests were conducted using prototypes constructed from stainless steel due to its lower price. Data were gathered with specimens of five distinct lengths: 3.0, 3.5, 4.0, 4.5, and 6.0 mm. The inclusion of the 6.0 mm specimen served the purpose of establishing consistent performances between the two materials, namely stainless steel and titanium. Consequently, a specimen measuring 6.0 mm in length, fabricated from titanium grade 2, was also subjected to three separate measurements. In Fig. 25, all the steel TORPs exhibit similar transfer functions. From 100 to around 1300 Hz, the vibrations display a comparatively higher degree of stability than those from 1300 to 4200 Hz. Above 4200 Hz, oscillations become more evident than the lower frequencies. Broadly speaking, the curves of the commercial TORPs are mostly at the highest magnitude, followed by those corresponding to the stainless steel TORPs with lengths of 3.0, 3.5, 4.5 and 4.0 mm.

As for Fig. 26, the primary focus is to compare the transfer functions associated with TORPs constructed from stainless steel and titanium. The curve of the titanium TORP has higher magnitude than that of the stainless steel one in lower frequencies, i.e., 100 to around 1100 Hz. Within this frequency interval, distinctions of approximately 50 mm/s/V between the two materials are observed. However, in higher frequency range,



(a) **(b)**

Figure 24: (a) The CAD drawing of Concept 2A in the side view in an ideal situation (b) The CAD drawing and prototype picture of Concept 2A in the side view in real situations. The TORP with length of 4.5 mm was taken as an example.

the two curves mostly overlap with each other. When taking the commercial TORPs into account, their magnitudes are higher than the titanium curve throughout all frequency range.

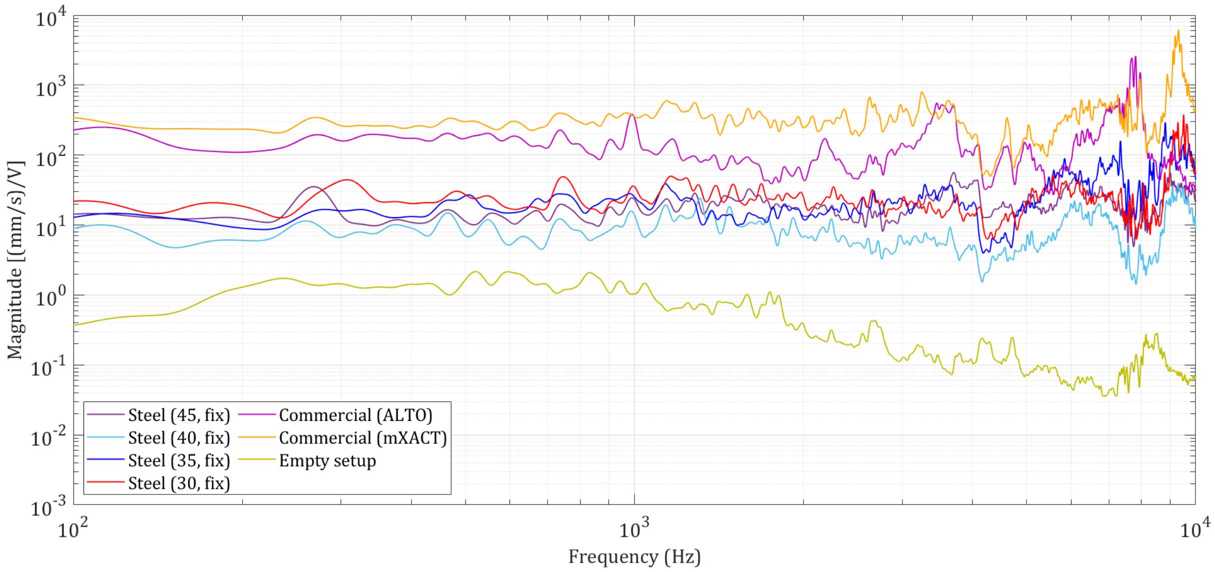


Figure 25: The transfer functions of Concept 2A (laser cut TORPs with fixed shafts) with lengths from 3.0 to 4.5 mm, commercial TORPs and empty setup

Simplicity

Since the bending process falls within the category of manufacturing procedures, the surgeon will only need to select the suitable length of TORPs for individual patients. As a result, there is no preparation time needed for this design.

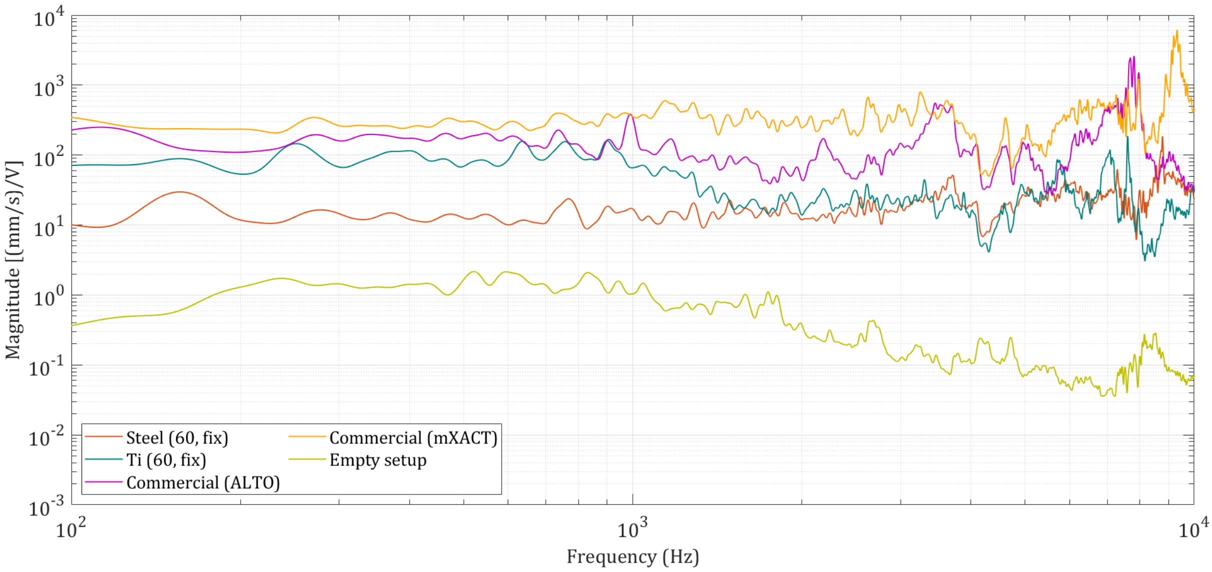


Figure 26: The transfer functions of Concept 2A (laser cut TORPs with fixed shafts) made of stainless steel and titanium, comparing with commercial TORPs and empty setup

6.5 Concept 2B: Metal Forming (Adjustable-Length Shaft)

Affordability

Similar to Concept 2A, the adjustable-length TORP offered a cost reduction by eliminating the need to order multiple sizes. A total quantity of 400 units can be ordered in a single procurement. After adding the cost of the bending tool, a total cost of 360 euros was calculated, resulting in an average cost of 0.9 euros. Consequently, this approach achieved the ideal value of the affordability.

Manufacturing Process

Since both Concept 2A and Concept 2B employed identical manufacturing methods, which was precise metal laser cutting, the accessibility of Concept 2B was graded equally to that of Concept 2A, both being assigned a grade of 1. Similarly, the implementation of this concept necessitated manual bending. However, a bend on the shaft was added to tailor the length of the TORP to the specific middle ear structure of individual patients. Consequently, an extra processing time of 10 minutes was incorporated, resulting in a cumulative processing time of 15 minutes.

Precision

The prototypes were bent into 3.0, 3.5, 4.0 and 4.5 mm long from the original 6.0 mm TORP using stainless steel material, as shown in Fig. 27. The detailed drawings and different angles corresponding to each length are indicated in Fig. 44, Appendix B. Base on the measurements of the DEMO technicians, the average MAE values have been organized in ascending order of length, presenting values of 0.74 %, 0.91 %, 2.70 %, 1.66 % and 3.94 %, respectively. It is noteworthy that the total average MAE of 2.33 % meets the criteria for ideal performance. In terms of the pass/fail assessment, all the stainless steel TORPs have exceeded the 1.0 mm threshold, suggesting a potential issue related to bending proficiency.

Sound Transmission Property

Similar to Concept 2A, four prototypes with varying lengths (3.0, 3.5, 4.0, and 4.5 mm) were constructed from stainless steel and currently undergoing testing. In order to facilitate a comparative analysis across the two materials, extra experiments were carried out involving a titanium prototype measuring 4.5 mm in length. Similar to Concept 2A, the transfer functions of the commercial TORPs have higher magnitudes generally as shown in Fig. 28. However, for the prototypes, the curves from high to low are 4.5, 3.5, 3.0 and 4.0 mm, in which the order differs from that of Concept 2A, as will be discussed in the next section.

In Fig. 29, a comparable pattern is observed in terms of material properties. The curves, from uppermost to lowermost, represent commercial TORPs, TORP composed of titanium, and TORP composed of stainless steel. In this case, the curves of commercial TORPs and titanium TORP have almost identical magnitudes in lower frequency range, i.e., 100 to 930 Hz. The average differences in frequencies below 1100 Hz are approximately 120 mm/s/V, exceeding the discrepancies observed in Concept 2A.

Simplicity

Although the bends were already prepared for the surgical procedure, it was possible that the length of a TORP may not precisely match the individual middle ear anatomy. Con-

Figure 27: The physical prototype of Concept 2B of different lengths. From top left to bottom right, the length is 4.5, 4.0, 3.5 and 3.0 mm.

sequently, surgeons often need to make minor adaptations to the zigzagged bend before implanting the prosthesis. This iterative adjustment process is relatively swift, which is estimated within 5 minutes, due to the pre-existing bend. Therefore, the outcome in the category of simplicity was assigned an ideal value.

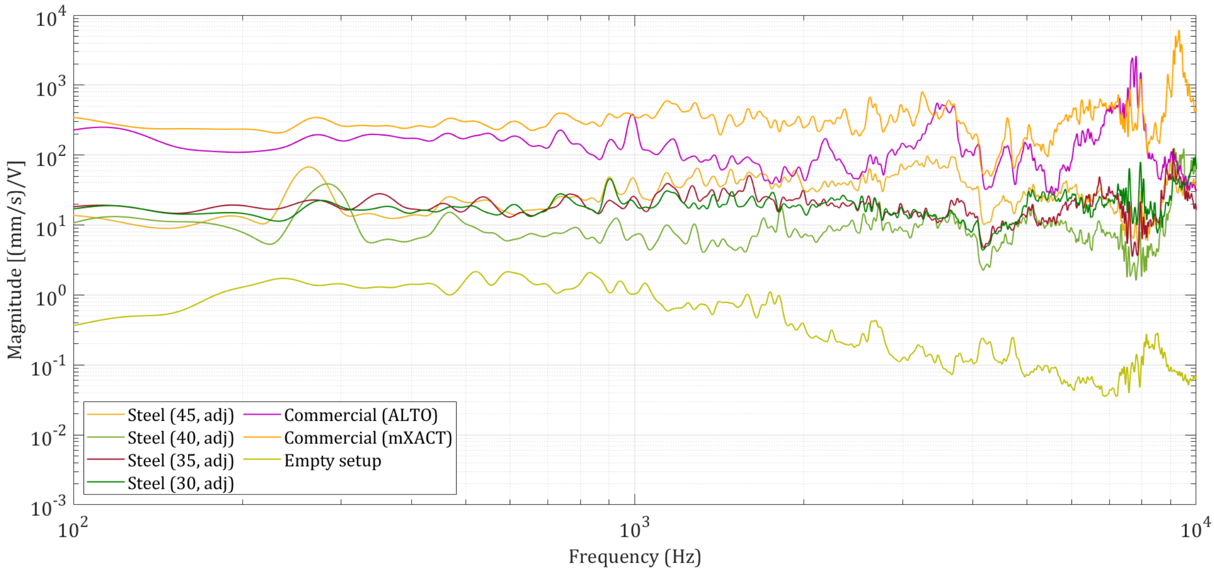


Figure 28: The transfer functions of the Concept 2B (laser cut TORPs with adjustable shafts) with lengths from 3.0 to 4.5 mm, commercial TORPs and empty setup

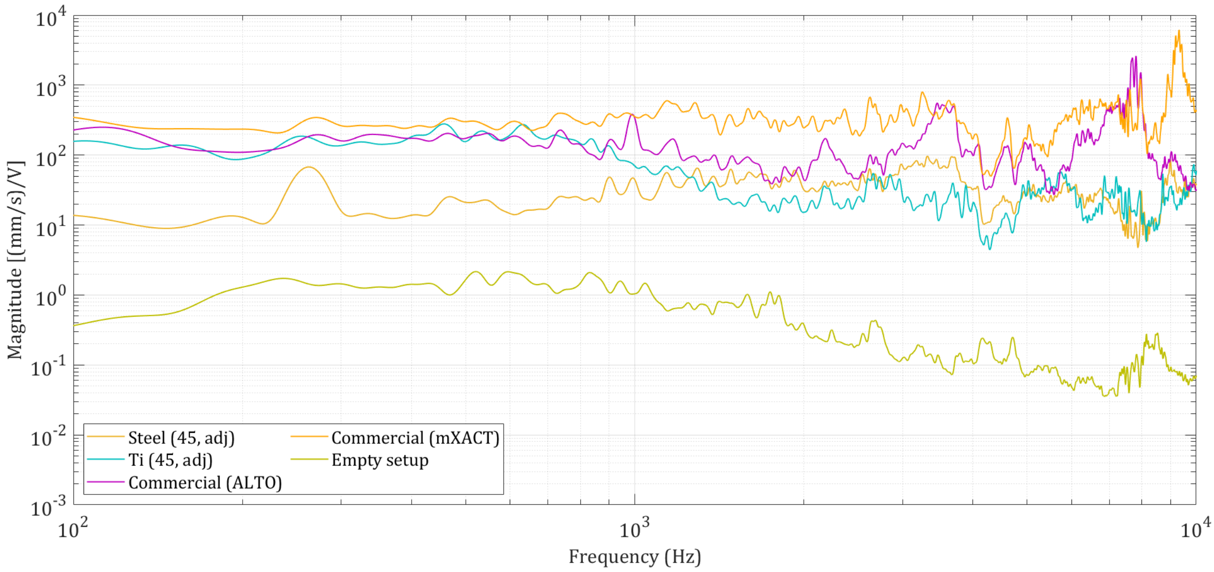


Figure 29: The transfer functions of the Concept 2B (laser cut TORPs with adjustable shafts) made of stainless steel and titanium, comparing with commercial TORPs and empty setup

Based on the above results, the final solution(s) could be selected and further developed. As shown in Table 5, the red texts indicate where the marginal value is not attained, and therefore the concept is excluded from the final solution and further discussed in the next section.

Criteria	**ALTO Dornhoffer**	**Concept 1 (3DP)**	**Concept 2A (laser cut, fixed shaft)**	**Concept 2B (laser cut, adjustable shaft)**
Affordability	Over 10 euros	Min. 29 euros	3.5 euros	0.9 euros
Manufacturing Process	Grade 2	Grade 1	Grade 1	Grade 1
Precision	-	2.51 %	2.22 %	2.33 %
Sound Transmission Property	-	0.98%	1.64%	1.64%
Simplicity (Preparation Time)	5 min.	None	None	5 min.

Table 5: Summary of the evaluated performances of the three concepts and the commercial product (ALTO Dornhoffer).

7 Discussion

Three concept solutions were generated in order to improve the usage of TORPs in LMICs in the aspects of affordability, manufacturing process, precision, sound transmission property and simplicity. In Table 5, the assessment results of the three designs were listed. Concept 1 exhibited an optimal sound transmission rate close to the commercial TORPs, featuring a stable structure and no preparation time. However, the expenses associated with 3D printing surpassed the marginal cost, and the use of Ti6Al4V material posed challenges in achieving the desired surface finish. In contrast, Concept 2A and 2B demonstrated favorable performance across most criteria. Nevertheless, the magnitudes of their transfer functions were comparatively smaller than those of the commercial counterparts, implying a somewhat reduced sound transmission capability. Notably, laser-cut TORPs proved to be a highly cost-effective alternative when compared to currently available middle ear implants. More detailed discussions based on individual concepts and specific criteria were conducted below.

7.1 Comparison to Commercial TORP Product

For the commercial product, ALTO Dornhoffer was considered the benchmark. The cost of ALTO Dornhoffer significantly exceeded its marginal value. Sound transmission property and precision were assumed to meet the standard and therefore not assessed. Despite the manufacturing process and simplicity achieving the ideal outcomes, the ALTO Dornhoffer TORP was deemed unsuitable for implementation in LMICs for this particular project.

As for Concept 1 (3DP TORP), it was excluded from the final solutions due to its cost surpassing the marginal value. Additionally, the labor-intensive surface finishing process hindered its viability as a potential commercial product despite of meeting the marginal performance for the manufacturing process criterion. Concerning transmission properties (see Fig. 30), it demonstrated a very similar behavior as the commercial TORP, which was mentioned in the previous section and therefore regarded as ideal. Precision and simplicity also aligned with the ideal values.

Regarding Concept 2A (laser cut TORP with fixed shaft), both the affordability and simplicity successfully met the ideal values. The post-processing involving bending was found to be acceptable using the bending mold, and therefore leading to a marginal performance for manufacturing process. As for precision, the error was small enough to meet the ideal value. However, the footplate occasionally exceeded the maximum width due to inconsistent manual bending. Based on the transfer functions, observations showed that the trend exhibited lower magnitudes at frequencies below 1700 Hz when compared to the commercial TORP. In contrast, for higher frequencies, the magnitudes of the curves were largely similar, although some minor oscillations were not perfectly aligned. When titanium was utilized as the material as Fig. 31, it demonstrated a behavior more closely resembled that of the commercial TORP. This observation suggests an ideal sound transmission rate for this concept solution.

Similarly, Concept 2B (laser cut TORP with adjustable shaft) had ideal performances in cost and preparation time, and a marginal one for manufacturing process. A slightly longer bending procedure was required due to the bent shafts. This ultimately contributed to a reduction in costs as it enabled the production of a single prosthesis size, subsequently customized to the desired lengths, rather than the manufacture of multiple lengths. As for precision, laser cutting successfully achieved high accuracy for the head and footplate diameters, resulting in negligible errors that align with the ideal specifications. However, excessive increases in dimensions were also observed for the footplate widths due to manual bending. For sound transmission property, the transfer functions acted very close to those of Concept 2A except for a lower magnitude in higher frequencies. Therefore, this criterion was considered ideal as well.

In conclusion, Concept 2A and 2B were both considered the final solutions for this project, as they fulfilled the predetermined assessing criteria.

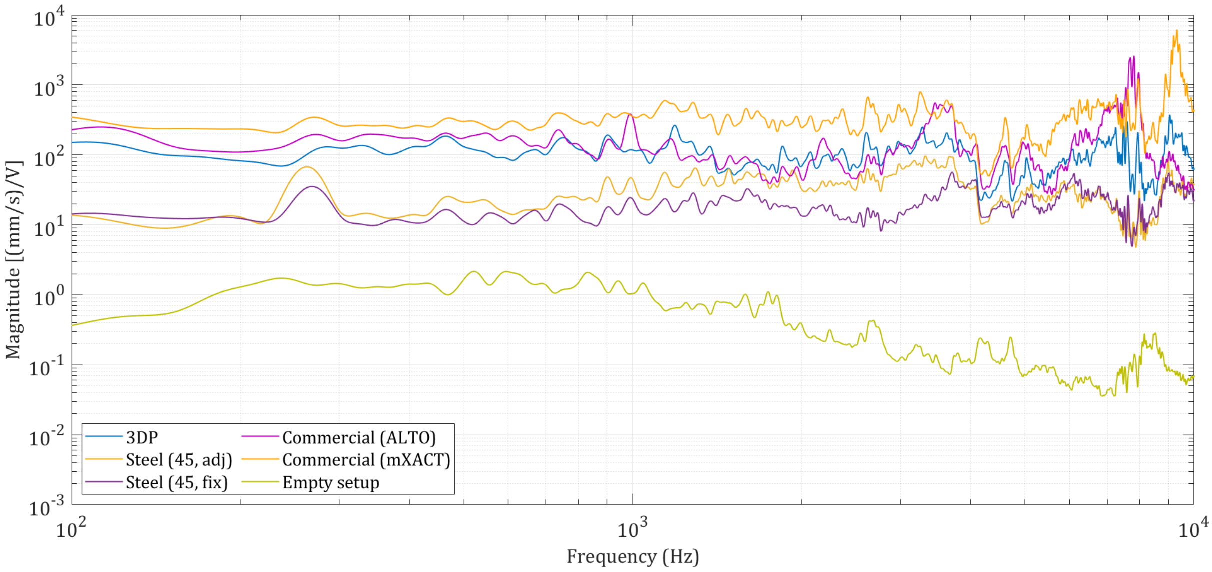


Figure 30: The transfer functions of Concept 1, Concept 2A and 2B made of stainless steel, commercial TORPs and empty setup

7.1.1 Discussion of Precision Measurement

As discussed in the above section, for Concept 2A and 2B, an additional critical dimension was being assessed, which was the distance from the footplate to the opposing bending edge. This assessment aimed to ensure that all dimensions remained within the prescribed limit of 1.0 mm, which corresponded to the width of the stapes footplate. As shown in Table 12, only four TORPs met these criteria. Nevertheless, these concepts were retained as the final solutions. The reason behind this decision was that achieving a single successful outcome was sufficient to establish the feasibility, as the bending procedure for footplate was the same for every laser cut TORP. However, it is advisable to consider more careful bending or to implement a systematic procedure in the future.

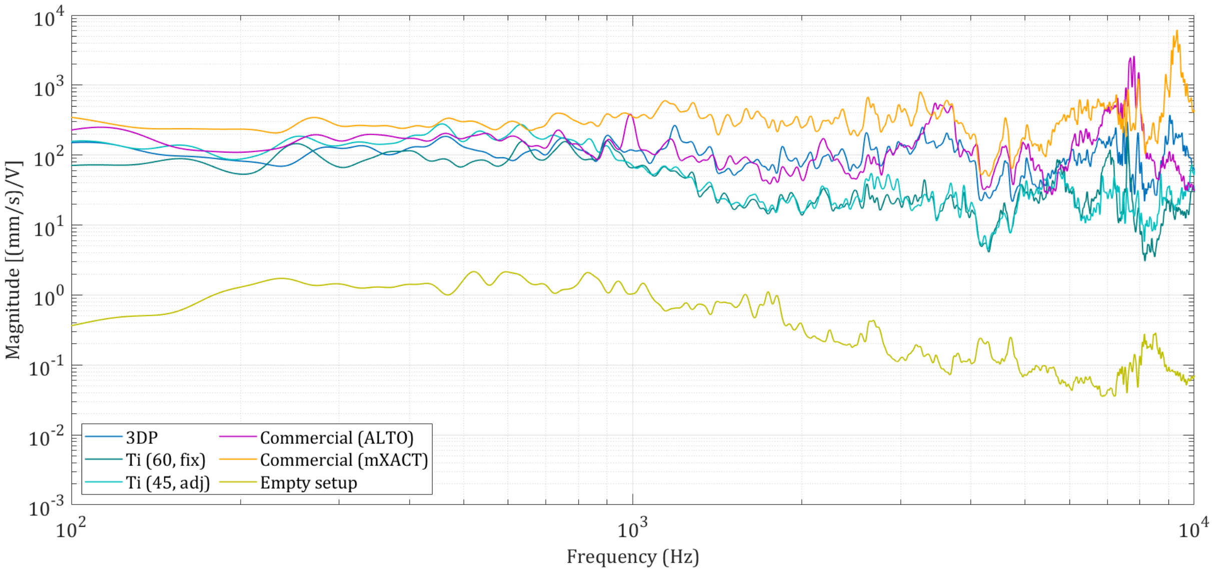


Figure 31: The transfer functions of Concept 1, Concept 2A and 2B made of titanium, commercial TORPs and empty setup

7.1.2 Discussion of Sound Transmission Results

For the sound transmission experiments, there were some aspects requiring discussion. Firstly, for all the TORPs, Oscillations became increasingly pronounced above 4 kHz. This observation indicates the challenge of measuring higher frequencies, and it is often encountered in previous literature. Koch et al. (2022) [14] indicated the reason might be LDV cannot effectively capture higher order modes of footplate movements, such as rocking, tilting, or rotational motion. And this limitation becomes particularly noticeable at higher frequencies (≥ 2 kHz), where the footplate movements significantly contribute to the overall movement of the stapes. However, despite of this limitation, the widespread adoption of this method can be attributed to its straightforward and practical application, making it one of the most commonly used techniques worldwide for determining middle ear transfer functions.

