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Design of a Video Otoscope Prototype with an Integrated Scanner for Hearing Aid Direct Digital Manufacturing: A Preliminary Study

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Featured Application: Cost-effective strategy for accurately diagnosing and monitoring auditory pathologies through applied artificial intelligence methodologies. Additionally, the production of customized hearing aids tailored for various medical and non-medical applications, including but not limited to sports, music, and military use.

Abstract: In the current landscape of hearing rehabilitation, ear mold manufacturing typically involves the injection of silicone into the external ear canal (EEC) of each patient. This invasive procedure poses several risks, including the potential for silicone residue retention and tympanic membrane perforation, which may necessitate surgical intervention. To mitigate these risks, we present the design of a video otoscope that integrates a scanner capable of capturing high-precision, real-time images of the EEC's geometry. The developed device allows (i) the generation of a 3D CAD model leading to the direct, quick, and low-cost production of customized hearing aids using 3D printing and (ii) the establishment of medical protocols for carrying out diagnoses and monitoring of hearing pathology evolution using methodologies based on Artificial Intelligence. Furthermore, the use of customized hearing aids that allow the application of Rhythmic Auditory Stimulation (RAS) and music therapy enhances audiology as an alternative and innovative way to treat cognitive and degenerative diseases, as well as pathological disorders.

Keywords: video-otoscope; hearing aids; 3D printing; hearing pathologies; ear protectors

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1. Introduction

Hearing loss affects a significant portion of the population, with projections indicating that nearly 2.5 billion people may experience some degree of hearing loss by 2050. The prevalence underscores the critical need for accessible and effective hearing care services

worldwide [1]. In fact, hearing loss leads to a lower quality of life and social, communicative, and emotional isolation, leading, in some cases, to depression [2,3].

Understanding the etiology behind the need for hearing aids involves exploring the different pathologies that lead to hearing loss. Hearing loss can be defined as conductive or sensorineural depending on the causes of hearing loss, as explained by Anastasiadou [4]. Depending on the severity of hearing loss, treatment options include hearing aids, cochlear implants, and other assistive technologies. Hearing loss assessment involves detailed audiometric testing to accurately diagnose the type and extent of hearing loss. This assessment includes pure-tone audiometry and tympanometry, along with Rinne and Weber tests, to distinguish between conductive and sensorineural hearing loss components [5].

A hearing aid is a device that is used in the rehabilitation of various types of deafness or hearing loss or for hearing protection purposes. Recent studies have revealed the potential of audiology, mainly through rhythmic RAS and music therapy, by hearing aid use. By integrating RAS and music therapy into their patients' treatment plans, healthcare professionals have discovered enhanced improvements in the quality of life and functional abilities of individuals with cognitive, degenerative, or motor disabilities compared to conventional therapies [6–10]. Regardless of hearing aid use purpose, the commitment to customized solutions across the range of audiology underlines the importance of personalized care to achieve the best possible results for patients and users of all ages and with different pathologies or specific needs, such as pediatrics applications, risk of hearing damage environments, military purposes, musicians, and others [10–14]. The selection of the style, type of hearing aid, material and design of the ear mold, and print quality are key factors in personalizing the adaptation of the hearing aid to the individual's needs, ensuring both performance and comfort [10,15–17].

Nevertheless, these choices also depend on factors such as the extent of ear loss, the individual's preference, anatomical considerations, and the audiologist's recommendations [16]. The goals of a custom hearing aid include ensuring adequate acoustic sealing, in-ear retention, acoustic signal modification, comfort, and pleasing aesthetics. These are the advantages of custom hearing aids compared to universal parts.

This paper presents a low-cost direct digital manufacturing methodology for obtaining customized hearing aids. A video otoscope prototype with an integrated scanner was designed and built for this purpose. This video otoscope will also allow the real-time acquisition of external ear canal (EEC) images, leading to quick diagnoses and evolution monitoring of hearing pathologies through AI methodologies.

The use of AI for diagnosing and recognizing ear pathologies has grown significantly in recent years. With the advancement of machine learning techniques and deep neural networks, it has become possible to create systems capable of accurately identifying various hearing conditions, often with results comparable to those of healthcare professionals. These software programs typically use medical images, such as audiograms, MRIs, CT scans, or even acoustic signals, such as otoacoustic emissions, to automatically diagnose conditions such as hearing loss, e.g., otitis, and other diseases characteristic of the inner ear. Among the most relevant applications, convolutional neural networks (CNNs) stand out, as they have been widely used for analyzing medical images. These algorithms are trained on large databases of otoscopic images and other related images to identify patterns that indicate the presence of pathology. A notable research study was carried out by Rony et al. [18], who developed an AI system to automatically detect acute otitis media through otoscopic images, achieving diagnostic accuracy greater than that of medical professionals in some cases. Additionally, software such as DeepHear developed by AlSamhori et al. [19] uses AI to analyze audiometry signals and help with the early detection of hearing loss. The system is based on recurrent neural networks (RNNs) and has been used to predict the evolution

of hearing loss in patients, contributing to more personalized treatments. These systems are particularly useful for diagnosis in remote areas or places with a shortage of specialized professionals. Other examples include OtoAI software, which applies AI algorithms to detect and classify inner ear pathology from MRI scans. The software is designed to be used in hospital settings, helping medical professionals make faster and more accurate diagnoses. The use of AI in diagnosing ear pathologies offers great advantages, such as reduced human errors, greater accuracy, and the ability to analyze large volumes of data in real time. However, the widespread implementation of these systems still faces challenges, such as the need for broad databases and rigorous clinical validation to ensure the reliability and safety of results.

The video otoscope with integrated scanner presented here allows the acquisition of EEC images in real time, avoiding submitting patients to radiation, e.g., in MRI or CT scans. Furthermore, it represents an economical and quick way to obtain the 3D EEC geometry CAD model for customized hearing aid 3D printing through the use of Open-Source 3D reconstruction software, such as COLMAP, developed by Schönberger and other researchers at the Technical University of Munich [20]. The versatility and efficiency that characterize COLMAP have made it a popular tool in 3D reconstruction projects in areas such as archaeology, architecture, and engineering. Moreover, it has also been used in academic and research environments [21]. In a clinical context, Scuoppo et al. [22] demonstrate the value of using advanced computational tools, augmented visualization, and 3D printing in pre-procedural planning for high-risk cardiac interventions, concluding the feasibility and safety of integrative augmented reality, simulations, and 3D printing in procedural planning. These technologies provide enhanced visualization, accurate prediction of device interference, and increased procedural confidence prior to cardiac intervention. Additive manufacturing (AM) offers significant cost and delivery time reductions due to the inherent characteristics of the manufacturing process. Compared to traditional machining, AM techniques are simpler to execute as they do not require detailed drawings, using nominal geometry based on computer models [23]. Nevertheless, open-source photogrammetry software, such as Meshroom [24] developed by AliceVision [25], or commercial solutions, such as Agisoft Metashape [26], can also be used.

2. Challenges and Innovations in Hearing Aid Fitting: From Conventional Molds to Digital Molds

2.1. Conventional Mold

The custom production of ear molds is a crucial component in the hearing device fitting process. According to recent research conducted in the United States, more than 60% of these devices require a specific ear mold to ensure a proper fit in the user's ear [8]. This mold is essential not only to ensure effective sound insulation but also to promote high-quality sound transmission and prevent audio loss. To obtain this mold, an accurate acquisition of EEC geometry is necessary to create a 3D model. This model is the basis for the additive printing of the ear mold, into which the electronic components of the hearing aid are integrated. Once assembled, the device is returned to the audiologist, who fits the device to the patient. However, if the fit is not perfect, the process of obtaining a new mold must be repeated, resulting in significant additional costs and time [27]. This complexity highlights the need for more efficient and accessible methods in the field of audiology, which justifies the development of the video otoscope with an integrated scanner presented here.

