

Patient-specific 3D-printed implants for reconstruction of elbow nonunion with bone defects: a case report and technical note

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Abstract

Distal humeral nonunion associated with extensive bone loss remains one of the most challenging reconstructive conditions in upper-extremity surgery. We present a technically demanding case treated using a patient-specific 3D-printed implant and discuss its potential advantages compared with alternative reconstructive strategies. This case report describes the management of a 59-year-old woman presenting with a hypertrophic distal humeral shaft nonunion three years after intramedullary nailing. Preoperative evaluation included bilateral Computed Tomography (CT) using a dedicated low-artifact acquisition protocol to enable contralateral humeral mirroring, three-dimensional virtual planning, and the design of a patient-specific implant. A custom-made Ti6Al4V implant featuring a cemented proximal stem, a porous metaphyseal interface, and a dual-flange distal fixation platform was manufactured based on the preoperative planning. Reconstruction was performed through a posterior approach with olecranon osteotomy using patient-specific cutting guides. Clinical and radiographic outcomes were prospectively assessed at 1, 3, 6, and 12 months postoperatively. Progressive improvements were observed in elbow motion, MEPS, TCI, and sleep quality (PSQI). By 12 months, the patient achieved near-complete ROM and excellent clinical scores, with radiographs showing full union and stable alignment. At 1 year, however, a fall resulted in proximal stem mobilization, while the distal fixation and porous interface remained stable. This case demonstrates that patient-specific reconstruction can achieve accurate anatomical restoration, stable fixation, and excellent functional recovery in selected patients with complex distal humeral nonunion and bone loss. It also highlights the potential advantages of customized implants, while emphasizing the importance of meticulous preoperative planning, complete implant fixation, and appropriate postoperative protection to minimize the risk of late mechanical failure. Although the present findings are encouraging, further clinical studies are required to establish the long-term effectiveness and broader applicability of this reconstructive strategy.

Key Words: nonunion; humerus; 3D printing; custom-made; computer-assisted; elbow.

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A septic non-unions of the humeral shaft and distal humerus represent a persistent challenge in orthopedic trauma surgery. Despite advances in fixation techniques and biological augmentation, non-union rates after humeral fractures remain between 2% and 10%, depending on fracture pattern, patient comorbidities, and previous surgical history.^{1,2} Anatomical complexity limited cortical bone stock, and the functional importance

of the elbow joint further complicate management, particularly in distal humeral involvement.¹⁻³

Non-unions are generally classified as hypertrophic or oligotrophic, according to the biological activity at the fracture site.³ Hypertrophic non-unions demonstrate excessive callus formation without adequate mechanical stability, whereas oligotrophic types exhibit minimal callus and reduced osteogenic potential. Both forms can lead to chronic pain, de-

formity, and significant loss of upper limb function.²⁻⁴ The gold-standard treatment for aseptic humeral nonunion involves achieving both mechanical stability and biological stimulation. Several fixation techniques have been proposed, including Open Reduction and Internal Fixation (ORIF) with double plating and autologous or synthetic bone grafting. Rollo *et al.* (2021)¹ demonstrated that dual-plate fixation combined with biological and artificial bone grafts provides reliable healing and satisfactory functional recovery in distal humeral non-unions. Similarly, Rollo *et al.* (2019)² reported high union rates using plate-and-bone-strut fixation, which enhances both rigidity and biological support.

However, complex scenarios such as those involving bone loss, deformity, or multiple failed revision surgeries—standard techniques may be insufficient. In these cases, patient-specific, custom-made implants designed through 3D printing and computer-assisted planning have emerged as promising alternatives.^{5,6} These technologies allow precise anatomical reconstruction, tailored mechanical alignment, and optimized bone-implant integration, potentially improving outcomes in otherwise intractable cases.

