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3D-printed customized semi-restrictive elbow prosthesis for severe pseudoarthritis following comminuted fractures of the distal humerus: A case report and review

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Abstract. Distal humeral fractures are infrequent occurrences in clinical practice and reports of nonunion following comminuted fractures of the distal humerus, particularly those resulting in pseudarthrosis formation and severe pseudoarthritis, are exceedingly rare. This report describes the utilization of a 3D-printed customized semi-restrictive elbow prosthesis as a treatment modality for severe pseudoarthritis following comminuted fractures of the distal humerus. A 51-year-old male presented to the orthopedic outpatient department with a history of left elbow joint pain and restricted movement persisting for >2 decades. Diagnostic imaging, including radiography and computed tomography (CT), revealed traumatic arthritis of the distal left humerus with pseudarthrosis formation. The treatment protocol involved comprehensive preoperative assessments, including electrocardiogram, chest CT, complete blood count, liver and kidney function tests, and coagulation profile. Following the completion of these evaluations, a total elbow joint replacement was performed using a 3D-printed, customized semi-restrictive elbow prosthesis, accompanied by muscle and ligament repair, within the orthopedics department. Postoperatively, the patient's left elbow wound exhibited satisfactory healing, with significant alleviation of pain and marked improvement in joint mobility. The patient was discharged on the 7th day after the operation and is required to have a follow-up checkup every month. This case report underscores the efficacy of employing a 3D-printed, customized semi-restrictive elbow prosthesis in the management of severe arthritis secondary to comminuted fractures of the distal humerus, particularly in cases with pseudarthrosis formation. The approach facilitates precise joint reconstruction and promotes optimal growth of prosthesis, bone, ligaments and tendons, demonstrating favorable clinical outcomes in postoperative functional recovery.

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Introduction

Distal humeral fractures in adults are relatively uncommon, with an incidence ranging from 5.7 to 8.3 cases per 100,000 individuals annually. Comminuted distal humeral fractures are even more infrequent and are typically the result of high-energy trauma, such as motor vehicle collisions or falls from significant heights. The management of these fractures presents considerable challenges due to substantial bone loss and frequent concomitant injuries to muscles and ligaments (1). The standard treatment approach for comminuted distal humeral fractures involves open reduction internal fixation. Nevertheless, the extensive comminution and bone loss associated with such trauma significantly increase the risk of nonunion. In certain instances, patients may experience complications such as internal fixation failure, secondary pseudarthrosis formation and persistent pain following nonunion. These cases are exceedingly rare and there is a paucity of literature documenting them (2).

The irregular bone defects and injuries to muscles and ligaments resulting from the non-union of distal humerus fractures and the subsequent formation of secondary pseudarthrosis present significant challenges for orthopedic surgeons. In recent years, advancements in anatomical and biomechanical knowledge, coupled with the development of more biocompatible and durable materials, have led to significant progress in elbow joint replacement surgery. Nevertheless, traditional elbow joint replacement procedures face certain limitations due to individual variations stemming from congenital or acquired factors. To enhance prosthesis design, a more comprehensive understanding of anatomy and biomechanics is required (3). With the rapid advancement of digital technology, 3D printing for custom prostheses offers a solution to individual anatomical differences, allowing for prostheses that closely mimic the patient's anatomical structure and enable personalized customization. This approach has emerged as a promising strategy for addressing complex bone defects and associated muscle and ligament injuries (4).

This case report details the clinical presentation and management of a 51-year-old male patient who sustained a comminuted fracture of the distal humerus as a result of a motor vehicle collision two decades prior. The patient initially underwent open reduction internal fixation; however, the postoperative course was complicated by nonunion, hardware failure and the subsequent formation of secondary pseudarthrosis, leading to chronic pain. The patient was subsequently treated with a semi-restrictive, 3D-printed custom elbow joint prosthesis. Given the complexity and rarity of this injury, the report underscores the critical role and necessity of employing semi-restrictive 3D-printed custom prostheses in the management of traumatic pseudarthrosis following comminuted distal humerus fractures. This report provides a comprehensive account of the patient's diagnostic and therapeutic journey.