The conventional method for creating EEC molds involves inserting a silicone blend into the patient's ear, to which a catalyst is added to solidify the material and generate the desired EEC geometry. This procedure must be performed in specialized clinics by

qualified professionals to ensure the required safety and accuracy. However, in cases where the obtained mold lacks accuracy, it becomes necessary to repeat the process. Furthermore, the quality of the mold is compromised by factors such as an excessive presence of wax, infections, or wounds in the ear, in addition to the possible inexperience of the audiologist. These circumstances increase the likelihood of an inadequate mold. Still more serious is that due to its invasive nature and potential for unexpected complications, including abrasions, trauma, inflammation, bruising, or injury to the tympanic membrane and internal auditory structures, and in severe cases, eardrum perforations, this procedure is viewed as the riskiest procedure performed by audiologists [28,29]. Furthermore, the existence of hidden mastoid cavities can bring about serious risks when filled with impression material, which requires surgical removal [28,30–33].

In the face of these challenges, adopting non-invasive, indirect ear contact procedures, such as EEC scanning, appears to be a safer and more comfortable alternative, offering significant advantages for both patients and hearing healthcare professionals.

2.2. Digital Mold

A study conducted by the U.S. Army Aeromedical Research Laboratory (USAARL Report No. 2020-06) presents a comparative analysis of traditional ear mold generation methods versus those employing ear scanning technologies. The emphasis on comfort arises from the understanding that the more comfortable the hearing protection device is, the more likely users will be to wear it consistently and for as long as necessary, especially in environments with noise levels considered hazardous [13].

Recently, new alternative technologies to traditional ear printing have been developed to eliminate the need for physical mold manufacturing. One such innovation is the Otoscan from Otometrics, a portable 3D ear scanner that creates digital 3D impressions of the ear. However, Otoscan still requires the introduction of a probe into the EEC, which can cause discomfort to the patient. Furthermore, to handle Otoscan effectively, significant learning about how the equipment works is necessary, which led its maker, Otometrics, to create a training program with 27 modules, including videos and questionnaires, to train health professionals in the use of the device [34]. Furthermore, the cost associated with Otoscan limits its use in clinics with reduced financial resources [35]. Although the use of lasers for 3D imaging acquisition is an established practice in several industries, the application of this technology to replicate the complexities of EEC has only recently been researched and implemented. Ear scanning devices, such as the Otoscan and Lantos instrumentation, employ 3D laser mapping techniques to create an accurate digital image of the ear canal, similar to the current practice of dentists constructing custom dental implants [36,37].

The Artec Space Spider from Artec 3D is another commercially available technology. This technology integrates a portable 3D scanner that uses structured blue light to scan small objects, transforming them into 3D models. A case study highlighted the use of the Artec Space Spider to scan the ear's external structure, aiming to create custom ear prostheses for cases of deformity [38]. This device is accompanied by Artec Studio software (Version 19) for processing and rendering scans. Like Otoscan, its cost may limit its use in environments with fewer financial resources [39].

Another innovation is TinyScan360°, a device designed for measuring ear canals. This scanner has already been successfully tested and shown to be extremely useful for fitting modern hearing aids, allowing for easy and individual customization for the user. TinyScan360°'s ability to accurately measure spaces as small as the ear canal clearly illustrates the flexibility and effectiveness of these technologies in medical applications. The 3D stereoscopic measuring system, with a design diameter of just 3 mm, allows contactless 3D

measurement, visualization, and reconstruction of small objects such as pipes and holes with diameters of less than 10 mm [39].

Despite significant advances and innovations in the field of auricular scanning, currently, available systems still have substantial limitations that restrict their applicability and effectiveness in broader contexts and with fewer financial resources. Despite being technologically advanced and precise, these devices continue to require the insertion of probes or membranes into the ear canal. Furthermore, the high cost of these systems represents a significant obstacle to their adoption, especially in clinics with limited financial resources, thus restricting access to these technologies in regions with lower purchasing power. Another critical aspect is the operational complexity of these devices. Many require specialized training to handle them effectively.

Additionally, given that they were designed for specific situations, such as adjusting hearing aids or creating ear prostheses, they may not be suitable for other applications required in audiology or otorhinolaryngology, such as quickly establishing a diagnosis or monitoring pathologies. The lack of a truly multifunctional system that can be used effectively in different clinical contexts and others, as reported in Section 1, is still a significant limitation. Given this scenario, it is imperative to develop a new solution that not only fills these shortcomings but is also more accessible from an economic point of view, comfortable, and efficient. The following section will explore the proposed innovative solution, which aims to overcome the aforementioned limitations by offering a more low-cost, adaptable, and safer tool for auricular scanning and other associated clinical uses.

3. Development of a Video Otoscope with an Integrated Scanner: A Low-Cost Approach

The direct digital manufacturing (DDM) methodology [40] was applied here to produce final customized hearing aids directly from digital files. This methodology has no limitations concerning the geometry to be produced. Additionally, it allows the usage of a wide range of materials and parts manufacturing in shorter times and with considerable cost savings. A video otoscope with an integrated scanner was developed to obtain the EEC geometry digital files. The concept was based on support for the video otoscope that will act as a reference system for the EEC geometry-image acquisition. This reference system is crucial to guarantee the image-acquired positions to build the EEC 3D CAD model to be produced by 3D printing. The images are captured through an actuator attached to the reference system, which performs longitudinal linear movements from the inside to the outside of the EAC. This concept is presented in detail in the following sections.

3.1. Video Otoscope Design

The initial phase of the system development focused on defining the technical and functional requirements of the device, followed by detailed hardware design. Ergonomic aspects were considered, such as user comfort and ease of handling, as well as the integration of technologies to guarantee the effectiveness and precision of the system. The device architecture was designed to be modular and easily adjustable, which facilitates its adaptation to different application scenarios. All elements were designed to be quickly assembled and disassembled. To guarantee the adaptation of the system to different ear morphologies, strategically positioned screws were considered, which, in addition to guaranteeing the stability of the system, enable personalized adjustment and manual insertion of the video otoscope into the ear canal. The video otoscope is coupled to an actuator that allows its controlled retreat and advancement within the EEC. This feature aims to facilitate accurate image collection throughout the ear canal, ensuring a reliable and adaptable experience for healthcare professionals and patients.

The configuration and adjustment of the video otoscope (Figures 1 and 2) are essential to guarantee an accurate and comfortable hearing examination. The vertical position of the video otoscope is adjusted through the support–headgear interface, see Figure 1. This system allows precise adjustment of the height of the video otoscope using a screw that secures the connection between the bracket and the headgear. The headgear can be repositioned and adjusted, providing a personalized adaptation to the user ensuring that the video otoscope is always at the desired height for the examination. Furthermore, the angular tuning of the video otoscope, both vertically and horizontally, is achieved through a spherical joint (Figure 2A). This joint is used to connect the part that supports the video otoscope fitting, which allows precise adjustments to the necessary angles. This configuration ensures that the video otoscope can be oriented in various directions, adapting to the specific anatomy of each patient's ear canal and ensuring that the examination is performed at the correct angle.