Secondly, when comparing different lengths for Concept 2A or 2B, there was no obvious order of transfer function magnitudes based on the lengths. During the literature study, it is known that the enhanced stiffness and reduced weight significantly enhance the transmission efficacy of TORP, which demonstrated the reason behind titanium being regarded as one of the most preferred materials for these implantable devices [15, 16]. Thus, for Concept 2A, ideally, the curve with the highest magnitude should correspond to the 3.0 mm TORP, as it features the least mass while maintaining identical stiffness in the fixed shafts. For Concept 2B, the different zigzagged structures lead to higher stiffness for longer TORPs, which have smaller bends. Therefore, ideally, the magnitudes from high to low should be TORPs in 4.5 to 3.0 mm. However, the difference in bending structures might lead to performances deviating from the statement, as entirely identical bending structures were not achievable in the current stage. (The masses are listed in Table 10 in Appendix D.

Thirdly, when comparing the titanium and stainless steel TORPs for Concept 2A and 2B, the titanium TORPs showed much higher magnitude in lower frequencies in both cases. The reason might be the stiffness or acoustic impedance of stainless steel is larger, resulting in a lower degree of vibration. Furthermore, mechanical strength is crucial for TORPs to withstand the mechanical loads and stresses within the middle ear. Stainless steel generally exhibits higher mechanical strength compared to Titanium Grade 2 [17]. For instance, the tensile strength of pure titanium is typically around 240 MPa, whereas stainless steel can vary widely, with 301 stainless steels having tensile strengths 1500-1700 MPa [17]. The acoustic properties of the implant material also play a role in sound transmission within the middle ear. Stainless steel has a higher acoustic impedance compared to titanium grade 2 [18]. Acoustic impedance mismatch between the implant and surrounding tissues can affect auditory outcomes. Titanium's closer acoustic impedance to that of bone and tissue makes it more suitable for TORPs, promoting better sound transmission and overall auditory performance. The differences were carefully taken into consideration, and both materials would be tested thoroughly. However, in conclusion, the stainless steel TORP exhibited slightly lower but comparable transfer functions to those of the commercial ones. Therefore, the corresponding titanium TORPs, which presented even better sound transmission results, were considered feasible as well.

Lastly, when comparing Concept 2A and 2B, which are the two variations of the laser cut TORP, the relationships were different for the four different lengths, as shown in Fig. 32. For 4.5 mm TORPs, the ones with adjustable shaft exhibited slightly greater magnitude compared to their counterparts with a fixed shaft. With nearly identical mass characteristics in this scenario, the sound transmission rate of Concept 2B seemed to be higher than that of Concept 2A in the current experiment setting. In the cases of 4.0 and 3.5 mm, the mass differences between Concept 2A and 2B became more pronounced, which might compensate the better transmission property and ultimately yield comparable magnitudes in their transfer functions. Finally, the 3.0 mm TORPs marked a pivotal point, with a significant 2.3 mg mass difference (refer to Table 10, Appendix D). In this case, the lightweight structural configuration of Concept 2A prevailed, resulting in a significantly larger magnitude. In summary, the assessment of the transfer functions of Concept 2A and 2B across varying TORP lengths revealed distinct dynamics shaped by the interplay of mass differentials and structure considerations.

7.2 Limitations and Future Directions

To further ensure the clinical application of the designed TORPs, future works have to be done to enhance the properties and minimize the efforts during surgeries and the costs based on the current limitations.

First of all, for Concept 1, a more systematic way of surface finishing can be arranged. For now, only sandpaper was used to reduce roughness on the titanium surface. Due the small dimension, some locations such as the corners and inner surface of the headplate ring were difficult to handle. Furthermore, manual finishing was difficult to control the degree of material removal as only visual inspection was adopted. Thus, some locations ended up to be thinner than the others after finishing, which might weaken the structure. Uniform sanding technique can be developed to ensure even pressure, stroke length, and sanding direction. This minimizes the variations in size and smoothness across different parts. Moreover, a sequence of sandpaper grits that progressively decrease in coarseness can be

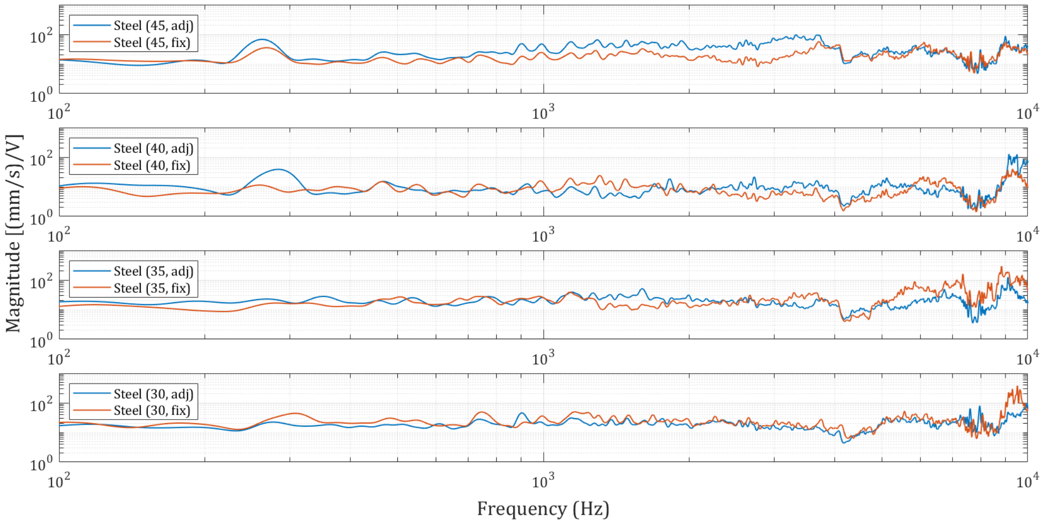


Figure 32: The comparison of the transfer functions of Concept 2A and 2B made of stainless steel for different lengths from 4.5 to 3.0 mm.

arranged. It is better to start with a coarser grit to remove imperfections and then move to finer grits for refining the finish. It is also recommended to consult finish-specialists working in a dental lab or in the jewelry industry on the methods of precise finishing of titanium other then sanding. To ensure the quality of the surface is comparable to commercial products, measurements such as laser scanning confocal microscopy and optical interferometry can be used to check the roughness without physically touching the surface.

Other than generating a systematic finishing method, an alternative SLM printing method can be adopted to eliminate the usage of supporting structures. For the plates, a larger radius or fillet with suitable angle can be adopted on the connection to the shaft. As for the thin shaft, a thicker diameter can be used as long as the visualization remains clear. However, the mass difference might change the sound transmission property and thus experiments and evaluation have to be conducted again.

There were several shortcomings of the laser cut TORPs in general which could be improved. For example, the bending of the footplate was difficult to locate at the center of the circle due to the small size. This occasionally resulted in the length exceeding 1.0 mm from the bending edge to the other side. And the bend could not reach 90 degrees.

As for Concept 2B, a more convenient bending tool can be designed for the surgeons to shorten the preparation time. In this project, a simple bending tool consisted of a mold and pressing tools with different sizes. But due to the small dimension, it often took longer time for alignment and fixation of the TORP pieces. An idea is to develop a stapler-like tool, on which the TORP can be fixed and aligned. The user can change the angle of pressing to adjust the shaft length according to the individual anatomy. Moreover, the procedures for bending the plates and the main shaft can be integrated into the same tool for simplification. However, the cost of the new bending tool set should also be affordable for LMICs.

Regarding the assessment methods, improvements can be made for the sound transmission experiments. Firstly, there is potential for redesigning and constructing the MMM using more robust materials instead of conventional 3D printing techniques. This alteration aims to enhance sound isolation and similarity to human middle ears. This might lead to improved repeatability of the results. Furthermore, there is an opportunity to enhance the analysis of transfer functions by expanding the dataset, thereby ensuring the repeatability of experimental results. Additionally, more suitable alignment, filtering, or averaging techniques can be explored if necessary.

In general, there are important procedures before the final concepts turn into approved prosthesis, such as sterilization, quality control, risk assessment, etc. In the sterilization phase, it is imperative to ensure that the chosen material is compatible with the selected sterilization method. Some materials may experience degradation or altered properties due to specific sterilization processes. Furthermore, the decision includes a range of factors, including the method's effectiveness in eliminating microorganisms, equipment availability, cost implications, and potential impacts on the TORP's structural and functional attributes.

Since the adopted manufacturing methods are rarely found in LMICs today, packaging and delivery are important as well. The selection of packaging materials must ensure that the TORP remains free from contamination and retains sterility during storage and transportation. The packaging design itself should provide secure housing for the TORP, safeguarding it against damage during handling and transport. Delivery logistics require meticulous planning. Determining the appropriate distribution channels, transportation methods, and storage conditions are essential to ensure the TORP's safe arrival at its destination.

8 Conclusion

The primary objective of this project is to develop an innovative Total Ossicular Replacement Prosthesis (TORP) design tailored for implementation in low- and middle-income countries (LMICs). The study introduced three distinct concept solutions that were assessed against five pre-established criteria. Concept 1 was created using selective laser melting (SLM), a subset of additive manufacturing (AM or 3DP). On the other hand, Concept 2 was created through precision laser cutting, featuring two variations: Concept 2A with a fixed shaft and Concept 2B with an adjustable shaft.

The evaluation results highlighted that Concepts 2A and 2B demonstrated greater promise for TORP designs. They exhibited associated costs of 3.5 and 0.9 euros, dimensional deviations of 2.22 % and 2.33 %, preparation times of 0 and 5 minutes, and performance levels in the manufacturing process and sound transmission that were nearly comparable to commercial products. Potential enhancements for the future include the development of a more user-friendly bending tool to ensure precise bending and alignment of the head and footplates and more comprehensive experiments for sound transmission property.

In summary, the findings indicate that Concept 2A and 2B using precision laser cutting outperformed the other options within the scope of the problem.

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Appendices

A Literature Study Report

The following literature study report was conducted as an initial review and data collection phase in preparation for the thesis project. It should be noted that only the substantive content has been included in the Appendix, while the title, table of contents, reference list, etc. were excluded. The numbering is independent of the report. Furthermore, it was graded separately prior to the submission of this report.

1 Introduction

When the ossicular chain is damaged and both malleus and incus are missing or nonfunctional, a total ossicular replacement prosthesis (TORP) can be installed to reconstruct the hearing conduction. TORP has been rapidly developing these days, and plenty shapes and materials have been investigated to improve the technology. For example, Grace Medical developed the ALTO system, see Fig. 33 (a), which has already been used clinically [1]. Due to its adjustability, surgeons can rapidly size the prosthesis during surgeries using the ALTO adjuster. This flexible design largely reduces the inventory and costs. Similar concepts were also delivered by SPIGGLE & THEIS in Fig. 33 (b) [2]. The shaft can be trimmed, and the shortened end is covered afterwards by either the shoe or the head to avoid sharp edges. Kurz introduced additional sizers to measure the distance between the malleus and the oval window, which ensures desired installation (see Fig. 33 (c)) [3].

(a) Grace Medical **(b)** SPIGGLE & THEIS **(c)** Kurz

Figure 33: Existing commercial TORP products

However, in low- and middle-income countries (LMIC), most of the current designs are not available locally because of the costs. The material and manufacturing technology of the designed TORP has to be locally available or can be ordered and shipped with a low cost. And the design should be easy enough to allow simple operation so the procedures can be easily learned by the local surgeons.

The purpose of this literature study is to gain more insights in the current manufacturing methods of small-sized parts in general due to the limited publications regarding TORP. According to the previous studies from Geert ten Have [4], the more suitable material is pure titanium for its higher stiffness, lighter mass, lower risks of failure, good biocompatibility, etc., and thus the scope is narrowed down. After this research, it is assume several cost-efficient manufacturing techniques which are available for LMIC will be concluded, refined and adopted in the further thesis study.

The research question is formulated broadly as: *"What are the more cost-effective methods to produce precision titanium products in LMIC?"* The researching direction should also be aimed to answer the sub-questions: *"By what manufacturing methods? In what shape/design? Does it fulfill the requirements for TORP materials?"* And the time range is set between 2002 and 2022. In this report, the background and the usage in LMICs of TORP are firstly mentioned in Section 1, along with the aim of this study and the work done previously. In Section 2, the methodology of collecting relevant articles is explained, and the assessing criteria are determined. Then the referenced manufacturing methods are introduced, analized and evaluated in Section 3 in the aspects of general titanium and TORP production. These methods are further compared with one another in Section 4. The direction and limitations of the possible solutions are suggested based on one or multiple existing methods. Finally, the conclusion is reached in Section 5.

2 Methodology

2.1 Search Strategy

To systematically access most of the information regarding the research topic, the PICO tool [5] was firstly used to frame the research question into possible searching terms (see Table 6). As the research type was majorly fixed in qualitative studies instead of qualitative and mixed ones, PICOS and SPIDER tool were not required for this study. And then the searching strings were constructed individually for the 3 databases used: Scopus, PubMed and IEEE Xplore, as shown in Table 7. Other than the literature publications, grey literature was also added via Google web search to include as many alternatives as possible and to ensure this study is up-to-date.

	Description	**Search terms**
P	Precision titanium products	Titanium AND (small-sized OR mini* OR tiny OR precis*)
I	Manufacturing methods	Manufact* OR prototype* OR produc* OR machin OR model* OR shap*
C	All existing methods	-
O	More cost-effective solutions	Cheap OR low-cost OR low-price* OR affordable OR inexpensive

Table 6: PICO framing

Database	**Searching string**
Scopus	TITLE-ABS (titanium) AND TITLE-ABS (small-sized OR mini* OR tiny OR precis*) AND (manufactur* OR prototyp* OR produc* OR machin* OR model* OR shap*) AND (cheap OR low-cost OR low-price* OR affordable OR inexpensive) AND NOT (electrode OR lithograph*) AND LANGUAGE (english) AND PUBYEAR > 2001 AND PUBYEAR < 2023 AND (LIMIT-TO (OA , "all"))
Pubmed	(titanium[tiab]) AND (small[tiab] OR mini*[tiab] OR tiny[tiab] OR precis*[tiab]) AND (manufactur* OR prototyp* OR produc* OR machin* OR model* OR shap*) AND (cheap OR low-cost OR low-price* OR affordable OR inexpensive) NOT (electrode OR lithograph*) AND english[la] AND 2002:2022[dp]
IEEE	("Document Title":titanium OR "Abstract":titanium) AND (manufactur* OR prototyp* OR produc* OR machin* OR model* OR shap*) AND (low-cost OR low-price* OR affordable OR inexpensive)

Table 7: Searching strings for the 3 databases

*Study Selection Process
After all literature with open access was gathered, irrelevant ones were deleted initially based on the title and abstract. The 91 articles left were then undergone full-text selection process using the below inclusion and exclusion criteria. Finally, 65 articles were used in this review. And the PRISMA flow diagram is shown in Fig. 34.

2.1.1 Inclusion Criteria

If the candidates contain any kind of manufacturing methods of pure titanium or titanium alloys and were published between 2002-2022, they would be included in the research. Not

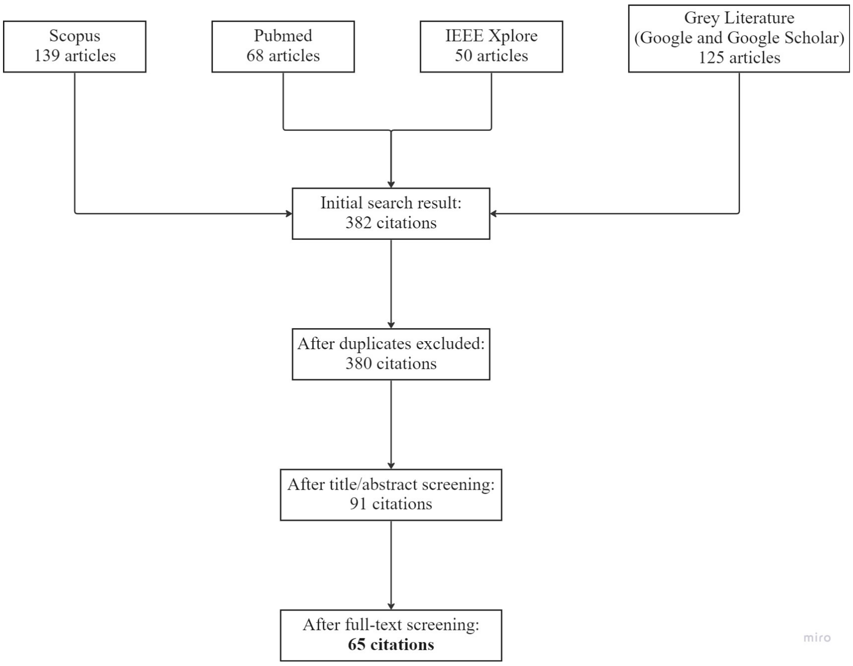


Figure 34: PRISMA flow diagram

only journal papers, but grey literature, such as international standards, thesis studies, product catalog, etc., were added for a wider perspective. Grey literature was gathered via Google and Google Scholar. Pertinent articles referenced in the selected ones were also used.

2.1.2 Exclusion Criteria

Apart from the literature outside of the defined scope, contents focusing on the below aspects were discarded. Articles in languages other than English were also excluded.

- Material comparison: When the research only compares titanium with other materials and proposes alternative material for manufacturing.
- Irrelevant materials: When the research only uses materials other than pure titanium or titanium alloys.
- Alloying process: When the research mainly elaborates and tries to improve the process or outcome of titanium alloying.
- Semiconductor fabrication: When the research only focuses on semiconductor process, including oxidization, wafer processing, lithography, ionization or any related operations which involve the usage of titanium.

2.2 Assessing Criteria

2.2.1 Criteria Definition

The goal of this systematic review is to obtain the optimal solutions to manufacturing precision titanium products cost-efficiently, which can be adopted to TORP production in LMIC. Thus, assessment is required to compare the existing methods, and the assessing criteria should meet the following:

- Affordability: The manufacturing technique should be financially affordable in LMIC. The local facilities should be possible to independently produce the products, or the products can be ordered and shipped at affordable cost. According to previous study, the fabrication cost of the mold is approximately \$980, while the cost of each TORP is \$1.2.
- Physical/mechanical properties: The products manufactured by the technique should possess adequate physical/mechanical properties for TORP. Pure titanium already acquires low density, good corrosion resistance, non-magnetic property, etc. However, with different processing methods, characteristics can be changed or improved, such as density, thermal expansion, biocompatibility, tensile strength (stiffness, ductility, fatigue, etc.), hardness, etc. [6]
- Simplicity: The amount of processing steps and the duration of processing time of the manufacturing technique should be minimal or optimal. It is also considered if the technique is a near-net-shape process, if extra polishing/finishing is required, or if extra machines/tools are needed.
- Precision: The manufacturing method should possess high dimensional accuracy even when producing tiny parts.

2.2.2 Relevant Tests and Measurements

Some of the assessing criteria require quantitative research and data for evaluation, such as the physical and mechanical properties. And the corresponding tests and measuring methods are introduced below.

Implants must meet strict standards to ensure high safety level, and there are special requirements for precise prostheses like TORP. In the physical aspect, several properties are considered. For example, density of the titanium will determine the mass and improve the image quality of computed tomography, such as magnetic resonance imaging (MRI) and X-ray. Moreover, density similar to human bones maintains the biological skeletal structure, which reduces the stress shielding phenomenon. Apart from calculating from the mass and volume, density can be measured by gas pycnometer for porous structures [7]. Thermal properties can be measured by differential scanning calorimetry (DSC) or differential thermal analysis (DTA) for temperature at the transitions [8], or by a dilatometer for temperature expansion. Surface structure and roughness determine the biocompatibility which facilitates recovery and reduces the possibility of infection. And those properties can be measured by a profilometer, a scanning electron microscope (SEM) or an X-ray photoelectron spectrometer (XPS) for microstructure [9].

Young's modulus can be obtained by a tensile test, and thus the stiffness, elasticity, ductility, tensile strength and corresponding mechanical properties are known, which are important for safety reasons. Hardness controls the resistance to wear and erosion. And it can be measured by Vickers hardness tester. Push-in and push-out tests are adopted to check the mechanical stability of the implants [10].

3 Results

Based on the nature of the general manufacturing methods, they are divided into powder metallurgy (PM), metal injection molding (MIM), additive manufacturing (AM) and metal forming [11]. Post processing such as machining and surface processing are also introduced, but not assessed as they are not required in all cases. Among the included citations, 12 articles were about PM, 5 were about MIM, 26 were about AM, 9 were about metal forming and 26 were about different machining methods, surface processing and finishing. Some literature covers multiple contents.

3.1 General Manufacturing Methods of Titanium and Assessment

3.1.1 Powder Metallurgy

PM, a metal-forming technology, has been widely applied on titanium manufacturing nowadays. The process consists of 3 steps: powder production, powder compaction and sintering. Firstly, the materials are manufactured into powders and mixed into uniform blend. After the powders are filled into dies or molds, they are pressed into the desired shape. Finally, the parts are placed into a furnace to be sintered and to achieve appropriate properties. Each of the steps can significantly change the densification, and therefore the properties of the manufactured parts [12].

Powder production can be divided in to 2 categories: blended elemental (BE) and pre-alloyed (PA) approach [13]. The differences in procedures between them and conventional wrought method are shown in Fig. 35 [13]. The lower hardness of BE powders leads to poorer properties of the products [13, 14, 15], and thus post heat treatments are required for improvement. One way is thermomechanical processing (TMP), e.g., forging and extruding, which effectively closes the residual pores. As for PA, powders are sintered before pressing, so pressure-assisted consolidation is required, which largely increases the cost. The compaction of powders could help achieve fully dense PM products if the green density was high enough [16].

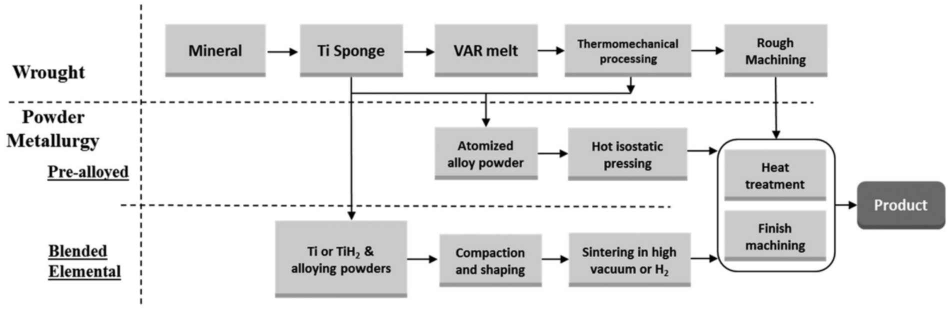


Figure 35: Comparison between wrought, BE and PA approaches [13]

After powder production, PM can be categorized into pressureless sintering, pressure-assisted consolidation and hot consolidation. Pressureless sintering includes vacuum and inert gas sintering, while the former is far more common, despite of its limitation of batch processing, than the latter. Hydrogen sintering was proposed by Li et al (2022). [17] as an alternative to vacuum sintering but causing lower hardness. Pressure-assisted consolidation covers hot isostatic pressing (HIP), vacuum hot pressing (VHP) and CIP-sinter-HIP (CHIP) process. Among all, HIP is the most common treatment. It allows densification of the products under lower temperature due to its isostatic nature. The mechanical properties can be further improved with TMP following. Alshammari and Bolzoni (2019) [18] observed the yield strength and hardness greatly increased with a β forging step. VHP was reported only beneficial to PA but not BE powders for small-amount plate production [19, 13]. And CHIP is a sustainable method and produces fully dense titanium alloys. As for hot consolidation, microwave (MW) sintering, spark plasma sintering (SPS), etc. were found introduced in the cited articles. According to Luo et al. (2012) [8], MW heating could reduce the thermal cycle time and improve mechanical properties if SiC susceptors were adopted to control the erratic heating of titanium. SPS showed much better mechanical properties then wrought pure titanium due to the further densification achieved by pulsed electric current and a higher cooling rate [13, 20]. Apart from the above, Vivek et al. (2014) [21] suggested the high velocity compaction technique by a vaporizing foil actuator (VFA), which led to even higher densification than the conventional methods such as HIP.

