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Fabrication of 3D-Printed Implant for Two-Stage Ear Reconstruction Surgery and Its Clinical Application

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Purpose: Ear reconstruction is one of the most difficult areas in the field of reconstructive surgery. Due to limitations of the current practice, a novel method of auricular reconstruction is needed. Major advancements in three-dimensional (3D) printing technique have rendered the process of ear reconstruction more favorable. Herein, we present our experience in designing and clinically using 3D implants in both 1st and 2nd stage ear reconstruction surgery.

Materials and Methods: After obtaining 3D CT data from each patient, a 3D geometric ear model was created using mirroring and segmentation processes. The 3D-printed implant design resembles but does not exactly match the normal ear shape, and can be inserted in harmony with the currently used surgical technique. The 2nd stage implant was designed to minimize dead space and support the posterior ear helix. The 3D implants were finally fabricated with a 3D printing system and used in ear reconstruction surgery in our institute.

Results: The 3D implants were manufactured for application to the currently used two-stage technique while maintaining the shape of the patient's normal ear. The implants were successfully used for ear reconstruction surgery in microtia patients. A few months later, the 2nd stage implant was used in the 2nd stage operation.

Conclusion: The authors were able to design, fabricate, and apply patient-specific 3D-printed ear implants for 1st and 2nd stage ear reconstruction surgeries. This design, combined with 3D bioprinting technique, may be a future alternative for ear reconstruction.

Key Words: Auricular reconstruction, 3D printing, auricular cartilage, scaffold

INTRODUCTION

Auricular reconstruction is a challenging procedure in the field of reconstructive surgery. Building a delicate three-dimensional (3D) cartilage framework and utilizing the limited skin flap of the temporal area to cover the framework with less tension render the entire procedure difficult.

Since Tanzer's[1] introduction of four-stage ear reconstruction in 1959, several modifications and improvements have been made, including the reconstructive methods proposed by Brent[2] and Nagata.[3] Currently, Nagata's[3] two-stage surgery is the most commonly performed auricular reconstruction procedure. Reinisch and Lewin[4] suggested a method using porous polyethylene framework and subsequently, alloplastic implants have been used on a case-by-case basis for over a decade. Autogenous costal cartilage is currently the most com-

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monly used,[1-3] although numerous limitations exist. First, donor-site morbidity is an issue.[5] Second, when using the patient's own costal cartilage, the framework has to be carved in the operating room, thus extending the total operation time.[6] In addition, the quality of the manually carved framework is dependent on the surgeon's ability and experience, leading to various results. Alloplastic frameworks were developed to overcome these disadvantages. However, uniform results have not been obtained since the implants are not customized for each patient. Therefore, a novel method of auricular reconstruction is still needed.

Major advancements in 3D printing technique[7] has made it possible for use in the field of ear reconstruction. Since most patients have unilateral microtia, a 3D-printed framework could be designed based on the contralateral unaffected ear. Several reports have been published regarding the 3D printing techniques used for ear reconstruction;[8-12] however, most remain at an experimental stage or are focused on developing 3D printing materials.

To fully utilize 3D printing in ear reconstruction, the technique must be applied to the currently used reconstruction method. The materials and printing technique used for the 3D scaffold are important, as well as the framework design. The authors have previously reported an ideal scaffold design,[13] and herein present their clinical experience designing a 3D implant used in surgery and creation of 3D-printed scaffold available for use at the 2nd stage of the most commonly used two-stage ear reconstruction surgery.

MATERIALS AND METHODS

3D implant modeling process

After obtaining DICOM data of each patient's unaffected external ear using 3D CT scan and analysis with a software program (Aview, Corelinesoft, Seoul, Korea), a 3D geometric ear model was created with mirroring and segmentation processes of the normal ear. This design was then modified using a modeling software (3D max) by remodeling certain parts that matched the currently used autologous costal cartilage-based framework. The 3D-printed ear design did not exactly resemble the normal ear shape, as the "C" shape formed by the tragus and incisura intertragica and the empty section in the concha area allows insertion of the implant without disrupting the subcutaneous pedicle.[13] The modeling process was followed by a smoothing procedure to soften the 3D model and a thinning process since a skin flap covers the framework after the operation (Figs. 1-3 and Supplementary Video 1, only online).