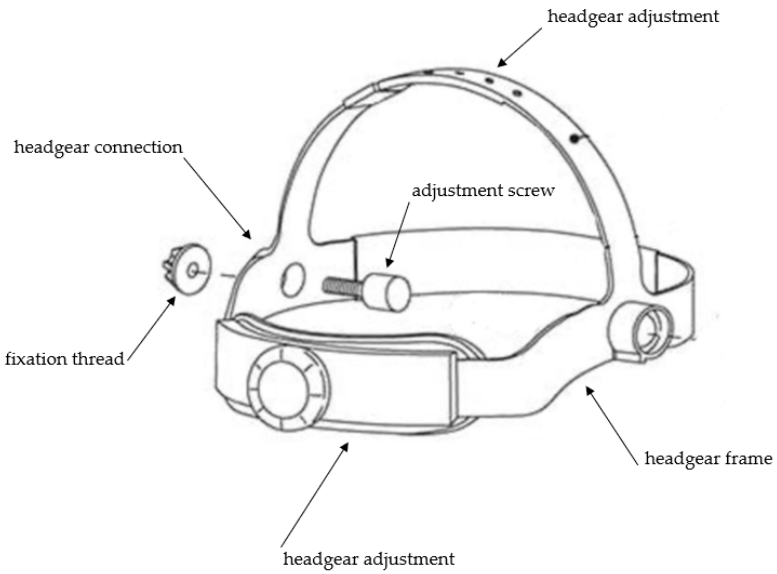

Figure 1. Video otoscope support components for height positioning.

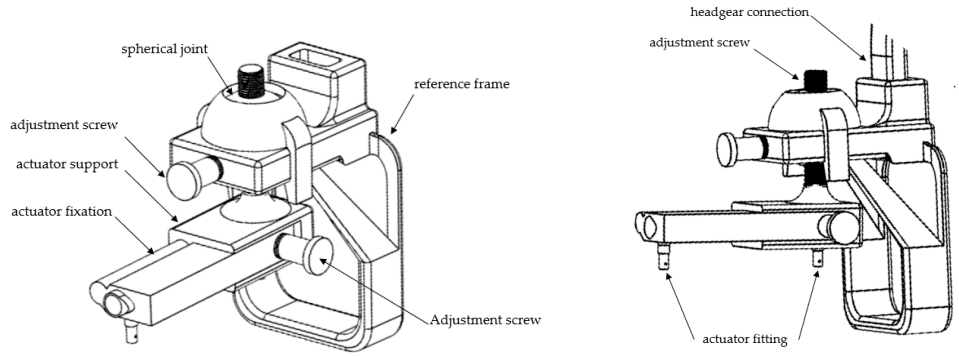

Figure 2. Video otoscope support components for angular positioning (**A**) and longitudinal axis fitting (**B**).

As referred before, the system was designed to be versatile, allowing the use of video otoscopes with different dimensions. This way, the video otoscope support comprises a set of easily interchangeable parts. These interchangeable parts allow the device to be adapted to accommodate video otoscopes of various sizes without compromising the stability or accuracy of the equipment. Changing parts is simple, ensuring that the process of adapting to different video otoscopes is quick and effective. Additionally, to ensure that the video

otoscope is always placed in the same way on the equipment, the part where it is attached plays a crucial role. The geometry of this part was carefully designed to prevent any rotation of the video otoscope along its longitudinal axis (Figure 2B). This design, created in Solidworks 2023 SP2.1, ensures that the video otoscope is always positioned in the same way, maintaining consistency in placement and, consequently, in the examination quality.

The device provides different and multiple adjustment points to adapt the system to different relative positions of the ear pinna. The headgear can be adjusted to allow the device to align correctly with the specific anatomy of the ear pinna of each patient. In addition, the ball joint, which includes a screw, allows for additional vertical adjustment, providing precise control over the positioning of the video otoscope in relation to the ear canal. These adjustment options ensure that the device can be adapted to a wide range of anatomical variations of the ear pinna. In addition, the headgear itself is fully adjustable. This adaptability is crucial to ensure that the video otoscope remains correctly positioned throughout the examination, regardless of variations in the size of the patient's head.

The device is symmetrical to allow the use of the video otoscope in either the left or right ear without additional adjustments. This symmetry avoids the need for specific components, ensuring the device can be used conveniently and efficiently in both ears. The linear movement of the video otoscope from the inside to the outside of the ear canal is controlled by a system driven by a controller. The actuator is activated to extend the video otoscope, i.e., to move it back in relation to the ear and vice versa. This mechanism allows the movement to be performed precisely and smoothly, ensuring that the video otoscope moves back in a controlled manner, guaranteeing the continued collection of high-quality images throughout the examination process.

3.2. Video Otoscope Prototype

Due to its versatility, fused deposition modeling (FDM) was the additive process selected to produce the various parts of the developed system. Figure 3 shows the developed prototype, and Table 1 shows the printing conditions used, including the USB camera connected to the Raspberry Pi.

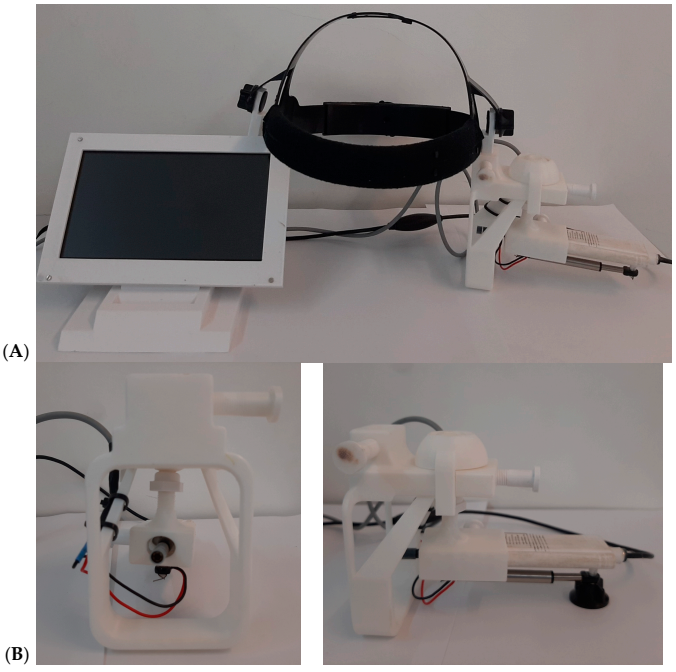

Figure 3. Prototype of the video otoscope support: (**A**) device overview and (**B**) video otoscope positioning detail.

Table 1. Control parameters for 3D printing by FDM.

Extrusion Temp. (°C)	Bed Temp. (°C)	Extrusion Speed (mm/s)	Print Filling (%)	Layer Height (mm)	Nozzle Diameter (mm)	Total Printing Time (hrs)
210	60	300	15	0.2	0.4	5.22

Images were collected using a USB camera intended for ontological inspection to validate the device developed from a functional point of view. This camera, characterized by its simplicity and portability, was connected to a Raspberry Pi microcomputer (the control and processing unit). The selection of these components aimed to achieve a balance between low cost, flexibility, and efficiency in acquiring the images necessary to validate the developed device.

A simple program was developed in Python (Python 3.11 with Library NumPy 2.0.0 and OpenCV-Python 4.10.0.84) to facilitate camera operation and image acquisition. The program allowed the camera to be controlled effectively, capturing images directly on the Raspberry Pi 5. This automated process simplified data collection, reducing manual intervention and ensuring greater consistency in results. Figure 4 illustrates examples of the collected images for different EECs: (A) EEC #1 and (B) EEC #2.

