metals

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3D-Printed Connector for Revision Limb Salvage Surgery in Long Bones Previously Using Customized Implants

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Abstract: In orthopedic oncology, revisional surgery due to mechanical failure or local recurrence is not uncommon following limb salvage surgery using an endoprosthesis. However, due to the lack of clinical experience in limb salvage surgery using 3D-printed custom-made implants, there have been no reports of revision limb salvage surgery using a 3D-printed implant. Herein, we present two cases of representative revision limb salvage surgeries that utilized another 3D-printed custom-made implant while retaining the previous 3D-printed custom-made implant. A 3D-printed connector implant was used to connect the previous 3D-printed implant to the proximal ulna of a 40-year-old man and to the femur of a 69-year-old woman. The connector bodies for the two junctions of the previous implant and the remaining host bone were designed for the most functional position or angle by twisting or tilting. Using the previous 3D-printed implant as a taper, the 3D-printed connector was used to encase the outside of the previous implant. The gap between the previous implant and the new one was subsequently filled with bone cement. For both the upper and lower extremities, the 3D-printed connector showed stable reconstruction and excellent functional outcomes (Musculoskeletal Tumor Society scores of 87% and 100%, respectively) in the short-term follow-up. To retain the previous 3D-printed implant during revision limb salvage surgery, an additional 3D-printed implant may be a feasible surgical option.

Keywords: extremity; revision; limb salvage surgery; 3D printing; customized; implant

Citation: Park, J.-W.; Kang, H.-G.; Kim, J.-H.; Kim, H.-S. 3D-Printed Connector for Revision Limb Salvage Surgery in Long Bones Previously Using Customized Implants. *Metals* **2021**, *11*, 707. https://doi.org/10.3390/met11050707

Academic Editor: Atila Ertas

Received: 2 April 2021
Accepted: 22 April 2021
Published: 26 April 2021

1. Introduction

Custom-made implants for limb salvage surgery pre-date modular implants; however, their extensive manufacturing duration remains a major drawback [1]. Modular endoprostheses are the most commonly-used implants that have been used to overcome the disadvantages of early custom-made implants [1–3]. They can be used by orthopedic oncology surgeons to provide surgical flexibility, and standardization of the implant pieces facilitates manufacturing. However, there are anatomic sites where a modular endoprosthesis cannot be used. Furthermore, the adjacent normal joint is often sacrificed during reconstruction using the modular implant due to limited bone stock for implant fixation. Recently, three-dimensional (3D)-printing has been introduced for medical applications, wherein custom-made implants can be fabricated in a few days or weeks. These 3D-printed custom-made implants have shown promising short- and mid-term surgical outcomes in orthopedic oncology [4–7].

For limb salvage surgery of the long bones, the modular endoprosthesis system is available for most anatomical locations. However, the 3D-printed custom-made implant has advantages in long bone surgery for preservation of normal adjacent joints, and in limb salvage surgeries for specific anatomical locations without an existing conventional tumor endoprosthesis. When limb salvage surgery with a conventional endoprosthesis including an artificial joint is required, intercalary replacement with joint-saving of the long bone is often possible with a 3D-printed custom-made implant.

Limb salvage surgery with an endoprosthesis is more vulnerable to mechanical failure than implants for arthroplasty without replacement of a major bone defect [8–11]. One of the concerns associated with custom-made implants is the higher probability of mechanical failure as the implant design is not standardized [12]. While the mechanical strength of the full solid-body implant fabricated by 3D-printing is comparable to those fabricated by forged, wrought, or casting [13], the lattice structure, that is an intended porotic structure to facilitate tissue integration around the implant, requires mechanical and clinical verification [6,7,14]. In this situation, the biggest concern in practice is overcoming failure of bone union or fracture of implant after performing limb salvage surgery with the 3D-printed implant. As most 3D-printed custom-made implants are not modular but rather a single unit, it is difficult to replace only the broken parts or those where the tumor has recurred nearby.

