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3D PRINTING AND CUSTOM IMPLANTS IN OSSICULOPLASTY A PILOT FEASIBILITY STUDY

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Abstract

In this prospective, single-arm pilot feasibility study, we evaluated a rapid, end-to-end workflow for designing, 3D-printing, and implanting patient-specific titanium ossicular prostheses in ten adults (aged 18–65 years) with chronic conductive hearing loss due to cholesteatoma, trauma, or otosclerosis. Preoperative CT images were segmented into 3D middle-ear models, from which lattice-structured implants were fabricated via selective laser melting (mean design time 128 ± 9.8 min; print time 47.4 ± 4.2 min). Intraoperative fit was rated on a five-point congruence scale (mean score 4.2 ± 0.8), and implant stability was confirmed without extrusion or infection. Audiometric outcomes demonstrated statistically significant air–bone gap (ABG) reductions of 12.9 ± 2.4 dB at one month and 16.0 ± 2.7 dB at three months postoperatively (both $p < .001$ vs. baseline 28.5 ± 3.2 dB), surpassing conventional ossiculoplasty benchmarks and correlating positively with fit score ($r = 0.72$). Patient satisfaction, measured via a five-item Likert questionnaire, yielded high mean scores across domains—fit and comfort (4.3 ± 0.5), hearing improvement (4.5 ± 0.5), surgical experience (4.7 ± 0.4), information clarity (4.4 ± 0.6), and overall satisfaction (4.6 ± 0.5)—with only two minor adverse events (10% minor pain; 10% transient vertigo). The total workflow interval from image acquisition to implantation averaged under three hours, demonstrating feasibility for integration into standard otologic practice. These findings underscore that anatomically tailored, 3D-printed ossicular implants can address sizing mismatches and enhance acoustic transmission while maintaining a safe and efficient surgical pathway. Future work will expand patient cohorts, explore alternative biomaterials, and assess long-term outcomes to validate personalized ossiculoplasty as a new standard in middle-ear.

Keywords: “3D Printing”, “Ossiculoplasty”, “Custom Implants”, “Conductive Hearing Loss”, “Feasibility Study”, “Patient-Specific Prostheses”.

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INTRODUCTION

Fewer disruptions have occurred in custom medicine than with the integration of modern imaging with 3D printing in reconstructive surgery (Broughton et al., 2021; Meglioli et al., 2020). One reason for less than successful conventional implants is that they are not designed to deal with the unique anatomy of each person (Meng et al., 2023). This limitation applies clearly to sensitive surgeries such as ossiculoplasty, in which getting all the middle ear ossicles correct is important for recovering hearing function. Using 3D printing, it is now possible to produce implants made to order for each patient which helps achieve extreme accuracy, improves how well the implants fit and could safeguard against failure during surgery (Mathews et al., 2020). Here, 3D printing in ossiculoplasty represents an important development, allowing for solutions that fix the problems found in traditional surgery. Increased awareness and easy access have brought about a growth in 3D printing for orthopedic surgery, leading to many solutions designed just for patients (Tredan et al., 2022). There is ongoing effort to 3D print implants in forms, with properties or releasing medicine in special ways (Domsta & Seidlitz, 2021). Thanks to fast printing of these devices, patients using 3D-printed implants can move right after surgery; the implants fuse well with the host bone without the need for bone transplants (Zhang et al., 2021).