Although minimizing residual pores is optimal, designed pores can reduce the implant weight and mimic human bone properties. The technique is often limited to AM but can also be achieved by PM if introducing space holder. The procedure is shown in Fig. 36 [22] and includes: (1) Mixing metal powder and space holder particles with bonding but no reactions. (2) Densifying the mixture by axial pressing. (3) Removing space holder by a catalytic process. (4) Sintering. ArDabrowski et al. (2010) [23] suggested paraformaldehyde as space holder for its inertness with titanium and the ability to decompose under low temperature. Higher permeability (allowing bone ingrowth), lower Young's modulus, lower yield and ultimate strength (preventing stress shielding effect) were observed after adding the pores. A lower corrosion resistance was induced but could be solved by surface modification. Ryan et al. (2008) [24] demonstrated the potential of using wax model as space holder with titanium slurry instead of powders to control porosity.

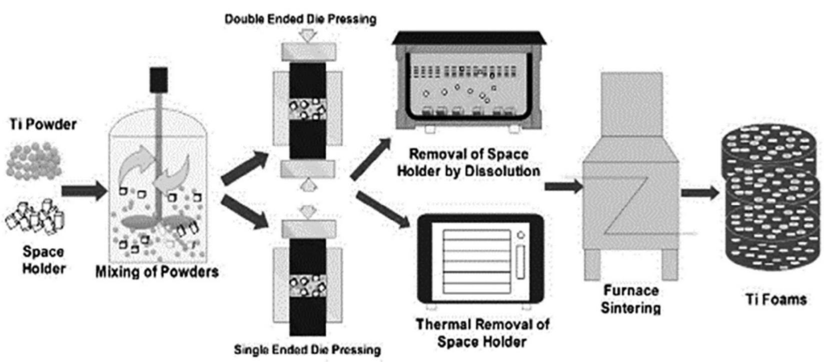


Figure 36: Procedure of PM with space holder [22]

Compared to the other manufacturing methods, PM has the advantage of lower fabrication costs due to its low energy consumption and less material wastes. But the investment in the machinery for the 3 steps is high. It is also capable of creating net- or near-net-shape parts with reduced machining operations and good surface finishing [14]. Thus, based on the assessing criteria set in Section 2, PM is assumed to have moderate affordability and simplicity (low processing time). The physical/mechanical properties differ depending on the methods used for powder production, compaction and sintering. And the usage of powder allows precise manufacturing, reaching a minimum dimension of around 1.5 mm. However, the accuracy is not optimal, and it often requires post machining.

3.1.2 Metal Injection Molding

As a subdivision of PM, MIM is another consolidation method which mixes metal powder with binder to copy industrial plastic injection molding. It consists of 4 steps: (1) Feedstock production (2) Injection molding (3) De-binding (4) Sintering [13]. More detail procedures can be seen in Fig. 37 [25]. Kadir et al. (2018) [26] emphasized the importance of the rheological properties of the feedstock. As the viscosity increased, the molding temperature would also be increased to ensure flowability and thus caused separation between powders and binder. Two-component metal injection molding (2C-MIM) was adopted by Mulser et al. (2012) [27] to join titanium to stainless steel. Large shrinkage difference between the 2 metals was observed but could be improved by adjusting the sintering temperature and particle size. Different from PM, MIM is suitable for mass production of smaller and more complicated products. However, the removal of binder could lead to distortion. Post treatments such as HIP and shot peening are then adopted to eliminate residual pores or crack initiation.

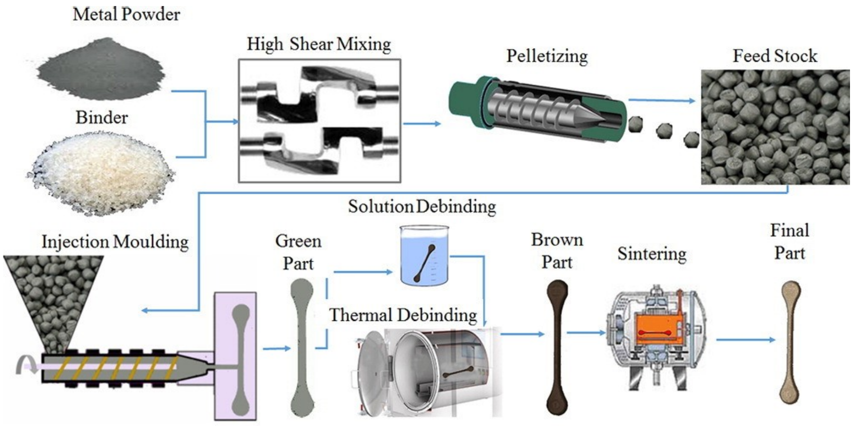


Figure 37: Procedure of MIM [25]

Assessed by the criteria above, MIM is rapid and can achieve good physical/mechanical properties with post treatments. However, it is less affordable under the nature of customized and small-volume production [28]. And the imprecision leads to complexity of the process despite that MIM might achieve small dimension as 2 mm.

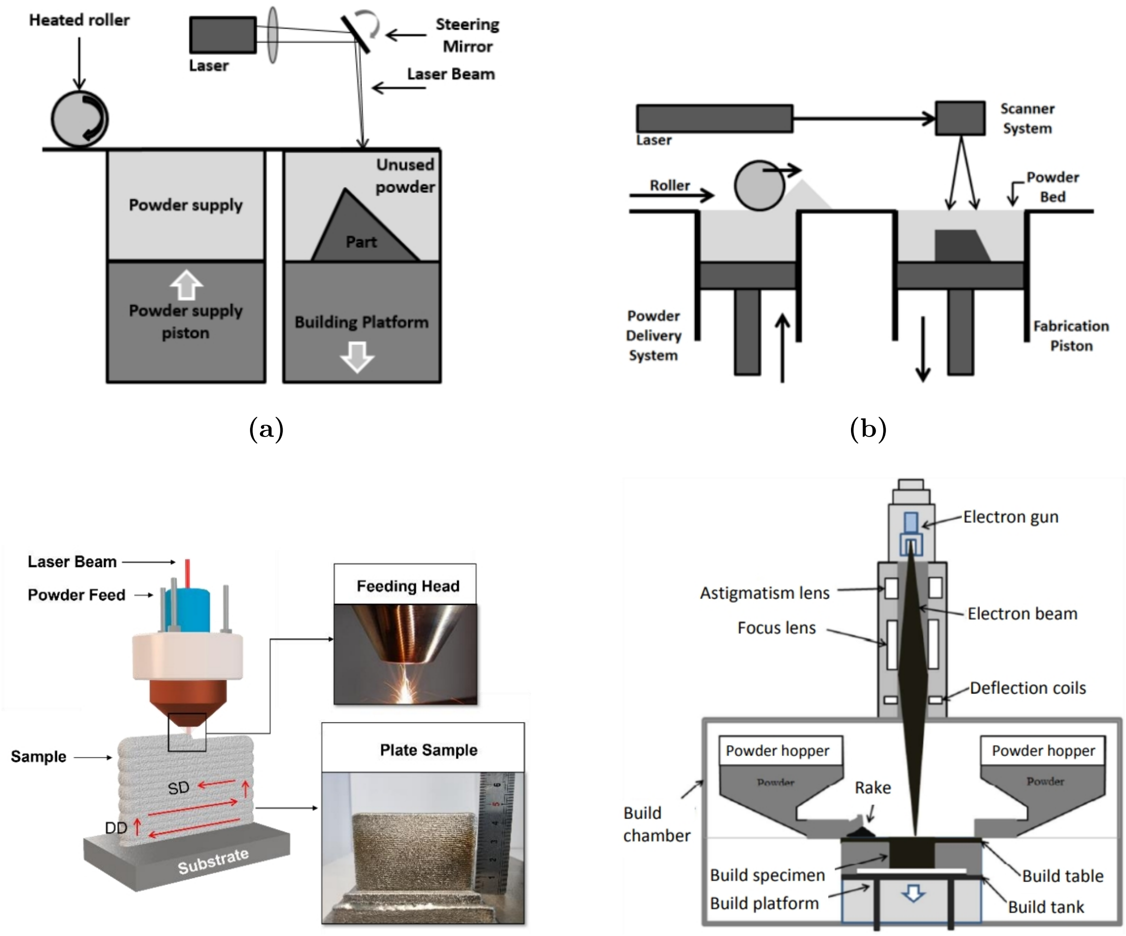
3.1.3 Additive Manufacturing

AM, or 3D printing, is a suitable option for customized, complicated and small-batch products. The whole process contains profiling/modeling, printing and post-processing. Firstly, the model can be constructed by computer-aided design (CAD) tools solely or be assisted with fringe projection profilometry [29] or other detection techniques. Complicated surface or internal structures are possible as the parts are printed layer by layer. Post-processing, such as support removal and debinding, might be required in the end.

A common printing process for titanium is powder bed fusion (PBF) which consists of selective laser melting (SLM), selective laser sintering (SLS) and direct metal laser sintering (DMLS). SLM (see Fig. 38 (a) [30]), among all metal printing methods, is used the most widely and has been optimized in different aspects [31]. Parameters such as laser power and diameter, scan speed, energy density, layer thickness, etc. [32] can be tuned to obtain the optimal properties. Depboylu et al. (2022) [31] suggested smaller layer thickness and less energy input could lead to better surface quality and less printing time. And the implant density would drop if the scan speed was too high. Other than the normally-used continuous-wave (CW) laser, Mizuguchi et al. (2021) [33] replaced it with pulsed laser on Ti-6Al-4V and confirmed the desired hardness and crystal grain size could be obtained by adjusting the pulse frequency and duty ratio. Mullen et al. (2009) [34] proposed the unit cell approach, of which the model was created as a bounding box with cuboids of the defined unit cell filled inside. The predetermined compressive strength and porosity for specific body locations could be achieved by changing the unit cell size and shape. Post-processing methods can be used to improve certain properties as well. For example, HIP could minimize pores and increase fatigue resistance [31, 35]. Copper ion and polydopamine (PDA) coating could increase the surface roughness and correspondingly improve the cellular adhesion and scaffold stability [9].

Similar to SLM, SLS (see Fig. 38 (b) [30]) and DMLS, which is a metal-based SLS, require less laser energy as it only needs to achieve temperature below melting point for sintering by very precise laser beam [10, 36, 37]. Although less articles were found for SLS and DMLS, Okazaki and Ashino (2020) [7] confirmed similar properties with implants produced by hot forging were possible, and thus DMLS could be used as an alternative to casting. Post-processing was also proposed by García-Gareta et al. (2017) [38], which increased the bioactivity of the implants by replacing uniform coatings with calcium phosphate (CaP) deposits. Other AM methods, such as electron beam melting (EBM) and laser directed energy deposition (LDED), were also investigated as shown in Fig. 38 (c-d) [39, 40]. EBM was successfully adopted on skull reconstruction by Ameen et al. (2018) [40] with sufficient strength and properties closer to real bones. However, the method was still expensive [41]. LDED, which is not a PBF method, used titanium powder generated by radio frequency plasma (RF) process, producing implants with a better combination of tensile strength and ductility [39].

Despite of the variety of AM methods, general advantages and disadvantages can be summarized. AM possesses unlimited degrees of freedom and can form planned internal structures, such as pores, which leads to implant properties closer to human bones and prevents the stress shielding effects [6, 42]. Usually, no extra tools are needed when printed directly from CAD models. The additive feature allows less waste, compared to traditional subtractive manufacturing. All the above advantages give AM a cost-time competitive characteristic if customized products are expected. Based on the assessing criteria, AM is simple and needs less processing time. The affordability depends on the amount and variation of the products made. Higher costs are expected for mass production, and even for single product as well when compared to conventional methods due to the high costs



(a) (b)

(c) (d)

Figure 38: Schematics of (a) SLM and (b) SLS [30] (c) LDED [39] (d) EBM [40]

of the printing machines. And the physical/mechanical properties are determined by the adopted methods and the printing orientation in some cases [43]. AM can achieve precise dimension up to 0.3 mm but the reliability might require dimension larger than 1 mm.

3.1.4 Metal Forming: Bulk and Sheet Forming

Metal forming deforms the shape of the raw material permanently by compression, shear, tension, etc. Based on the volume-to-surface area ratio, the processes can be divided into bulk and sheet metal forming [44].

Bulk metal forming has higher volume-to-surface area ratio and includes a variety of operations. For example, forging is a conventional metal forming which produces parts stronger than most of other processes. However, the inability of forming complicated and detailed structures often demands additional machining and surface processing and reduces the simplicity. In the articles collected in this review, they were often attached to another manufacturing method, such as PM or AM, to further improve the implant quality. As a post heat treatment mentioned above, forging sealed the residual pores (mainly in the middle instead of near the surface) to increase the density, strength and Vickers hardness and decrease elongation value. Finer lamellar microstructure was also observed due to fast cooling during forging [18, 45]. Gaseous isostatic forging (GIF) was a procedure similar to HIP but with separate heating furnaces for parts before and after pressurization. This allowed to reach higher pressure and reduce the time under high temperature, which increased the production rate [13]. An overall improvement in tensile and fatigue properties were achieved despite of the additional costs. Apart from forging, other cold deformation, such as rolling, compression and severe plastic deformation (SPD) were reported to increase ductility without increasing Young's modulus. However, the increase in Young's modulus was inevitable with the increase of fatigue strength [46, 47]. Some common bulk forming processes, rolling, forging, extrusion and drawing are shown in Fig. 39 [48].

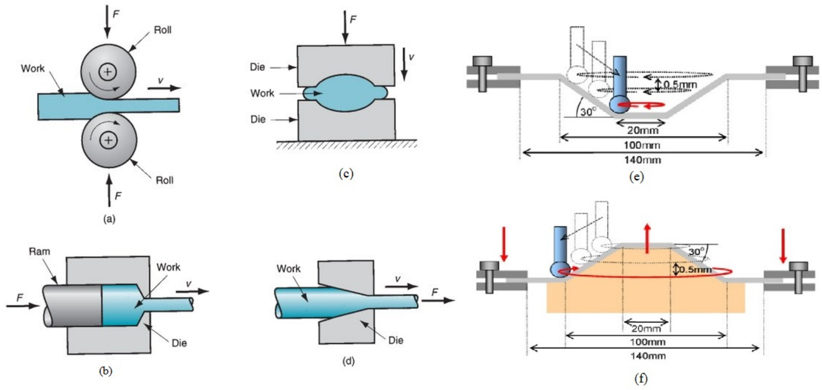
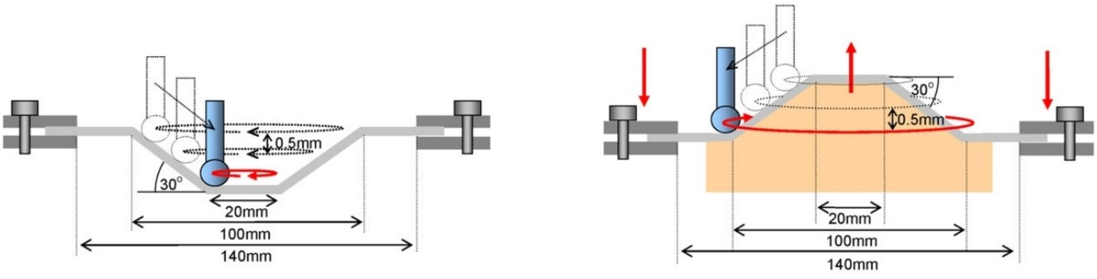


Figure 39: Schematic of (a) rolling (b) forging (c) extrusion and (d) drawing [48]

Unlike bulk forming, sheet forming has a lower volume-to-surface area ratio, and formability is the crucial property which indicates how easy the sheet can be deformed into the desired shape without necking, thinning or fracture [49]. A common process is incremental sheet forming (ISF) which adopts a multi-step process to improve the geometric accuracy compared to traditional ones like stamping, hydroforming and deep drawing [50]. ISF is cheaper to produce one-off shapes and can be simply performed on conventional CNC milling machines [51]. However, early fracture is often observed and thus the parameters including feed rate, friction, tool shape and size, sheet thickness, etc. have to be carefully planned. Sakhtemanian et al. (2018) [52] reported a smaller vertical step down of the tool could decrease thinning effect, decrease hardness and tensile strength, improve surface quality and avoid grain size distortion. But a longer process time was required. Two common methods of ISF are single-point incremental forming (SPIF) and two-point incremental forming (TPIF). A sheet is clamped at the edge during SPIF with a single tool performing indentation, while during TPIF, the tool is performed against another die, support or indenter as shown in Fig. 40 [53].

In conclusion, metal forming is a cheap and fast method to produce parts with good physical/mechanical properties. However, the products often require post treatments such as machining or surface finishing to improve the precision, and thus increase the complexity. The dimension of both bulk and sheet forming can reach a small dimension, fulfilling the requirement of TORP production.



(a) **(b)**

Figure 40: Schematics of (a) SPIF and (b) TPIF with a male die [53]

3.1.5 Post Processing: Machining and Surface Finishing

Most manufacturing methods require post processing, like machining and surface finishing, to refine or improve the part shape or surface. Firstly, machining, or subtractive manufacturing, has a huge variety of operations involving different cutting tools and planning. The common ones are turning, milling, drilling, grinding, abrasive waterjet cutting, wire electrical discharge, etc. [15, 20, 54, 55, 56]. Some processes bring in surfactant or lubricant to improve surface roughness and reduce cutting force [57, 58]. Other than the above, Almeida et al. (2006) [59] introduced laser processing in sheet manufacturing for its advantages of being non-contact (no tool wear), high energy density (smaller heat affected zone), flexibility on parameter control and better edge quality. If the laser power, speed, material, route planning, gas supply (to restrict oxygen reaction), overlapping rate and other parameters were carefully selected, laser processing could be a promising alternative. Tambani et al. (2020) [60] also reported a new technology, green machining, which performed cutting on powder compaction before sintering. Less force was required for it, but the balance between cutting speed and feed rate was crucial to reduce heat generation and achieve better surface roughness.

Other than cutting, joining techniques, like welding and brazing, are also discussed in some articles. Radiation (laser) and tungsten inert gas (TIG) welding were introduced by Rodrigues et al. (2017) [61]. Laser welding used high-energy light beam to melt and join metals, and TIG welding adopted a tungsten electrode to form an electric arc and join parts with the protection of inert gas. Both methods could be used to improve mechanical behavior, but TIG welding was more affordable. On the other hand, Adamus et al. (2015) [56] used electron beam welding (EBW) and observed nonuniformity in the heat-effected zones. Despite that EBW could concentrate the energy to a smaller area, proper planning and/or simulation might be required for better control. Moreover, Jing et al. (2022) [62] adopted vacuum brazing on honeycomb samples and achieved desired balance between strength and ductility of the joints.

Surface finishing and coating are occasionally performed at the end of the manufacturing process. Due to high safety requirements for implants, they are mainly used to improve biocompatibility, consisting of inertness and activeness. Biointertness avoids foreign body response and reduces the possibility of inflammation and bacterial adhesion, while bioactive property increases integration between implant and tissues [6, 47]. The nature of this research is focused on LMIC, and thus these processes might not be crucial and cost effective.

Common surface modification techniques can be categorized into mechanical, chemical and physical. Mechanical methods can roughen the surface by processes such as sandblasting [63, 64] and polishing (electropolishing [54], diluent [15], etc.), or smoothen by ball burnishing [57] or milling [6]. Surface micropattern planning is a more intricate mechanical method which can increase wettability by laser surface texturing (LST) [65] or pulsed laser ablation [66]. Chemical ones include etching (to reveal the surface structure) [59, 55], anodic oxidation [63], chemical deposition, etc. Finally, physical modification only involves different types of energy transferring like ion implantation, physical vapor deposition, and thermal spraying [6].

Coating can further improve some bio-related properties such as corrosion resistance and cell viability. Hydroxyapatite (HA) is one of the most popular material due to its high similarity to human bone structure. It was reported in several articles to effectively improve osteoconductivity using sol gel, sol gel-dip coating [22] and plasma spraying [67]. Other than HA, yttria-stabilized zirconia (YSZ) was coated using plasma spray–physical vapor deposition by Dercz et al. (2021) [68]. Not only the biocompatibility was improved, but also a lower Young's modulus was achieved.

3.2 Existing Manufacturing Methods of Titanium TORP and Assessment

There has been multiple existing production methods for titanium TORP, such as AM, investment casting, machining, etc. However, most options require manual fabrication during surgeries by skilled surgeons as every middle ear is unique.

AM is commonly investigated in journal articles since it eliminates the step of manual fabrication as it can produce complex and patient-specific shapes. AM also offers the possibility of finite element method (FEM) and thus can be used on novel designs. Seivur et al. (2022) [69] proposed a novel S-shaped prosthesis and analyzed by FEM to confirm the feasibility before AM. Milazzo et al. (2020) [70] also designed a variety of TORPs and selected the optimal one with FEM. However, AM is generally more expensive than investment casting or machining.

If cost-effectiveness is a priority, investment casting might be a better solution. It involves creating a wax pattern of the prosthesis, then surrounding it with a ceramic shell. The wax is melted out, and the remaining ceramic shell is filled with molten titanium, which solidifies into the desired shape. Precise and complex shapes can be produced, and the ceramic shell can be reused multiple times, making it cost-effective. And this method is currently adopted in Green Pastures Hospital, Nepal.

Another common cost-effective method is machining. It involves cutting titanium into the desired shape using a computer numerical control (CNC) machine. This method can produce accurate and consistent shapes, and it is often used for smaller TORPs. Machining is generally more expensive than investment casting, but it may be more cost-effective for smaller and simpler shapes.

4 Discussion

4.1 Result Discussion

Given that the characteristics of TORP as small, customized and diverse in forms, the existing methods are evaluated in these aspects of the assessing criteria. PM, MIM, AM and metal forming are compared with one another. And the criteria are prioritized in the order of affordability, precision, physical/mechanical properties and simplicity. The affordability is based on small-scale production of customized parts requiring high precision. The precision means the possibility to produce finely-designed parts with high accuracy under small dimension. Based on the previous study, the designed TORP length ranges from 2.5 to 5 mm and the diameter of the wire is around 0.3 mm. The target design should at least achieve the above dimensional criteria. And the physical/mechanical properties before any post treatments are compared. The simplicity refers to the steps of the processes excluding extra machining or surface modification.

Priority is analysed between every two criteria. In Table 8, the more crucial feature will receive 1 point. Therefore, the total points of each property is accumulated, and weighted factors are assigned to determined the final marks. According to the scores shown in Table 9, the weighted scores are 15, 16, 22 and 22, respectively. Therefore, the most suitable methods are AM and metal forming. Further planning are suggested below.

	Affordability	Simplicity	Physical/Mechanical Properties	Precision	Total	**Value Assigned**
Affordability		1	1	1	3	**4**
Simplicity	0		0	0	0	**1**
Physical/Mechanical Properties	0	1		0	1	**2**
Precision	0	1	1		2	**3**

Table 8: Weighting table

Method Criterion	PM	MIM	AM	Forming
Affordability	++	+	++	+++
Precision	+	++	+++	+
Physical/Mechanical Properties	+	++	+	+++
Simplicity	++	++	+++	+
Total Score	6	7	9	8
Weighted Score	15	16	22	22

Table 9: Evaluation table of the manufacturing methods for TORP. The rating scales are +++ (good, score 3), ++ (moderate, score 2) and + (poor, score 1).

