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*Original Research Article*

# Additive manufacturing of patient-specific ear canal wall implants: a preclinical workability study

**A. Jalalian[1*], F. B. van der Beek[2], J. Perez Y Perez[2,3], S. A. J. E. A. Lagerweij[2,4], M. L. Schrijvers[4], and S. Arastehfar[1]**

[1] *Department of Design, Production, and Management, University of Twente, Enschede, The Netherlands*
[2] *Department of Otorhinolaryngology, Medisch Spectrum Twente, Enschede, The Netherlands*
[3] *Department of Computer Science, University of Twente, Enschede, The Netherlands*
[4] *Department of Otorhinolaryngology, Head and Neck Surgery, University Medical Center Groningen, The Netherlands*
[*] *Corresponding author, email: a.jalalian@utwente.nl*

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*Abstract: Reconstruction of the posterior ear canal wall remains surgically demanding because implants must combine shape fidelity, intraoperative adjustability, mechanical integrity, and reliable handling in a confined anatomical space. Additive manufacturing offers patient-specific solutions with high geometric accuracy and design freedom, which are particularly relevant for ear canal wall implants, where fit and surgical workability strongly influence outcome. This study evaluated the preclinical workability of patient-specific 3D-printed hydroxyapatite ear canal wall implants from an Ear-Nose-Throat (ENT) surgeon's perspective, with emphasis on handling, fit, drillability, and preservation of integrity after adjustment. Workability was assessed through in vitro cadaveric testing, ENT-surgeon observation, and a Likert-scale questionnaire addressing placement, precision, and adaptability. The implants could be positioned and manipulated well, and precise intraoperative adjustment was feasible using a fine diamond burr. Good overall fit was achieved after limited drilling-based modification. However, the material showed sensitivity to brittle failure under unfavorable drilling conditions, indicating that handling technique and drilling parameters are critical. These preliminary findings suggest that 3D-printed hydroxyapatite ear canal wall implants are promising for patient-specific reconstruction because they combine geometric customization with practical intraoperative adjustability. At the same time, their workability remains technique-sensitive and requires further validation.*

## I. Introduction

Reconstruction of the posterior ear canal wall remains a persistent challenge in otologic surgery. Canal wall down procedures can create a postoperative cavity that is prone to chronic otorrhea, debris retention, dizziness with temperature exposure, and the need for repeated cleaning, which has motivated continued interest in canal wall reconstruction and cavity obliteration strategies [1,2].

Porous hydroxyapatite has been established as a clinically usable material for posterior auditory canal wall reconstruction, reporting no extrusion in a cohort followed for at least two years and showing that long-term reconstruction was feasible in selected cases [3,4]. In addition, these studies suggest that durable success depends not only on the biomaterial characteristics of the implant materials, but also on epithelial coverage, middle-ear conditions, and surgical handling [3,4].

Hydroxyapatite has remained attractive for ear canal reconstruction because of its biocompatibility and osteoconductive character. Preclinical data shows bone ingrowth at the implant interface and favorable behavior in moist conditions, which is highly relevant for middle-ear surgery [5]. However, hydroxyapatite implants are also associated with practical limitations. Their ceramic nature can make them brittle, and clinical success depends on achieving an accurate fit while avoiding fracture, displacement, or soft-tissue complications [3–5]. In other words, beyond biological compatibility, the material should tolerate manipulation, permit controlled adjustment, and maintain integrity after reshaping.

Additive manufacturing offers a promising route to address this gap. In otolaryngology, 3D printing is increasingly used for preoperative planning, guides, models, and patient-specific implants [6,7]. Systematic reviews in otolaryngology and otology describe patient-specific 3D printing as promising but also emphasize that the evidence remains limited by low study quality, insufficient clinical reporting, and a lack of objective comparative outcomes [6,7]. A case series on patient-specific 3D-printed tegmen implants further illustrates the potential of custom implant geometry in temporal bone surgery, showing rapid intraoperative placement and high contour accuracy [8]. For ear canal wall implants, these advantages are especially relevant, where a patient-specific implant can in principle improve fit and reduce intraoperative reshaping, but this benefit is only clinically meaningful if the printed material also performs well during handling and surgical adjustment.

Despite longstanding interest in hydroxyapatite, patient-specific manufacturing, there is still little surgeon-centered evidence on the workability of prefabricated ear canal wall implants. Most published studies focus on long-term clinical outcomes, obliteration success, or biocompatibility, whereas practical intraoperative questions remain less well defined [3–5]. Can the implant be manipulated safely? Can it be drilled or trimmed with precision? Does it retain integrity after adjustment? And does patient-specific geometry translate into reliable placement in the operative field?