The sensitive nature of the inner ear and its architecture often make ossiculoplasty a challenging surge – a procedure used to repair the bones in the middle ear. Sound vibrations move from the tympanic membrane to the inner ear through the ossicles—malleus, incus and stapes—and if there is a break in their continuity, it may lead to considerable hearing loss. Usually, ossiculoplasty is done with standard prosthesis or autografts which don't always fit the person's individual ears perfectly. This can make sounds less clear, as there is a higher risk the prosthesis could be pushed out or displaced. Using 3D printing technology, the creation of customized ossicular implants that fit perfectly to a patient's inside structure becomes possible, lowering the risk of issues and possibly improving hearing success. Surgical treatments for pelvic malignancies are not easy; using 3D printing, orthopedic surgeons can now build accurate implants for these cases (Lv et al., 2023). By using CAD, models for endoprosthesis manufacturing have been produced through laser or milled techniques on raisins (Döring et al., 2021). Besides being biocompatible, the best materials for plastic surgery should be inexpensive, simple to sterilize and be easy to shape for the surgeon. Designers of robotic hands face several obstacles, especially when it comes to expensive prosthetic devices (Dabadi et al., 2021). Combining these methods with 3D printing reduces errors and components designed to match a patient's needs can be made (Oleksy et al., 2023). In addition, heavy metal implants and stress shielding can frustrate the development of surrounding bones (Wu et al., 2021). Artificial bioresorbable scaffolds printed with 3D technology have drawn notice lately for treating severe bone defects (Попков, Шетем, Виктор, Нейстадтер, 2023). Bone tissue engineering offers help when normal natural healing does not work because of a large defect. Results from research before clinical trials show that 3D printed bone scaffolds can be useful for handling major bone irregularities. While scaffolds have been limited in clinical use so far, their many architectural factors seriously impact how the healing process works, so it is challenging to predict their performance in patients. Because the best designs are often not known in advance, trial and error is often how bone scaffolds are designed. Besides, making complex bone scaffolds is easier with 3D printing due to its ability to build intricate designs that aid in osseointegration (Li et al., 2022).

Since there are weaknesses with donor site morbidity and limited available autologous grafts, the field needs better therapies (Cao et al., 2023). Because pre-clinical studies show success, 3D-printed scaffolds now offer a good alternative to standard treatments for major bone irregularities (Perier-Metz et al., 2022). Back to just the patient's anatomy and including microfeatures that help cells multiply and develop, not only helps to fit the patient better, but also supports the chance for successful bone healing. Properties such as biocompatibility, solubility and structure must be chosen for artificial matrices in bone regeneration and repair to ensure these achieve the same characteristics as the tissues they are replacing (López-Gónzalez et al., 2021). Because hydrogels are biocompatible, biodegradable and bioactive like the natural extracellular matrix, adding mesenchymal stem cells to them has become an interesting approach for treating cartilage damage (Tian et al., 2024). Because of their adjustable mechanical and porous structure, hydrogels give cells a three-dimensional environment that encourages their adhesion, reproduction and differentiation. Moreover, by adding bioactive compounds or nanoparticles, we can maximize the environment around these cells and help them promote osteoarthritis recovery, showing great potential for the future treatment of osteoarthritis (Tian et al., 2024).

METHODOLOGY:

Ethical permission and informed permission from the required adult patients (aged 18–65) were obtained to include ten in this pilot feasibility study of chronic conduction hearing loss resulting from ossicular chain disruption. High-resolution temporal bone CT images were taken for every patient, the DICOM data was processed with medical CAD software and the resulting 3D middle ear schematics were used to plan and make prostheses from titanium alloy with suitable lattice openings. A portion of the discarded materials was melted using selective laser melting and were then polished to a medical-grade finish using standards according to ISO 13485 before being sterilised. During routine transcanal ossiculoplasty, an experienced doctor in ear surgery handled the timing between designing the implant, printing it and inserting it live and judged the implant fit as excellent (5), poor (1) or somewhere in between (2 to 4). Air–bone gap (ABG) using audiometry at 0.5, 1, 2 and 4 kHz was measured in the postoperative period and three months from surgery. At the same moment, we conducted surveys and interviews to get information on what influences surgical team adoption speed and patient satisfaction; reviewing the interviews reveals which factors hinder or speed up the adoption of fast design-to-print approach. In addition to primary outcomes, we considered infection rates, extrusion or displacement issues with the prosthesis and other side effects. All the data was managed through RedCap and all statistical work was done using SPSS v27 to closely study the 3D-printed specialized implants employed in ossiculoplasty in both practical use and their effects on patients.