This case report describes the clinical management and radiological outcome of a 59-year-old woman with aseptic distal humeral shaft nonunion treated using a patient-specific 3D-printed implant. The report focuses on the pre-operative planning process, implant design, surgical technique, and clinical and radiographic outcomes at 12 months, highlighting the potential role of personalized implants in the reconstruction of complex distal humeral bone defects.

Case Report

A 59-year-old woman was referred to our Special Surgery Unit because of persistent pain and functional impairment of the right arm, three years after Intramedullary Nailing (IMN) for a humeral shaft fracture using three non-locking proximal screws and one distal screw (Figure 1). Physical examination revealed shortening and external rotational deformity of the right humerus. Standard radiographs and Computed Tomography (CT) confirmed a hypertrophic nonunion of the distal humeral shaft with partial displacement (Figure 1).

The patient was 1.60 m tall, weighed 86 kg, and had a Body Mass Index (BMI) of 33.2 kg/m². Her medical history was significant for chronic alcohol abuse, advanced liver cirrhosis, hypertension, and esophageal varices. She had an American Society of Anesthesiologists (ASA) score of 4.⁷ The Non-Union Scoring System (NUSS)⁸ was 23 before the initial fracture and increased to 36 at the time of nonunion diagnosis. Pain intensity, assessed using the Visual Analog Scale (VAS),⁹ was 4 at rest and 7 during upper-limb activity. The Pittsburgh Sleep Quality Index (PSQI) was 15.¹⁰

Three years after the initial fixation, elbow function remained severely impaired. The patient demonstrated an average elbow flexion of 97°, an extension deficit of 36.2° compared with the contralateral side, pronation of 83.4°, and supination of 85.3°. The Mayo Elbow Performance Score (MEPS)¹¹ was 72 points, while the Trochleocapitellar Index (TCI)¹² measured 0.13.

The diagnosis of aseptic nonunion was established based on the absence of clinical signs of infection, normal in-

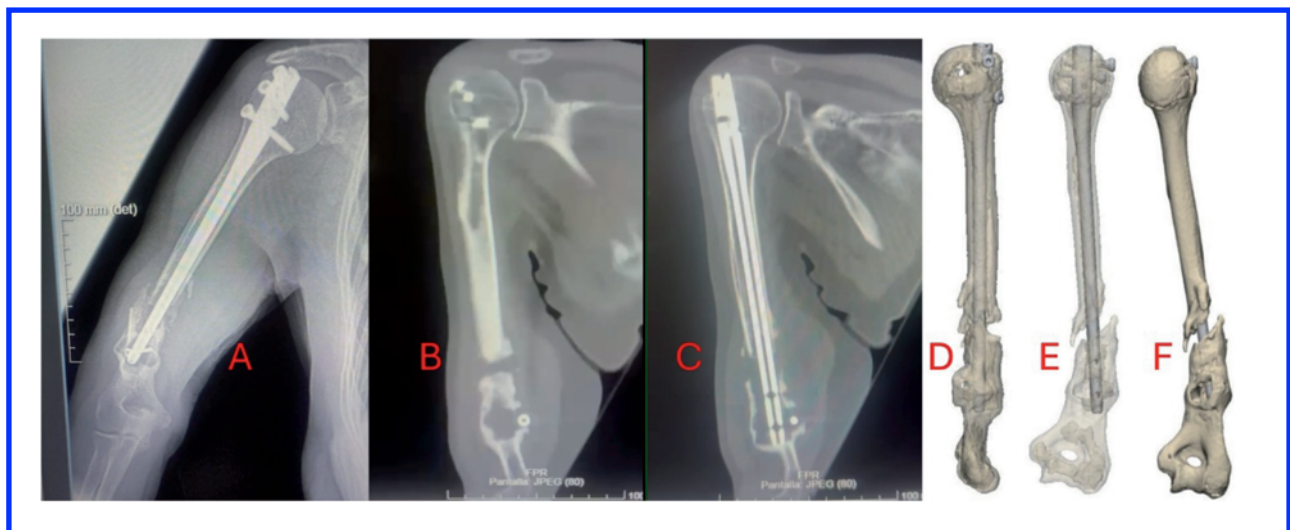


Figure 1. Radiographic and 3D-CT Evaluation of the Distal Humeral Reconstruction.