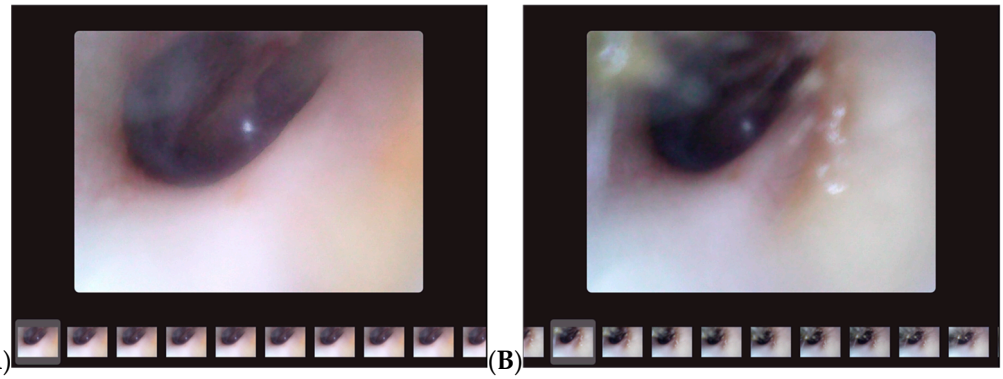

Figure 4. Example of image acquisition for different external ear canals (EECs): (**A**) EEC #1 and (**B**) EEC #2.

The 3D CAD model (Figure 5) is then built by superimposing, according to a reference system, the various 2D images captured at different angles, thus allowing a reliable representation of the geometry of the patient's ear canal. The images are then processed by specialized 3D reconstruction software, which uses computer vision algorithms to generate the 3D CAD model of the ear canal, as mentioned before. Once the 3D reconstruction is obtained, the model can be used to produce custom hearing aids. This process begins by converting the digital model into a file suitable for 3D printing, such as an STL file. From this file, a 3D printer produces a physical mold that precisely replicates the anatomy of the patient's ear canal. Depending on the material used in printing, the mold can be used directly or as a base to manufacture devices such as hearing aids or ear protectors.

This approach brings great advantages, such as greater precision in adapting the hearing aids to the ear canal and consequent increase in comfort and effectiveness for the patient. Furthermore, the use of 3D printing allows for rapid and personalized production, reducing the time between diagnosis and availability of the hearing aids to the patient, in addition to increasing their quality, considering that the adjustment is based on the specific anatomy of each individual patient.

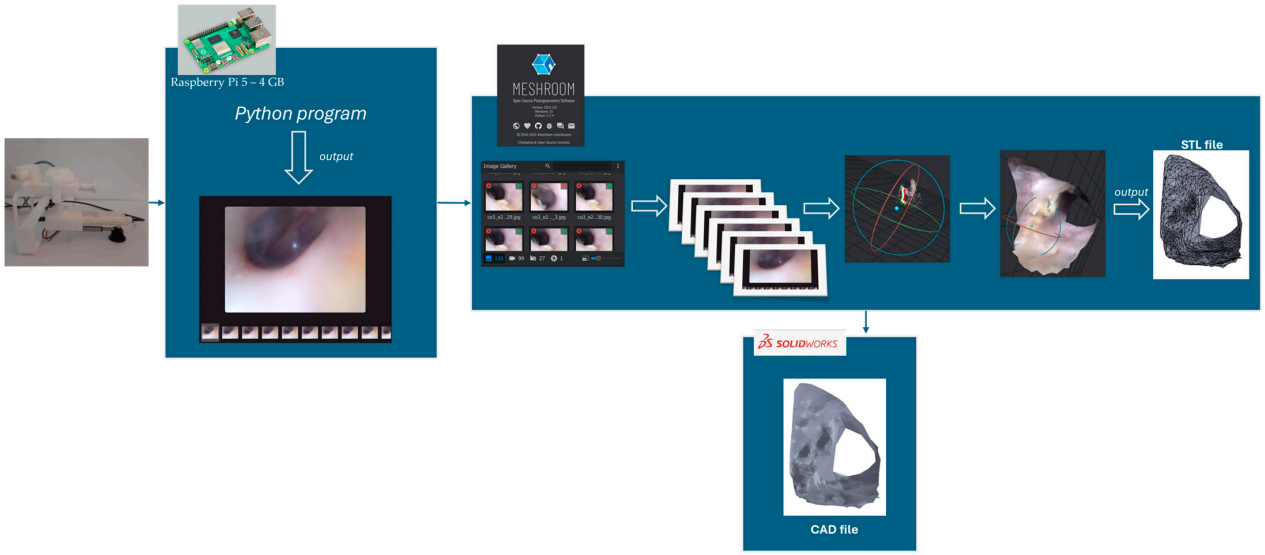

Figure 5. Workflow of the methodology used.

Having technically validated the functionality of the developed device, it is now necessary to determine the receptivity of its use by the medical team and patients. In the following section, validation tests for the proposed video otoscope will be described and analyzed based on the responses from surveys conducted with speech therapists and patients. These validation tests involved both the evaluation of the technical performance of the video otoscope and the users' perception regarding its comfort and ease of use during the examination. These tests covered a diverse set of conditions, including analyzing the adaptability of the equipment to different ear morphologies. In addition, qualitative and quantitative analyses were carried out to identify the primary deficiencies of the equipment and proposed improvements. The evaluations included issues related to patient comfort and ease of handling by healthcare professionals, considering different user profiles and challenges faced in real clinical contexts.

4. Video Otoscope with an Integrated Scanner Prototype Validation

The development and adoption of new medical devices, such as the new video otoscope, requires systematic evaluation to ensure their effectiveness, efficiency, and acceptance by healthcare professionals, which is essential to ensure that they meet the needs of healthcare professionals and provide a satisfactory and efficient user experience [41].

According to the International Organization for Standardization (ISO), usability is defined as "the extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" [42]. To validate the new system, it is essential to measure not only its technical efficiency but also the user's experience of using the equipment in real clinical environments.

Clinical performance is related to the equipment's ability to provide accurate, reliable, and safe results when used in real situations. In the case of the video otoscope, clear and detailed visualization of the structures of the EEC and tympanic membrane is crucial. Indicators such as complete visualization and the ergonomics of the equipment are fundamental to validating the device as a valuable tool in clinical practice. An efficient device reduces examination time, improves patient comfort, and increases diagnostic accuracy, which are essential characteristics in the clinical context of performing otoscopy. This includes diagnostic or therapeutic efficacy, safety for the patient and the healthcare professional, compliance with current international standards for the use of medical devices, and minimizing the risks and adverse effects associated with the use of the equipment. On the

other hand, the device must also be able to adapt to the different anatomies of the EEC and head without compromising the performance of the function for which it was designed, maintaining its performance over time under normal conditions of use (i.e., reliability) [43].

The construction of the video otoscope prototype followed a set of stages illustrated in Figure 6 and is now at the prototype evaluation stage.