Case report

The patient was a 51-year-old male patient who had suffered a left distal humerus fracture in a motor vehicle collision 20 years prior, which was immediately managed by an open reduction internal fixation procedure at a local hospital. Postoperatively, the wound exhibited satisfactory healing; however, 1 year post-surgery, it was observed that the fracture had not healed adequately. At that juncture, a second autologous iliac bone grafting surgery was recommended to the patient, who declined the procedure and opted for continued observation at home. At 2 years subsequent to the initial surgery, the internal fixation device broke. Due to financial constraints, the patient elected to have the internal fixation removed and received only plaster fixation without any additional interventions. Annual radiographic examinations revealed the gradual formation of a pseudoarthrosis in the left elbow, accompanied by pain and restricted mobility. At 6 months prior, the patient presented at Chengdu Qingbaijiang District People's Hospital (Chengdu, China) seeking surgical intervention to enhance his quality of life. We proposed a treatment plan using 3D-printed customized semi-restrictive elbow prosthesis. The patient and his family expressed the need for careful consideration of the proposed intervention at home, and no further actions were taken. The patient was admitted to Chengdu Qingbaijiang District People's Hospital for treatment in December 2024. Following thorough deliberation by the patient and his family and the preparation of customized 3D-printed products, the surgical procedure was conducted in January 2025. The present study is a single-center case report focusing on the use of 3D-printed personalized elbow joint prosthesis technology, which should be classified as a clinical individualized customized treatment plan rather than 'experimental treatment' in the strictest sense. This study was approved by the Ethics Committee of our Hospital, approval number: 202451 and conducted in accordance with the Declaration of Helsinki.

Upon admission, digital radiography and computed tomography (CT) were employed to evaluate the imaging condition of the left elbow (Fig. 1A-D). The imaging results indicated the absence of a normal joint structure in the left elbow, with the formation of a pseudoarthrosis accompanied by multiple osteophytes. The preoperative physical examination revealed that the elbow joint could not be extended (-25˚), and the range of flexion was limited (25-90˚; Fig. 1E and F). The results of the preoperative laboratory tests fell within normal parameters, and both the electrocardiogram and chest computed tomography (CT) scan revealed no abnormalities, indicating that the patient was generally deemed suitable for the surgical procedure. Detailed indicators are presented in Table SI.

Following a comprehensive evaluation of the patient's medical history, physical examination and supplementary diagnostic tests, the orthopedic team arrived at the following diagnoses: i) An old fracture of the distal humerus; and ii) traumatic pseudarthrosis of the left elbow joint. After an in-depth departmental discussion, it was advised to undertake a semi-restrictive, custom 3D prosthesis-assisted surgical procedure on the left elbow joint. This procedure involves replacing the distal humeral joint component and reconstructing the ligaments and tendons of the elbow joint (5). The semi-restrictive prosthesis features a relatively loose hinge, permitting 5-7˚ of rotational movement and 5-10˚ of varus/valgus movement between the humerus and ulna. This design aims to reduce stress at the implant-bone-cement interface, thereby decreasing the risk of periprosthetic fractures and prosthesis loosening. Utilizing 3D-printed models to simulate the surgical procedure enables the formulation of precise and effective strategies tailored to the specific circumstances of joint reconstruction in individual patients. In designing custom 3D-printed prostheses, careful consideration was given to the intricate structure of the elbow joint and various critical factors, such as prosthesis size, compatibility, the configuration of ligament and tendon suture holes and the integration of the prosthesis with the bone contact surface. These considerations aim to facilitate the successful integration of bone, tendons and ligaments (5,6).

The 3D customized prosthesis is fabricated from Ti-6Al-4V alloy in conjunction with hydroxyapatite. This combination exhibits superior osseointegration and biocompatibility. The hydroxyapatite component facilitates the attachment and integration of tendons and ligaments due to its bone-like trabecular structure (7). The prosthesis was designed using Mimics software (version 20.0; Materialise) and manufactured via 3D printing technology by Beijing Chunli Co., Ltd. Prior to the fabrication of the custom prosthesis, it was necessary to acquire detailed data of the patient's elbow joint, develop a precise prosthesis model, and subsequently execute the printing and testing procedures to validate the design. The entire process, from data acquisition to finalization, typically spans a duration of two weeks (8).