4.2 Possible Solutions: Recommendations and Limitations

The possible solutions are highly dependent on the mapping of production. If a near-net product is desired, PM and MIM will not be the suitable solutions since both require long preparation time and high costs for the molds and tools, while forming demands lots of machining. Detailed internal and porous structures can be easily achieved by AM. Among all metal AM methods, LDED provided a better modulus of toughness and a more freeform generation than the common SLM [71]. Stable physical/mechanical properties are important for the durability of implants. However, if AM is adopted, ordering parts from external providers is recommended than setting up the system locally which is very expensive.

If post machining is allowed, metal forming might be a even cheaper way to obtain products with good physical/mechanical properties. The titanium can firstly be cast or forged into wires or plates. The production method currently conducted in Green Pastures Hospital by Dr. Michael Smith is molding due to its simplicity and low cost. However, the sharp edges remain and can damage the surrounding tissues. A feasible solution is to adopt the current system and apply surface finishing, such as sandblasting, grinding or polishing. Another proposal is to produce pure titanium into plates and uses abrasive water jet cutting, wire electrical discharge or laser cutting to achieve the intermediate shape. Due to the ductility of pure titanium, the wire or plate can then be trimmed and/or bended to the final structure.

5 Conclusion

Based on the literature obtained, manufacturing methods for titanium were reviewed following the PRISMA method and assessed using the pre-determined criteria. Two possible solutions were proposed based on the forms of the products. If a near-net and complex structure is preferred, laser-directed energy deposition (LDED) is a suitable option, which omits the post machining step and possesses acceptable physical/mechanical properties. For total ossicular replacement prosthesis (TORP) with simpler structure, it can be molded either into wire-shape with extra surface finishing, or into plate and then cut into the final form. In conclusion, 2 proposals are given and will be tested in the further research to obtain the most feasible one. The final solution is expected to improve the usage of TORPs in middle ear surgeries of low- and middle-income countries.

B Three-View CAD Drawings of the Design Solutions

The below CAD drawings give more detailed information of the three concept solutions. The units are all in millimeter.

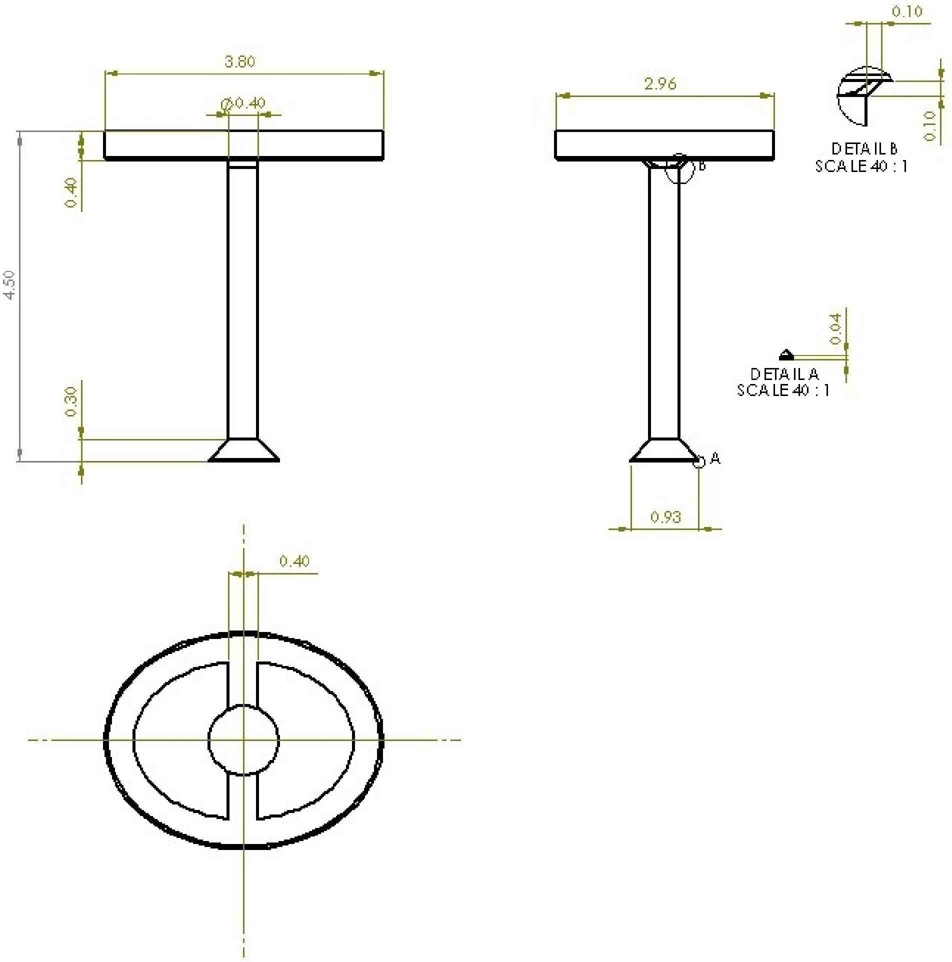


Figure 41: CAD drawing of Concept 1: additive manufacturing (SLM)
Only the prototypes with length of 4.5 mm were printed for this concept.

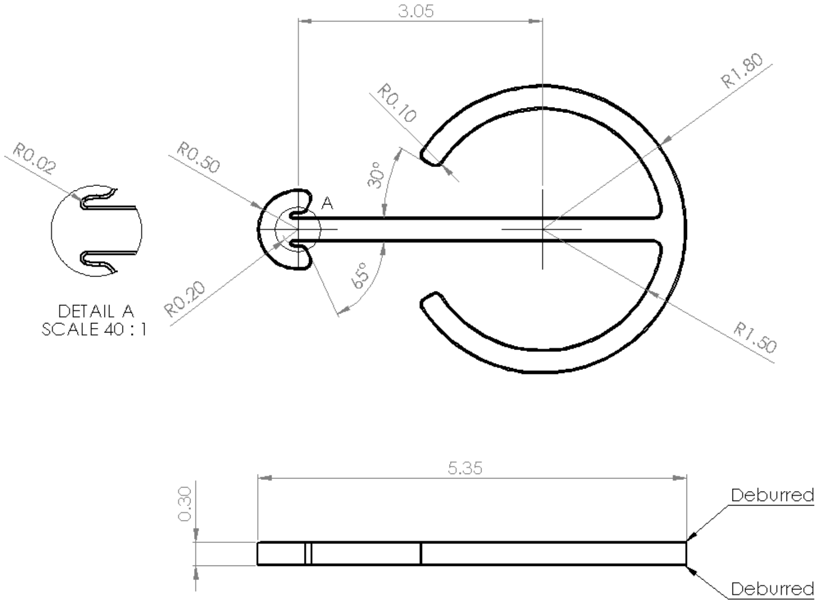


Figure 42: CAD drawing of Concept 2A and 2B: metal forming (laser cutting) before bending. The shaft length is 3 mm in this drawing as an example, while the extra 0.05 mm serves as tolerance for bending. The contour was deburred after laser cutting.

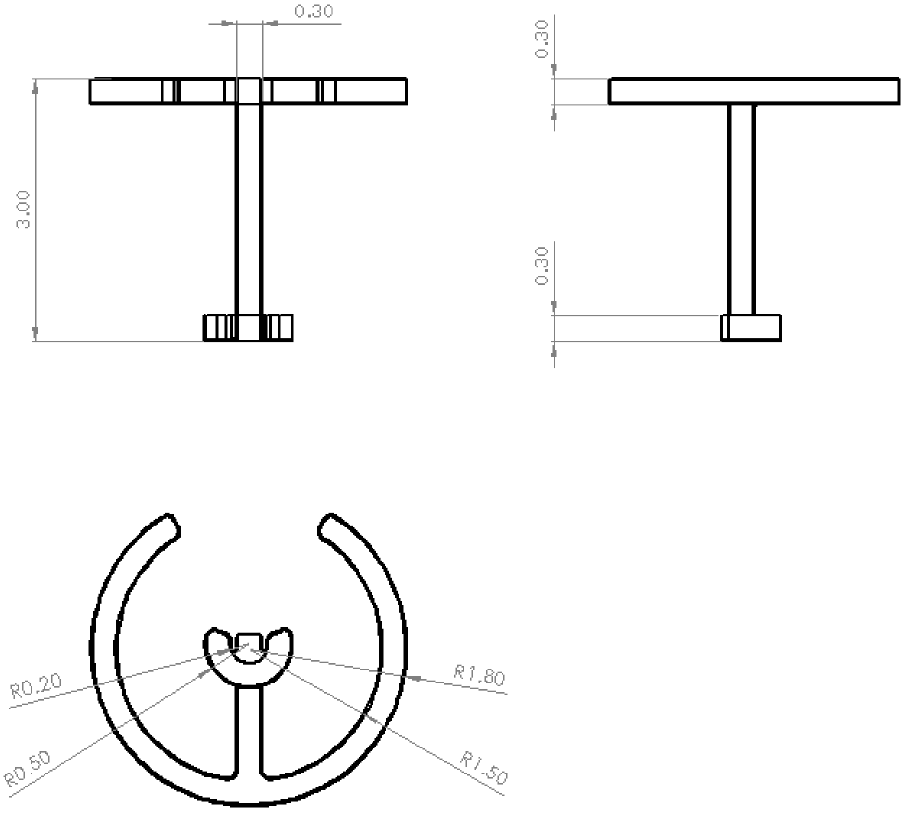


Figure 43: CAD drawing of Concept 2A: metal forming (laser cutting) after bending. The model is 3.0 mm long, as an example.

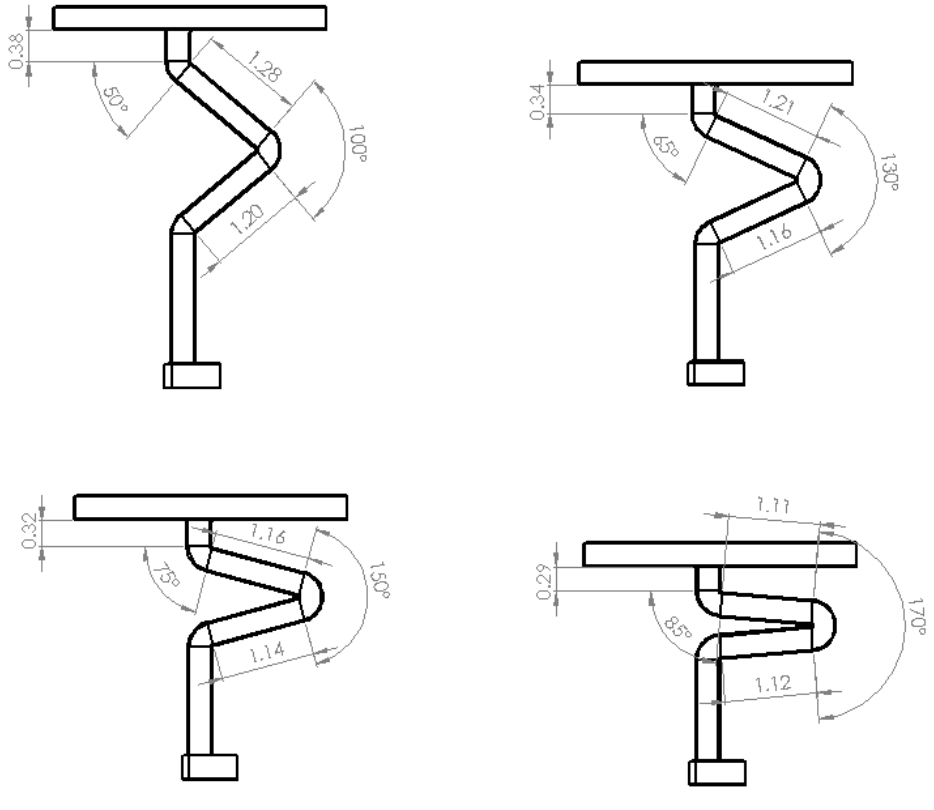


Figure 44: CAD drawing of Concept 2B: metal forming (laser cutting) after bending with adjustable lengths. From top left to bottom right, the TORPs are 4.5, 4.0, 3.5, 3.0 mm in length.

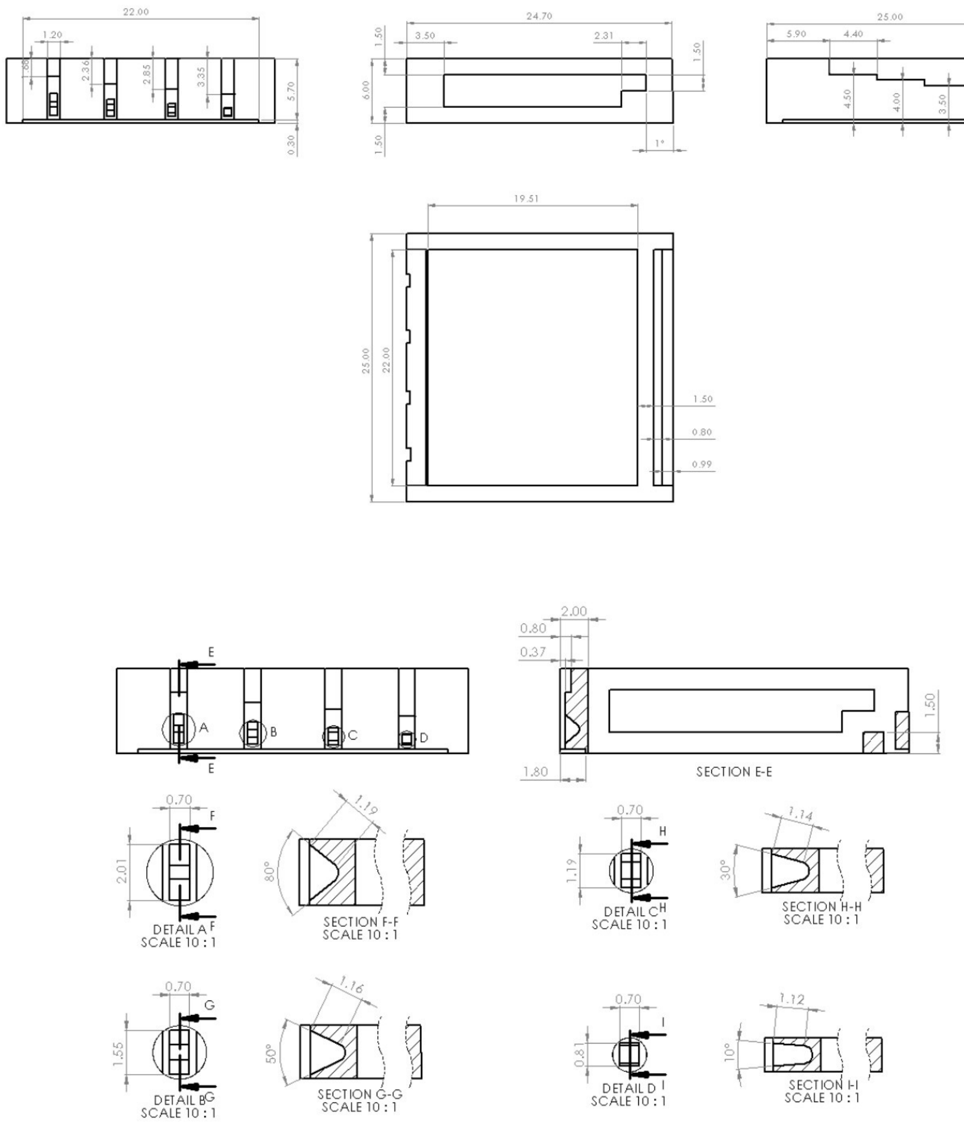


Figure 45: CAD drawing of the bending tool

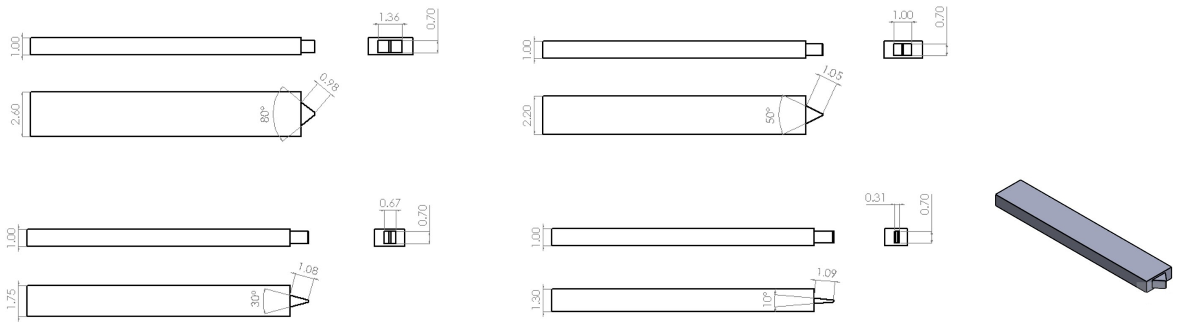


Figure 46: CAD drawing and schematic of the pressing tool

C Visualization of the Preparation Process for Concept 2 after Laser Cutting

In Fig. 47, the illustration presents a sequence of three steps outlining the process of bending the head and footplates. Initially, the laser-cut plate is positioned within the bottom groove, aligning with the specific section to achieve the desired shaft length. This alignment ensures the accurate placement of the headplate's center against the wall's edge. Subsequently, the shaft is folded upwards to match the wall. Finally, the footplate is bent downwards onto the top of the wall.

For users seeking an adjustable shaft, the procedure detailed in Fig. 48 can be followed to create a zigzagged bend. In the initial step, a 6.0 mm long TORP is positioned within one of the grooves, dependent on the desired final length. Following this, a pressing tool is utilized in steps 2 and 3 to insert the shaft into the designated socket. Eventually, a TORP with an adjustable shaft is formed.

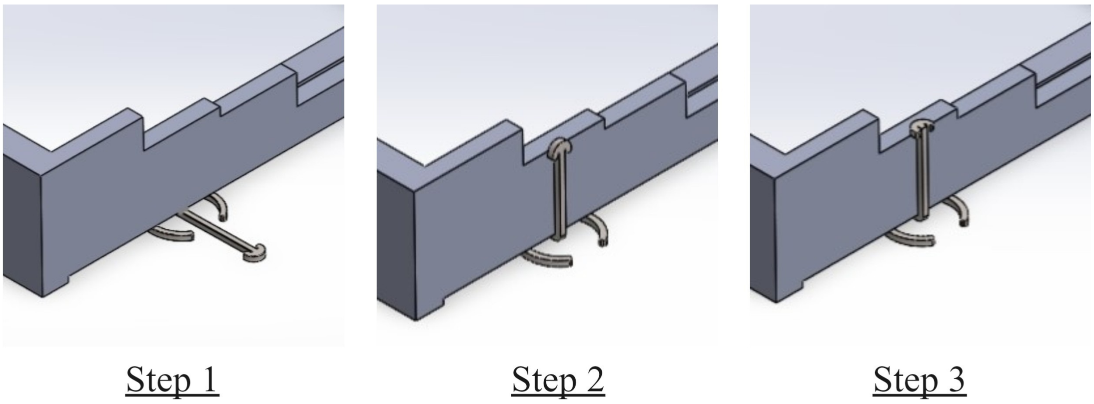
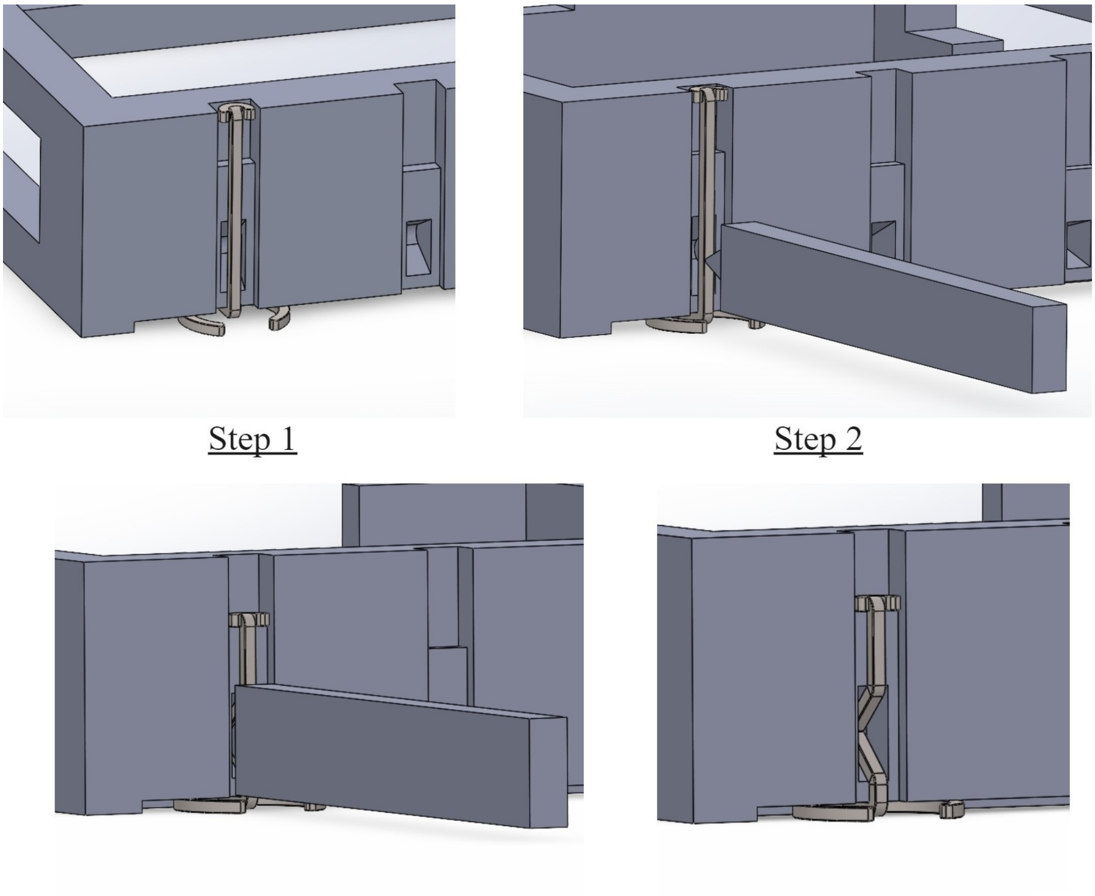


Figure 47: The three steps for bending the head and footplates using the bending tool. A TORP of Concept 2A with the length of 4.5 mm is bent in this example.



Step 1

Step 2

Step 3

Step 4

Figure 48: The four steps for forming the zigzagged structure using the bending tool. The TORP is bent from 6.0 mm to 4.5 mm as an example.

D The Data of the Precision Measurements of Each Prototype

The weights of the TORPs were measured using a precision scale (AE50, Mettler Toledo, Greifensee, Switzerland). And the data are listed in the below Table 10. The three tests stand for three different specimens.

TORP	**Test 1 (mg)**	**Test 2 (mg)**	**Test 3 (mg)**	**Average Mass (mg)**
Commercial	16.2	-	-	16.2
1 (4.5 mm)	9.0	10.1	8.9	9.3
2A (titanium, 6.0 mm)	6.2	6.5	6.3	6.3
2A (stainless steel, 6.0 mm)	12.7	-	-	12.7
2A (stainless steel, 4.5 mm)	11.4	11.4	10.9	11.2
2A (stainless steel, 4.0 mm)	11.0	10.8	11.1	11.0
2A (stainless steel, 3.5 mm)	10.5	10.3	10.7	10.5
2A (stainless steel, 3.0 mm)	10.0	10.2	9.8	10.0
2B (stainless steel, 4.5 mm)	12.4	11.9	12.0	12.1
2B (stainless steel, 4.0 mm)	12.4	12.4	12.4	12.4
2B (stainless steel, 3.5 mm)	11.7	11.3	-	11.5
2B (stainless steel, 3.0 mm)	11.9	12.2	12.7	12.3

Table 10: The mass for different TORPs

In Table 11 and 12, a detailed listing of critical dimensions is provided for the three concept solutions. The true values indicate the desired dimension which show in the CAD drawings in Appendix B. To assess the accuracy of the measurements, errors were computed by comparing these measured values against the true values.