A 59 years old female, Diagnostic imaging three years after surgical Fixation of humeral distal shaft by Intramedullary Nail: A) Postoperative anteroposterior radiograph demonstrating a failed intramedullary fixation of the distal humeral diaphysis with hardware loosening and extensive metaphyseal bone loss; B) Sagittal CT reconstruction showing nonunion at the distal diaphyseal level with cortical thinning and irregular callus formation; C) Postoperative CT scan following implantation of the bone loss of the distal humeral; D-F) Three-dimensional CT reconstructions depicting the extent of non union of the distal humeral shaft bone.

flammatory markers, and preoperative radiological assessment. Intraoperatively, multiple deep tissue samples were obtained for microbiological culture according to our institutional protocol, and all cultures were negative, confirming the aseptic nature of the nonunion.

Following CT acquisition, a dedicated digital surgical planning process was carried out in collaboration with biomedical engineers. Using bilateral CT-based three-dimensional reconstruction and contralateral humeral mirroring, a patient-specific implant and customized cutting guides were designed to restore the native anatomy and optimize fixation. Implant design, engineering validation, additive manufacturing of the Ti6Al4V custom implant, post-processing, sterilization, and quality-control procedures required approximately 4 weeks before definitive implantation (Figure 2). This planning phase also included

multiple surgeon–engineer meetings to optimize implant geometry, fixation strategy, and surgical execution.

Perioperative antibiotic prophylaxis consisted of intravenous cefazolin (2 g) administered within 30 minutes before skin incision, followed by two postoperative doses according to our institutional protocol.

The patient subsequently underwent surgery in the supine position through a posterior approach to the humeral diaphysis (see Supplementary materials, Surgical appendix). The operative procedure lasted approximately 4 hours, with an estimated blood loss of 1.2 L. During the hospital stay, the patient received a total of eight units of packed red blood cells.

The postoperative course was uneventful (Figure 3). The patient remained hospitalized for 10 days and subsequently completed a structured rehabilitation program