The surgical procedure of this patient was as follows (Fig. 2): Following the administration of general anesthesia, the patient was placed in the supine position. Standard aseptic procedures were employed to disinfect and drape the left elbow, designating it as the surgical field. An air pressure tourniquet was applied to the left upper limb to occlude the blood supply to the distal region. A longitudinal incision, ~15 cm in length, was performed on the posterior aspect of the left elbow. The tissues were meticulously dissected in layers to reveal the distal humerus and the olecranon of the ulna. Intraoperatively, a pseudarthrosis was identified at the distal humerus and the native elbow joint was observed to be contracted and ankylosed, exhibiting no mobility. Additionally, the ulnar nerve was noted to be displaced and compressed. Following isolation and safeguarding of the ulnar nerve, the triceps brachii muscle insertion was detached from the posterior aspect of the olecranon process

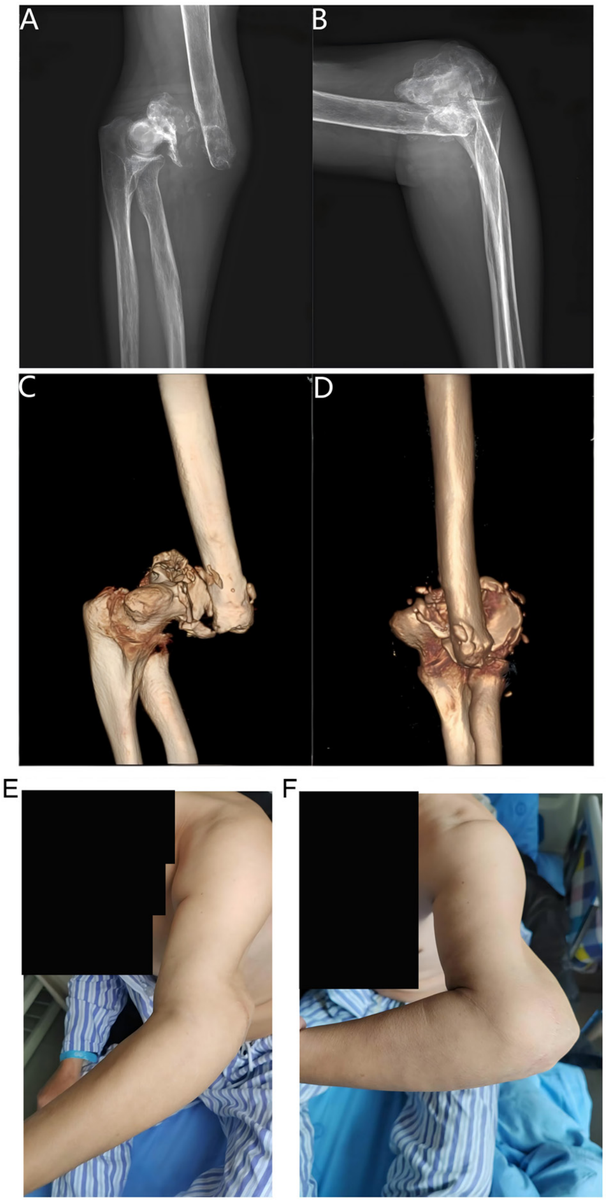

Figure 1. (A) Preoperative X-ray oblique view image; (B) preoperative X-ray lateral view image; (C) preoperative CT 3D oblique view image; (D) preoperative CT 3D anteroposterior view image. (E) Preoperative elbow extension was limited to -25°; (F) Preoperative active elbow flexion range was 25-90°.

of the ulna, rotating it proximally. Subsequently, the contractured elbow joint was released, the pseudarthrosis was excised along with the surrounding hyperplastic tissues and the insertion points of the medial and lateral collateral ligaments were detached from the superior aspects of the medial and lateral condyles of the humerus. The distal humerus and proximal ulna were reshaped and reconditioned, and then the trial mold was inserted into the medullary cavities of both the distal humerus and proximal ulna, ensuring that the trial mold exhibits proper adherence. Bone cement was applied to the coatings on both the humeral and ulnar aspects of the prosthesis, which was then inserted into the medullary cavity and adjusted to the appropriate angle. The prosthesis was secured in an extended position, ensuring satisfactory attachment. After the bone cement had cooled, it was verified that the elbow joint's flexion, extension and rotation movements were in the ideal state. C-arm fluoroscopy confirmed the effective positioning of the prosthesis. The ulnar nerve was repositioned anteriorly, sutured and anchored to the subcutaneous tissue. The detached collateral ligament was sutured and secured within the designated hole of the prosthesis. A hole was drilled in the olecranon of the ulna, allowing for the suturing and fixation of the triceps brachii tendon to the olecranon. Subsequent passive movement of the elbow joint yielded satisfactory results. The tourniquet was released to achieve thorough hemostasis, followed by layered suturing and the application of appropriate pressure bandaging with sterile dressings. The surgical procedure was thereby concluded.