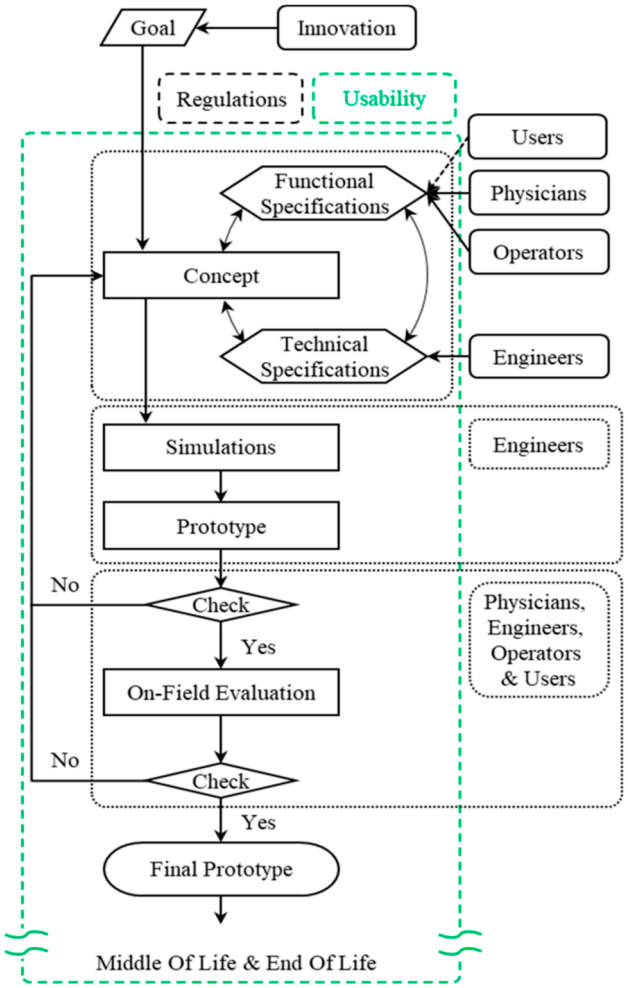

Figure 6. Usability-oriented model for the design of medical devices [41].

The analysis of ergonomics and patient safety is essential to ensure that the use of the device does not compromise the comfort or physical integrity of the patient, so the device's design has been thought out to address these aspects as well. The construction of this device took into account its physical and functional adaptation following the safety and efficiency standards required in the medical device industry [44].

A clinical trial was carried out to validate and verify this prototype of the video otoscope in which feedback was obtained from health professionals in the area, as well as from users of the device, to collect qualitative and quantitative data on usability, ergonomics, and satisfaction with the equipment [42]. The feedback was collected by self-administering two questionnaires, one for health professionals and one for device users.

The questionnaire is a crucial tool to ensure that the new video otoscope meets the needs of healthcare professionals, namely audiologists and patients while contributing to advances in clinical practice and medical technology. Analysis of the results will make it possible to identify areas for improvement and validate the device as a practical and efficient solution in otoscopy.

The application of this questionnaire aims to provide valuable feedback that will contribute to the optimization of the otoscope, both in terms of performance and acceptance in the clinical context. This evaluation aims to ensure that the new device is effective and safe for diagnosis and to identify ways of improving the healthcare professional's experience, positively impacting the quality of patient care.

The first part of the questionnaire collects detailed information about the condition of the patient's outer ear, allowing audiologists and other healthcare professionals to assess the specific characteristics of the EEC and eardrum, which are essential for comparing the performance of the conventional otoscope and the new device. Analysis of the physical aspects of the ear, such as the length and diameter of the EEC and the presence of cerumen and/or foreign bodies in the EEC, or pathologies, are critical for determining the effectiveness of the otoscope in a variety of conditions. The questionnaire then consists of short closed-answer questions, which assess aspects such as the difficulty in handling the video otoscope, the ability to adjust to the curvature of the EEC, and the learning curve to identify barriers to its effective use. The authors believe that the design of a device should be guided by the needs and limitations of the end users—based on the principle of user-centered design. The questionnaire collects direct audiologist feedback, allowing for improvements based on real user experiences. The usability of a medical device is fundamental to ensuring that healthcare professionals can use it efficiently and safely without compromising the quality of care.

Questions are performed to assess the efficiency of the video otoscope and explore its comfort, stability, and ease of use. These aspects include the following: (i) the fixation of the equipment in the patient's external auditory canal, (ii) the depth of insertion, and (iii) the clarity/sharpness of the image obtained, all of which determine the success of the clinical examination. The Likert scale used in the questions makes it possible to capture subjective levels of satisfaction and difficulty, translating qualitative opinions into quantitative data that can be analyzed statistically, from difficulty in handling to overall satisfaction with the equipment. These measurements are useful for identifying patterns in the user experience, allowing for iterative device validation based on empirical feedback.

In addition, open questions are inserted into the questionnaire so that professionals can identify specific limitations that could be improved in the device. This qualitative information offers a more detailed view of the areas that need adjustment, whether related to ergonomics, equipment performance, or comfort during prolonged use. According to the Technology Acceptance Theory [45], perceived usefulness and ease of use are key determinants of technology adoption. Collecting criticisms and suggestions helps the researcher to align the device according to the users' expectations.

The patient's perspective was also taken into account through a questionnaire using a Likert scale, where 1 corresponds to very dissatisfied/very difficult and 5 to very satisfied/very easy, whose questions focus on the new device's satisfaction, comfort, and ergonomics. The degree of satisfaction using the video otoscope compared to conventional otoscopy was also taken into account. As with the questionnaire aimed at healthcare professionals, the open questions were considered an opportunity for device optimization in future versions.

In this first validation phase, 11 health professionals answered the questionnaire, with a minimum of one year's professional experience and a maximum of 28 years, with an average of 7.9 (SD $\pm$ 10.08) years of experience (Figure 7). This variation in the length of professional experience was intentional to understand new professionals' adherence to the technology and, on the other hand, to see if the technology could be a barrier for professionals with more years of experience with ingrained habits of using conventional otoscopy. Each professional underwent two evaluations (right and left ear) for 22 experi-

ences with the new device. Concerning the adjustment and fixation, the average response to question 1—Difficulties in fixing/stabilizing the equipment to the participant's head—was 3.09 (SD ± 1.3), with a mode of 4 for a maximum response of 5, corresponding to very satisfied/very easy, according to the Likert scale. Regarding the second question—Difficulties in positioning the acquisition system inside the EEC (with maximum depth) ensuring the safety of the participant—the average was 2.67 (SD ± 0.73), with a mode of 3. Question 3—Difficulties in adjusting the center of the image for the best visualization of the participant's tympanic membrane—had an average response of 2.86 (SD ± 1.03) and a mode of 3. With regard to question 4 of this item on adjusting and fixing the new device, entitled How easy was it to start using the video otoscope, the average response was 3.29 (SD ± 1.35), with a mode of 4. Finally, the answers to question 5—How long did it take you to familiarize yourself with the device's controls?—revealed an average of 3.33 (SD ± 1.06), with a mode of 3. Overall, we can see that with regard to adjusting and attaching the new device, the average response was 3.03 (SD ± 1.14), with a mode of 3.

