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Patient-specific instrumentation technology enhances clinical outcomes in total elbow arthroplasty

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Abstract

Objective To evaluate and compare the outcomes of utilizing patient-specific instrumentation (PSI) technology, which incorporates personalized three-dimensional (3D) preoperative planning and customized 3D printing (3DP) osteotomy guides, against those achieved with traditional instruments in total elbow arthroplasty (TEA).

Methods A retrospective study was conducted to analyze the clinical data of 20 patients diagnosed with elbow arthritis who underwent TEA at the Center for Joint Surgery, The First Hospital Affiliated to Army Medical University, China, between January 2010 and July 2023. Patients were categorized into two groups according to the surgical techniques employed: 9 patients underwent personalized preoperative 3D planning and used customized 3DP osteotomy guides for TEA (3DP group); another 11 patients underwent TEA using traditional instruments and experience-based techniques (traditional group). The intraoperative fluoroscopy frequency, Mayo elbow performance score (MEPS), and Mayo elbow score before and after surgery in both groups were recorded. Additionally, in the 3DP group, changes in the imaging indicators such as the angle between the axis of humerus medullary cavity and the hinge axis of elbow (H-H angle), the angle between the axis of middle ulna medullary cavity and the hinge axis of elbow (MU-H angle), the angle between the axis of proximal ulna medullary cavity and the hinge axis of elbow (PU-H angle) were assessed before and after surgery.

Results No significant differences were observed in the baseline characteristics between the 3DP group and the traditional group ($P > 0.05$). We followed all patients for a period ranging from 12 to 36 months, with an average follow-up duration of 14.8 months. When comparing the two groups, the 3DP group required fewer intraoperative fluoroscopic view ($P < 0.01$). Postoperatively, the 3DP group showed notable improvements in the H-H angle, MU-H angle, and PU-H angle, all of which were significantly better than those in the traditional group ($P < 0.01$). Despite these advantages, the postoperative MEPS and Mayo elbow function scores did not differ significantly between the 3DP and traditional groups ($P > 0.05$).

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Conclusion Compared with traditional surgical methods, the use of PSI technology with preoperative 3D planning and customized 3DP osteotomy guides can significantly reduce the number of intraoperative fluoroscopies, which enhances both the efficiency and safety of TEA. PSI technology facilitates more accurate angle correction during elbow arthroplasty, ensuring precise osteotomies and effective correction of joint deformities.

Keywords Elbow arthritis, 3D-printed personalized guides, Three-dimensional reconstruction, Elbow arthroplasty

Introduction

Total elbow arthroplasty (TEA) is increasingly applied to patients with end-stage elbow lesions caused by various conditions, such as advanced rheumatoid arthritis (RA), traumatic arthritis, comminuted fractures of the distal humerus in the elderly, nonunion or malunion following distal humeral fractures, flail elbow, and elbow ankylosis. TEA can significantly improve upper limb function and enhance quality of life (QOL) [1–6]. Despite its benefits, the progress of TEA has trailed behind that of total hip arthroplasty (THA) and total knee arthroplasty (TKA) in several aspects. The evolution of implant designs, surgical instruments, and the integration of cutting-edge technologies in TEA has been considerably slower. Moreover, the increase in the number of TEA procedures performed annually is much less pronounced when compared with THA and TKA. Consequently, while TEA does offer substantial improvements, there have been no groundbreaking advancements in patient outcomes or satisfaction levels. Additionally, TEA continues to be associated with a range of complications, and revision surgeries remain especially complex and challenging. Pogliacomi et al. [7] evaluated 20 patients with nonunion of the distal humerus treated with TEA. Radiographic scoring was utilized to assess the position and signs of component loosening. Their findings revealed a complication rate of 30%, with the development of postoperative complications and radiolucent lines in stages II, III, and IV serving as predictive factors for a poor prognosis. Additionally, we observed in our clinical practice that the design of current prostheses can cause postoperative lateral displacement of the forearm, leading to a noticeable lateral prominence in the proximal forearm in some patients, which fails to correct elbow deformities through surgery, thereby affecting the outcomes of TEA.

Given the relative stagnation in revolutionary improvements in current prosthesis designs, achieving efficient and precise osteotomies, improving surgical efficiency, ensuring the rapid and accurate placement of the prosthesis during surgery, and avoiding complications such as fractures and suboptimal prosthesis positioning, while enhancing surgical safety, remain our primary goals. Although robotic-assisted and intelligent navigation technologies have made significant developments in the fields of THA and TKA, these advancements have not yet been widely integrated into TEA. With the rapid evolution of 3D printing technology, its applications in orthopedics and other fields are becoming increasingly widespread [8]. Studies have shown that preoperative personalized planning and the use of customized positioning/osteotomy guides can improve the accuracy of osteotomies, reduce the number of intraoperative fluoroscopies, and enhance prosthesis alignment, all of which contribute to better surgical outcomes [9]. The design and application of customized surgical guides in trauma and orthopedic surgery are also continuously evolving. In this study, we present the pioneering application of PSI technology using preoperative 3D planning and customized 3DP osteotomy guides in TEA, which can not only improve the accuracy of osteotomies and correct the angles of elbow arthroplasty, but also significantly shorten the learning curve for surgeons.