Table I. Comparison of exercise and functional status of patients before operation and 6 months after operation.

Parameter	Before operation	6 months after operation
Flexion, °	83	125
Extension, °	-25	0
Pronation, °	42	82
Supination, °	40	78
VAS score	7	0
MEP score	25	97

VAS, Visual Analogue Scale; MEPS, Mayo Elbow Performance.

Following the surgical procedure, the patient's vital signs remained stable and the wound exhibited smooth healing without any complications. Functional exercises and weight-bearing activities were initiated on the second postoperative day. During the initial 0 to 6 weeks post-surgery, it is advised that the patient utilizes a forearm sling to immobilize the elbow joint. During this period, passive movements including flexion, extension, pronation and supination should be encouraged to the greatest extent possible. From weeks 7 to 12 post-surgery, resistance training and active movements in flexion, extension, pronation and supination should commence. By 12 weeks, the patient may resume full activities of the elbow joint, thereby restoring normal daily functions.

Regular follow-ups were conducted with the patient postoperatively, observing notable improvements in elbow joint mobility and function at 1 week, 1 month, 3 months and 6 months. At the 6-month postoperative mark, the patient's flexion, extension, pronation, supination, Visual Analogue Scale (VAS) score and Mayo Elbow Performance Score (MEPS) showed significant enhancements compared to preoperative levels (Table I) (6). Images of the patient's flexion and extension movements at 6 months post-surgery are presented in Fig. 3.

Osseointegration denotes the development of functional, active bone tissue at the interface between the bone and the prosthesis, occurring without the interposition of soft tissues (9). Radiographic evaluation conducted on the first postoperative day indicated that the prosthesis was securely fixed, with no evidence of loosening (Fig. 4A and B). At 6 months following the procedure, radiographs revealed the formation of active bone tissue at the bone-prosthesis interface (Fig. 4C and D).