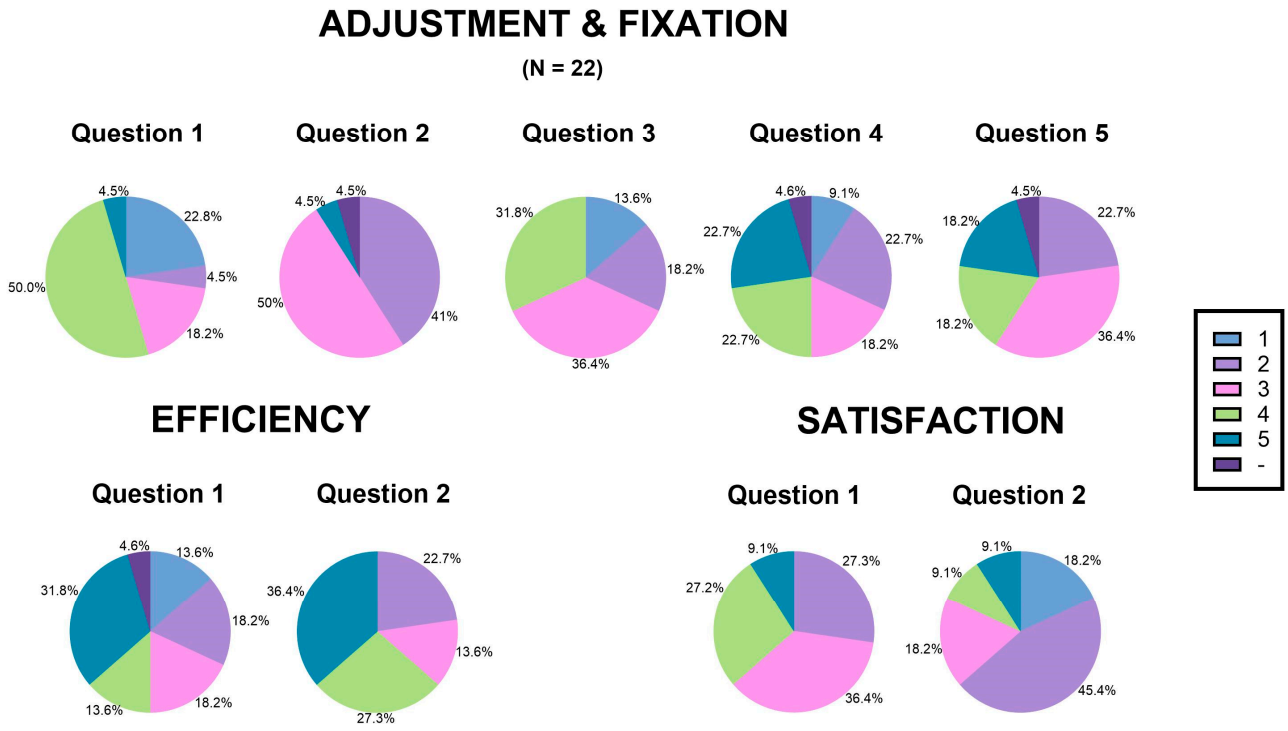

Figure 7. Results of the questionnaire to health professionals regarding adjustment and fixation of the video otoscope.

Regarding the efficiency of the new video otoscope, we were asked two questions: the first on the complete visualization of the tympanic membrane and the second on the visualization of the entire external auditory canal, obtaining average answers of 3.18 (SD ± 1.62) and 3.77 (SD ± 1.19), with a mode of 5 in both questions. Overall, on the effectiveness of the new device, we found an average response of 3.48 (SD ± 1.44) with a mode of five (maximum value).

Satisfaction with the new device was assessed through two questions: the first, How satisfied are you with using the video otoscope?, and the second, which focused on the comfort and ergonomics of the equipment, entitled Does the equipment seem ergonomic and comfortable for long-term use in your clinical practice? The answers to these questions had a mean of 3.18 (SD ± 0.98) and 2.45 (SD ± 1.21), with a mode of 3 and 2, respectively. An overview analysis of satisfaction on the part of the Health professionals who took part in this pre-test of the new device shows that the average response was 2.88 (SD ± 1.14),

with a mode of 2. Open-ended questions and suggestions for improvement were put forward, which essentially focused on attaching the equipment to the patient's head, with the possibility of the professional pulling the EEC, and on the ergonomics of the device with a view to greater comfort, which is in line with the responses obtained in the questionnaire.

The results of the questionnaire addressed to patients (N = 10, 1 of the questionnaires was not considered since the patient did not answer all the questions) revealed that their level of satisfaction with the use of the video otoscope is 4.1 (SD ± 0.64) on the Likert scale, with a mode of responses equal to 4 (Figure 8). Compared to conventional otoscopy, the patients' opinion points to a good degree of satisfaction with this new device, with an average of 3.7 (SD ± 1.42) and a mode of 5. When asked about the ergonomics and comfort of the device, the participants' answers point to an average of 3.1 (SD ± 1.29) on the Likert scale, with a mode of answers equal to 3. Facing the question, "Would you recommend this device to a family member or friend?", the majority of participants (80%) said yes.

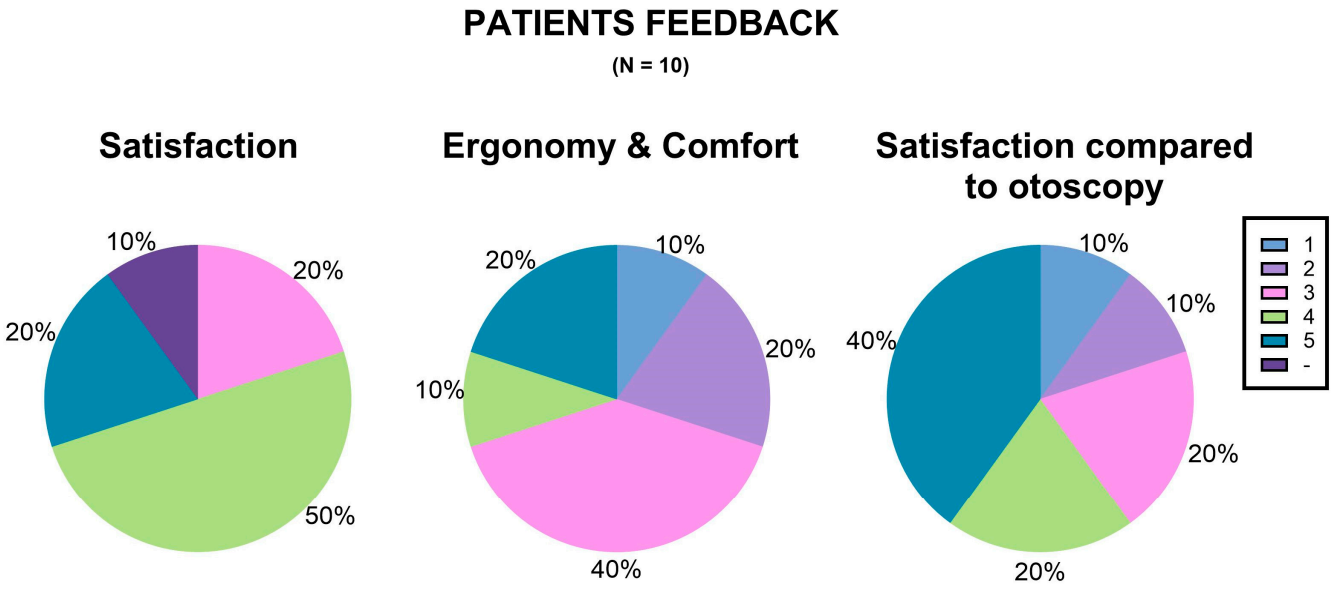

Figure 8. Results of the questionnaire to patients regarding their level of satisfaction with the use of the video otoscope.

In the open-ended questions, participants mentioned improving the fit of the head support for greater comfort.

At this stage of development, it is possible to observe that this prototype version is already at a stage where it is producing results with some consistency. However, given the results obtained in the pre-test, the prototype's next iteration should consider improving patient comfort and improving the device's fastening system.

The optimization proposals presented as results of the usability tests will increase the developed device's effectiveness, comfort, and adaptability. Improvements to be taken into account for the next iteration include the following: (i) changing geometry to unobstructed manual retraction, (ii) reducing camera diameter, (iii) increasing insertion angle flexibility, (iv) button integration for image capture, and (v) simplifying the harness attachment system. Implementing these optimization proposals is crucial for the otoscope to respond to clinical needs in a more robust way, facilitating the work of speech therapists and increasing patients' well-being.