For Concept 1, the average error was determined based on errors of the headplate major and minor axes, the footplate diameter and the total length. In the case of Concept 2A and 2B, the average errors were derived from a comparison of the headplate diameter, footplate width 1 and the total length. The assessment of the footplate width 2 was conducted using a pass/fail criterion, as indicated in the final columns of Table 12.

Concept No.	Headplate Major Axis			Headplate Minor Axis			Footplate Diameter			Total Length			
	True Value (mm)	Measurement (mm)	Error (%)	True Value (mm)	Measurement (mm)	Error (%)	True Value (mm)	Measurement (mm)	Error (%)	True Value (mm)	Measurement (mm)	Error (%)	Average Error (%)
1 (4.5 mm)	3.80	3.76	-1.05	2.96	2.95	-0.34	0.93	0.86	-7.53	4.50	4.55	1.11	2.51

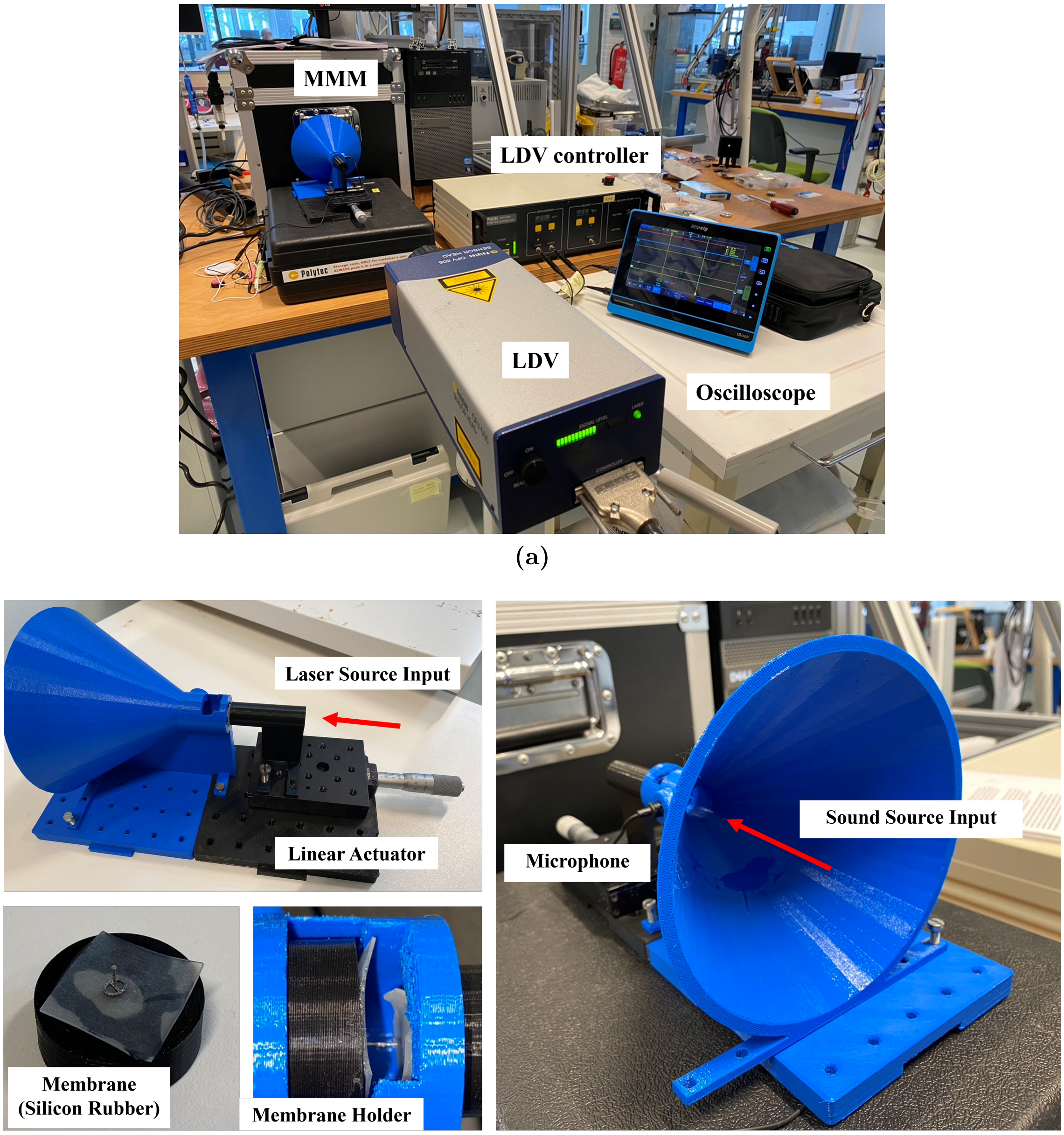
Table 11: The true values, measurements and errors of the critical dimensions of a prototype of Concept 1

Concept No.	Headplate Diameter			Footplate Width 1			Total Length				Footplate Width 2		
	True Value (mm)	Measurement (mm)	Error (%)	True Value (mm)	Measurement (mm)	Error (%)	True Value (mm)	Measurement (mm)	Error (%)	Average Error (%)	Target Value (mm)	Measurement (mm)	Pass/Fail
2A (titanium, 6.0 mm)	3.6	3.5	-2.78	1.00	1.03	3	6.00	6.26	4.33	3.37	1.00	0.66	TRUE
2A (stainless steel, 6.0 mm)	3.6	3.58	-0.56	1.00	1.01	1	6.00	5.96	-0.67	0.74	1.00	1.46	FALSE
2A (stainless steel, 4.5 mm)	3.6	3.59	-0.28	1.00	1.02	2	4.50	4.48	-0.44	0.91	1.00	1.41	FALSE
2A (stainless steel, 4.0 mm)	3.6	3.64	1.11	1.00	1.02	2	4.00	3.8	-5.00	2.70	1.00	0.71	TRUE
2A (stainless steel, 3.5 mm)	3.6	3.63	0.83	1.00	1.01	1	3.50	3.39	-3.14	1.66	1.00	0.73	TRUE
2A (stainless steel, 3.0 mm)	3.6	3.63	0.83	1.00	1.02	2	3.00	2.73	-9.00	3.94	1.00	0.86	TRUE
2B (stainless steel, 4.5 mm)	3.6	3.64	1.11	1.00	1.01	1	4.50	4.74	5.33	2.48	1.00	1.53	FALSE
2B (stainless steel, 4.0 mm)	3.6	3.61	0.28	1.00	1.03	3	4.00	3.97	-0.75	1.34	1.00	1.08	FALSE
2B (stainless steel, 3.5 mm)	3.6	3.61	0.28	1.00	1.03	3	3.50	3.35	-4.29	2.52	1.00	1.05	FALSE
2B (stainless steel, 3.0 mm)	3.6	3.53	-1.94	1.00	1.03	3	3.00	3.12	4.00	2.98	1.00	1.16	FALSE

Table 12: The true values, measurements and errors of the critical dimensions of a prototype of Concept 2A and 2B

E Supplementary Information of the Sound Transmission Experiments

In Fig. 49, the physical experiment setup is demonstrated.



(a)

(b)

Figure 49: (a) The overview of the experiment setup (b) The detailed physical structures of the MMM setup. Some important components are indicated in the figures.

The below Fig. 50 to 62 demonstrate the repeatability of the designed MMM experiment.

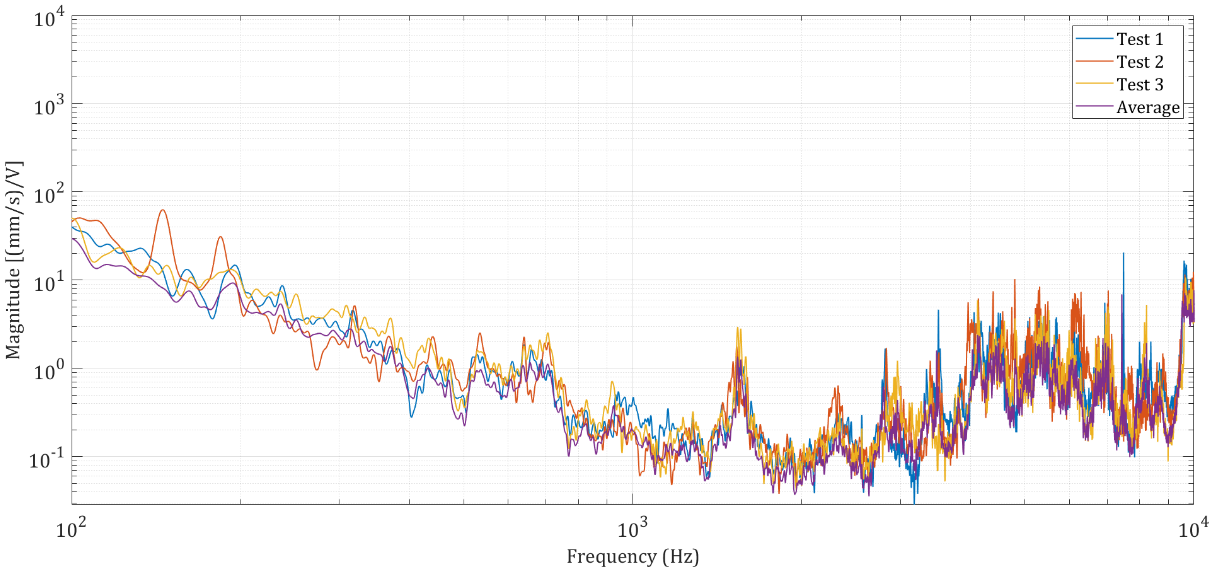


Figure 50: The three transfer functions obtained for ALTO Dornhoffer in three repetitions and the average transfer function based on them

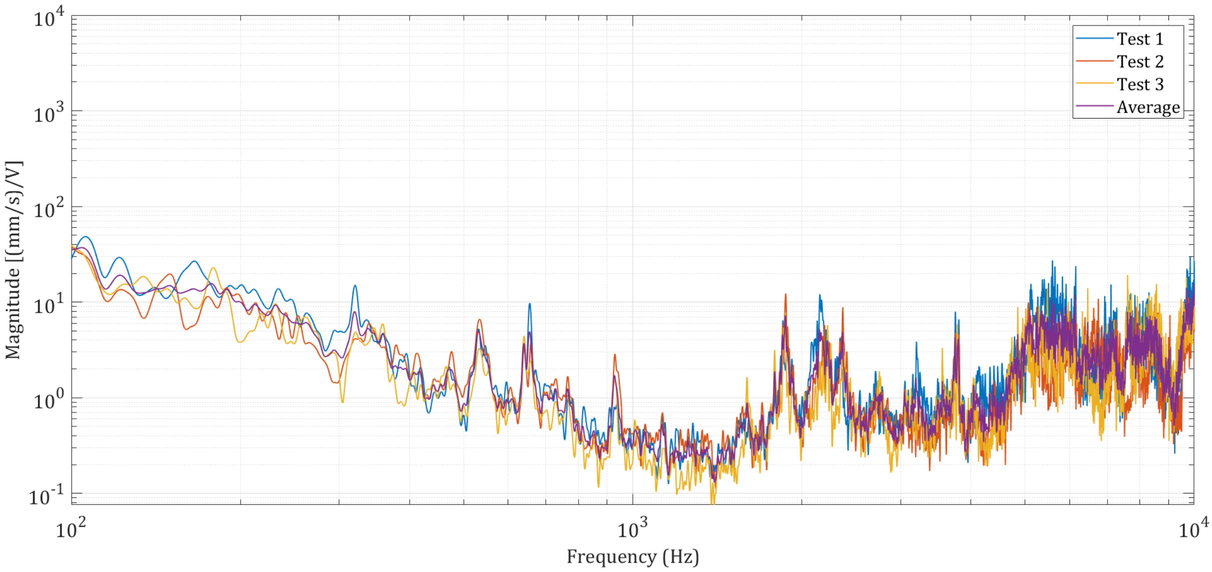
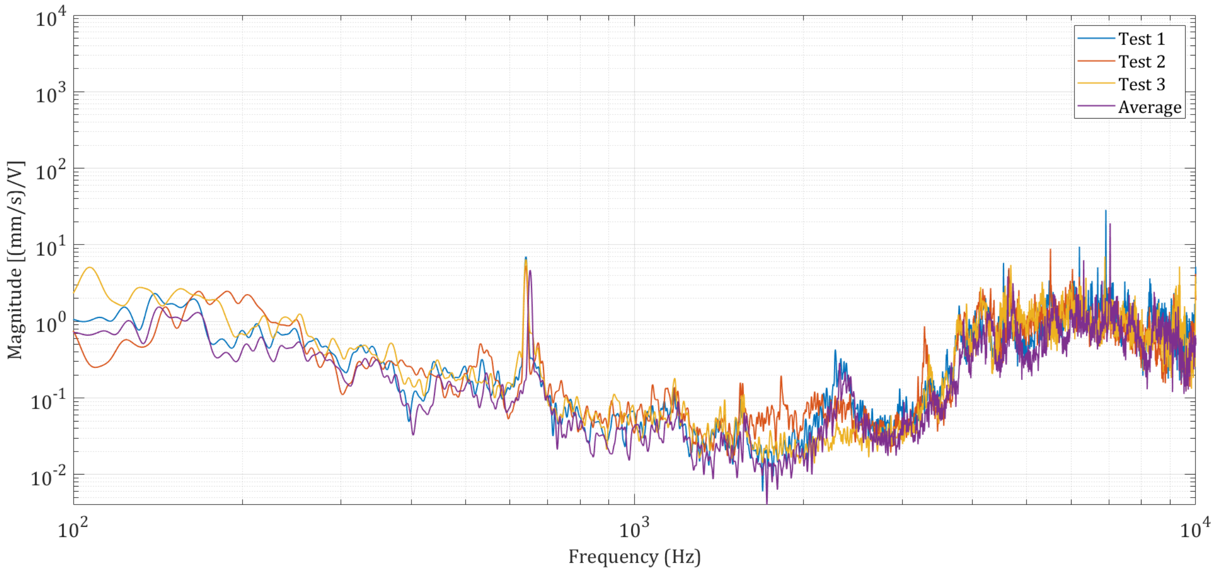
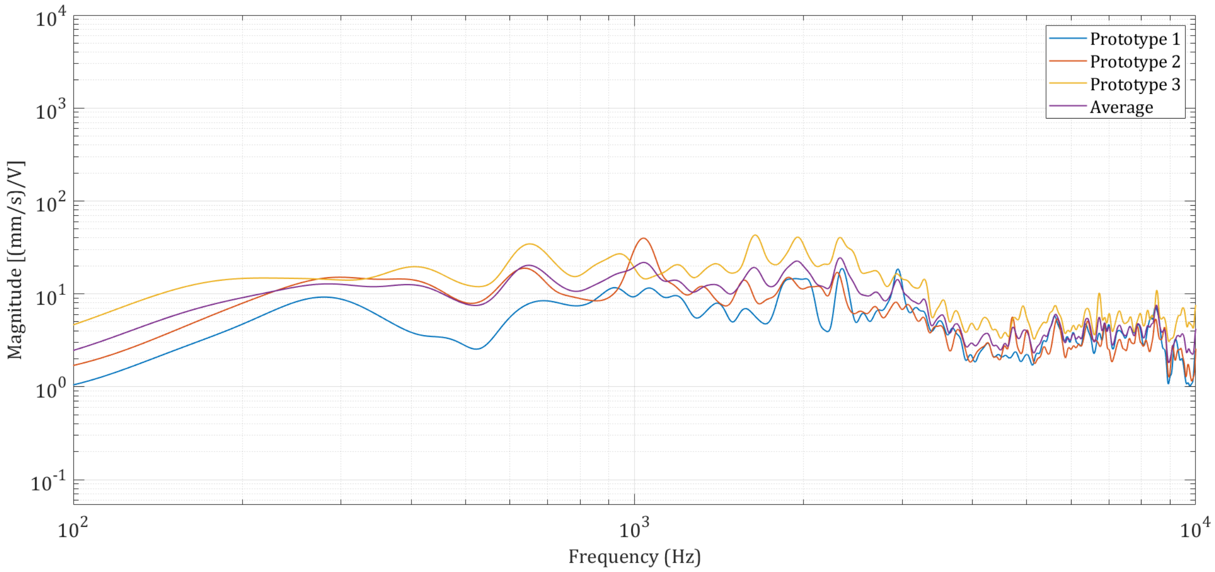


Figure 51: The three transfer functions obtained for mXACT Offcenter in three repetitions and the average transfer function based on them

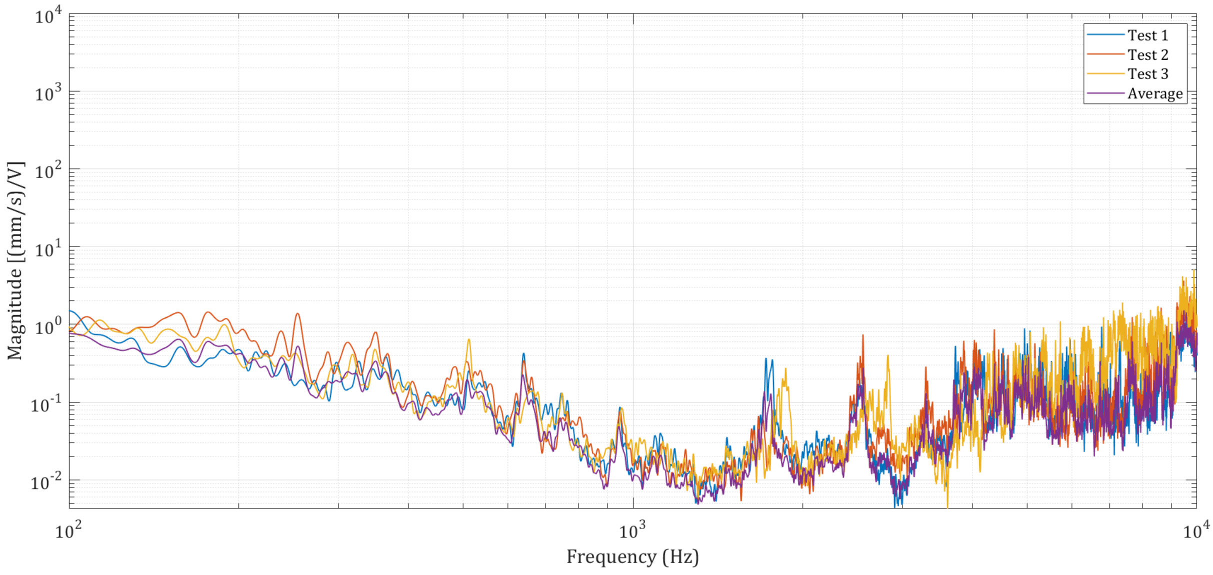


(a)

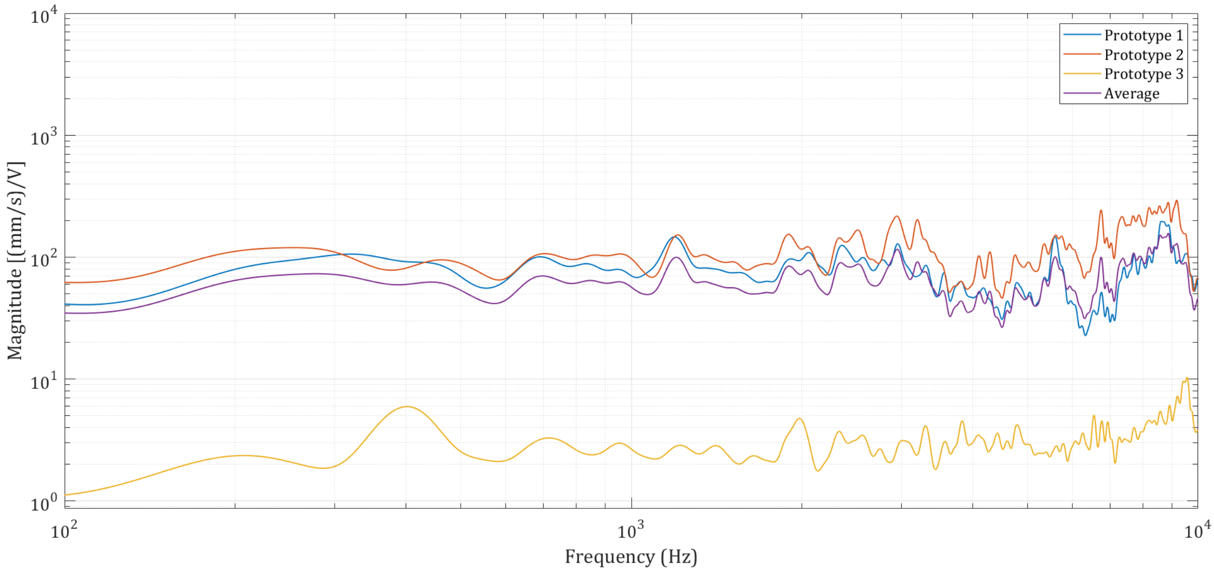


(b)

Figure 52: (a) The three transfer functions obtained for the same laser cut titanium prototype (6.0 mm, fixed shaft) in three repetitions and the average transfer function based on them (b) The three average transfer functions obtained for three laser cut titanium prototypes (6.0 mm, fixed shaft) and the total average transfer function calculate from them

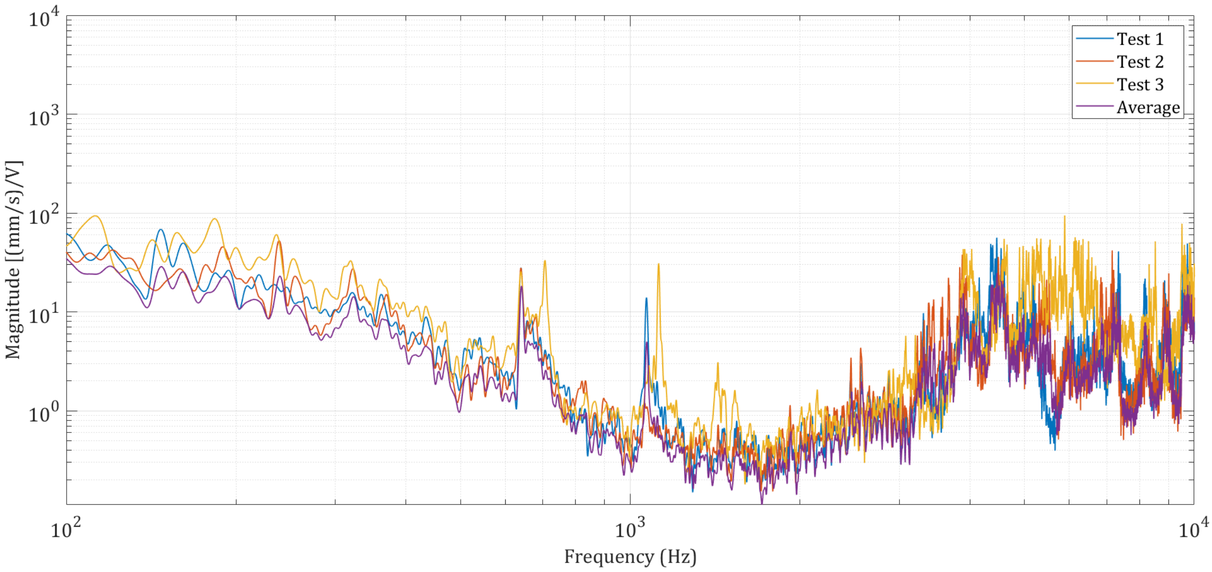


(a)