Therefore, the aim of the present study was to evaluate the preclinical workability of patient-specific 3D-printed hydroxyapatite ear canal wall implants from an Ear-Nose-Throat (ENT) surgeon's perspective. By focusing on the practical aspects, this study addresses a translational step that is often overlooked between material development and broader surgical adoption.

# II. Material and methods

## II.I. Study design

The study assessed material-related behavior with *in vitro* cadaveric surgical use, thereby addressing both the manufacturability-related consequences of the implant material and the practical intraoperative handling of the additively manufactured implant. Cadavers in fresh-frozen state were used. The cadavers were donated for science in general according UMCG protocol. These cadavers were assigned to the ENT-department for research and education of ENT-surgeons in training within the academic hospital.

The central premise of the study was that additive manufacturing makes it possible to produce patient-specific implants with complex geometry and high anatomical conformity, but that these geometric advantages are only clinically meaningful if the resulting implant also performs well during surgical placement and adjustment. For that reason, the present work focused not only on fit, but also on drilling behavior, risk of fracture, and retention of functional integrity after reshaping.

Three patient-specific hydroxyapatite implants were manufactured for one patient in this study. They were produced by Lithoz using their ceramic printer; see [9] for technical explanation of the lithography-based ceramic manufacturing process developed by Lithoz. The implants did not contain porosity. The implants represented the ear canal wall that was sacrificed during mastoidectomy for improved access and sight. To make sure the mastoid bone can be obliterated, the ear canal wall implant replaced and extended the ear canal wall into the epitympanum (middle ear cavity region).

To design the patient-specific implants, first, critical anatomical landmarks were identified on the preoperative CT scan of the temporal bone of an anonymized patient. Then, the region of interest was segmented in 3D Slicer. After that, the segmented model was exported and used as the basis for implant design.

## II.II. Materials and manufacturing

The investigated implants were patient-specific for otologic reconstruction. As such, they were not conventional intraoperatively built-up reconstruction. This distinction is important from an additive manufacturing perspective. In conventional reconstruction approaches, materials such as hydroxyapatite cement are shaped manually during surgery. In contrast, the present study addressed implants with predefined anatomical form before surgery, allowing the ENT-surgeon to work with an implant that already approximated the target ear canal wall geometry. This patient-specific prefabrication is one of the principal advantages of additive manufacturing in medical engineering, because it enables customized geometry, reproducibility of shape, and potentially faster and more intuitive surgical placement.

In the context of ear canal wall reconstruction, additive manufacturing is particularly relevant because the posterior ear canal wall has a complex three-dimensional shape and must match the local mastoid geometry with sufficient accuracy to support stable placement. The patient-specific fit can facilitate unmistakable implant placement, shorten surgery, and potentially reduce complications. However, the brittle ceramic scaffold materials may remain vulnerable to fracture, even if their geometry is optimized. Thus, additive manufacturing offers clear geometric and translational advantages, but these must be evaluated together with the mechanical and practical behavior of the printed implant.

## II.III. Evaluation framework

The protocol defined three main domains for evaluating workability: placement, precision, and adaptability. Placement referred to handling and insertion of the

implant, with particular attention to risk of breakage or deformation. Precision referred to the ability to obtain a proper fit in a confined anatomical region, including assessment of visibility, local fit to mastoid surfaces, and overall precise fit. Adaptability referred to the extent to which the implant could be reshaped by drilling or cutting without unacceptable loss of function or integrity.

## II.IV. Surgeon-based workability testing

The study was performed in the drilling lab at University Medical Center Groningen (UMCG). The protocol defined an assessment by otologic surgeons using direct observation, structured interviews, and a Likert-scale questionnaire. The workability tests focused on handling during insertion, behavior in narrow anatomical spaces, fit to the mastoid, and response to intraoperative adjustment.

For placement, an experienced ENT-surgeon from UMCG with 18 years of ear surgery was asked to assess how easily the implant could be handled and inserted and whether fracture or deformation risk was present. For precision, the otologic surgeon evaluated visibility in the anterior epitympanum, clarity of positioning, and fit to different parts of the mastoid. For adaptability, he assessed how the implant responded to drilling or cutting, whether cracks or damage occurred after modification, and whether functional integrity remained preserved after adjustment.