2nd stage 3D implant modeling process

The obtained 3D geometric ear model was used to design the base contour of the temporal area in the 3D implant model based on the shape of the affected ear, and the posterior auricular area was designed to match the 1st stage implant to minimize dead space and support the posterior helix. Since the skin graft procedure is required in the 2nd stage operation, the 2nd stage implant requires adequate width to prevent postoperative skin contracture. Next, smoothing was performed and modeling was complete (Fig. 4 and Supplementary Video 2, only online).

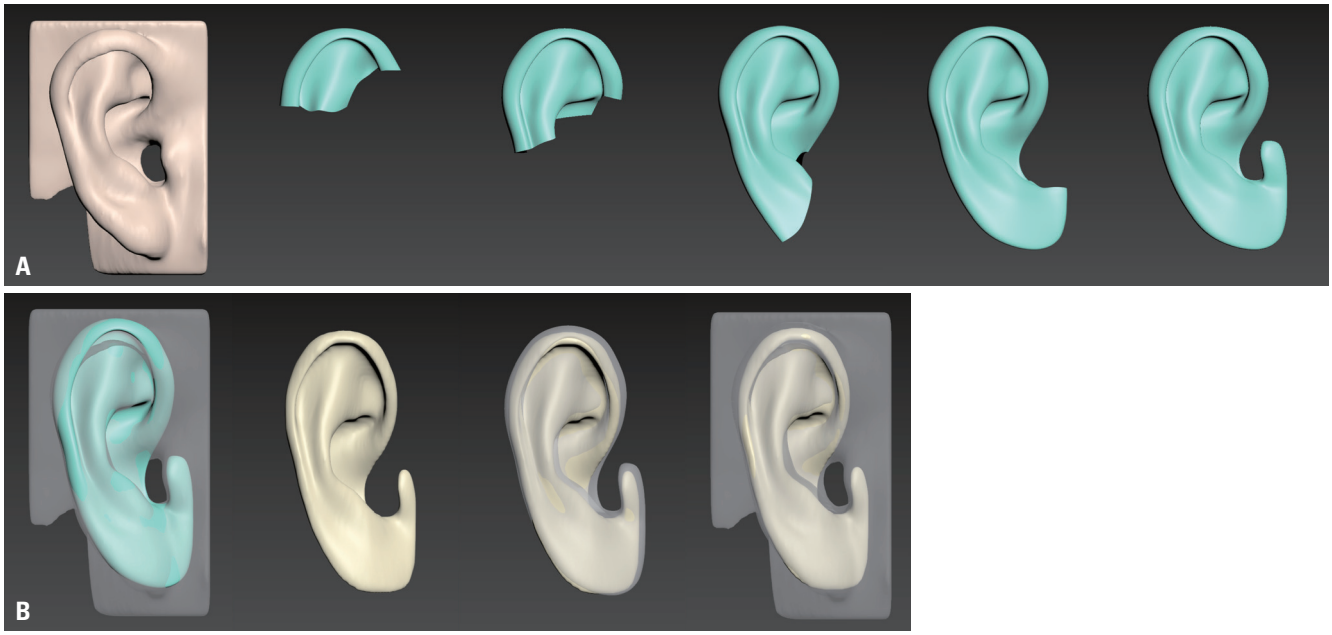

Fig. 1. Modeling process of the 1st stage 3D-printed ear model. After obtaining a CT image of the patient, the implant was designed using a software. A section surrounding the tragus and incisura intertragica was cut to not disrupt the subcutaneous pedicle when inserted into the pocket (A). To avoid disruption of vascularity and difficulty in inserting the implant into the skin flap, the 3D scaffold was modified to be thinner than the real ear (B). 3D, three-dimensional.