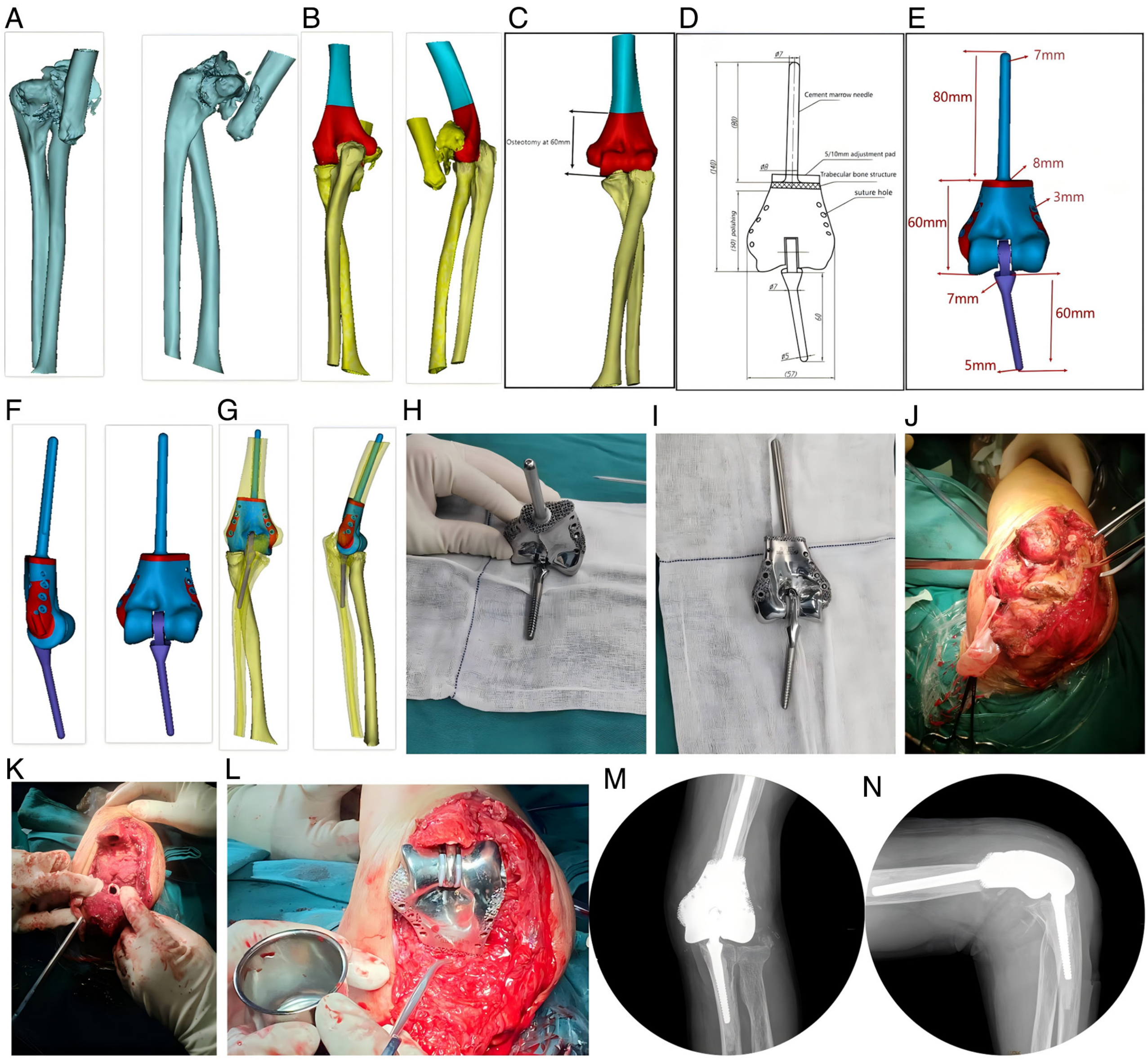

Figure 2. The design process and surgical procedure for the 3D-printed prosthesis. Panels (A-G) illustrate the customization of the prosthesis, tailored to the patient's specific size and modulus requirements; (A) Preoperative 3D CT images; (B) 3D reconstruction images by simulation software; (C) the calculated osteotomy length by simulation software; (D) 3D printing prosthesis design plan by simulation software; (E) detailed 3D prosthesis design with specific specifications by simulation software; (F) lateral and anteroposterior images of the 3D printing prosthesis designed by simulation software; (G) post-installation morphology images of the 3D printed prosthesis designed by simulation software. Panels (H and I) depict the physical manifestation of the 3D-printed custom prosthesis. Panel (J) shows that during the operation, the elbow joint's shape was obscured, resulting in the formation of a pseudo-joint. Panels (K and L) present the morphology following osteotomy during the operation and the morphology post-implantation of the prosthesis. Panels (M and N) demonstrate the optimal positioning of the 3D-printed custom prosthesis as observed through intraoperative fluoroscopy.

Discussion

This case report adheres rigorously to the 2013 version of the Consensus-based Clinical Case Reporting guidelines, providing a detailed account of a rare instance involving a comminuted fracture of the distal humerus, non-union of the fracture, failure of internal fixation and the formation of a pseudoarthrosis (10). Such occurrences are exceedingly uncommon in clinical practice, necessitating further investigation into the complex etiology, atypical bone defects and treatment strategies for elbow pseudoarthrosis. The present literature review revealed no prior case reports addressing elbow pseudoarthrosis or its treatment and reconstruction utilizing 3D customized printing technology. Consequently, this report represents the first documentation of such cases. Nonetheless, previous research has demonstrated the successful application of 3D printing technology for the repair of irregular bone defects. In addressing irregular bone defects at the proximal end of the humerus, Hu *et al* (3) successfully employed 3D printing technology to customize a proximal humerus prosthesis and reconstruct the injured rotator cuff, yielding favorable clinical outcomes. Huang *et al* (11) successfully applied a 3D-printed technology in combination with Ortho-Bridge system to treat femoral intertrochanteric fractures in elderly patients, achieving excellent clinical outcomes. The patient in question sustained a comminuted fracture of the distal humerus as a result of a