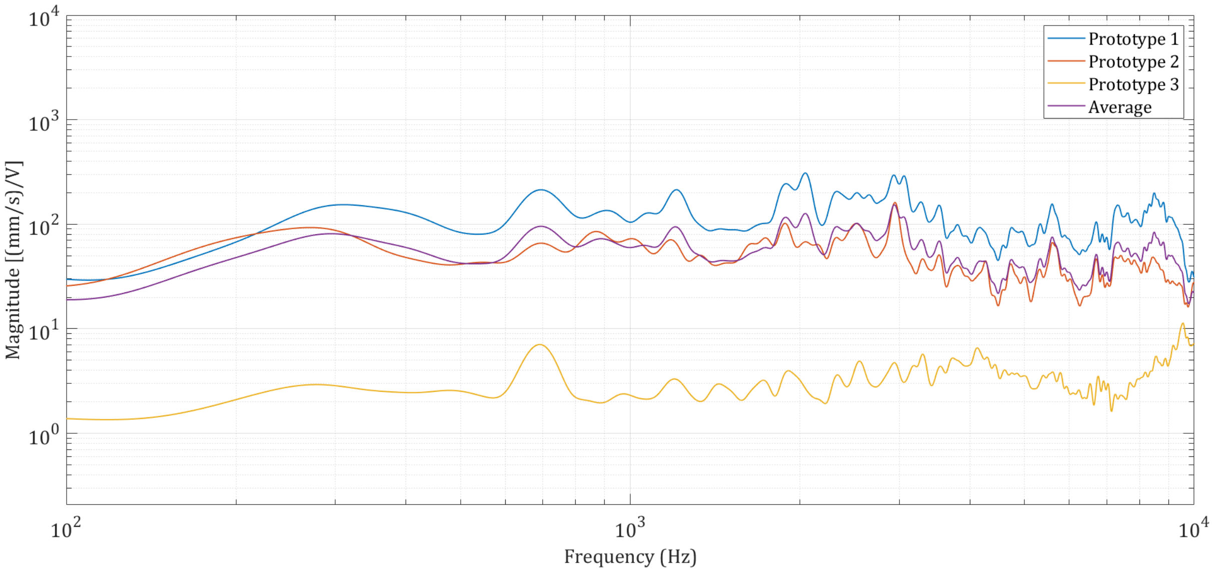


(b)

Figure 53: (a) The three transfer functions obtained for the same laser cut stainless steel prototype (6.0 mm, fixed shaft) in three repetitions and the average transfer function based on them (b) The three average transfer functions obtained for three laser cut stainless steel prototypes (6.0 mm, fixed shaft) and the total average transfer function calculate from them

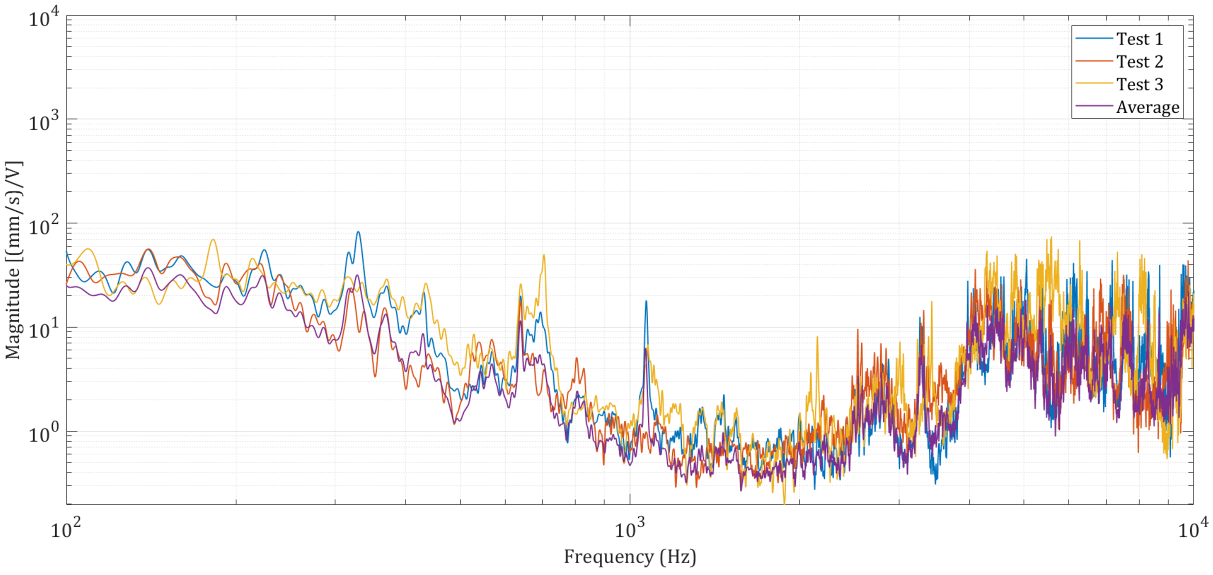


(a)

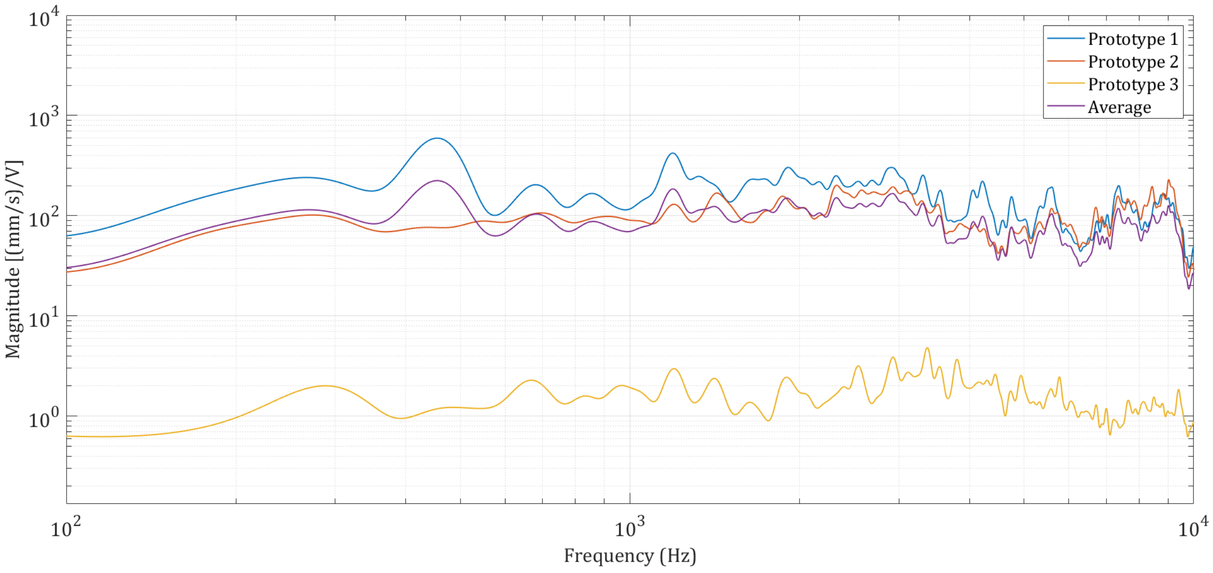


(b)

Figure 54: (a) The three transfer functions obtained for the same laser cut stainless steel prototype (4.5 mm, fixed shaft) in three repetitions and the average transfer function based on them (b) The three average transfer functions obtained for three laser cut stainless steel prototypes (4.5 mm, fixed shaft) and the total average transfer function calculate from them

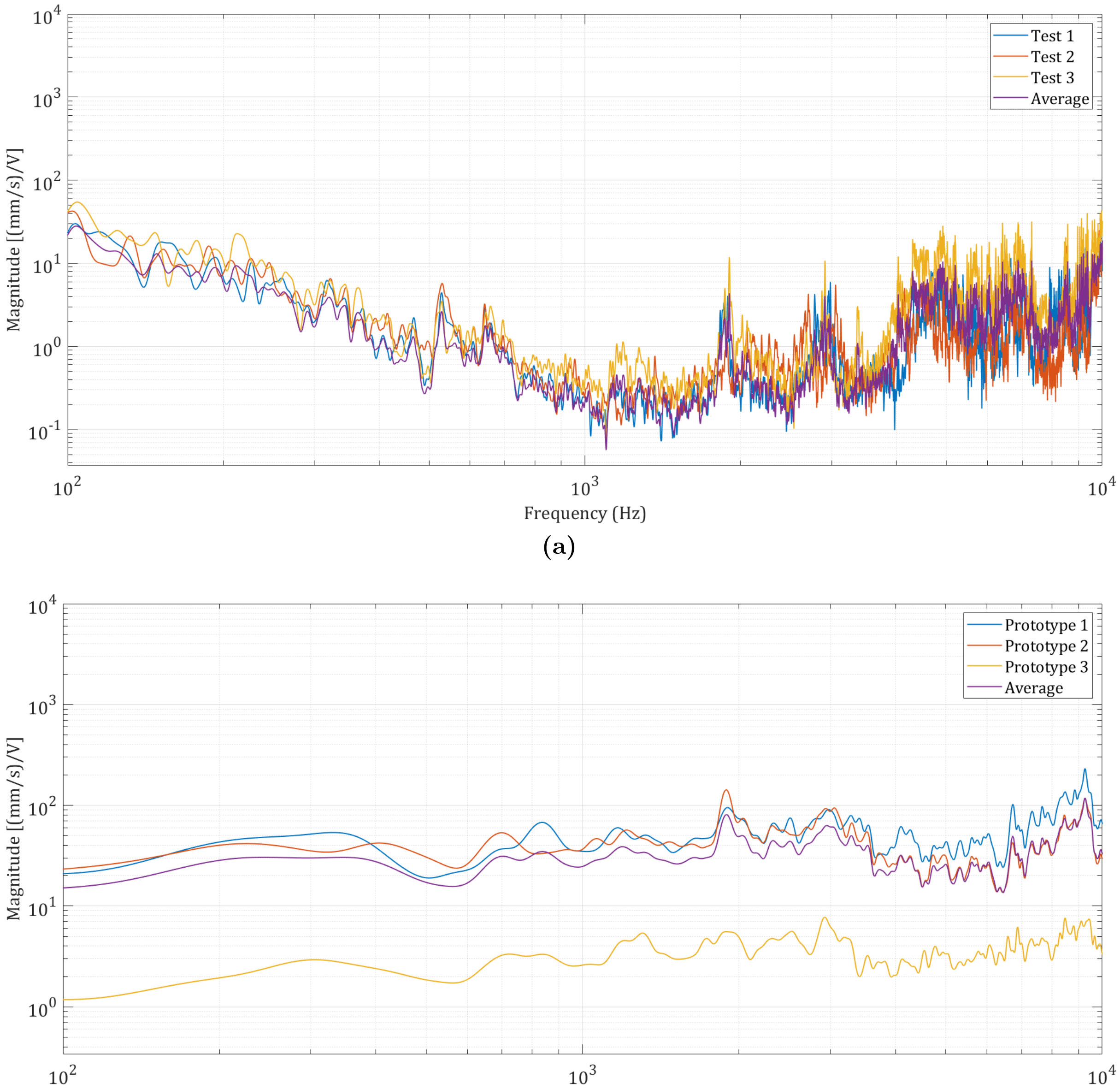


(a)



(b)

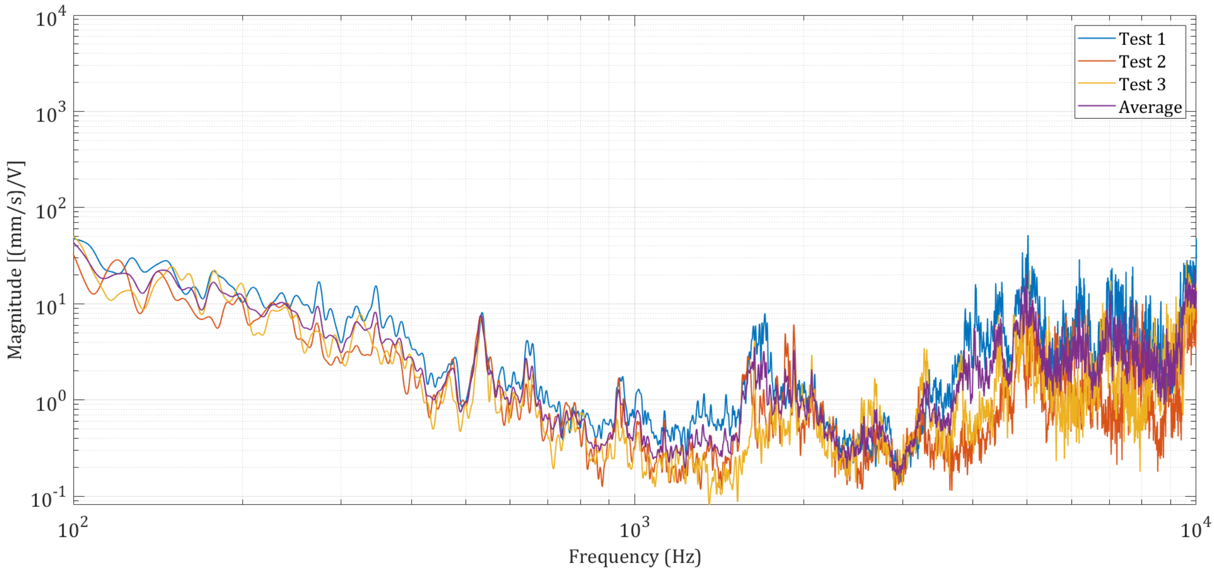
Figure 55: (a) The three transfer functions obtained for the same laser cut stainless steel prototype (4.0 mm, fixed shaft) in three repetitions and the average transfer function based on them (b) The three average transfer functions obtained for three laser cut stainless steel prototypes (4.0 mm, fixed shaft) and the total average transfer function calculate from them



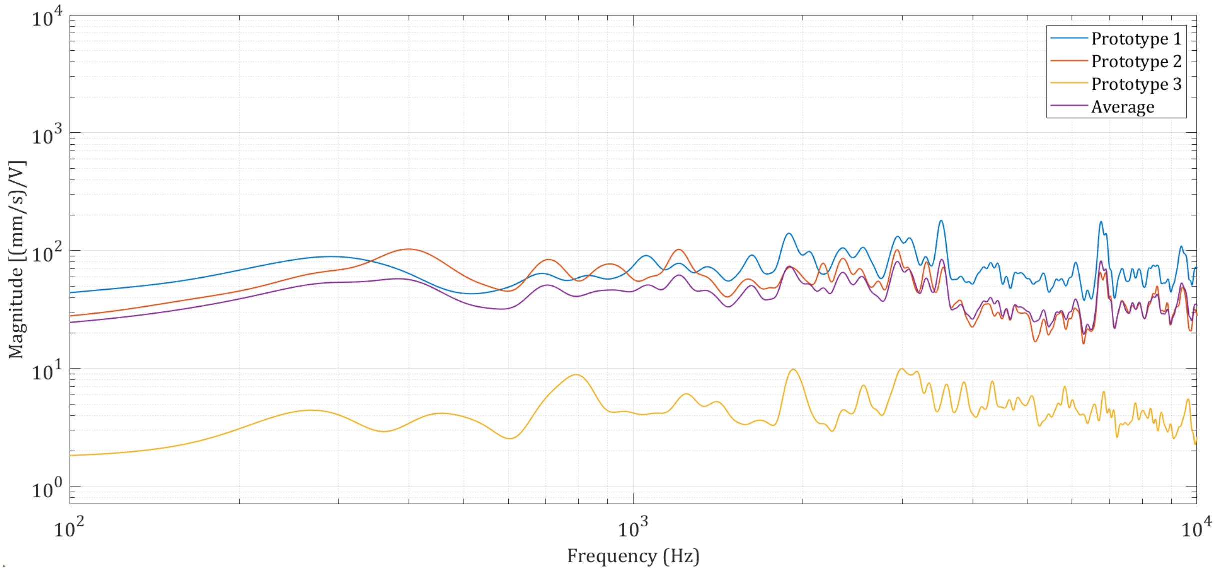
(a)

(b)

Figure 56: (a) The three transfer functions obtained for the same laser cut stainless steel prototype (3.5 mm, fixed shaft) in three repetitions and the average transfer function based on them (b) The three average transfer functions obtained for three laser cut stainless steel prototypes (3.5 mm, fixed shaft) and the total average transfer function calculate from them

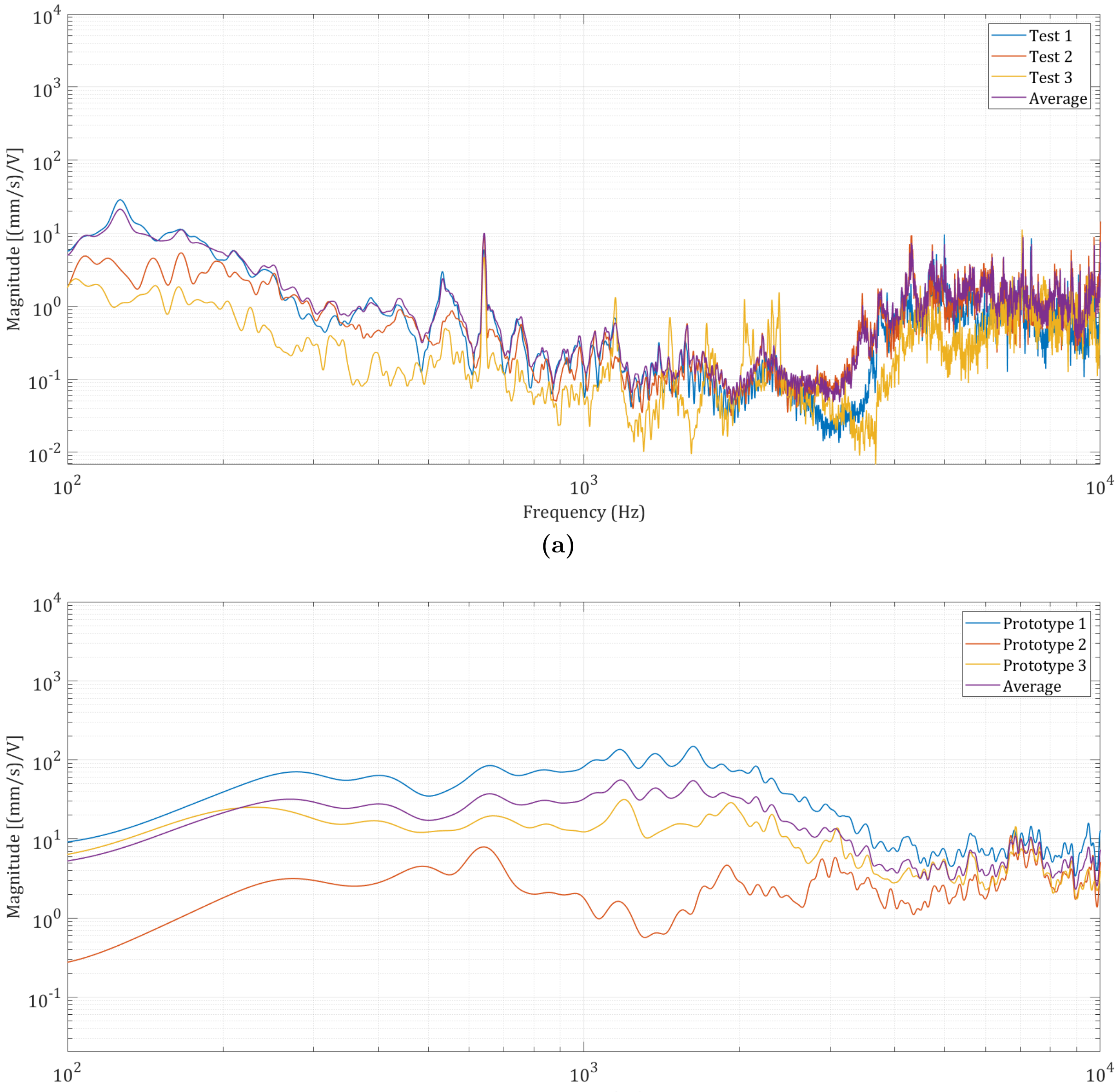


(a)



(b)

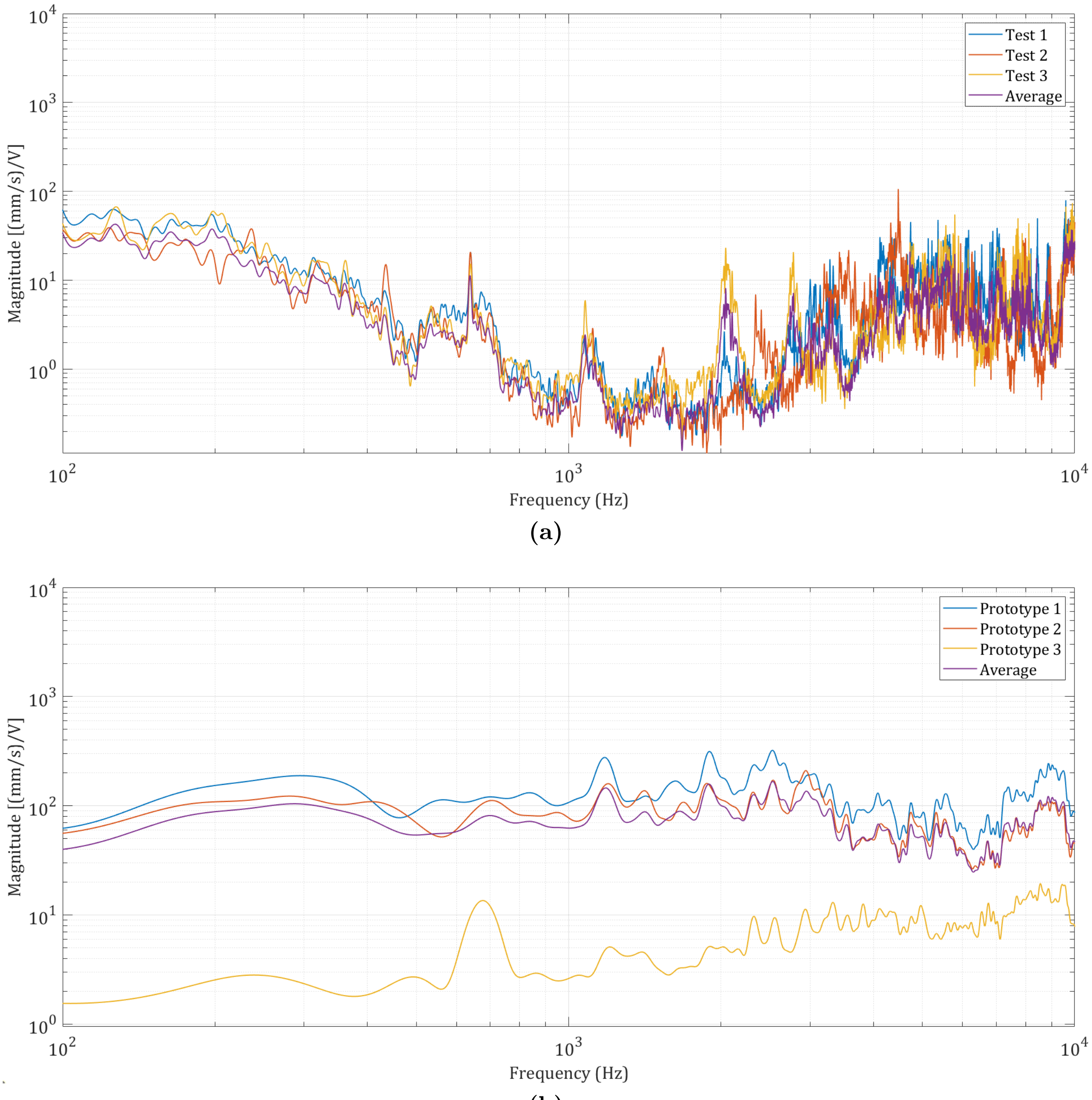
Figure 57: (a) The three transfer functions obtained for the same laser cut stainless steel prototype (3.0 mm, fixed shaft) in three repetitions and the average transfer function based on them (b) The three average transfer functions obtained for three laser cut stainless steel prototypes (3.0 mm, fixed shaft) and the total average transfer function calculate from them



(a)

(b)