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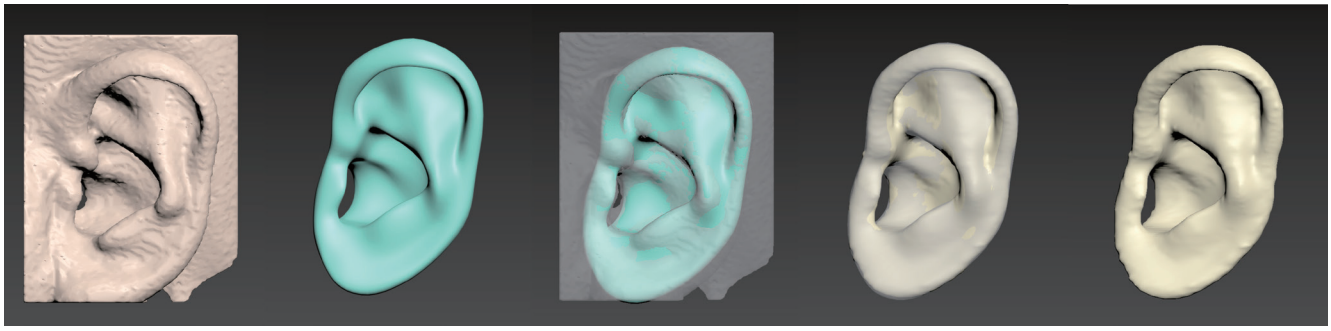

Fig. 2. In this patient, the helix root and tragus were connected to add stability to the implant, since the W-shaped incision was not needed to secure the subcutaneous pedicle due to the absence of remnant ear lobule.

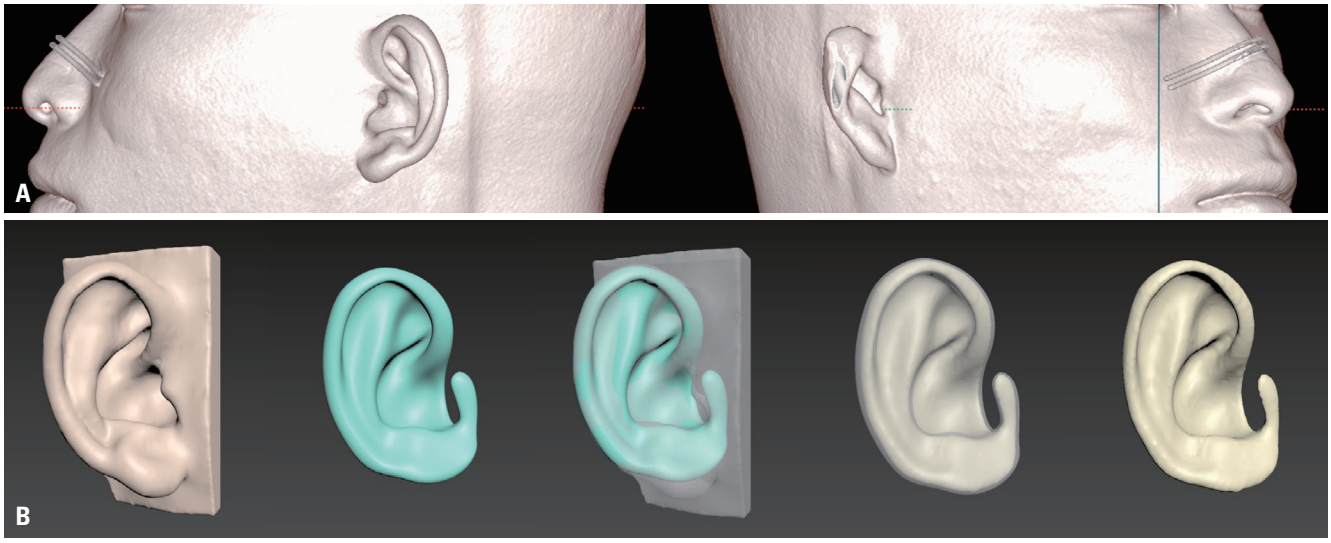

Fig. 3. CT image of both ears of a microtia patient (A) and the modeling process (B).