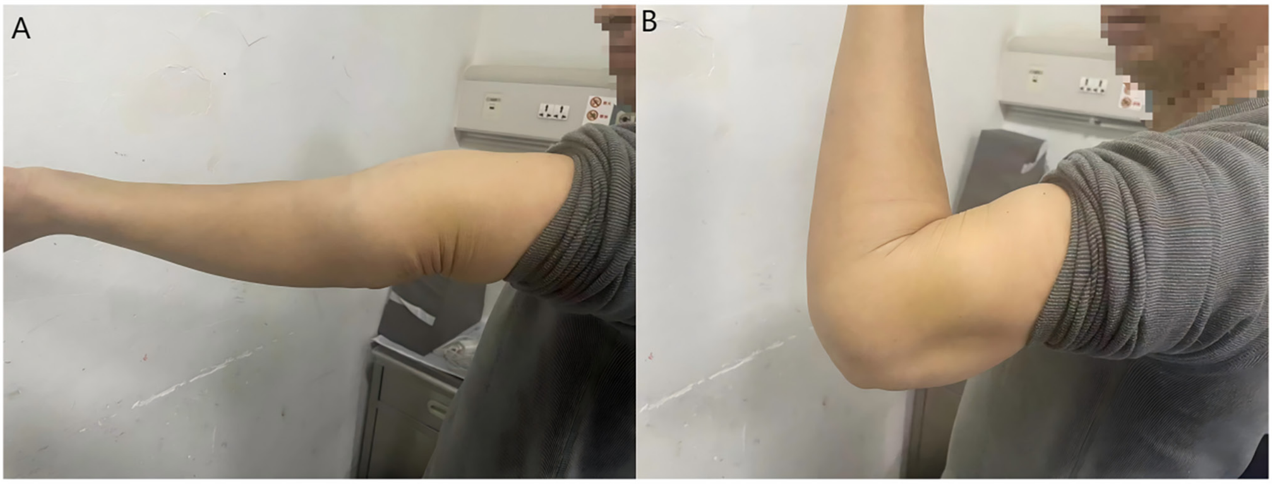

Figure 3. The patient's range of motion at 6 months after the operation. (A) Flexion (125˚) and (B) extension (0˚).