However, the work does not end with the improvement proposals presented. It is essential to continue the development process to ensure the video otoscope meets the clinical needs in an effective and safe manner, applying the suggested changes and carrying

out new validation tests. Future testing should include a larger sample of users to ensure the device is tested in different scenarios and patient profiles, allowing for continued refinement of design and functionality. Furthermore, integrating new technologies that can further improve the performance of the video otoscope should be explored, making it an even more efficient and versatile tool for clinical use. For example, incorporating AI for the automatic analysis of obtained images could significantly facilitate diagnosing and monitoring pathologies. By implementing advanced machine learning algorithms and neural networks, the system will be able to identify patterns associated with ear pathologies, highlighting possible abnormalities quickly and accurately. This feature would not only reduce the time required for analysis by healthcare professionals but also minimize the possibility of human errors during image interpretation.

Furthermore, using AI could contribute to the development of a dynamic and constantly evolving database, fed by previous diagnoses and new medical discoveries, allowing for a continuous learning process for the system. This way, the video otoscope would be more than just a diagnostic tool; it might serve as a clinical decision support platform. Furthermore, the use of additional sensors to monitor the positioning of the video otoscope during the examination could provide real-time feedback, improving the accuracy of the procedure.

5. Conclusions

The introduction into the market of a video otoscope with an integrated scanner at an affordable cost, providing low-cost customized hearing aid manufacturing, opens new horizons for the application of audiology as an alternative and innovative method in the treatment of cognitive and degenerative diseases as well as in the monitoring of otological pathologies. This subject deserves to be explored. The prototype validation tests allowed the identification of some limitations to the model, for which researchers are building solutions adjusted to the needs of both healthcare professionals and customers. After overcoming the limitations, further validation testing is required. Despite this process, the incorporation of AI into the prototype is crucial to meeting our proposal for a completely innovative prototype on the market, managing to combine in a simpler and safer process the ability to create a 3D ear mold and simultaneously monitor pathologies. As such, the following steps of this work will be to optimize the device presented to make it an integrated and commercialized solution.

It is expected that the use of the video otoscope presented here results in (i) no risks for the patient; (ii) a drastic time reduction to obtain the EEC geometry; and (iii) an increasing ability to capture high-resolution and quality EEC geometry images. In fact, the device will not only avoid the risks associated with silicone injection, but it will also allow the DDM of hearing aids from the 3D CAD model generation. As the images are captured in real time, it is possible to establish, by using AI methodologies, medical protocols for carrying out more accurate diagnoses and efficient monitoring of EEC pathology evolution, e.g., exostoses progression with more accuracy at all times. Furthermore, a significant reduction in the time required to obtain a hearing aid and a substantial reduction in the manufacturing process cost due to the efficiency associated with DDM application can also be expected.

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References

1. World Health Organization (WHO). *Deafness and Hearing Loss*; Springer: Berlin/Heidelberg, Germany, 2019.
2. Hampson, R. Hearing Aids. *Eur. Geriatr. Med.* **2012**, *3*, 198–200. [CrossRef]
3. Tsakiropoulou, E.; Konstantinidis, I.; S2, K.; Kotsani, A. Hearing Aids: Quality of Life and Socio-Economic Aspects. *Hippokratia* **2007**, *11*, 183. [PubMed]
4. Anastasiadou, S.; Al Khalili, Y. Al Hearing Loss. In *StatPearls*; StatPearls Publishing: Treasure Island, FL, USA, 2023; Volume 22, pp. 1–7.
5. Tanna, R.J.; Lin, J.W.; De, O.; Affiliations, J. *Sensorineural Hearing Loss*; StatPearls Publishing: Treasure Island, FL, USA, 2023.
6. Ye, X.; Li, L.; He, R.; Jia, Y.; Poon, W. Rhythmic Auditory Stimulation Promotes Gait Recovery in Parkinson's Patients: A Systematic Review and Meta-Analysis. *Front. Neurol.* **2022**, *13*, 940419. [CrossRef] [PubMed]
7. Moreno-Morales, C.; Calero, R.; Moreno-Morales, P.; Pintado, C. Music Therapy in the Treatment of Dementia: A Systematic Review and Meta-Analysis. *Front. Med.* **2020**, *7*, 160. [CrossRef] [PubMed]
8. Stewart, C. Usage of Various Hearing Aids by US Market Share 2021 | Statista. Available online: https://www.statista.com/statistics/664453/different-hearing-aids-used-by-the-market-in-us/ (accessed on 13 December 2024).
9. Braun Janzen, T.; Koshimori, Y.; Richard, N.M.; Thaut, M.H. Rhythm and Music-Based Interventions in Motor Rehabilitation: Current Evidence and Future Perspectives. *Front. Hum. Neurosci.* **2022**, *15*, 789467. [CrossRef] [PubMed]
10. Fligor, B. Clinical Verification of Custom-Fitted Musicians' Earplugs. Available online: https://www.audiologyonline.com/articles/clinical-verification-custom-fitted-musicians-11373 (accessed on 13 December 2024).
11. Bower, C.; Reilly, B.K.; Richerson, J.; Hecht, J.L. Hearing Assessment in Infants, Children, and Adolescents: Recommendations Beyond Neonatal Screening. *Pediatrics* **2023**, *152*. [CrossRef] [PubMed]
12. Du, Y.; Homma, K.; Saunders, W.R. Noise Attenuation Performance of Deep-Insert Custom Earplugs under Single and Double Hearing Protection. *Noise Control Eng. J.* **2008**, *56*, 183–202. [CrossRef]
13. Stefanson, J.R.; Ahroon, W. Evaluation of Custom Hearing Protection Fabricated from Digital Ear Scanning and Traditional Methods. USAARL Report No. 2020-06. Available online: https://apps.dtic.mil/sti/pdfs/AD1090021.pdf (accessed on 13 December 2024).
14. Ramakers, G.G.J.; Kraaijenga, V.J.C.; Cattani, G.; Van Zanten, G.A.; Grolman, W. Effectiveness of Earplugs in Preventing Recreational Noise–Induced Hearing Loss: A Randomized Clinical Trial. *JAMA Otolaryngol. Head. Neck Surg.* **2016**, *142*, 551–558. [CrossRef] [PubMed]
15. Uslu, O. Earmolds Primer: Custom Earmolds Essentials. Available online: https://www.audiologyonline.com/articles/earmolds-primer-custom-earmolds-essentials-24101 (accessed on 13 December 2024).
16. Online CEUs, Job Listings, and Journal for the Audiology Profession | AudiologyOnline. Available online: https://www.audiologyonline.com/ (accessed on 13 December 2024).
17. Pirzanski, C. Earmolds and Hearing Aid Shells: A Tutorial | The Hearing Review. Available online: https://hearingreview.com/hearing-products/accessories/earmolds/earmolds-and-hearing-aid-shells-a-tutorial (accessed on 13 December 2024).
18. Rony, M.A.H.; Fatema, K.; Raiaan, M.A.K.; Hassan, M.M.; Azam, S.; Karim, A.; Jonkman, M.; Beissbarth, J.; Boer, F.D.; Islam, S.M.S.; et al. Artificial Intelligence-Driven Advancements in Otitis Media Diagnosis: A Systematic Review. *IEEE Access* **2024**, *12*, 99282–99307. [CrossRef]