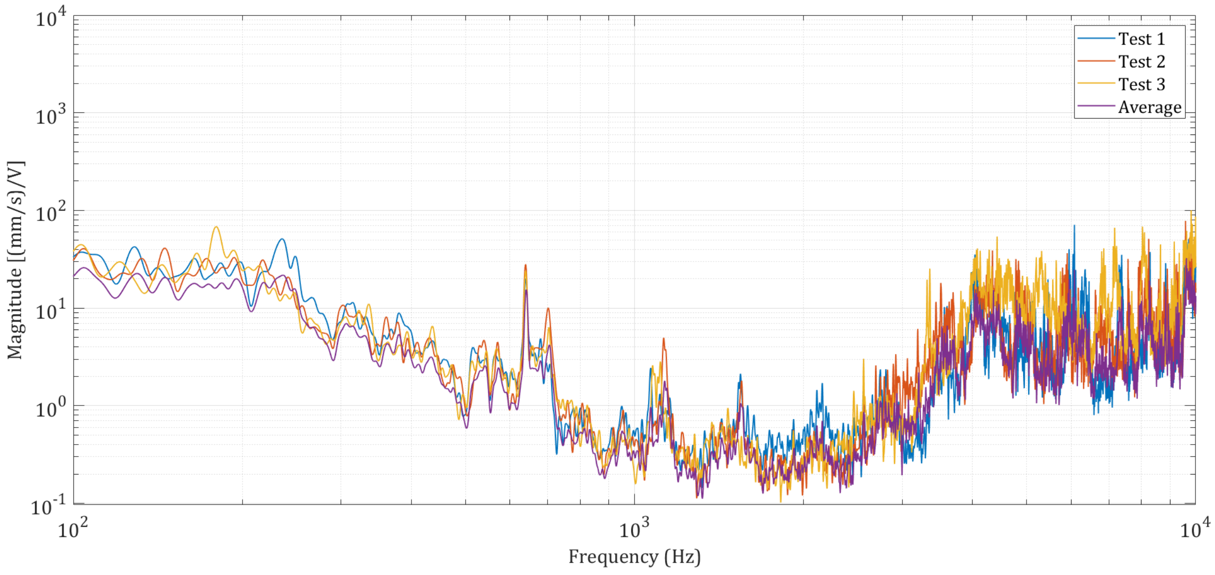
Figure 58: (a) The three transfer functions obtained for the same laser cut titanium prototype (4.5 mm, adjustable shaft) in three repetitions and the average transfer function based on them (b) The three average transfer functions obtained for three laser cut titanium prototypes (4.5 mm, adjustable shaft) and the total average transfer function calculate from them



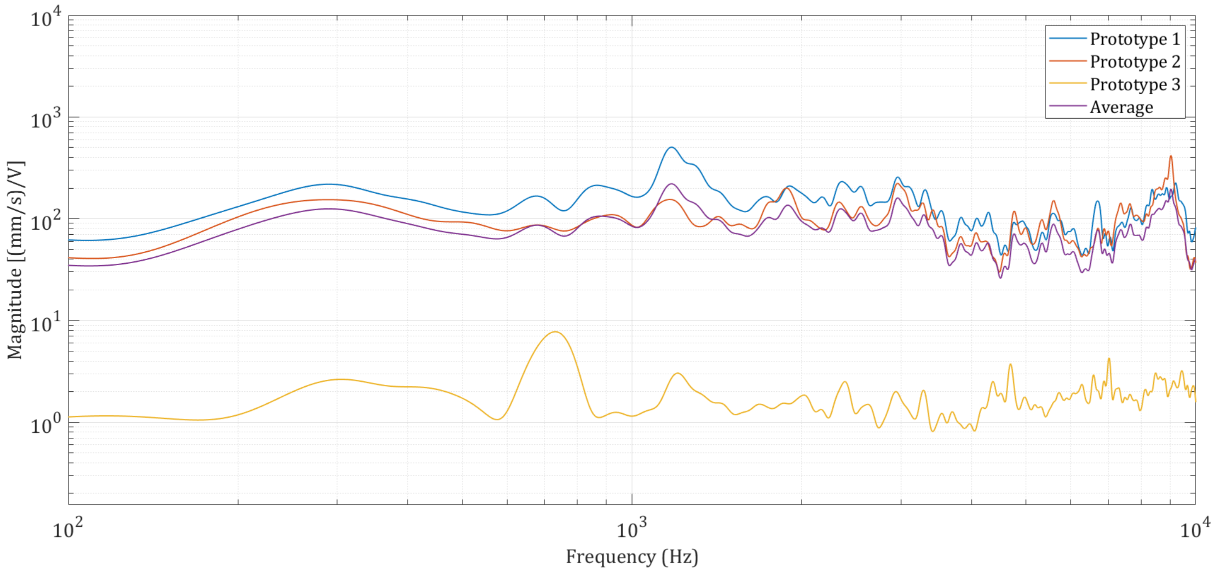
(a)

(b)

Figure 59: (a) The three transfer functions obtained for the same laser cut stainless steel prototype (4.5 mm, adjustable shaft) in three repetitions and the average transfer function based on them (b) The three average transfer functions obtained for three laser cut stainless steel prototypes (4.5 mm, adjustable shaft) and the total average transfer function calculate from them

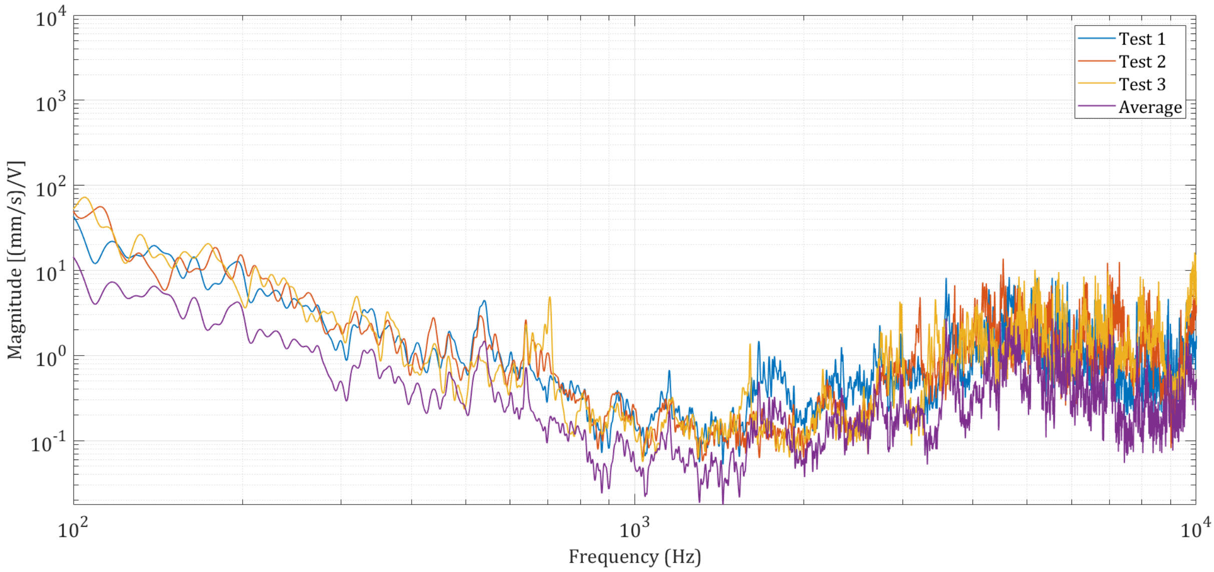


(a)

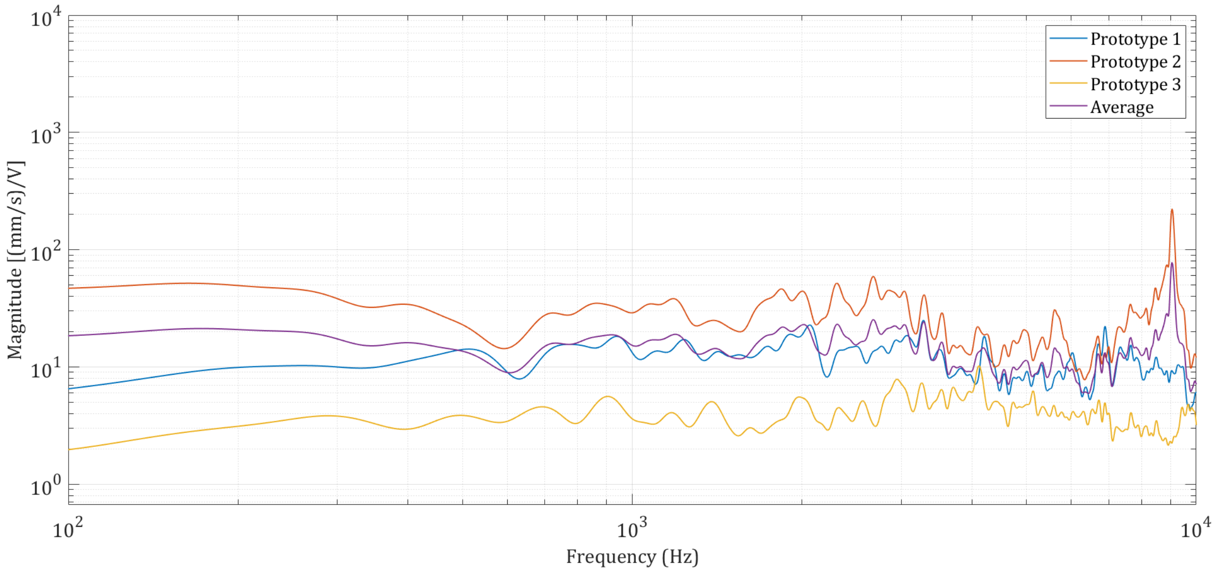


(b)

Figure 60: (a) The three transfer functions obtained for the same laser cut stainless steel prototype (4.0 mm, adjustable shaft) in three repetitions and the average transfer function based on them (b) The three average transfer functions obtained for three laser cut stainless steel prototypes (4.0 mm, adjustable shaft) and the total average transfer function calculate from them

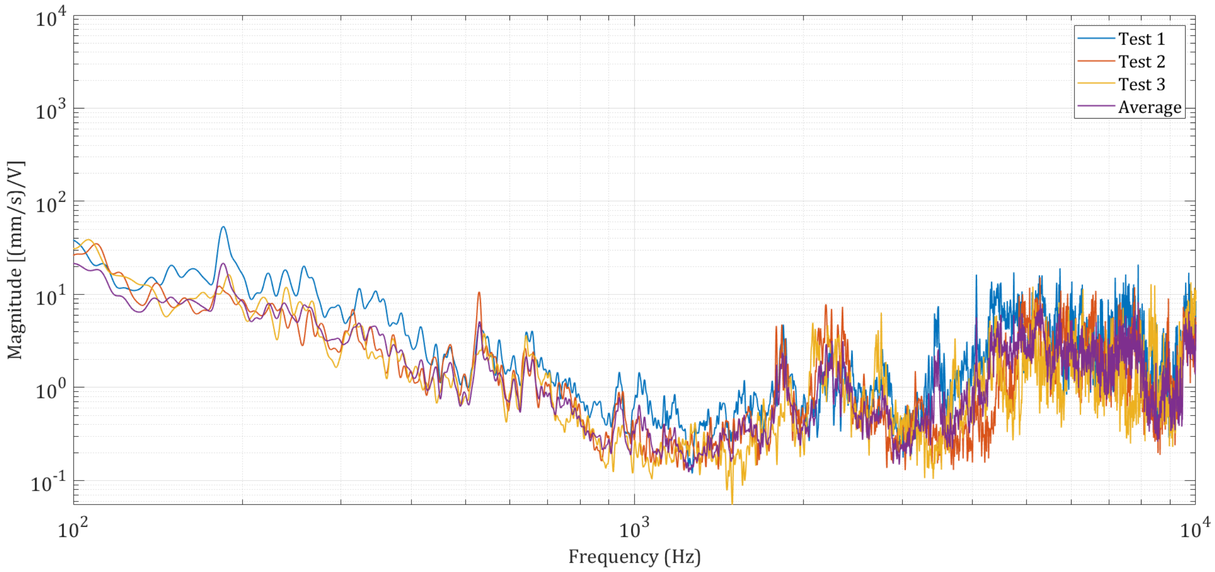


(a)

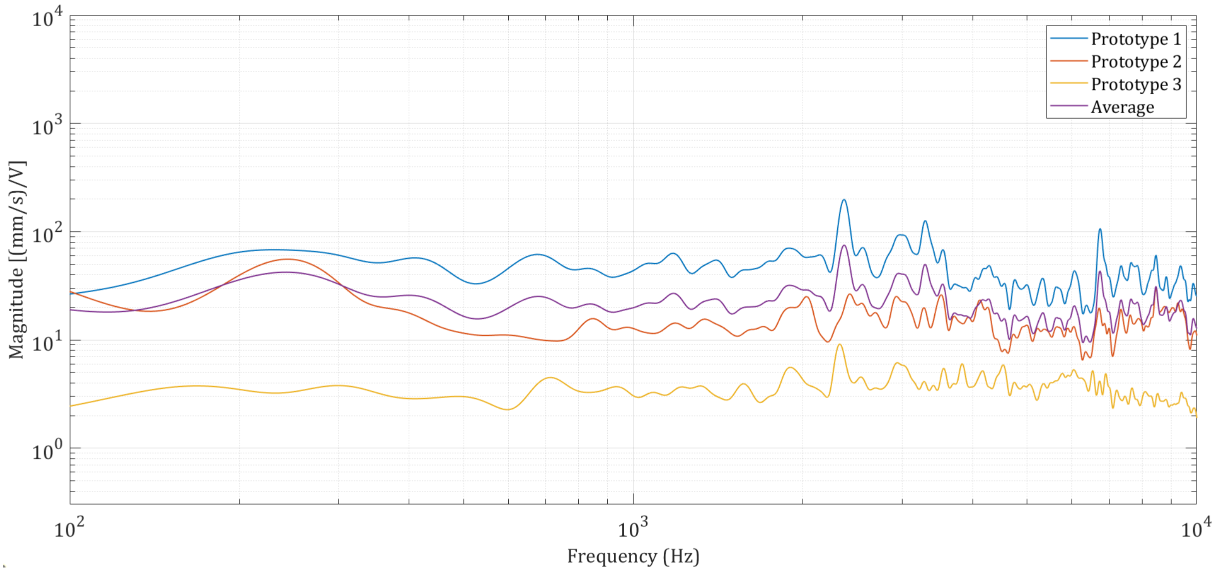


(b)

Figure 61: (a) The three transfer functions obtained for the same laser cut stainless steel prototype (3.5 mm, adjustable shaft) in three repetitions and the average transfer function based on them (b) The three average transfer functions obtained for three laser cut stainless steel prototypes (3.5 mm, adjustable shaft) and the total average transfer function calculate from them



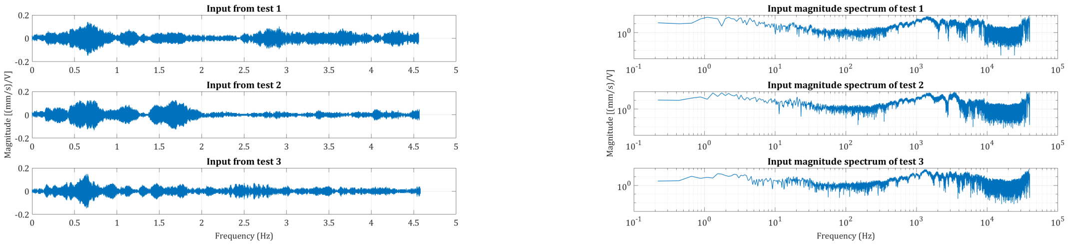
(a)



(b)

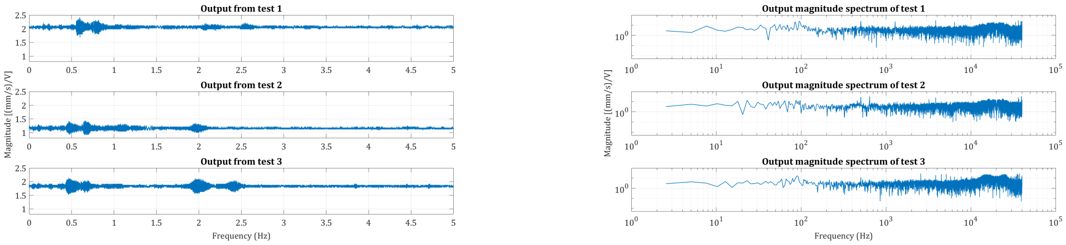
Figure 62: (a) The three transfer functions obtained for the same laser cut stainless steel prototype (3.0 mm, adjustable shaft) in three repetitions and the average transfer function based on them (b) The three average transfer functions obtained for three laser cut stainless steel prototypes (3.0 mm, adjustable shaft) and the total average transfer function calculate from them

The below transfer functions indicate the data processing steps following the flowchart shown in Fig. 16. And Concept 1 is taken as an example. In Fig. 63 and 64, the signals were cropped to the same length, which was 5 seconds, to the same starting points. Then, they were calculated to obtain the three separate transfer functions in Fig. 65. By removing the influence of the empty setup (Fig. 66 (b)), evident differences could be observed in Fig. 66 (a). The above steps were repeated for other two prototypes to obtain the average transfer function along with the LPF. Finally, after limiting the x-axis from 0.1 to 10 kHz, the transfer functions were ready to be grouped and compared with each other (see Fig. 67). LPF was chosen as the filtering method to remove high-frequency noise or unwanted components from the signals. This can be useful when measuring the response of the middle ear to acoustic stimuli, as it helps focus on the lower-frequency components that are more relevant to auditory function.



(a) **(b)**

Figure 63: (a) The three input chirp signals from 0.1 to 10 kHz measured by the microphone in time domain (b) The three input chirp signals in frequency domain on a 3DP TORP



(a) **(b)**

Figure 64: (a) The three output vibration signals measured by the LDV in time domain (b) The three input vibration signals in frequency domain on a 3DP TORP

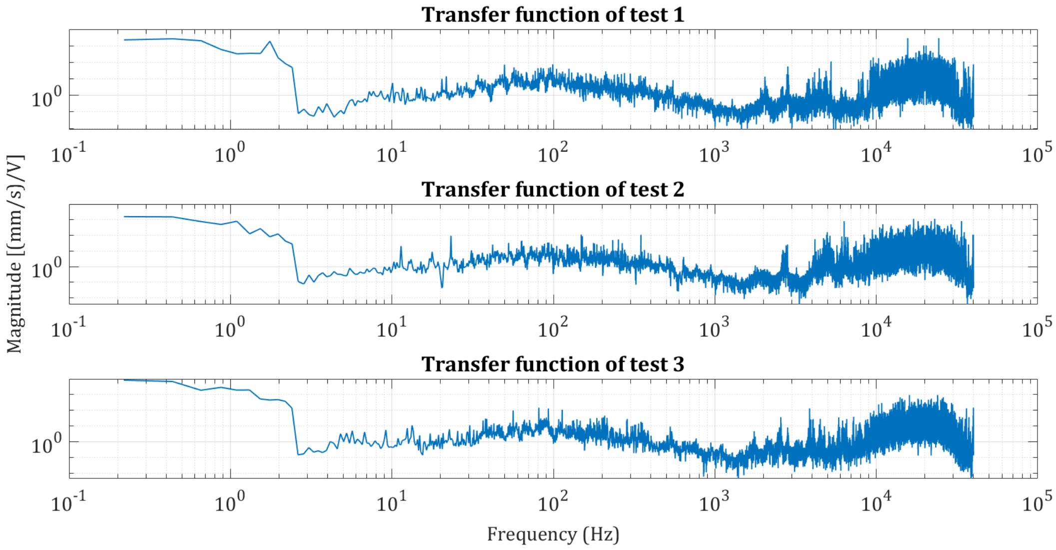
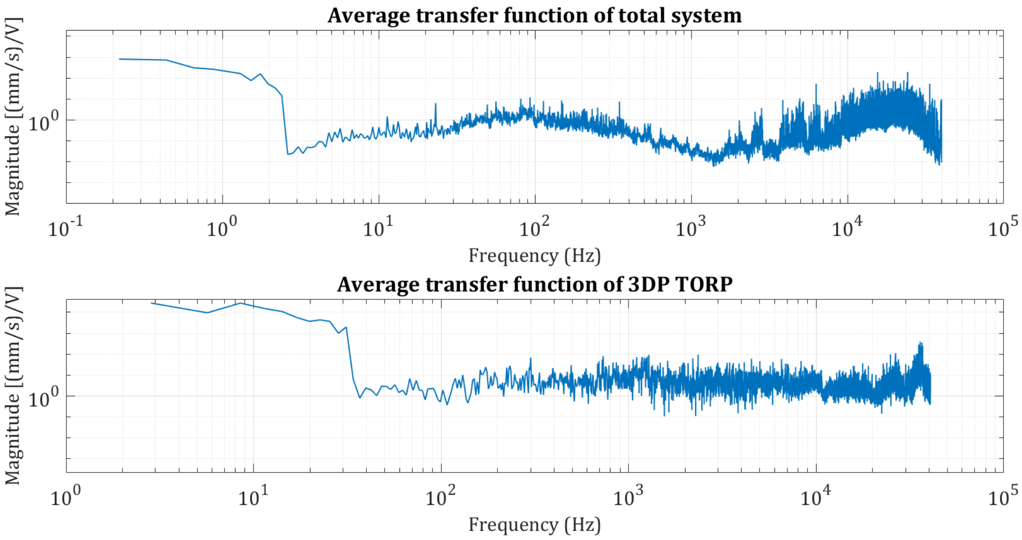


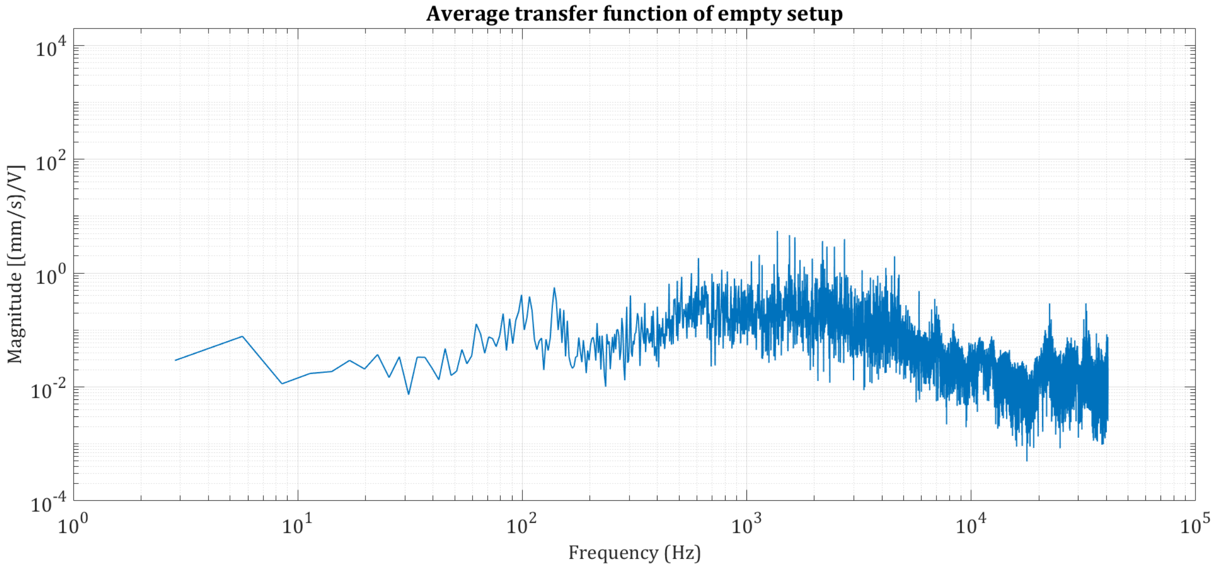
Figure 65: The three transfer functions calculated by the input and output signals shown in Fig. 63 and 64



Average transfer function of total system

Average transfer function of 3DP TORP

(a)



Average transfer function of empty setup

(b)

Figure 66: (a) The average transfer functions of the three curves shown in Fig. 65, before and after dividing that of the empty setup (b) The transfer function of the empty setup

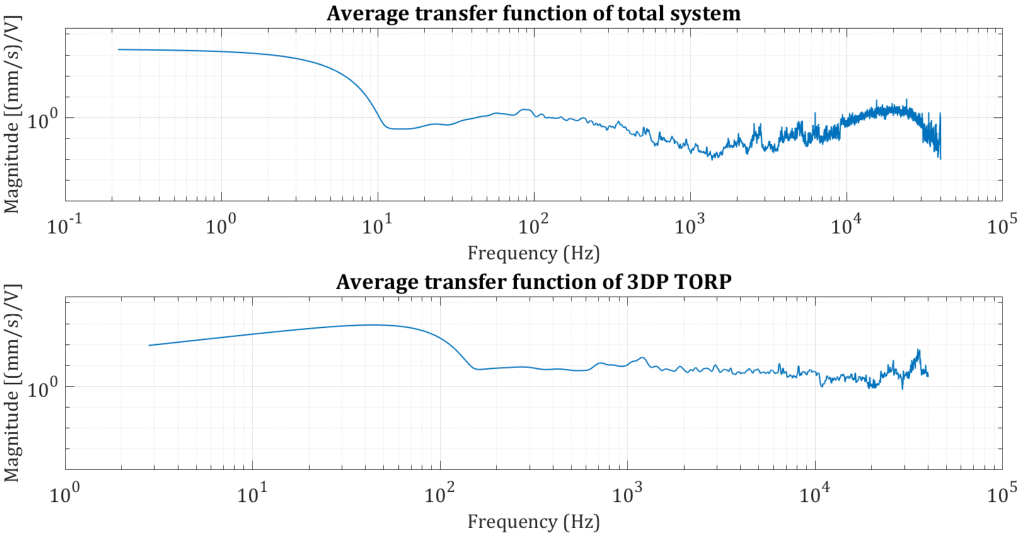


Figure 67: The average transfer functions after LPF before and after dividing that of the empty setup

The following figures correspond to 20, 22, 25, 26, 28, 29, 30 and 31 before LPF for more thorough inspection.