3D printing process

The 3D implant model designed following the above-mentioned process was finally fabricated with a 3D printing system (TnR Mesh; T&R Biofab, Seoul, Korea) using fused deposition modeling (FDM), as previously published by the authors. FDA-approved polycaprolactone (PCL; molecular weight=65000 g/mol; Sigma-Aldrich, St. Louis, MO, USA) was used to print the scaffold for ear reconstruction surgery.[13]

RESULTS

The 3D-printed ear implants designed for both 1st and 2nd stage ear reconstruction were fabricated using CT data of five patients who were treated at our institution from 2021 to 2022. All of the patients were adults with unilateral microtia and never received any ear reconstruction procedures.

Fabrication of 3D-printed implants

The 3D-printed implants were fabricated to reflect the contralateral unaffected ear size and 3D form. The design allowed the implant to be applied to the currently used Nagata's[3] two-stage ear reconstruction surgery, where lobular transposition is performed using a W-shaped incision and the skin flap formed by this incision left attached to serve as the subcutaneous pedicle. The 2nd stage implants were produced in the manner mentioned in the Materials and Method section, where the base of the temporal area and the posterior auricular area were referenced to the affected ear and 1st stage implant, respectively (Fig. 5).

Clinical application

In the 1st stage reconstruction, if a remaining ear lobule was present, a pocket was made after lobular transposition using a W-shaped incision, and then, the implant was inserted into the pocket. This process took approximately half the average time spent on the traditional ear reconstruction using autogenous costal cartilage. Immediately after the surgery, symmetry regarding the size and shape with the contralateral unaffected ear was confirmed. The 2nd stage reconstruction was performed 3 months later. An incision was made at the posterior part of the reconstructed ear, and the designed 3D im-

plant was placed inside to elevate the ear at the same angle as the unaffected ear. Then, the implant was covered with superficial temporal fascia flap, and full thickness skin graft was performed. Postoperative CT views of the patients are shown in Fig. 6.