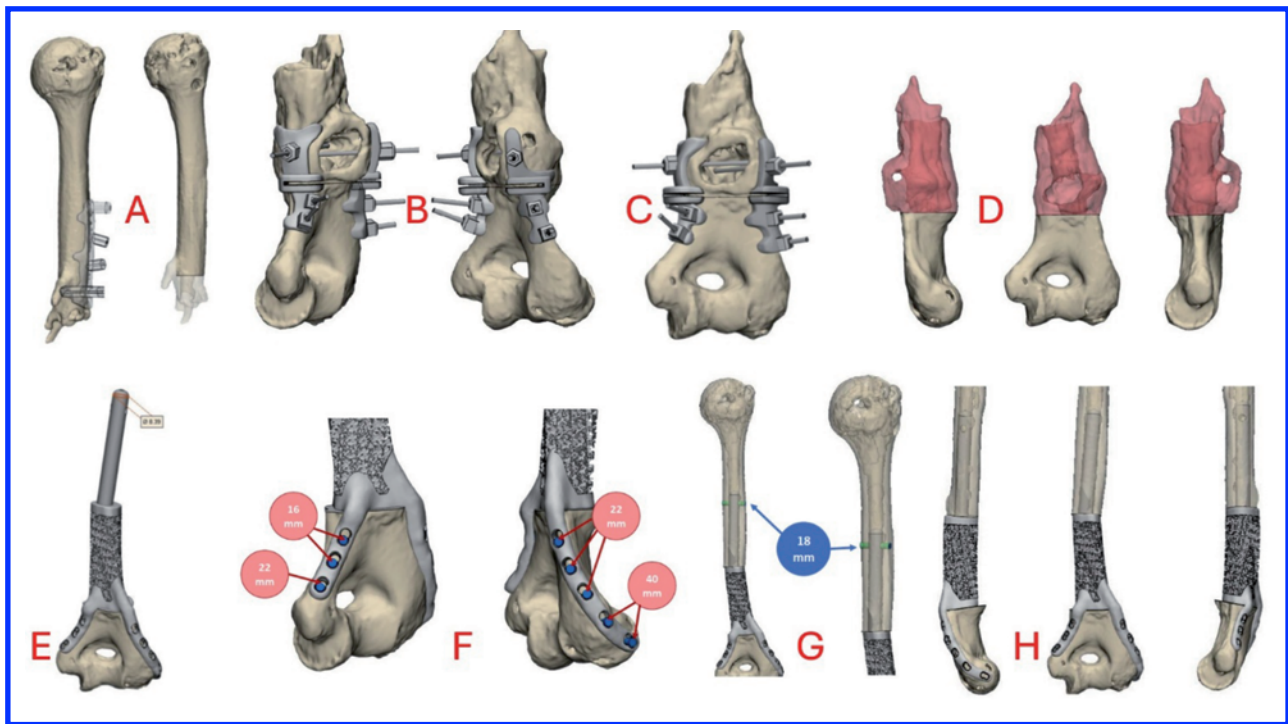


Figure 2. Preoperative 3D planning and custom-made implant design for distal humeral reconstruction.

A) Three-dimensional reconstruction of the humerus illustrating the extent of distal bone loss and the initial positioning of the patient-specific cutting guides; B-C) Detailed views of the distal humerus with the cutting guides secured using 1.6-mm Kirschner wires, demonstrating planned osteotomy planes and alignment channels for screw trajectory. These images reproduce the guide fixation strategy described in the surgical technique protocol, where the hexagonal and square sleeves correspond to the intended screw directions; D) Segmentation of the resection model showing the distal fragment to be removed (highlighted in red) and the planned resection boundary based on the patient's CT anatomy; E) Design of the custom-made implant, consisting of a proximally cemented stem and a porous-coated metaphyseal transition zone for biological integration with the host bone; F) Screw trajectory mapping on the distal fixation platform, indicating the planned lengths (16, 22, and 40 mm) and the alignment of 2.7mm screws channels with the guide-derived drill paths; G) Final virtual assembly of the implant with the proximal humerus, demonstrating restoration of limb length and alignment (18-mm correction shown); H) Multiview depiction of the completed construct, illustrating distal flange contact, porous interface coverage, and the configuration of the bicortical screw fixation. These renderings confirm that the distal fixation holes correspond precisely to the guide-generated trajectories, as described in the technical guideline.