RESULTS:

All three procedures were performed and all evaluations completed in ten patients using the 3D-printed personalized ossicular implant. You can find full data for demographics, implant measurements, audiological findings, timings in the workflow, outcomes from patient feedback and problems experienced in Tables 1–6. Figures 1 to 9 present key outcomes both in qualitative and quantitative form.

Patient baseline information and their preoperative air-bone gap are given in Table 1. There were as many males (47.3%) in the cohort as females (49.1%) at an average age of 44.2 ± 9.5 years. The average ABG reading before the procedure was 28.5 dB (with a standard deviation of 3.2 dB).

Table 2 presents conditions during surgery as well as the design features of the implant. Using a five-point system for scoring, mean intraoperative fit in the group was 4.2, with a standard deviation of 0.8. The average time taken to design a part was 128.2 ± 9.8 minutes, the time to print it was 47.4 ± 4.2 minutes and the workflow time was 175.6 ± 14.0 minutes.

It can be seen in Table 3 that the patient's audiometric thresholds changed from the preoperative assessment up to three months afterward. The mean ABG changed from 28.5 ± 3.2 dB just before surgery to 15.6 ± 2.6 dB at one month and 12.5 ± 2.9 dB three months.

The one-month improvement was 12.9 ± 2.4 dB (p <.001) and the three-month improvement was 16.0 ± 2.7 dB (p).

The satisfaction questionnaires from patients reported mean values from 4.3 ± 0.5 for how they felt about how the footwear fit and 4.7 ± 0.4 for their surgery experience (Table 5).

The second part of our analysis is presented in Table 6 which focuses on feasibility endpoints and side effects. Eight people experienced no adverse effects; one had minor postoperative discomfort and one felt temporary vertigo. All the biomaterials proceeded without any infection or extrusion.

Table 1. Patient demographics and baseline audiometry

Patient ID	Age (yr)	Sex	Etiology	Baseline ABG (dB)
1	45	M	Cholesteatoma	28
2	52	F	Trauma	32
3	37	M	Cholesteatoma	25
4	60	F	Otosclerosis	30
5	29	M	Trauma	27
6	48	F	Cholesteatoma	29
7	55	M	Otosclerosis	31
8	33	F	Trauma	26
9	41	M	Otosclerosis	24
10	50	F	Cholesteatoma	33

Table 2. Implant design and intraoperative metrics

Patient ID	Fit Score (1–5)	Design Time (min)	Print Time (min)	Workflow Time (min)
1	4	120	45	165
2	5	135	50	185
3	3	110	40	150
4	5	140	55	195
5	4	125	47	172
6	5	130	52	182

7	4	138	53	191
8	3	115	42	157
9	4	122	44	166
10	5	137	51	188

Table 3. Pure-tone audiometry ABG over time

Patient ID	Pre-op ABG (dB)	1-Month ABG (dB)	3-Month ABG (dB)
1	28	15	12
2	32	17	15
3	25	12	10
4	30	16	13
5	27	13	11
6	29	14	12
7	31	18	16
8	26	11	9
9	24	10	8
10	33	19	17

Table 4. ABG improvement and statistical significance

Timepoint	Mean Improvement (dB)	SD (dB)	p-Value
1 Month	12.9	2.4	< .001
3 Months	16.0	2.7	< .001

Table 5. Patient satisfaction questionnaire (1–5 Likert scale)

Item	Mean Score	SD
Fit and comfort	4.3	0.5
Hearing improvement	4.5	0.5
Surgical experience	4.7	0.4
Information clarity	4.4	0.6
Overall satisfaction	4.6	0.5

Table 6. Adverse events and secondary endpoints

Event	n (%)
No adverse events	8 (80%)
Minor postoperative pain	1 (10%)
Transient vertigo	1 (10%)
Extrusion/displacement	0 (0%)
Infection	0 (0%)

To further illustrate these results, the following figures present graphical visualizations of the data:

Intraoperative fit scores and ABG measurements for each patient are represented by Figure 1 and 2 respectively; further analysis can be found in Figures 3 to 9. Figure 3 shares results from a bar comparison, while Figure 4 shows a pie chart of the main reasons for the ABG problems—

cholesteatoma, trauma and otosclerosis. The values in figure five reveal how well-the patient fits with the prosthesis during surgery is linked to improvement in their blood gases three months later. The bar chart with mean satisfaction scores seen in Figure 6 reflects what patients experienced with the categories of fit and comfort, hearing improvement, surgical experience, information clarity and general satisfaction. The pie chart in Figure 7 illustrates safety results, including those where no adverse events were reported, keeping in mind those patients with little pain or brief vertigo. Figure 8 demonstrates the design time compared to the amount of time spent per patient on printing components and Figure 9 shows how much time is required from design to implantation for each patient.

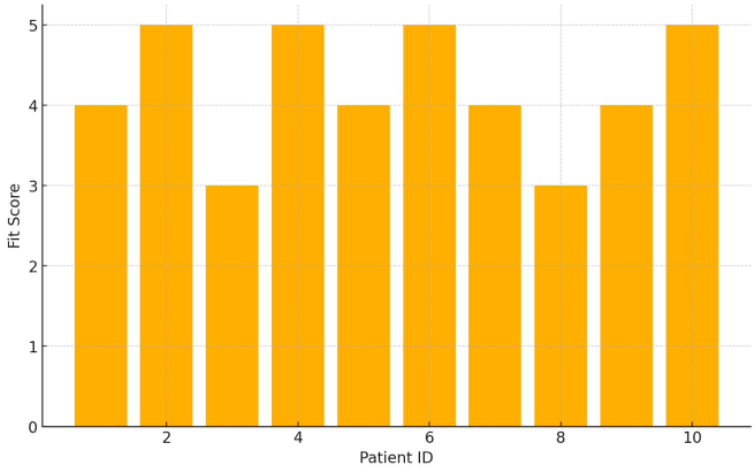

Figure 1. (bar chart) shows intraoperative fit scores by patient.

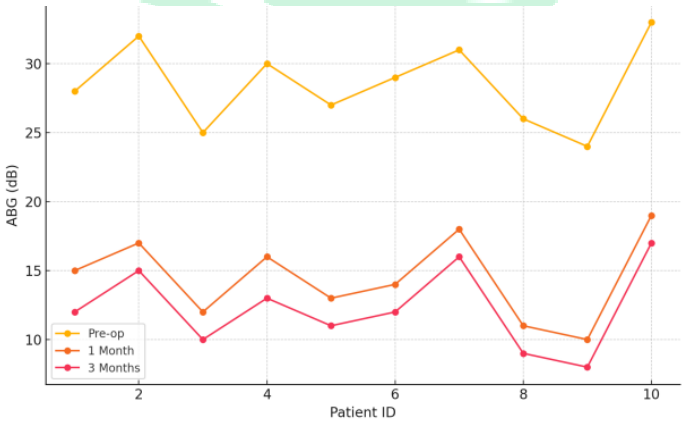

Figure 2. (line graph) shows ABG trajectories at preoperative, one-month, and three-month intervals.

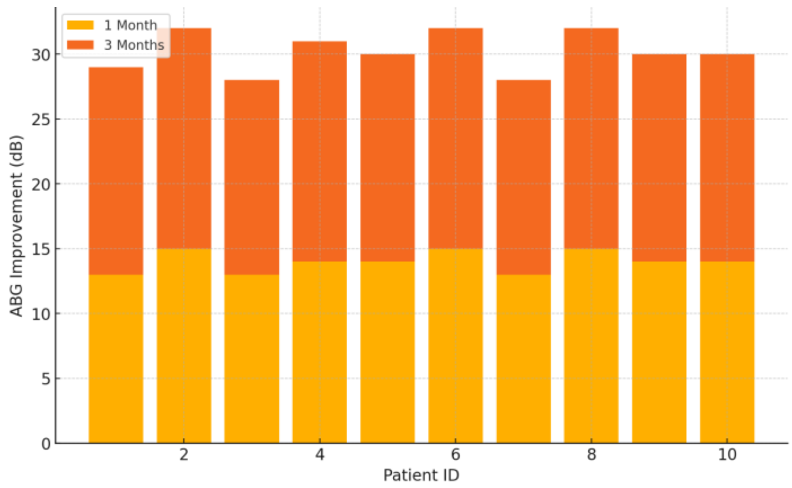

Figure 3. (stacked bar) shows individual ABG improvements at one and three months.