19. AlSamhori, J.F.; AlSamhori, A.R.F.; Amourah, R.M.; AlQadi, Y.; Koro, Z.W.; Haddad, T.R.A.; AlSamhori, A.F.; Kakish, D.; Kawwa, M.J.; Zuriekat, M.; et al. Artificial Intelligence for Hearing Loss Prevention, Diagnosis, and Management. *J. Med. Surg. Public. Health* **2024**, *3*, 100133. [CrossRef]
20. Schonberger, J.L.; Frahm, J.-M. Structure-From-Motion Revisited. In Proceedings of the IEEE Conference on Computer Vision and Pattern Recognition, Las Vegas, NV, USA, 27–30 June 2016; pp. 4104–4113.
21. Sarlin, P.E.; Dusmanu, M.; Schönberger, J.L.; Speciale, P.; Gruber, L.; Larsson, V.; Miksik, O.; Pollefeys, M. LaMAR: Benchmarking Localization and Mapping for Augmented Reality. In *Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics)*; Springer: Berlin/Heidelberg, Germany, 2022; Volunme 13667 LNCS, pp. 686–704. [CrossRef]
22. Scuoppo, R.; Catalano, C.; Costagliola, E.; Cannata, S.; Pasta, S.; Gandolfo, C. Augmented Reality and Computational Simulations for the Preprocedural Planning of Transcatheter Aortic Valve Replacement After Previous Transcatheter Mitral Valve Replacement. *Biomechanics* **2024**, *4*, 730–737. [CrossRef]
23. Cusator, A.; Key, N.L. Development of a Novel Transonic Fan Casing Making Use of Rapid Prototyping and Additive Manufacturing. *Appl. Sci.* **2024**, *14*, 8400. [CrossRef]
24. Meshroom Manual—Meshroom V2023.1.0 Documentation. Available online: https://meshroom-manual.readthedocs.io/en/latest/ (accessed on 13 December 2024).
25. AliceVision | Photogrammetric Computer Vision Framework. Available online: https://alicevision.org/ (accessed on 13 December 2024).
26. Setiyadi, S.; Mukhtar, H.; Cahyadi, W.A. A Comparative Study of Affordable Photogrammetry Software for Reconstructing 3D Model of a Human Foot. In Proceedings of the 2021 IEEE 7th International Conference on Smart Instrumentation, Measurement and Applications (ICSIMA), Bandung, Indonesia, 23–25 August 2021; Volume 2021, pp. 286–291. [CrossRef]
27. Customizable PU-Based Resins for 3D Printed Hearing Aids | Covestro AG. Available online: https://web.archive.org/web/20200924204612/https://solutions.covestro.com/en/highlights/articles/stories/2019/3d-hearing-aids (accessed on 19 December 2024).
28. Cho, S.D.; Jang, J.H.; Kim, H.; Cho, Y.S.; Kim, Y.; Koo, J.W.; Song, J.J. Earmold Foreign Bodies in the Middle Ear Necessitating Surgical Removal: Why Otology Specialists Should Screen Candidates for Hearing Aids. *Clin. Exp. Otorhinolaryngol.* **2020**, *14*, 235–239. [CrossRef] [PubMed]
29. Beyer, C.; Younker, S. Preventing Medical Errors for Audiologists—2011 Update. Available online: https://www.audiologyonline.com/articles/preventing-medical-errors-for-audiologists-806 (accessed on 13 December 2024).
30. Yoshioka, S.; Inuzuka, E.; Kato, H.; Naito, K.; Suzuki, Y.; Hattori, T. Surgical Removal of Hearing Aid Ear Mold Impression Material from the Middle Ear: A Report of Two Cases. *Fujita Med. J.* **2017**, *3*, 72–75. [CrossRef]
31. Verdam, F.; Tange, R.; Thomeer, H. Impression Material in the External and Middle Ear: An Overview of the Literature and a Stepwise Approach for Removal. *J. Int. Adv. Otol.* **2016**, *12*, 345–352. [CrossRef] [PubMed]
32. Lee, H.M.; Yi, K.I.; Jung, J.H.; Lee, I.W. Hearing Aid Silicone Impression Material as a Foreign Body in the Middle Ear. *Am. J. Otolaryngol.* **2017**, *38*, 108–111. [CrossRef] [PubMed]
33. van den Boer, C.; van Spronsen, E.; Holland, C.T.Q.; Ebbens, F.A.; Waterval, J.J. Clinical Approach After Complicated Ear Mold Fitting: A Case Series of Six Patients and Evaluation of Literature. *Ann. Otol. Rhinol. Laryngol.* **2019**, *128*, 1141–1146. [CrossRef]
34. Phillips, J. Otoscan—3D Ear Scanning: The Future Is Now! Available online: https://www.audiologyonline.com/articles/otoscan-3d-ear-scanning-future-24421 (accessed on 13 December 2024).
35. Natus Otometrics Otoscan: Clinical Review | Hearables. Available online: https://hearablesonline.co.uk/natus-otometrics-otoscan-review/ (accessed on 19 December 2024).
36. Gregoret, L. How Does the Lantos 3D Scanning System Work? Available online: https://www.audiologyonline.com/ask-the-experts/does-lantos-3d-scanning-system-26157 (accessed on 13 December 2024).
37. 3DM Scans the Future of Hearing Care | The Hearing Review. Available online: https://hearingreview.com/hearing-products/accessories/earmolds/3dm-scans-the-future-of-hearing-care (accessed on 19 December 2024).
38. McMillion, M. How Dr. Sheryl Lewin Uses Artec Space Spider to Create Beautiful New Ears for Microtia Patients. Available online: https://www.artec3d.com/cases/lewin-ear (accessed on 16 December 2024).
39. AIT Austrian Institute of Technology GmbH. 3D Non-Contact Measurement of Ear Canals and Small Holes. Available online: https://www.ait.ac.at/news-events/single-view/detail/7709?cHash=1f2d12750ac20f4e2d97b96e63bf4e03 (accessed on 16 December 2024).
40. Gibson, I.; Rosen, D.; Stucker, B.; Khorasani, M. Direct Digital Manufacturing. *Manuf. Eng.* **2021**, *142*, 525–554. [CrossRef]
41. Formicola, R.; Amici, C.; Mor, M.; Bissolotti, L.; Borboni, A. Design of Medical Devices with Usability in Mind: A Theoretical Proposal and Experimental Case Study Using the LEPRE Device. *Designs* **2023**, *7*, 9. [CrossRef]
42. *ISO 9241-11:2018*; Ergonomics of Human-System Interaction—Part 11: Usability: Definitions and Concepts. ISO: Geneva, Switzerland, 2018. Available online: https://www.iso.org/standard/63500.html (accessed on 16 December 2024).

43. Lundberg, T.; Biagio de Jager, L.; Swanepoel, D.W.; Laurent, C. Diagnostic Accuracy of a General Practitioner with Video-Otoscopy Collected by a Health Care Facilitator Compared to Traditional Otoscopy. *Int. J. Pediatr. Otorhinolaryngol.* **2017**, *99*, 49–53. [CrossRef] [PubMed]
44. Ward, J.R.; Clarkson, P.J. An Analysis of Medical Device-Related Errors: Prevalence and Possible Solutions. *J. Med. Eng. Technol.* **2004**, *28*, 2–21. [CrossRef]
45. Fayad, R.; Paper, D. The Technology Acceptance Model E-Commerce Extension: A Conceptual Framework. *Procedia Econ. Financ.* **2015**, *26*, 1000–1006. [CrossRef]