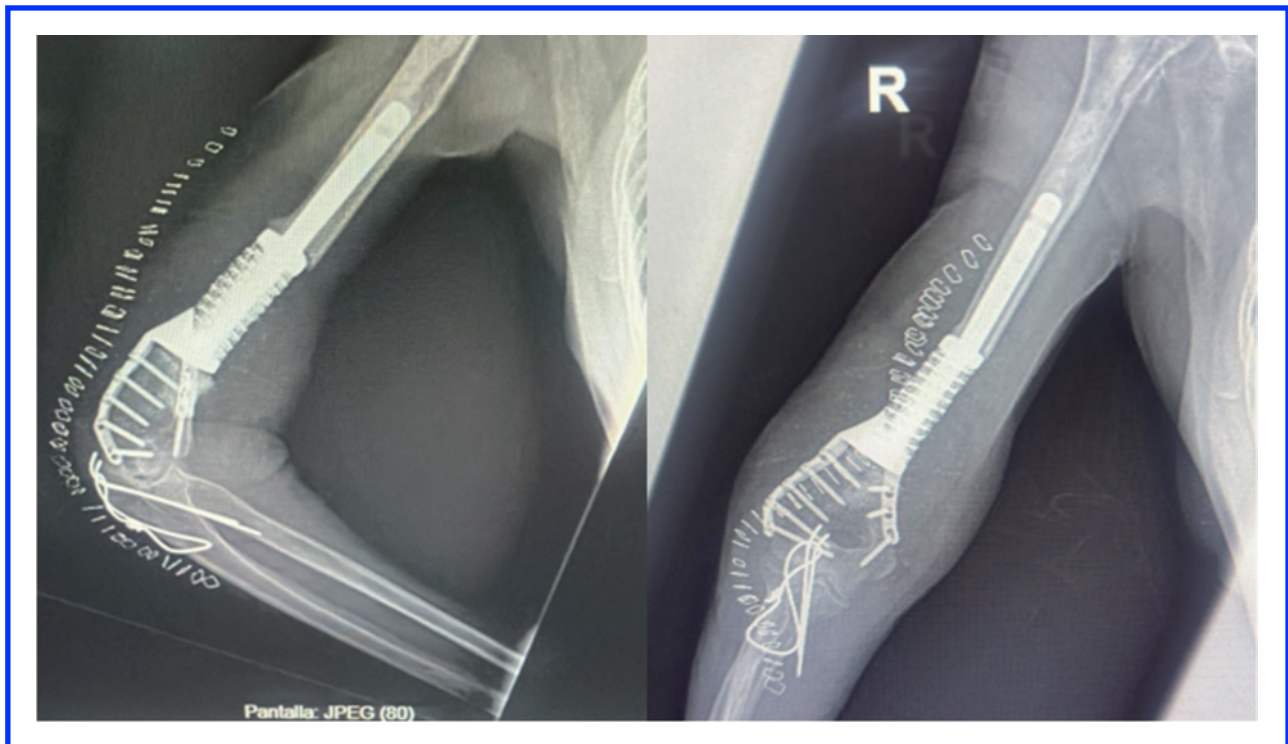


Figure 3. Postoperative radiographs following custom distal humeral reconstruction. The proximally cemented intramedullary stem is well aligned within the humeral canal, with no evidence of malposition or subsidence.

(see Supplementary materials, Rehabilitation appendix). Clinical and radiographic follow-up evaluations were performed at 1, 3, 6, and 12 months after surgery.

At the 1-month follow-up, pain had decreased substantially, and functional use of the limb had improved. Elbow flexion increased from 97° to approximately 110°, while the extension deficit improved from 36.2° to 27°. Pronation and supination remained essentially unchanged at approximately 82°. The MEPS improved to 56 points, reflecting early functional recovery. Radiographs demonstrated maintained alignment and initial callus formation. The PSQI improved to 8, and the TCI increased to 0.27. At the 3-month follow-up, continued rehabilitation resulted in further functional improvement. Elbow flexion reached 122.3°, and extension loss decreased to 16.7°. Forearm pronation and supination recovered to approximately 90°, approaching symmetry with the contralateral limb. The MEPS increased to 84 points, corresponding to a good clinical outcome. Radiographs showed progressive fracture consolidation without evidence of implant-related complications. The PSQI improved to 6, while the TCI remained stable at 0.27.

At the 6-month follow-up, the patient had regained a nearly functional range of motion for daily activities. Elbow flexion reached 131.4°, with an extension deficit of only 8.3°. Pronation and supination were symmetrical to the contralateral side. The MEPS improved to 88 points, indicating an excellent functional result. Radiographic as-

essment confirmed advanced fracture union with maintained mechanical alignment. The PSQI further improved to 4, and the TCI remained unchanged at 0.27.

At the 12-month follow-up, the patient had returned to unrestricted activities of daily living. Elbow flexion reached 136.5°, with only a minimal extension deficit of 3–5°, while full forearm rotation was maintained. The final MEPS was 90 points, confirming an excellent clinical outcome. Radiographs demonstrated complete union of the distal humerus with stable implant alignment. The PSQI improved to 3, and the TCI remained stable at 0.27.