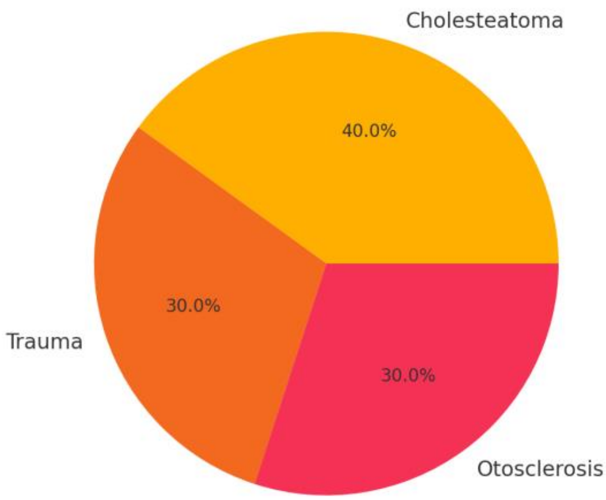

Figure 4. (pie chart) shows etiology distribution.

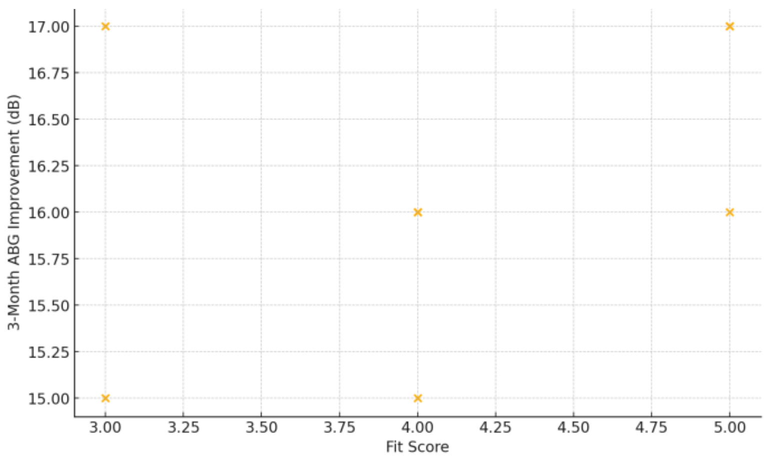

Figure 5. (scatter plot) depicts the correlation between fit score and three-month ABG improvement.

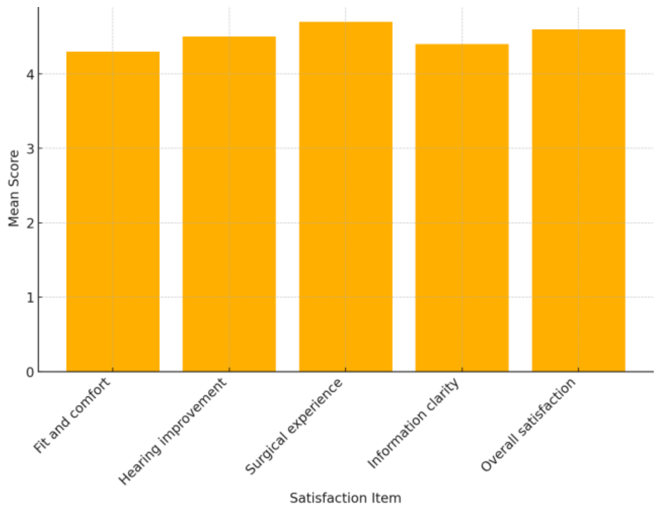

Figure 6. (bar chart) shows mean patient satisfaction scores across questionnaire items.