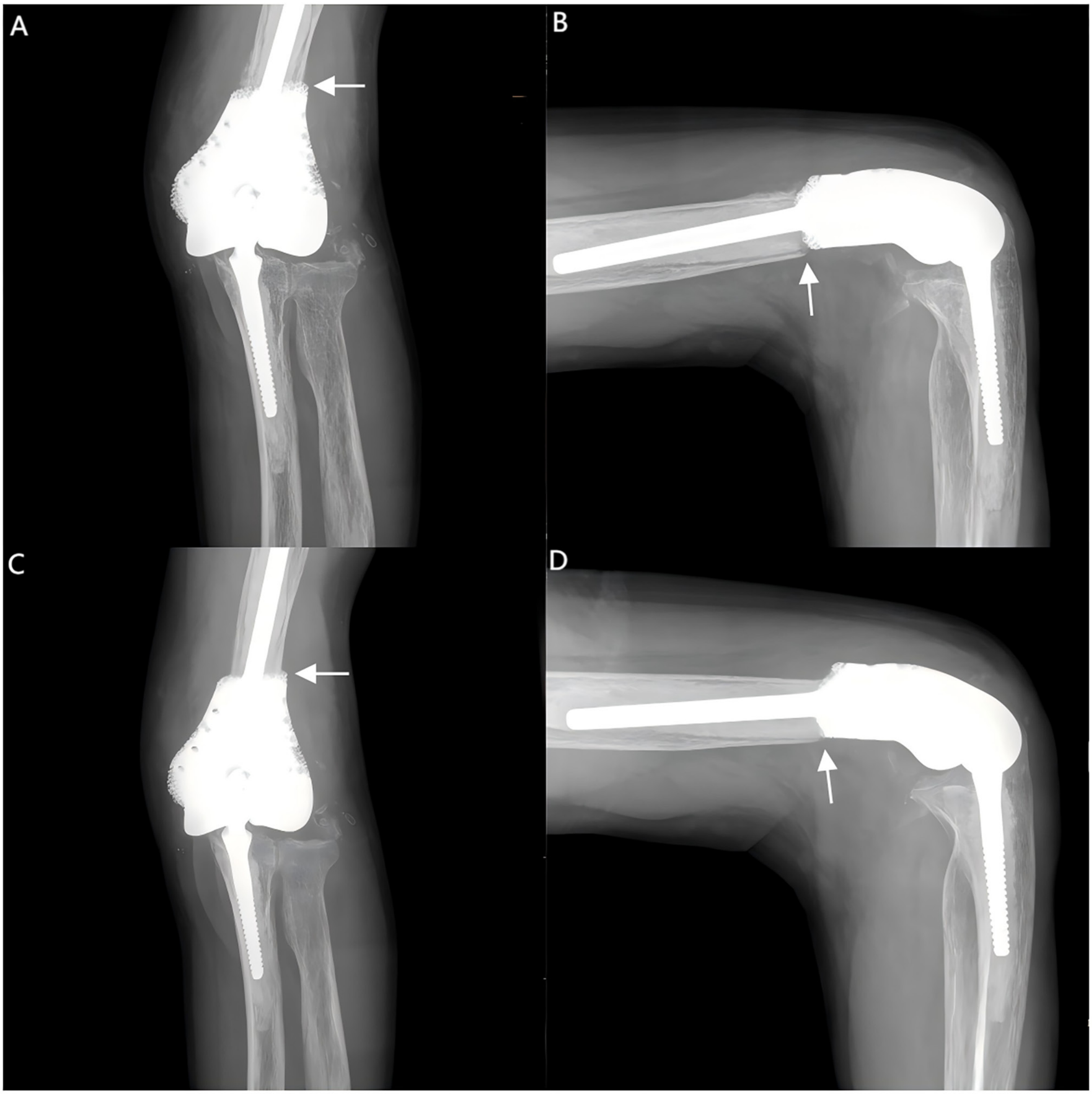

Figure 4. (A) Day 1 anteroposterior X-ray; (B) day 1 lateral X-ray; (C) 6-month anteroposterior X-ray; (D) 6-month lateral X-ray. The arrows indicate the integration status of the prosthesis with the bone interface.

motor vehicle accident two decades prior. The fracture subsequently failed to heal, leading to the failure of internal fixation and necessitating multiple surgical interventions. Following the removal of the internal fixation, a pseudarthrosis gradually developed in the patient's elbow, accompanied by significant bone defects and injuries to muscles and ligaments. At the time of presentation to our department, the patient endured chronic, severe pain in the elbow joint, which was intolerable and had resulted in a marked decline in his quality of life. Conservative treatments had proven ineffective. In cases of chronic advanced inflammatory joint disease, characterized by debilitating pain, stiffness or instability that adversely affect quality of life, surgical intervention is recommended (12).

In the management of this disease, several traditional approaches warrant consideration, including open reduction with iliac bone grafting and internal fixation, as well as various forms of elbow joint replacement: Restrictive, semi-restrictive and unconstrained. While these methods may provide short-term pain relief, the presence of severe irregular bone defects, along with significant muscle and ligament injuries, necessitates an evaluation of their long-term efficacy (13). Open reduction and internal fixation using iliac bone grafts are associated with considerable blood loss, extended operative duration, delayed recovery and an inability to fully reconstruct bone defects, resulting in a high likelihood of fracture non-union (2). Unconstrained elbow joint replacement demands optimal bone quality and intact ligaments; otherwise, it is susceptible to dislocation, with Ewald's capitello-condylar prosthesis exemplifying this category (14,15). Restrictive elbow joint prostheses, characterized by a stable hinge design, offer the greatest stability but are subject to high stress, making them prone to loosening; Dee's prosthesis is a notable example of this type (14,15). In recent years, the semi-rigid prosthesis has emerged as the most widely utilized type. This prosthesis features a relatively loose hinge, permitting 5-7 degrees of rotational movement and 5-10 degrees of varus/valgus movement between the humerus and the ulna. This design mitigates stress at the implant-bone-cement interface, thereby significantly reducing the incidence of periprosthetic fractures and prosthesis loosening. The Coonrad-Morrey prosthesis exemplifies this category (13). In a study conducted by Cil *et al* (16), 91 patients with non-healing distal humerus fractures were treated using the Coonrad-Morrey prosthesis, with an average follow-up period of 6.5 years. Patient satisfaction was reported at 78%, with a mean MEPS of 81. Complications included aseptic loosening (13%), infection (5%), periprosthetic fractures (4%), surgical wound dehiscence (13%), implant component fractures (5%) and radial-ulnar nerve injury. Notably, 25% of the prostheses required revision, with 19 cases attributed to mechanical failure and 4 cases to infection. Additionally, the rates of asymptomatic radiolysis and hinge wear were substantial, at 17 and 37% respectively, primarily due to inadequate bone ingrowth and high activity levels (11). Therefore, these options were not considered in the present study.