Herein, we present a surgical method that utilizes an additional 3D-printed implant in revision limb salvage surgery to preserve the previous 3D-printed custom-made titanium alloy implants in long bones.

2. Materials and Methods

Two representative patients underwent revision surgeries using a 3D-printed connector to connect the previous 3D-implant to the host bone. The reasons for revision surgeries after the 3D-printed limb salvage surgeries were tumor recurrence and implant fracture. The previous implants achieved bony union radiographically at the junctions between the implant and the host bone, and neither patient underwent revision surgery due to non-union at the junction. Rather than removing all implants, the revision surgeries were performed in a manner that preserved the previous implant as much as possible. The 3D-printed customized implants were designed using the Materialise Interactive Medical Image Control System (Materialise; Leuven, Belgium) and Magics 22 (Materialise; Leuven, Belgium) and fabricated using an electron beam melting-type (EBM) 3D-printer (ARCAM A1, Arcam AB, Mölndal, Sweden) with Ti6Al4V (Ti6Al4V-ELI Per ASTM 136). The custom-made implant was created by the MEDYSSEY Company (Jecheon, Korea) and certified by the Ministry of Food and Drug Safety. All study participants provided informed consent, and the study design was approved by the appropriate ethics review board (NCC2017-0129).

For the 3D-printed connector, two junctional parts for the previous implant and remaining host bone were designed first. The connector body was subsequently designed for the most functional position or angle by twisting or tilting. The junction to the previous metal implants and the bodies were mainly solid structure, while the junction to the remaining host bone partly had lattice structure for contact surface with the bone. The lattice structure had 750 um pores [7,15]. The main concept of the 3D-printed connector is that it mimics that of a modular prosthesis, with an assembly mechanism to insert one piece into another (Modular Universal Tumor and Revision System, Implantcast, Buxtehude, Germany; Global Modular Replacement System, Stryker, Kalamazoo, MI, USA). The previous 3D-printed implant was tapered on the inside, and the 3D-printed connector encased the outside of the previous implant. The 1.5-mm gap between the previous implant and the new one was filled with bone cement. The metal artifact around the previous 3D-printed implant that was seen in the computed tomography (CT) images was removed and smoothed as much as possible, though there was a risk of error during the modelling process. For both patients, the design of the implant used in the first surgery was saved as an STL file; in the CT images taken for the new implant, the previous implant part was not modelled by dealing with metal artifacts but was replaced by fusion of the implant design data.

The first patient reported here was a 40-year-old man who underwent treatment for a desmoplastic fibroma, a locally aggressive intermediate tumor, in his forearm [14]. He had undergone orthopedic surgery on the same side of both forearm bones and had used an external fixator for fracture fixation five years ago. It is not clear whether the tumor had originated from the fracture site or had entered the screw holes of the previous external fixator, but the tumor involved both forearm bones. There was no distant metastasis. Bilateral limb salvage surgery for the forearm bones was performed using two 3D-printed custom-made implants for the radius and the ulna (Figure 1A–E). One year postoperatively, local tumor recurrence was detected at the proximal junction of the ulnar implant. The radial implant showed good fixation in both proximal and distal junctions. The first revision surgery was performed to remove the recurred tumor and to make a single forearm bone by fusion of the proximal and distal remnant bones. However, fusion at the proximal part failed and a second revision surgery was planned (Figure 1F–H).