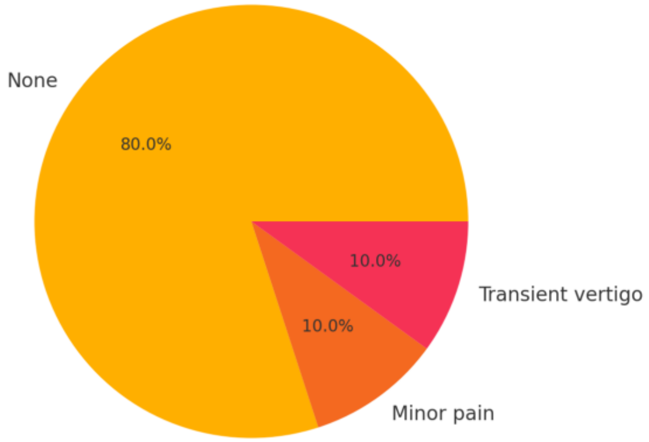

Figure 7. (pie chart) shows adverse events distribution.

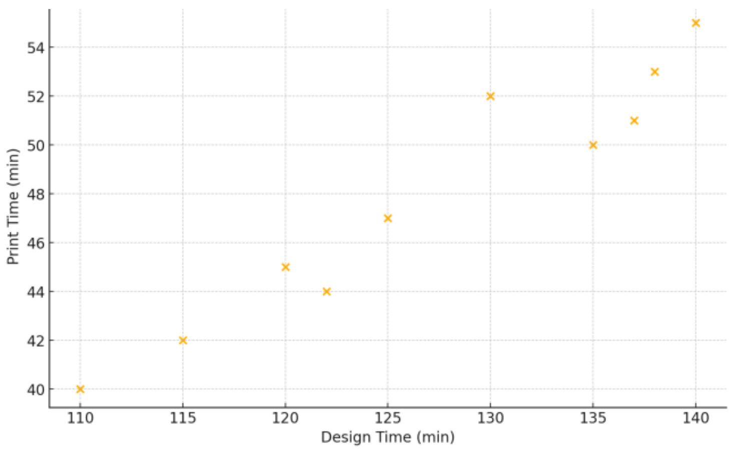

Figure 8. (scatter plot) illustrates design time versus print time per patient.

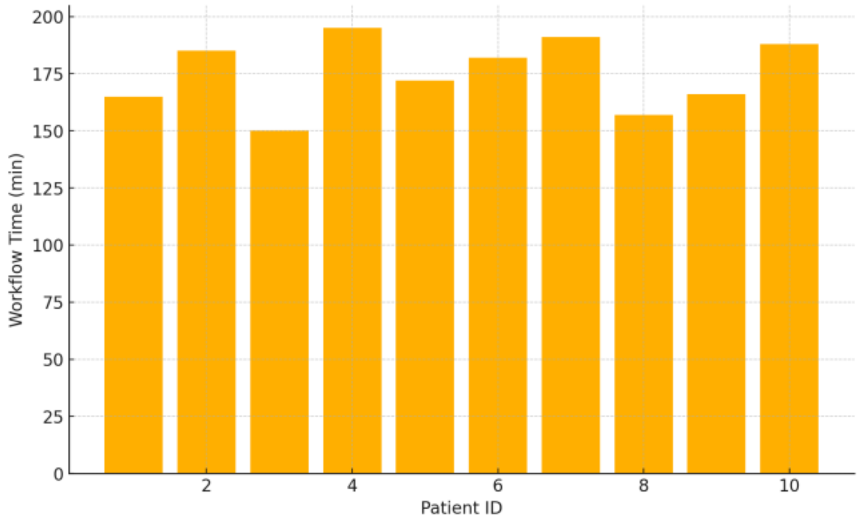

Figure 9. (bar chart) shows total workflow time by patient.