One year after surgery, the patient sustained a fall while intoxicated, resulting in proximal stem mobilization of the custom-made implant (Figure 4).

Objective

The study aimed to minimise artefacts caused by prostheses, screws, or osteosynthesis along the bilateral humeral axis while preserving diagnostic image quality of bone and soft tissues and enable valid reconstructions for 3D planning and STL export.

Discussion

The present case highlights the role of patient-specific implants in managing complex distal humeral nonunions with segmental bone loss, an area in which conventional fixation frequently fails to provide durable stability.¹⁻⁴ The

use of bilateral 3D CT modeling and contralateral humeral mirroring enabled highly accurate anatomical reproduction, allowing the surgical team to define osteotomy planes and customize implant geometry with a precision increasingly recognized as essential in upper-extremity reconstruction.^{5,6,13} Such individualized preoperative planning is particularly advantageous in cases with multiplanar deformity, bone loss, or multiple prior surgeries, where restoration of limb length, axis, and rotation is challenging using standard implants.^{6,14}

The biomechanical performance of the implant is strongly influenced by its Ti6Al4V alloy, which offers a Young's modulus far closer to cortical bone than cobalt–chromium or stainless steel. This reduces stress shielding and supports more physiological load transmission.^{5,6,13} Its high tensile strength and excellent fatigue resistance are crucial in distal humeral reconstructions, where the remaining bone stock is often osteopenic and exposed to repetitive torsional and bending stresses during daily activities.^{3,4} The porous metaphyseal transition zone augments frictional interlock and may enhance biological integration, thereby improving long-term resistance to cyclic loading.

The dual-flange distal construct and guide-derived locking screw trajectories produced a multiplanar fixation pattern capable of resisting the complex loading envi-

ronment of the distal humerus, consistent with recent biomechanical evidence regarding fixation stability in this region.¹⁵ The elongated screw holes provided controlled intraoperative adjustment without sacrificing final locking capability. However, the proximal fixation represented a critical vulnerability. Although the cemented stem provided axial stability, the omission of the two planned 4-mm diaphyseal screws likely reduced torsional resistance. Cement alone may not adequately counteract rotational forces, particularly in patients with compromised bone quality, elevated NUSS scores, or cirrhosis,⁷⁻⁹ and likely contributed to the late proximal mobilization following the patient's fall.

Alternative reconstructive strategies for extensive distal humeral bone loss include structural allografts, vascularized fibular grafts, revision internal fixation combined with biological augmentation, and megaprosthesis reconstruction. Structural allografts can restore bone stock but are associated with delayed incorporation, graft resorption, nonunion, and infection. Vascularized fibular grafts provide biological reconstruction with excellent healing potential but require microsurgical expertise, prolonged operative time, and may result in donor-site morbidity. Revision fixation with double plating and bone grafting remains the preferred option when adequate bone stock is preserved; however, it becomes increasingly challenging in the presence of major bone loss, multiplanar deformity, or multiple previous failed procedures.^{1,2} Megaprosthesis reconstruction offers immediate structural stability but sacrifices native bone and is generally reserved for oncologic indications or unreconstructable bone loss in elderly, low-demand patients.^{16,17} Compared with these alternatives, patient-specific 3D-printed implants enable anatomical restoration tailored to the individual defect, precise preoperative planning, optimized screw trajectories, and preservation of the remaining native bone while restoring limb alignment.^{5,6,13,14} Nevertheless, they require advanced imaging, dedicated engineering and manufacturing processes, increased costs, and meticulous surgical execution to achieve durable fixation.