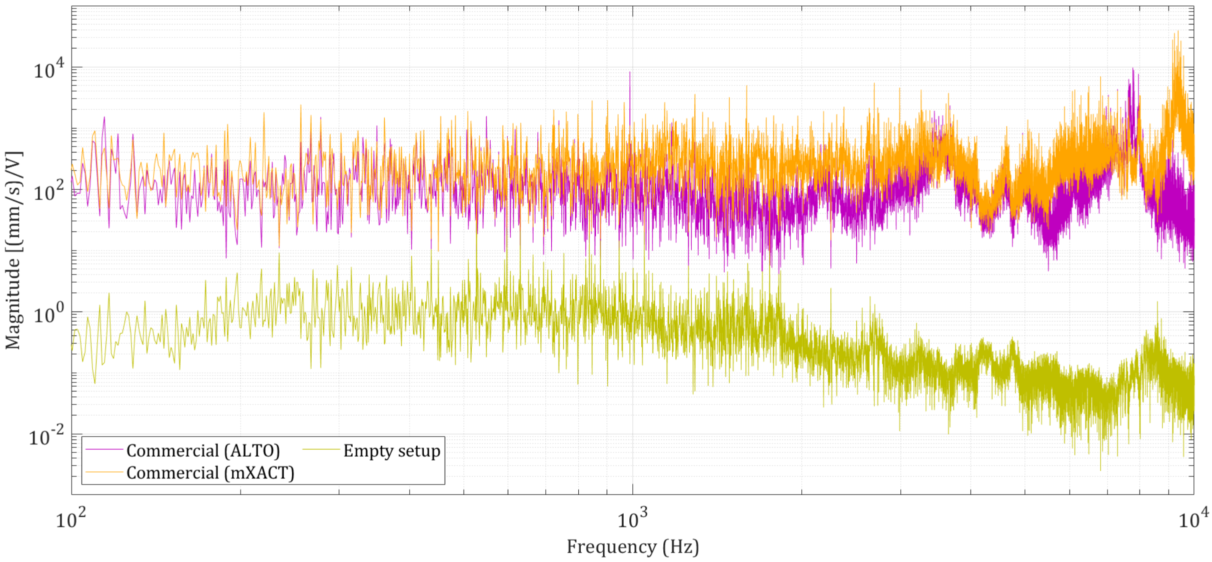


Figure 68: The unfiltered transfer functions of commercial TORPs and empty setup

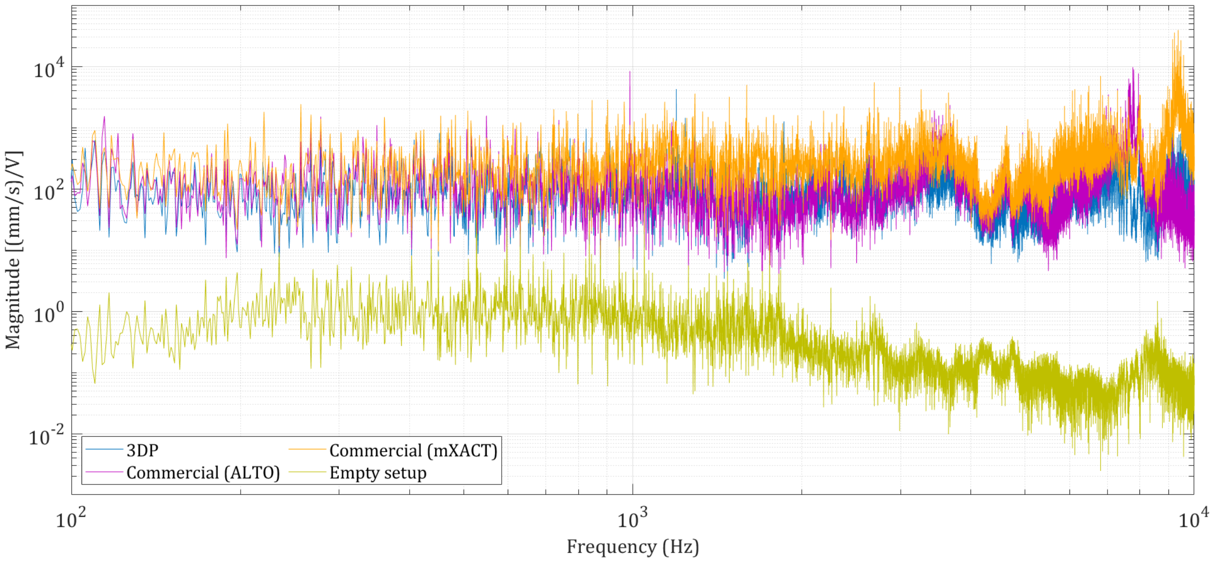


Figure 69: The unfiltered transfer functions of Concept 1 (3DP TORP), commercial TORPs and empty setup

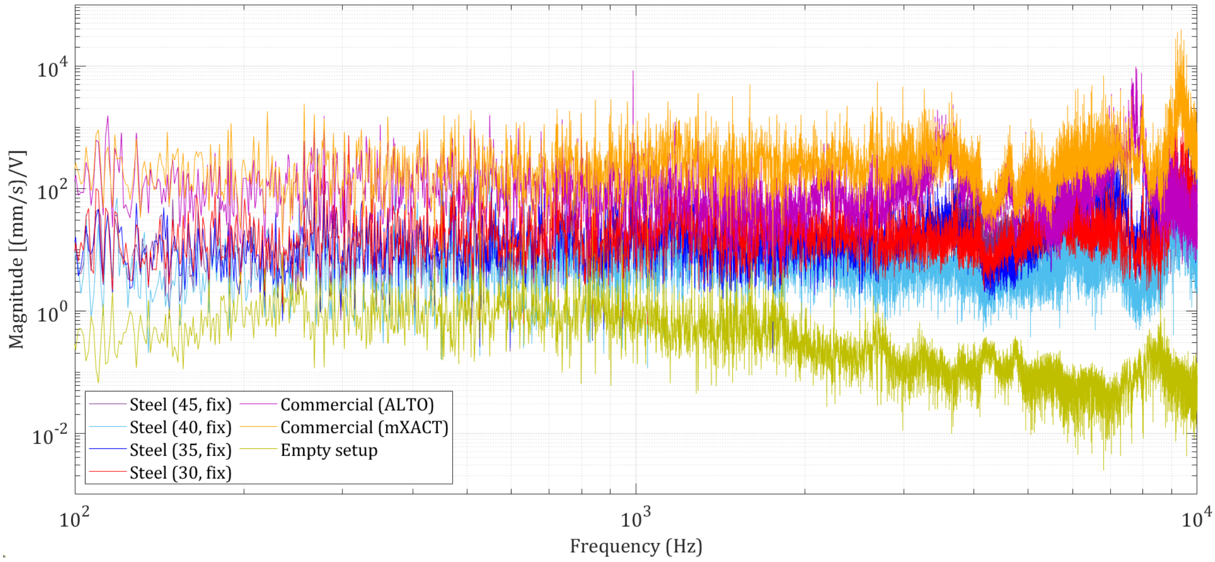


Figure 70: The unfiltered transfer functions of Concept 2A (laser cut TORP with fixed shaft), commercial TORPs and empty setup

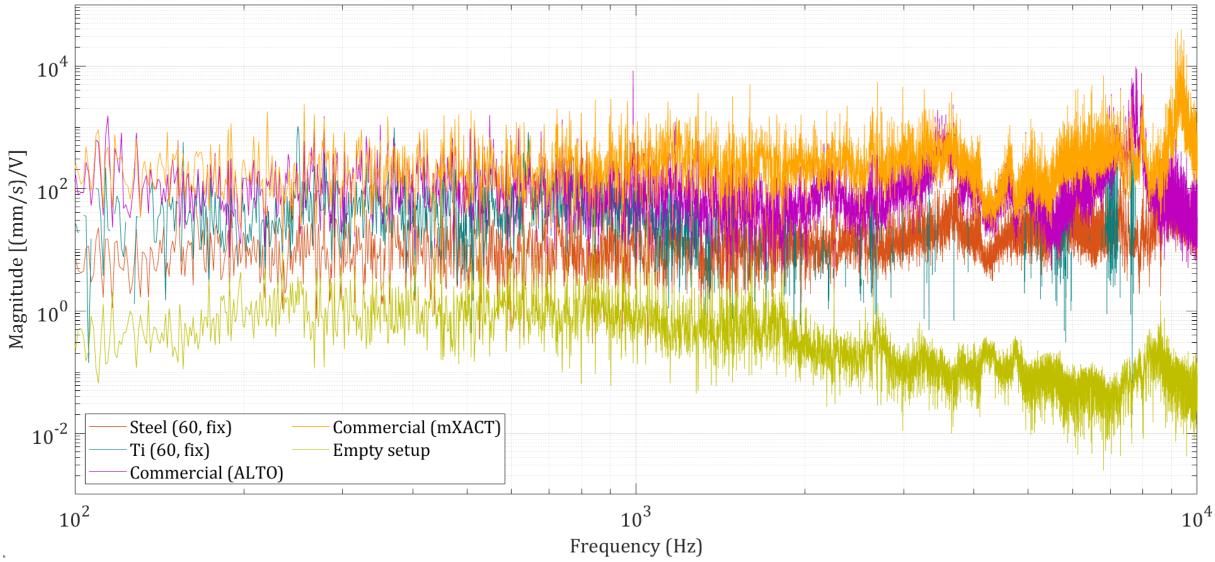


Figure 71: The unfiltered transfer functions of Concept 2A made of stainless steel and titanium, comparing with commercial TORPs and empty setup

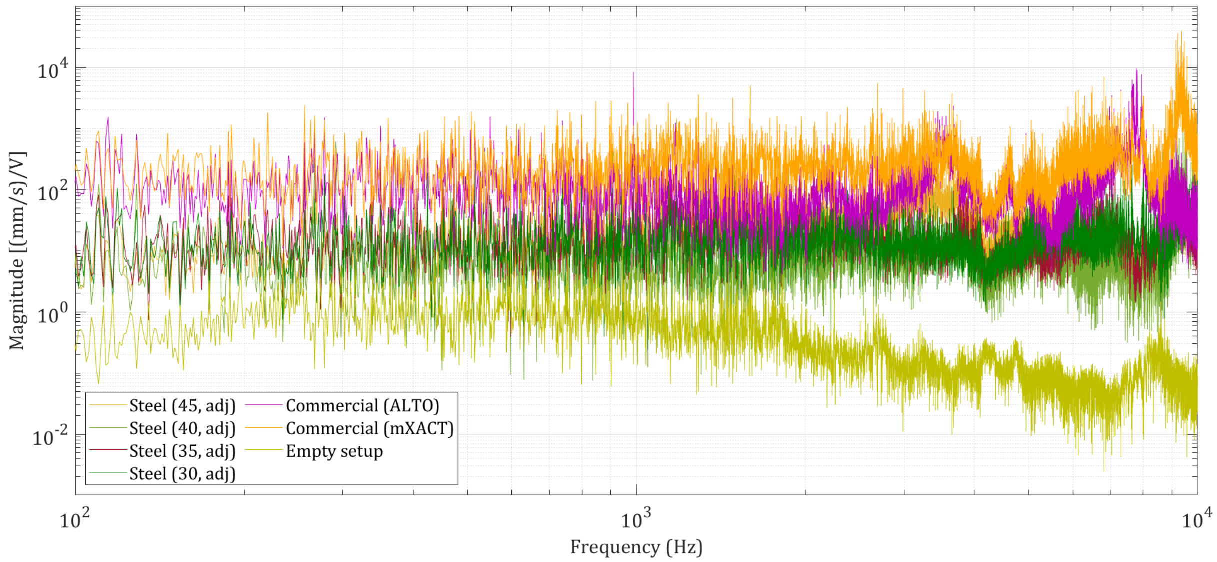


Figure 72: The unfiltered transfer functions of Concept 2B (laser cut TORP with adjustable shaft), commercial TORPs and empty setup

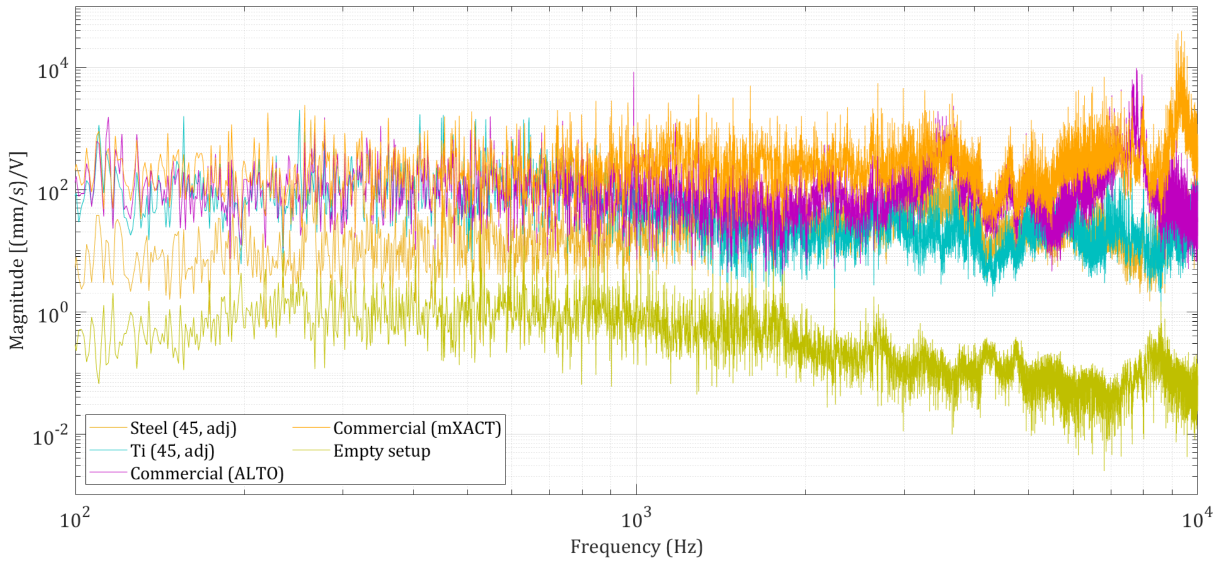


Figure 73: The unfiltered transfer functions of Concept 2B made of stainless steel and titanium, comparing with commercial TORPs and empty setup

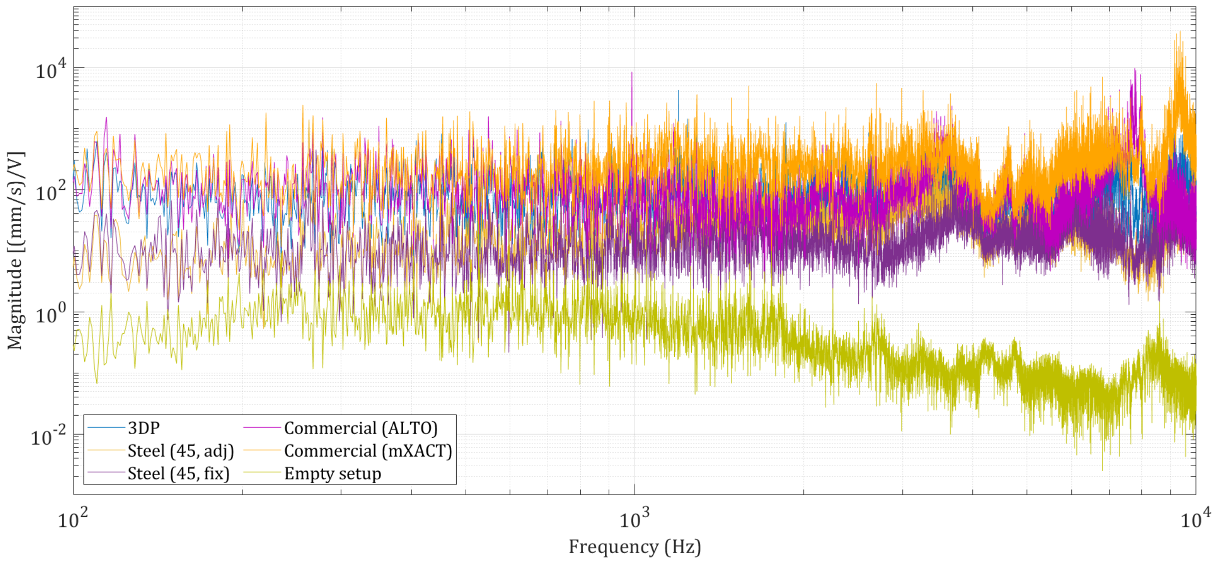


Figure 74: The unfiltered transfer functions of Concept 1, Concept 2A and 2B (stainless steel), commercial TORPs and empty setup

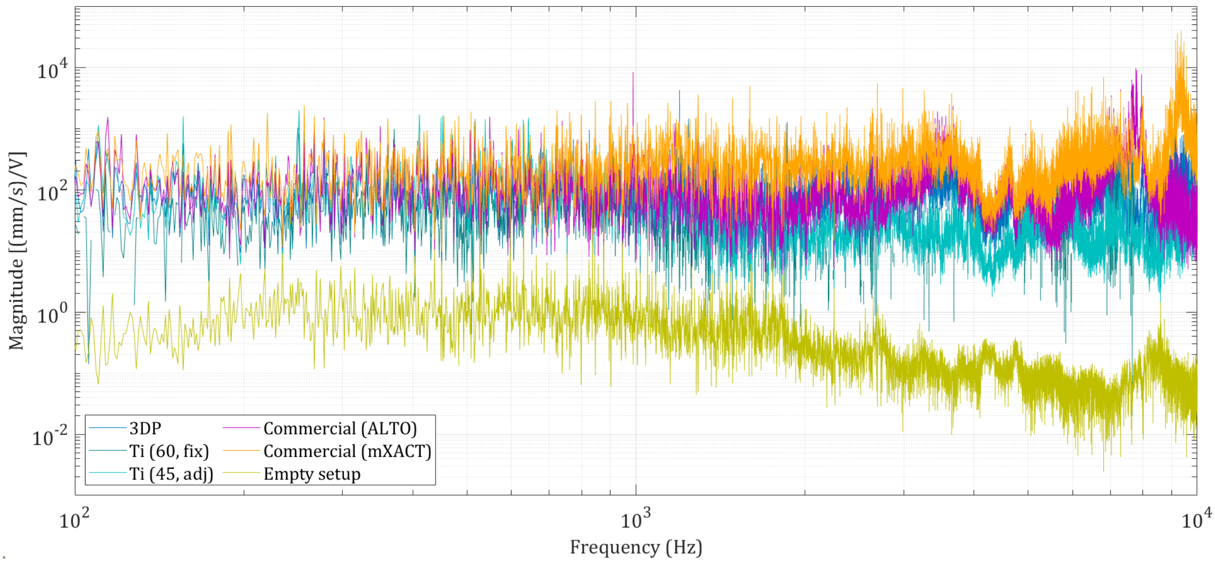


Figure 75: The unfiltered transfer functions of Concept 1, Concept 2A and 2B (titanium), commercial TORPs and empty setup

The RMSEs were computed for the three concept solutions to assess and compare their sound transmission properties in Table 13. The frequency spectrum was divided into three distinct bands: 0.1 to 1 kHz, 1 to 4 kHz, and 4 to 10 kHz. Subsequently, the comprehensive frequency range of 0.1 to 4 kHz was utilized for the final evaluation, while the range of 0.1 to 10 kHz was employed to provide an overall perspective across all tested frequencies. The percentage errors for each concept were derived from the RMSE values of the ALTO Dornhoffer reference. To conduct the assessment, the errors for all lengths within Concept 2A made of stainless steel were averaged, and identical process was conducted for Concept 2B as well.

TORP	Frequency Range: 0.1 - 1 kHhz		Frequency Range: 1 - 4 kHz		Frequency Range: 4 - 10 kHz		Frequency Range: 0.1 - 4 kHz		Frequency Range: 0.1 - 10 kHz	
	RMSE	**Percentage Error**	**RMSE**	**Percentage Error**	**RMSE**	**Percentage Error**	**RMSE**	**Percentage Error**	**RMSE**	**Percentage Error**
ALTO Dornhoffer	1792.9	-	191.8	-	446.9	-	915.0	-	673.5	-
mXACT Offcenter	1799.6	-0.38%	381.6	-98.98%	1077.9	-141.18%	962.1	-5.15%	1032.9	-53.36%
1 (4.5 mm)	1793.0	-0.01%	122.5	36.15%	114.5	74.37%	906.1	0.98%	578.7	14.07%
2A (titanium, 6.0 mm)	1795.5	-0.15%	28.1	85.35%	35.7	92.01%	901.4	1.49%	569.6	15.43%
2A (stainless steel, 6.0 mm)	1792.6	0.02%	19.9	89.61%	36.1	91.92%	899.8	1.67%	568.6	15.58%
2A (stainless steel, 4.5 mm)	1793.1	-0.01%	23.0	87.99%	26.0	94.18%	900.1	1.63%	568.5	15.60%
2A (stainless steel, 4.0 mm)	1793.4	-0.03%	8.0	95.81%	13.3	97.02%	900.0	1.64%	568.2	15.64%
2A (stainless steel, 3.5 mm)	1793.1	-0.01%	20.9	89.09%	73.0	83.67%	900.0	1.63%	570.9	15.24%
2A (stainless steel, 3.0 mm)	1793.0	0.00%	23.3	87.85%	71.9	83.90%	900.0	1.64%	570.8	15.25%
2B (titanium, 4.5 mm)	1799.3	-0.36%	31.4	83.61%	27.7	93.81%	903.4	1.27%	570.6	15.28%
2B (stainless steel, 4.5 mm)	1792.4	0.03%	53.8	71.96%	27.7	93.80%	900.7	1.56%	568.9	15.53%
2B (stainless steel, 4.0 mm)	1793.3	-0.02%	9.3	95.13%	29.9	93.32%	900.0	1.64%	568.5	15.59%
2B (stainless steel, 3.5 mm)	1791.9	0.06%	21.3	88.91%	26.6	94.06%	899.4	1.70%	568.1	15.66%
2B (stainless steel, 3.0 mm)	1793.1	-0.01%	17.9	90.65%	29.1	93.50%	900.0	1.64%	568.5	15.59%

Table 13: The RMSEs and corresponding percentage errors of different TORPs in five different frequency ranges: 0.1 - 1 kHz, 1 - 4 kHz, 4 - 10 kHz, 0.1 - 4 kHz and 0.1 - 10 kHz.