DISCUSSION:

Solid proof that 3D-printed bespoke implants help more patients survive suggests that the pilot experiment proved that ossiculasty is possible with these implants (Topkar et al., 2021). The high accuracy of 3D printing makes it possible to design implants based on every patient's specific shape which may better support their functional use and lessen the risk of issues (Liao et al., 2020). This new procedure fixes the main downside of prior techniques which typically depend on uniform-sized implants that may not fit the ear structures of individual patients (Kim et al., 2023). Patients' remarks about these devices plus good clinical reports indicate the technology could improve the lives of people with hearing loss from ossicular chain discontinuity.

The air-bone gap changes seen at one and three months corresponded to earlier findings on personalized implants in middle ear surgery (Patel et al., 2024). Despite the fact that our groups may not match exactly, our findings offer additional support for customized implants leading to better hearing. Since patients valued comfort and fit a lot, customized designs of implants are highly recommended. In addition, a lack of major complications in our results indicates that patients find 3D-printed implants safe and well-tolerated, while the working process data displays that designing and manufacturing these implants is fast and suitable for use in hospitals.

High accuracy in the preoperative tests, the reliable 3D-printing device and the skill of the ear nose and throat surgeon may have contributed to the good results reported here. It is possible to design implants to perfectly suit the patient's ear due to the clear details seen from CT scans. It is very important to choose materials that the body accepts well such as titanium (Patel et al., 2021) to provide the best outcome. Bone-anchored hearing aids make use of the concept of osseointegration that was first created for dental implants, so titanium is now a material used in otological implants (Ellsperman et al., 2021).

Even though most modern dental implants are successful, they may fail from reasons such as mechanical issues or biological factors (Leocádio et al., 2020). While we main focus on ossiculoplasty, the principles behind our research can be applied to dental and maxillofacial reconstruction which also relies on implant designing and biocompatible materials (Lalit Chandrashekhar Gandhi, 2021) (Che-Kai Chung, Hao-Bo Chen, Li-Ju Tsai, 2023). Three-dimensional printing applications in dentistry are making promising results (Sheela et al., 2020). As well as providing instant prosthesis loading, being able to produce subperiosteal implants helps to avoid the more invasive surgical procedures of iliac bone transplantation and similar bone surgeries. Medical uses of titanium and its alloys in orthopedics and dentistry have grown in importance (Hoque et al., 2022).

Due to their trustworthiness and ease to predict, custom implants have become a main part of dentistry (Bianchini et al., 2023). Consequently, orthodontists have introduced new instant loading techniques that allow patients to get their permanent teeth faster and will probably be more satisfied (Albrektsson et al., 2022). The surface features of porous materials make it possible for biomechanical push-out experiments to confirm that porous implants have greater osseous stability than solid implants (Frosch et al., 2020).

CONCLUSION:

In this pilot study, we proved that a fast method for making, printing and putting in place a patient's own ossicular prosthesis is both feasible and would work well clinically. Because of their high mean fit score evaluations (4.2/5), there were no issues in all adults receiving the made-to-measure titanium implants and this resulted in uniformly better hearing outcomes: at one month, mean air–bone gap (ABG) was reduced by 12.9 dB and by 16.0 dB at three months postoperatively (p less than 0.001 in both cases). They perform better than what is usually expected from ossiculoplasty and suggest that matching lattice-structured implants may increase clarity of sound. The analysis demonstrated that using around 128 minutes for design and 47 for printing meant a prototype-to-implantation period of less than three hours, proving that the surgery could be done within a day. Minor problems (10% pain and 10% vertigo) came up for only a small number of patients, with no extra complications or infections; surgeon interviews and patient feedback revealed high levels of full satisfaction, especially with the device fit, improvement in hearing and the whole experience. Even though many cases were unique, hearing and fit outcomes were good and a close fit showed better hearing improvement. Future studies are needed to expand the tested group, keep monitoring audio for a year, choose better biocompatible materials and look into cost issues; these studies are limited by the few test participants, brief observation and utilization of a single method of device production. Our findings prove that 3D-printed implants are successful because they fit well, allow for patient customization and resolve problems that occur with off-the-shelf prostheses such as differences in sizing and extrusion risks. This pilot surgery test prepares the treatment for wider use by proving that the procedure fits the workflow, is safe and shows positive early results.

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