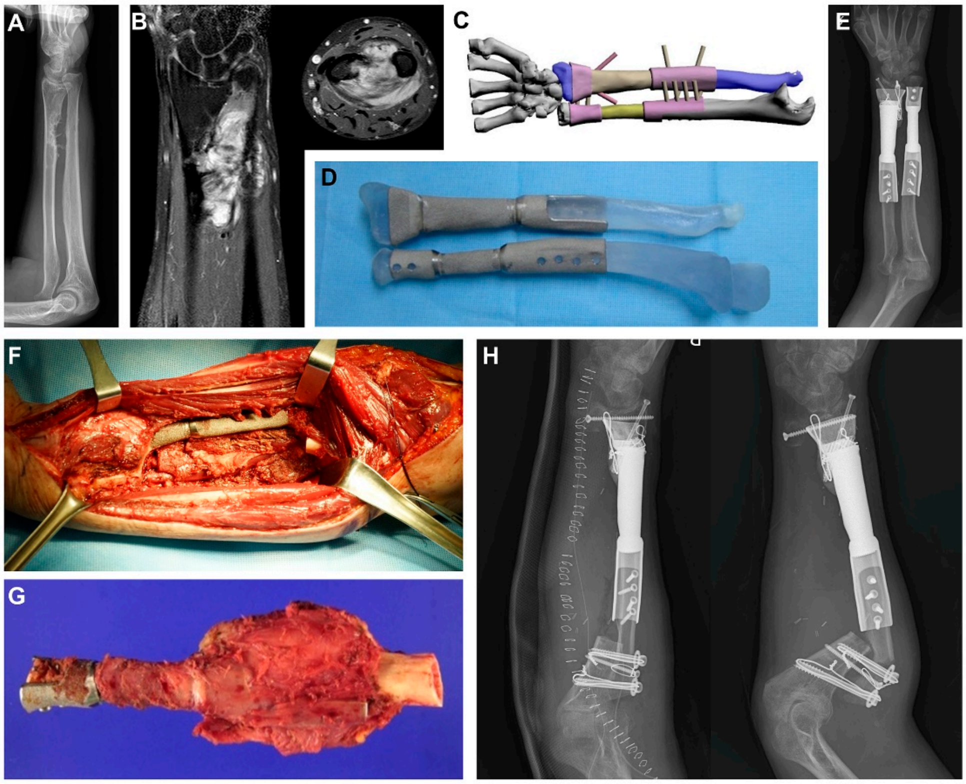

Figure 1. Failure of the 3D-printed implants in both forearm bones [14]. (**A**) A preoperative plain radiography and (**B**) gadolinium-enhanced T1-weighted magnetic resonance image showing desmoplastic fibroma arising from both forearm bones. (**C**) A graphic design and (**D**) photograph of 3D-printed implants. (**E**) A postoperative plain radiograph after limb salvage surgery. Photographs showing (**F**) removal of the ulnar implant with a recurrent tumor and (**G**) a specimen. (**H**) Plain radiographs showing immediate postoperative status after the first revision surgery (**left**) and mechanical failure 4 months later (**right**).

The second representative patient was a 69-year-old woman who had chondrosarcoma at the left distal half of the femur without distant metastasis. She had a limb length discrepancy of 10 cm due to a childhood history of osteomyelitis in the contralateral femur. The patient underwent limb salvage surgery using a 3D-printed customized implant for the distal part of her right femur with retention of the natural knee joint, and acute shortening of the right femur for partial correction of limb length discrepancy (Figure 2A–C). The patient could ambulate independently three months postoperatively. However, six months postoperatively, she slipped, and the proximal part of the implant was broken between the implant body and the fixation plate. The unexpected implant fracture was analyzed and the main causes of the fracture were stress concentration at the broken junction and internal defects of the 3D-implant. The distal junction to the knee joint was well-fixed. The first revision surgery was performed with additional dual plates with expectation of bony union or extracortical bone bridge to the porous structure of the implant body. However, 21 months later, mechanical failure occurred and a second revision surgery was planned (Figure 2D–F).