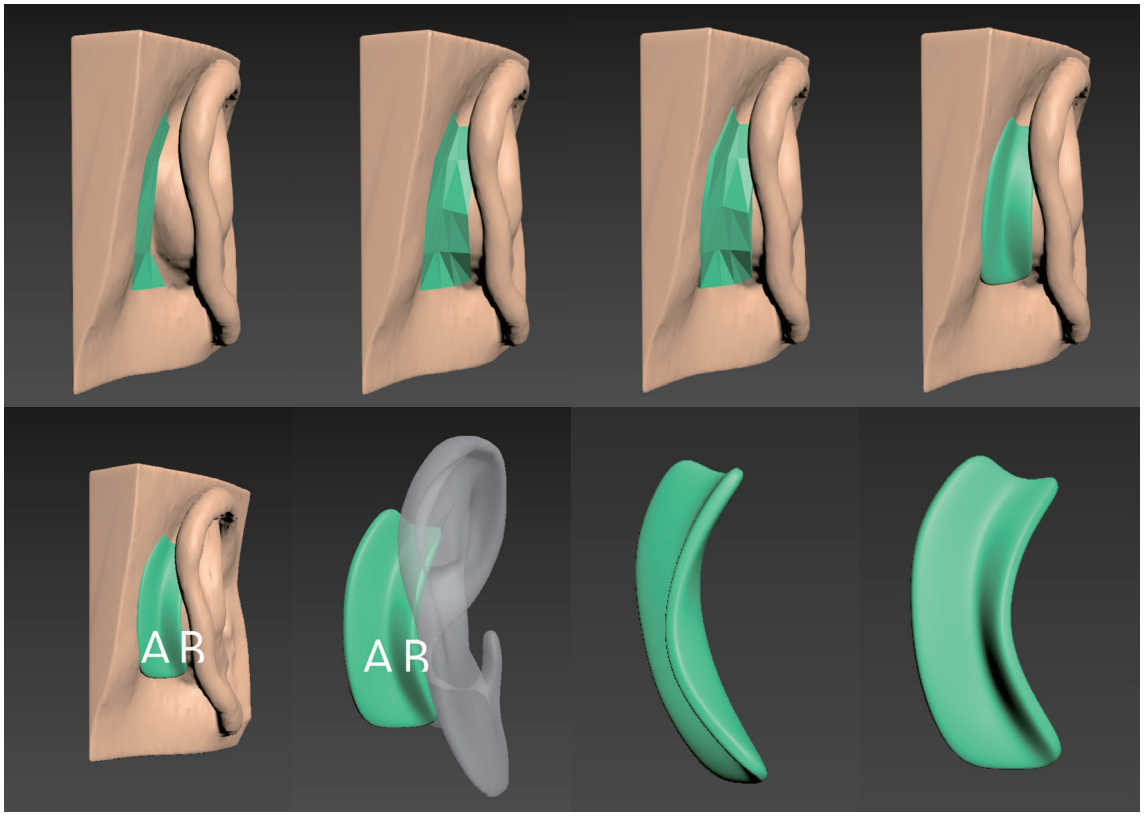

Fig. 4. Modeling process of a 2nd stage implant. The contour of this implant was based on both the affected ear (part A) and the 1st stage implant (part B) to minimize dead space and support the posterior helix.