## II.V. Questionnaire and scoring

Quantitative evaluation was performed using an 8-item Likert questionnaire specifically developed for ear canal wall implant workability (Table 1). Each item was scored on a 5-point scale. The questionnaire structure directly reflects the additive manufacturing focus. The success of the 3D printed implants could not be judged by geometry alone, instead, the clinical value of additive manufacturing had to be assessed through surgeon-relevant endpoints.

*Table 1: The questionnaire.*

| **Domain** | **Question** | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|---|
| Placement | How great is the risk of fracture of the implant during handling and insertion? | Very low risk | Low risk | Neutral / average risk | High risk | Very high risk |
| Placement | How easy is it to handle and insert the implant without risk of fracture or deformation? | Very difficult | Difficult | Neutral / average | Easy | Very easy |
| Precision | Assessment of visibility in the anterior epitympanum after placement. | Very poor visibility | Poor visibility | Neutral / average visibility | Good visibility | Very good visibility |
| Precision | How well does the implant fit on different parts of the mastoid? Do some parts of the implant fit better than others? | Very poor fit | Poor fit | Neutral / variable fit | Good fit | Very good fit |
| Precision | Assessment of “precise fit”. | Very imprecise | Imprecise | Neutral / average precision | Precise | Very precise |
| Adaptability | How does the implant material respond to drilling? | Very poor – fractures easily | Poor | Neutral / moderate | Good | Very good – does not fracture |
| Adaptability | How precisely can the implant be adjusted by drilling? | Very imprecise | Imprecise | Neutral / average precision | Precise | Very precise |
| Adaptability | To what extent is the functional integrity of the implant preserved after drilling? | Very poor – integrity greatly reduced | Poor | Neutral / average | Good | Very good – integrity preserved |

# III. Results and discussion

## III.I. Quantitative questionnaire findings

The completed questionnaire is presented in Table 2. An excellent fit score was achieved after additional drilling, and the surgeon recommended the use of a fine diamond burr with care to avoid excessive speed. For this, standard cutting and diamond burrs in ear surgery were used allowing high rotational speed of up to approximately 80,000 revolutions per minute. The diameter range varied from 0.5 to 6 mm, and the burrs were made of stainless steel or featured a diamond coating.

When grouped by domain, the mean placement score was 2.5/5, where a lower fracture-risk score is favorable, but a mid-range handling score indicates neither easy nor difficult manipulation. The mean precision/fit score was 4.0/5, suggesting generally favorable fit and precision once the implant had been adjusted. The mean adaptability score was 4.0/5, indicating good drillability and high modification precision, but with only moderate preservation of integrity after drilling. The overall mean across the eight completed items in Table 2 was 3.6/5, which points to promising but not problem-free workability.

*Table 2: The scores and interpretations.*

| **Domain: item** | **Score** | **Interpretation** |
|---|---|---|
| Placement: fracture risk during handling/ insertion | 2/5 | Low perceived fracture risk during handling/insertion |
| Placement: handling ease | 3/5 | Neutral handling ease |
| Precision: visibility in the anterior epitympanum | 3/5 | Moderate visibility in anterior epitympanum |
| Precision: fit to mastoid surfaces | 5/5 | Excellent fit to mastoid after adjustment |
| Precision: precise fit | 4/5 | Good precise fit |
| Adaptability: response to drilling | 4/5 | Good response to drilling |
| Adaptability: drilling precision | 5/5 | Very precise drilling-based adjustment |
| Adaptability: preservation of functional integrity after drilling | 3/5 | Moderate retention of functional integrity |

## III.II. Qualitative workability findings

Figure 1 shows steps of the *in vitro* cadaveric test process. The qualitative notes identify four main themes. First, placement and manipulation were considered very good, suggesting that the implant could be handled and positioned effectively. Second, fit improved substantially after drilling, with the anterior point shortened and the posterior side noted as a region that could potentially be longer in future designs. Third, drilling with a fine diamond burr enabled precise reshaping, whereas cutting with scissors was described as imprecise and associated with unpredictable fracture. Fourth, material brittleness remained a practical concern, as one specimen fractured when drilled at high speed.