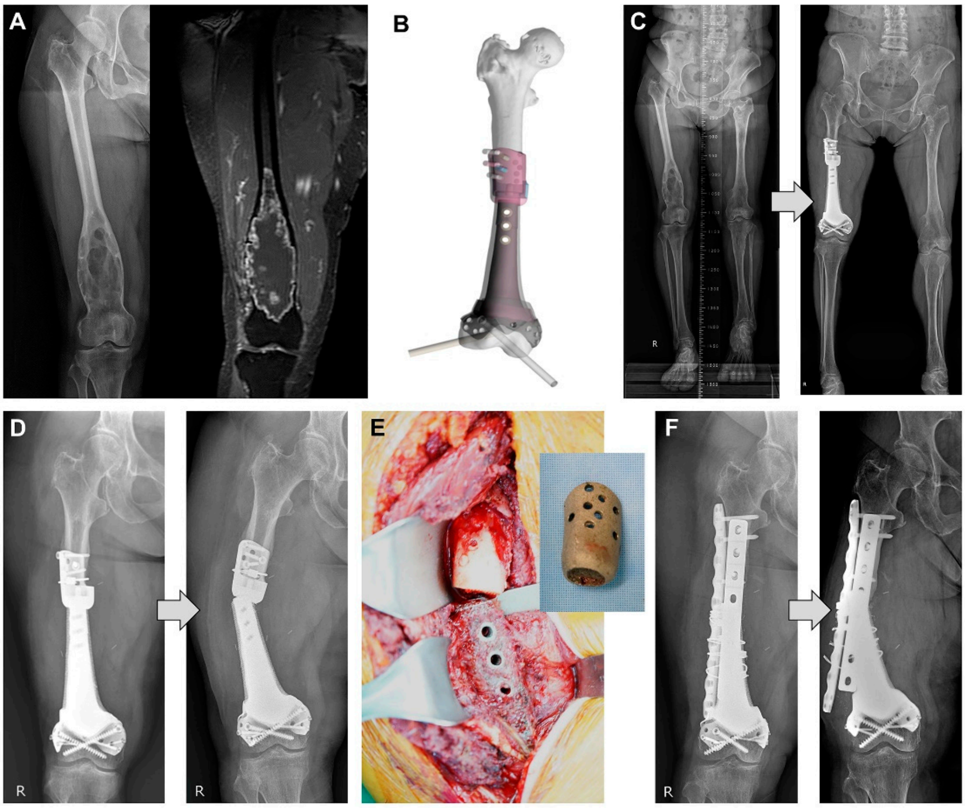

Figure 2. Failure of the 3D-printed implants in the right distal femur. (**A**) A preoperative plain radiography and gadolinium-enhanced T1-weighted magnetic resonance images showing chondrosarcoma in the right distal femur. (**B**) A graphical design of the 3D-printed implant. (**C**) A preoperative (**left**) and postoperative teleradiogram (**right**) after limb salvage surgery. (**D**) Photographs showing implant fracture at 6 months postoperatively. (**E**) Intraoperative photographs and the removed broken proximal part. (**F**) Plain radiographs showing immediate postoperative status after the first revision surgery (**left**) and another mechanical failure 21 months later (**right**).

3. Results

3.1. Forearm

For the patient who underwent single forearm bone surgery, the proximal part of the previous radial implant and the proximal ulna needed to be connected while maintaining the distal part, including the wrist joint. The wrist and hand function in the salvaged forearm was normal; however, thumb extension was limited due to soft tissue adhesion of the thumb flexor muscles. The elbow joint function was originally limited from 0 to 90 degrees due to radial head dislocation secondary to a childhood trauma. The proximal part of the previous radial implant was half the cylindrical plate that originally wrapped the proximal radial shaft. The junctional part of the 3D-printed connector up to the previous radial implant was designed to have a metal insert replace the space of the original radial shaft and the remaining half of the cylindrical plate from the opposite direction of the previous implant. The second junctional part was designed for the proximal ulna near the elbow joint, and this comprised two-thirds of a cylindrical plate with multiple holes for the screws and suture. The functional position of the forearm rotation was set at 15 degrees toward pronation from the neutral position. The body of the 3D-printed connector was twisted to the functional rotational position (Figure 3A–D).