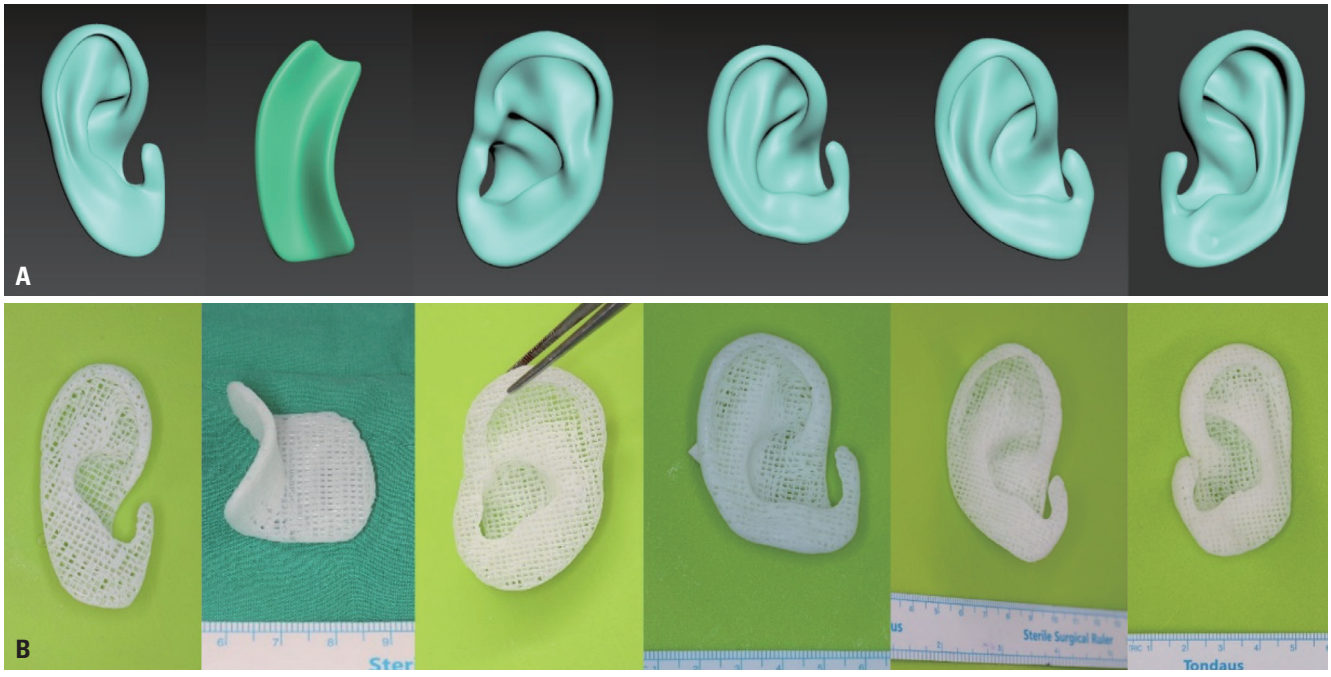

Fig. 5. Design models (A) and the actually fabricated 3D-printed ear models (B) of the five patients who underwent ear reconstruction at our institute. 3D, three-dimensional.

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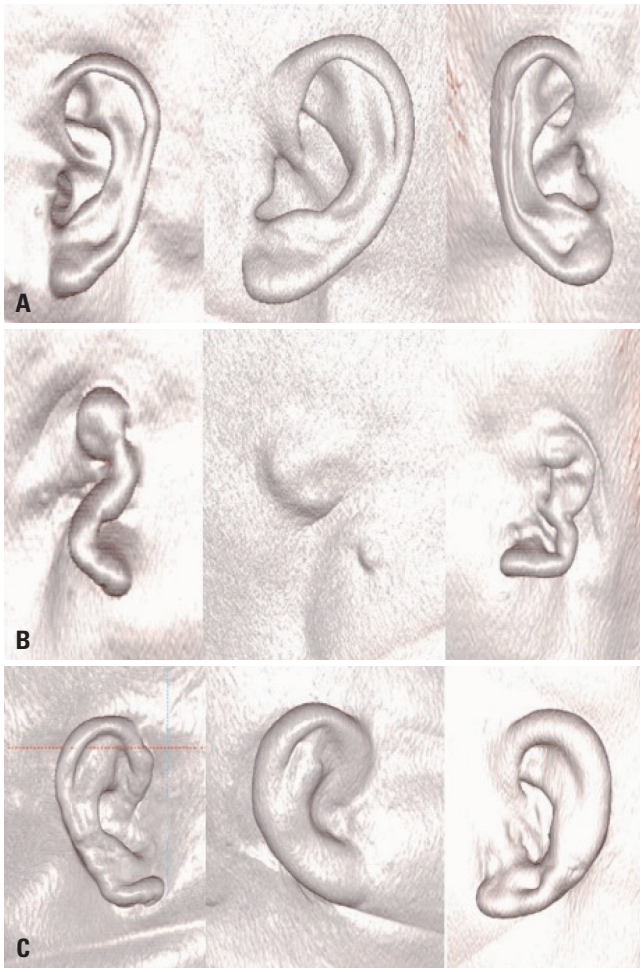

Fig. 6. Preoperative (A: unaffected ear, B: affected ear) and postoperative (C: after 2nd reconstruction) CT views of three microtia patients.