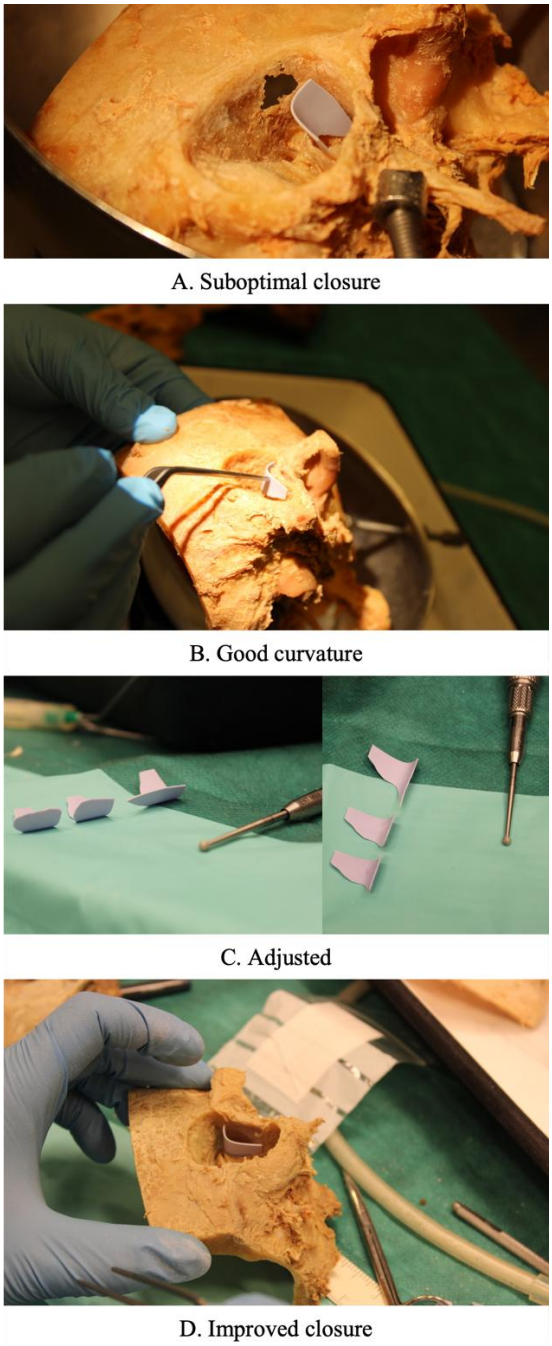



*Figure 1: In vitro cadaveric test process.*

These findings align well with the protocol background, which anticipated a trade-off between workability and brittleness in hydroxyapatite implants. The present pilot observations support the view that hydroxyapatite can be modified intraoperatively with useful precision, but that procedural details, especially burr type and drilling speed, are critical. In practical terms, the material appears workable rather than forgiving: it can perform well in skilled hands but mishandling or overly aggressive drilling may trigger fracture.

Targeted design modifications, such as increased wall thickness or structural reinforcement, could reduce fracture risk and improve handling. Although some modifications can reduce fracture risk, they may come with drawbacks. For example, an increased wall thickness deteriorates surgical vision lines during surgery. Providing guidelines for ENT-surgeons on how to modify the implants (e.g. rotation speed and burr type) based on early experiments could be advantageous to reduce the fracture risk. Current experiments were mostly based on trial and error. More studies are needed to define the boundaries of modification opportunities.

### III.III. Practical implications

Adjustments were made to the implants by using a fine 3 mm diamond burr and scissors. The adjustments required approximately 10 minutes. During drilling, two implants remained intact when drilled carefully, whereas one fractured after drilling at a speed above 40,000 rpm. Drilling performance improved for lower rotational speeds. Cutting with the scissor was possible but less accurate. The anterior tip was reduced from approximately 2.0 cm to 1.2-1.6 cm. However, the cutting caused unpredictable fracture.

## IV. Conclusions

This pilot preclinical evaluation indicates that 3D printed hydroxyapatite ear canal wall implants have promising workability. The results of the *in vitro* cadaveric test suggest that the 3D printed implants can be manipulated effectively, reshaped precisely with a fine diamond burr, and brought to a good or excellent fit after adjustment. At the same time, the material remains vulnerable to brittle failure, particularly under aggressive drilling conditions, and only moderate preservation of integrity after reshaping was observed.

Overall, the current evidence supports additively manufactured hydroxyapatite as a workable but technique-sensitive material for patient-specific ear canal wall reconstruction. The study was conducted by one surgeon and one patient, and future work will include more surgeons and repeated surgeon evaluations, objective mechanical testing, and comparison with alternative materials such as bioactive glass. One promising improvement could be adding porous structure for improved fixation, which will be studied in our future work.

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#### Author's statement

Conflict of interest: Authors state no conflict of interest. Informed consent has been obtained from all individuals included in this study. Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

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