In the present case, a significant osseous defect was observed at the distal end of the humerus, accompanied by injuries to the surrounding musculature and ligaments. Traditional prosthetic solutions often fail to adequately address the dual requirements of bone integration and ligament reconstruction in such complex cases. According to the research conducted by Abar *et al* (17), 3D-printed customized structures not only facilitate bone integration but also preserve the joint surface and subchondral bone, thereby enhancing bone ingrowth and formation. Furthermore, Hu *et al* (3) demonstrated the successful application of 3D printing technology in fabricating an irregular proximal humeral prosthesis and reconstructing the damaged rotator cuff, resulting in favorable clinical outcomes. Consequently, given the advancements in current medical technology, the utilization of 3D printing technology may be recommended to design a fully compatible prosthesis. In contrast to conventional approaches, 3D-printed custom prostheses can achieve precise anatomical alignment by fitting well with the distal end of the humerus and the proximal end of the ulna. This alignment not only aids in preserving normal tissue structures and reducing both blood loss and surgical duration, but the hydroxyapatite-composed trabecular structure also facilitates bone and ligament ingrowth. This process promotes the repair and attachment of tendons and ligaments surrounding the elbow joint, thereby enhancing the joint's function and stability (18). A follow-up examination conducted 6 months post-surgery revealed active bone ingrowth at the prosthesis-bone interface, with no evidence of asymptomatic radiographic opacity. These findings suggest that the 3D-printed customized trabecular bone structure achieved superior bone integration.

Of note, this technology facilitates the creation of prostheses that closely replicate a patient's anatomical structure, thereby enabling personalized customization. It has emerged as a promising strategy for addressing complex bone defects and associated injuries to muscles and ligaments (3,4). However, it is important to acknowledge that the inherent complexity of the human body presents numerous challenges that require resolution (9). Consequently, 3D printing for custom prostheses is generally not recommended for applications involving original fractures, unless the fracture is so severely compromised that reconstruction is deemed impossible (19). Cost is a significant factor that should not be ignored. The literature included in the present review lacked specifications concerning cost. In this case, the price of a 3D customized prosthesis was more than double that of an ordinary prosthesis. Fortunately, the local basic medical insurance covered a portion of the cost.

This study is subject to certain limitations, most notably the relatively short follow-up period of only 6 months. Despite this, the patient's VAS score, MEPS and range of motion in the elbow joint demonstrated significant improvement and the bone-prosthesis interface exhibited successful osseointegration. These promising outcomes have prompted us to report and substantiate the potential advantages of this technique. The present study intended to conduct extended follow-up assessments to acquire a more comprehensive understanding of the prosthesis's long-term efficacy. It is important to acknowledge that the production of 3D-printed customized materials presents several challenges, including issues such as uneven shrinkage, material wastage, adhesive removal, microbial contamination and resolution limitations. Furthermore, the morphological characteristics and surface roughness of the implants can markedly influence cellular behaviors, such as proliferation, adhesion, differentiation and corrosion (18). Consequently, further research is necessary to enhance the quality and performance of these products.

Based on the findings of the present study, it can be concluded that 3D-printed customized materials offer several advantages in addressing irregular bone defects and traumatic pseudarthrosis. First, for irregular bone defects resulting from complex etiologies and medical histories, individualized implants can be fabricated to ensure an optimal fit between the prosthesis and the bone. Second, the prosthesis's rough and porous trabecular structure facilitates the ingrowth of bone, tendons and ligaments, thereby promoting osseointegration. Third, advancements in 3D printing technology now allow for the rapid production of customized implants tailored to the specific needs of each patient. Consequently, 3D printing technology addresses the limitations of traditional elbow joint replacement methods in managing complex elbow joint conditions, offering new hope for the treatment of such intricate diseases.

In conclusion, the utilization of a 3D-printed, custom-designed semi-restrictive elbow joint prosthesis presents a viable treatment option for addressing irregular and extensive bone defects resulting from the non-union of distal humeral comminuted fractures, particularly in instances of traumatic pseudoarthrosis.

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Availability of data and materials

The data generated in the present study may be requested from the corresponding author.

Authors' contributions

BZ was responsible for the case diagnosis and treatment, as well as writing and analysis of the discussion in the manuscript. XLZ contributed to the data analysis and collection. YXC analyzed patient data. ZBH provided treatment advice. PL collected CT scan data and analyzed the discussion. BZ was responsible for the study conception and revisions to the manuscript. All authors have read and approved the final manuscript. ZBH and PL confirm the authenticity of all the raw data.

Ethics approval and consent to participate

This study received approval from the Chengdu Qingbaijiang District People's Hospital Research Ethics Committee. The protocol and informed consent form were reviewed and approved on January 4th, 2025, with a subsequent simplified review conducted on January 10th, 2025. The study adheres to ethical standards as outlined by the committee. The patient provided written informed consent for participation.

Patient consent for publication

The patient provided written informed consent for publication of his data, including case information and images.

Competing interests

The authors declare that they have no competing interests.

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