DISCUSSION

Since Tanzer's introduction of auricular reconstruction, various reconstruction procedures have been developed and many in-depth review articles published.[14-17] Despite numerous studies and research, total ear reconstruction continues to be very challenging for surgeons due to the ear's complex anatomy.[11] An accurately designed framework and the material used are important factors for successful reconstruction. Currently, the most commonly used material is autogenous costal cartilage,[2,5] but it has several risks and disadvantages. First, the donor-site morbidity may be problematic.[5] The donor-site scar can be aesthetically unpleasing and chest wall deformity can develop over time, caused by the absence of costal cartilage. Second, autograft absorption may lead to unpredictable results.[18] To overcome these limitations, novel implants have been developed, such as porous polyethylene (Medpor®, Stryker, MI, USA).[19] When using alloplastic frameworks, molding becomes easier and the supporting structure stronger. However, implant exposure or skin flap necrosis rates increase when using these materials.[20] In addition, large area of skin coverage is required when using Medpor®, which could lead to skin contracture or mismatch of skin color and skin thickness.[21] Due to these concerns regarding the ear framework, a 3D-printed bio-scaffold ear model was used. We previously introduced the 3D printing method and design of the custom-made 3D scaffold suitable for ear reconstruction surgery.[13] The results showed that the 3D implant was successfully used in a clinical setting.

The 3D-printed ear framework has many advantages over autogenous costal cartilage or other artificial materials, such as porous polyethylene. First, patient-specific and accurate designing of the ear model is possible. CT scans were used to obtain favorable and accurate ear models. Accurate extraction of the unaffected ear was possible by delineating different surrounding tissues and selecting specific auricular cartilage tissue.[13] Second, donor-site morbidity is not a concern. Third, the combination of materials used for the implant can be chosen, making it possible to achieve both ideal strength and resorption rate. Fourth, the subcutaneous pedicle can be preserved, skin flap vascularity is superior, and postoperative complication rate, including rate of infection, exposure, or skin necrosis, can be reduced when using the 3D-printed ear model.[3] Lastly, when using 3D printing-based PCL structures for auricular cartilage, the framework has excellent mechanical properties and slow biodegradability.[22]

Despite several reports on different models and designs of 3D-printed ear models,[8-12] their clinical application has seldom been introduced as the previously reported 3D-printed scaffolds were difficult for clinical application. Simply designed "identical" ear models can cause difficulties in real operative fields, since the implantation procedure may cause harm to the vascularity of the skin flap by harming the subcutaneous pedicle emphasized for blood supply in Nagata's method.[3] In contrast, our proposed 3D-printed ear framework does not disrupt the subcutaneous pedicle during insertion into the pocket. The reconstruction results of the five patients included in this trial showed that the proposed 3D-printed framework can provide sufficient vascularity and lower the risk of exposure or infection.

Numerous problems remain to be solved and issues considered in the field of ear reconstructive surgery. Further research and clinical studies should be performed to ensure a safe, aesthetically satisfying, and stable tissue substitute for auricular cartilage and extend the use of 3D-printed implants. In addition, the ethical and legal issues surrounding human stem cells should be addressed regarding biomaterial and cell printing technology.

In conclusion, in summary, we successfully designed and fabricated patient-specific 3D-printed ear implants and clinically proved that the implant for ear reconstruction surgery was suitable for the currently used two-stage method in microtia patients. The novel design combined with bioprinting technique may be an ideal alternative for ear reconstruction.

SUPPLEMENTARY DATA

Video 1. Video of the modeling process of 1st stage ear reconstruction 3D model.
Video 2. Video of the modeling process of 2nd stage ear reconstruction 3D model.

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AUTHOR CONTRIBUTIONS

Conceptualization: In Sik Yun. Data curation: In Sik Yun. Formal analysis: Oh Young Joo and In Sik Yun. Funding acquisition: In Sik Yun. Investigation: Oh Young Joo and In Sik Yun. Methodology: In Sik Yun. Project administration: In Sik Yun. Resources: Eun-Ju Lee, Jin-Hyung Shim, and In Sik Yun. Software: Eun-Ju Lee, Jin-Hyung Shim, and In Sik Yun. Supervision: Young Seok Kim, Tai Suk Roh, Hyun Woo Cho, and In Sik Yun. Validation: In Sik Yun. Visualization: In Sik Yun. Writing—original draft: Oh Young Joo and In Sik Yun. Writing—review & editing: Oh Young Joo, Tae Ho Kim, and In Sik Yun. Approval of final manuscript: all authors.

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