This case illustrates both the strengths and limitations of custom-made implants. Advantages include high-precision planning, faithful reproduction of osteotomy geometry, optimized screw positioning, and the ability to treat bone defects and deformities that are not amenable to conventional implants.^{5,6,13,15} Limitations include production time, cost, dependency on high-quality imaging, and reduced intraoperative flexibility once the implant has been manufactured. Furthermore, long-term mechanical success depends critically on completing all planned fixation steps, especially proximal screw implantation, to maximize resistance to physiological and accidental loading. Overall, patient-specific 3D-printed implants represent a promising solution for distal humeral nonunions with bone loss, offering anatomical customization and favorable biomechanical performance. Ensuring full execution of the planned proximal fixation is essential to prevent late loosening and to achieve durable outcomes, especially in patients with compromised bone quality or major systemic comorbidities.



Figure 4. One-year follow-up radiograph demonstrating proximal stem mobilization after a fall.

Conclusions

This case demonstrates that patient-specific reconstruction can achieve accurate anatomical restoration, stable fixation, and excellent functional recovery in selected patients with complex distal humeral nonunion and bone loss. It also highlights the potential advantages of customized implants while emphasizing the importance of meticulous preoperative planning, complete implant fixation, and appropriate postoperative protection to minimize the risk of late mechanical failure. Although the present findings are encouraging, further clinical studies are required to establish the long-term effectiveness and broader applicability of this reconstructive strategy.

List of abbreviations

3D, Three-Dimensional
ASA, American Society of Anesthesiologists
BMI, Body Mass Index
CT, Computed Tomography
IMN, Intramedullary Nailing
MEPS, Mayo Elbow Performance Score
NUSS, Non-Union Scoring System
ORIF, Open Reduction and Internal Fixation
PSQI, Pittsburgh Sleep Quality Index
ROI, Region of Interest
ROM, Range of Motion
STL, Stereolithography File Format
TCI, Trochleocapitellar Index
Ti6Al4V, Titanium–6% Aluminum–4% Vanadium alloy
VAS, Visual Analog Scale

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Conflict of interest

The custom-made implant described in this case report was manufactured by Valor Implant. Valor Implant also covered the publication fee for this article. The company had no role in the study design, clinical management of the patient, data collection, analysis or interpretation of the data, preparation of the manuscript, or decision to submit the manuscript for publication. The authors declare no other conflicts of interest.

Ethics approval

Ethics Committee approval was not required for this case report according to institutional regulations, as the surgical treatment was performed as part of standard clinical care. Written informed consent was obtained from the patient for the procedure and for publication of anonymized

clinical and radiological data. The report was prepared in accordance with the principles of the Declaration of Helsinki of 1964, as revised in 2013, concerning human and animal rights.

Contributions

Giacomo Mazzei and Jose Carlos Orihuela, conceptualization; Giacomo Mazzei, Ignacio Maria Silva Rossi and Alberto Alvarez Jimenez: methodology, software, formal analysis, and data curation; Luis Bahillo O'Mahoney, validation and writing, original draft preparation; Francisco Castellano Torres, investigation; Giuseppe Rovere, resources; Luigi Meccariello, writing, review and editing; Giuseppe Rovere and Luigi Meccariello, visualization; Giuseppe Rovere: supervision and project administration. All authors have read and agreed to the published version of the manuscript.

Informed consent

Written informed consent was obtained from the patient for inclusion in this case report and for publication of anonymized clinical and imaging data.

Patient consent for publication

Written informed consent was obtained from a legally authorized representative(s) for anonymized patient information to be published in this article.

Availability of data and materials

All data relevant to this case report are included in the article and its supplementary materials. Additional anonymized data may be made available by the corresponding author upon reasonable request, subject to applicable privacy and confidentiality requirements.

Declaration of Generative AI and AI-assisted technologies in the writing process

The authors declare that no Generative AI or AI-assisted technologies were used in the writing process of this manuscript.

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Online supplementary material:

Surgical appendix.

Rehabilitation appendix.

Custom-made implant planning appendix.

Acquisition settings (add without modifying the original ROI).