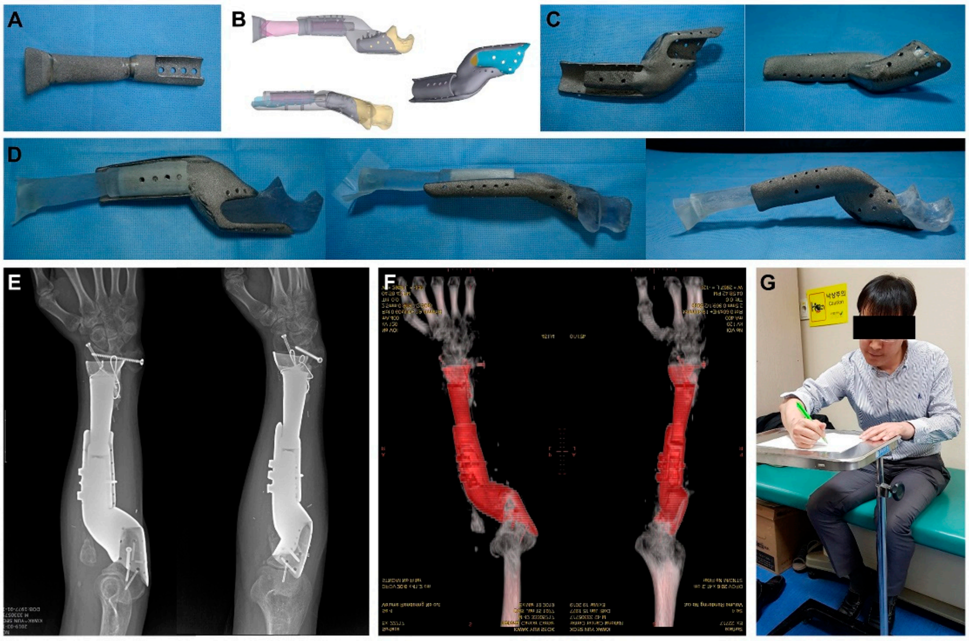

Figure 3. Revision limb salvage surgery using 3D-printed connector in the forearm. (**A**) A photograph of the previous 3D-printed implant for the radius. (**B**) Graphic designs of the 3D-printed connector and (**C**,**D**) photographs of the 3D-printed connector for single forearm bone surgery preserving the previous 3D-printed radial implant. Postoperative (**E**) plain radiographs and (**F**) computed tomography reconstruction images after second revision surgery using the 3D-printed connector. (**G**) A photograph showing functional position of the forearm during writing.

In the second revision surgery, the broken screws and the remaining part of the proximal radius were removed. The wrist joint was stable after the first revision surgery, and the host bones near the wrist were firmly bonded to the previous 3D-printed implant. The proximal part of the previous 3D-printed implant and the ulnar remnant near the elbow joint were fixed using the 3D-printed connector. The fixation between the old and new 3D-printed implants was achieved by winding three wires through a matched hole with bone cement. The 3D-printed connector and the proximal ulna showed conforming stability after inserting the bone into the implant, which was designed to sufficiently enclose the bone and fixed using screws (Figure 3E–F). The patient recovered the original range of motion of his elbow (0–90 degrees) at 10 weeks postoperatively and was able to write with his forearm in the 15-degree pronation position (Figure 3G). The wrist and elbow function were well-maintained without mechanical failure until the last follow-up at 26 months after the second revision surgery. The Musculoskeletal Tumor Society (MSTS) score at the last visit was 26 (87%).

3.2. Femur

For the patient who underwent revision surgery using the 3D-printed connector for the femur, the femoral shaft of the previous implant body and proximal femur needed to be connected while maintaining the distal part, including the knee joint. The knee joint had an extension lag of 10 degrees due to acute shortening of the femur, though independent ambulation without pain was possible. Furthermore, partial correction of the limb length discrepancy led to an improvement in gait, and the left heel that did not touch the ground during ambulation before the limb length correction, could touch the ground while walking after the correction (Figure 4D). The junctional part of the 3D-printed connector to the previous broken 3D-printed custom-made implant was a full cylinder that surrounded the remaining previous implant. Another junctional part was designed as a one-third plate with screw holes to fix the proximal femur near the hip joint. The body of the 3D-printed connector was designed to restore the tilting angle of the femur from the mechanical axis of the lower limb (Figure 4A,B).

Figure 4. Revision limb salvage surgery using 3D-printed connector in the femur. (**A**) A graphic design of the 3D-printed connector. (**B**) Photographs of the previous 3D-printed implant (duplicated), broken implant (duplicated), and the 3D-printed connector. (**C**) Intraoperative photographs before and after application of the 3D-printed connector. (**D**) Preoperative teleradiograph and photograph showing the chondrosarcoma of the right distal femur and limb length discrepancy of 10 cm (**left**), and final postoperative pictures (**right**). (**E**) Photographs showing normal knee joint function.

In the second surgery, all the metal plates and screws were removed, leaving the knee joint below the shaft of the broken 3D-printed customized implant used in the first surgery. The 3D-printed connector was connected by inserting the shaft of the previous 3D implant into the 3D-printed connector. The gap between the old and new 3D-printed implant was filled with bone cement. The remaining proximal femur on the hip side was fixed by multiple screws. The patient resumed walking on crutches at 2 weeks after the second operation and was able to walk without crutches without pain at 10 weeks postoperatively. The range of motion of the knee joint was normal without extension lag (Figure 4C–E). At 10 months after the second revision surgery, the MSTS score was 30 (100%).

4. Discussion

When a megaprosthesis is fabricated by 3D printing, it is often difficult to implement a modular-type; therefore, it is fabricated as a single mass. After limb salvage surgery using a megaprosthesis, revision surgeries are often required for a variety of reasons, including local recurrence and mechanical failure. One of the concerns regarding the use of a 3D-printed customized implant in limb salvage surgery is that it makes revision surgery difficult. In this study, an additional 3D-printed implant was introduced during revision without removing all of the previously inserted 3D-printed implant. The surgical results using the additional 3D-printed connector implant were acceptable in the short-term follow-up.

The metal-to-metal fixation mechanism is still a problem in the 3D-printed implant. The locking screw mechanism has not been introduced in 3D-printed implants as the male and female screw threads are hard to implement due to insufficient precision and roughness of the electron beam melting-type 3D-printed product. Therefore, cemented fixation to the intended gap between the implants was mainly utilized in these patients.

This study has some limitations. It was a preliminary study based on a small number of patients with a short follow-up. Although the short-term surgical results were promising, they are difficult to generalize. These results imply that the 3D-printed connector implant is a surgical option to consider when revision surgery after previous limb salvage surgery using a 3D-printed customized implant is needed, and retaining the previous 3D-printed implant totally/partially would be beneficial. Regarding the mechanical property of the 3D-printed implants, long-term follow-up clinical data and biomechanical data is required. There was no serious mismatch between the 3D connector and previous implant or remaining bone. However, deformation of the 3D-printed customized implant by residual stress and contraction was not accurately measured in this paper.

In conclusion, to retain the previous 3D-printed implant during revision limb salvage surgery, an additional 3D-printed implant may be a feasible surgical option.

Author Contributions: J.-W.P. conceptualized, interpreted the patient data and implant designs and was a major contributor in writing the manuscript. H.-G.K. was a primary implant designer and visualized the illustrations. J.-H.K. and H.-S.K. contributed to validation of the implant designs. All authors have read and agreed to the published version of the manuscript.

Funding: This research was supported by the Industrial Strategic Technology Development Program ('P0008805′), funded by the Ministry of Trade, Industry & Energy (MOTIE, Korea).

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board of National Cancer Center, Korea (NCC2017-0129, 1 June 2017).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflicts of Interest: The authors declare no conflict of interest.

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