This study retrospectively reviewed the clinical data of 20 patients who underwent TEA at our Center between January 2010 and July 2023. We compared TEA procedures assisted by PSI technology with those performed using traditional methods. Our aim was to evaluate the benefits of preoperative 3D planning and customized 3DP osteotomy guides, with the hope of promoting broader adoption of this advanced technology.

Materials and methods

Inclusion and exclusion criteria

Inclusion Criteria: (1) Patients with late-stage RA, post-traumatic arthritis, or elderly patients with comminuted fractures of the distal humerus; (2) Patients exhibiting clinical symptoms, such as activity-related pain and limitations in daily activities; (3) Radiographic images showing joint space narrowing, significant joint deformity, or malalignment.

Exclusion Criteria: (1) Patients with acute or chronic elbow infections; (2) Patients with severe coagulation disorders or serious cardiovascular diseases that cannot tolerate anesthesia and surgery; (3) Patients with neuromuscular diseases; (4) Patients unable to cooperate with postoperative rehabilitation and follow-up.

General information

This study included a total of 20 patients, who were divided into the following two groups based on the surgical techniques used.

The 3DP group included 9 patients underwent surgery using preoperative 3D planning and customized 3DP osteotomy guides. This group consisted of 4 males and

5 females, with an average age of 54.6 ± 6.1 years (range: 40 to 67 years); the traditional group included 11 patients underwent surgery using traditional osteotomy methods. This group consisted of 5 males and 6 females, with an average age of 53.0 ± 6.5 years (range: 45 to 63 years). Surgeries in both groups were performed by the same senior surgeon.

This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement and guidelines for reporting, and has been approved by the hospital's Ethics Committee, with the approval number KY2024098.

Preoperative 3D planning and 3DP customized osteotomy guide design

For the 3DP group, 3D reconstruction was performed based on preoperative CT scans, and the entire process of implanting the prosthesis was simulated to design customized surgical osteotomy guides. Routine thin-slice CT scans of the elbow joint were completed using Siemens equipment (Germany), with a slice thickness of 1.0 mm. DICOM data were extracted and imported into 3D MIMICS software for the 3D reconstruction of the lesion and surrounding tissues. The reconstructed data were then imported into SIEMENS NX 3D design software. Under the guidance of the surgeon, engineering designers measured anatomical parameters from the 3D reconstructed bone model, including the humerus-elbow-wrist (HEW) angle, ulnar mid-axis angle, and ulnar proximal angle. Based on the bone morphology, the optimal position for prosthesis placement was determined, and the various surfaces for osteotomy were reverse-engineered. Customized osteotomy guides were designed by integrating the original bone morphology. The humeral guide was designed with a handle and Kirschner wire (K-wire) positioning holes to facilitate fixation during surgery. The ulnar guide had two versions. No. 1 featured a window for prosthesis insertion, while No. 2 included a tunnel for ulnar intramedullary positioning (Figs. 1, 2 and 3). The designed guide data were converted to STL format and imported into a 3D printer, using polylactic acid (PLA) high molecular material produced by Beijing Tiertime Technology Co., Ltd. (China) as the raw material. The preoperative 3D reconstruction and customized guide designs are shown in the figures below (Figs. 4).

Surgical techniques

The patient was positioned laterally on the healthy side, and a sterile tourniquet was applied during the procedure. An 8–10 cm incision was made along the medial aspect posterior to the elbow. The skin, subcutaneous tissues, deep and superficial fascia, and fat were sequentially incised. Care was taken to identify and mobilize the ulnar nerve along the medial border of the triceps muscle, creating a subcutaneous soft tissue bed on the medial side of the elbow. Next, the distal triceps muscle was carefully detached from the distal medial humerus to expose the posteromedial joint capsule. The ulnar collateral ligament was released from its insertion on the medial epicondyle of the humerus, and the triceps tendon insertion was detached from the olecranon of the ulna. Further dissection laterally exposed the radial margin of the olecranon and the triangular soft spot area, revealing the radial head. In cases of radiocapitellar impingement, the radial head was resected. The annular ligament was also released, and continued lateral dissection exposed the joint capsule, which was completely excised. The lateral collateral ligament was cut from its insertion on the lateral epicondyle of the humerus, allowing the ulna to be dislocated posteromedially and exposing the joint cavity. After thorough debridement, the customized osteotomy guide for the humeral side was placed, ensuring a snug fit with the distal humerus. The size of the humeral prosthesis was determined to be XS. Two 2.0 mm K-wires were used to securely fix the guide. Using an oscillating saw, four osteotomy planes were created according to

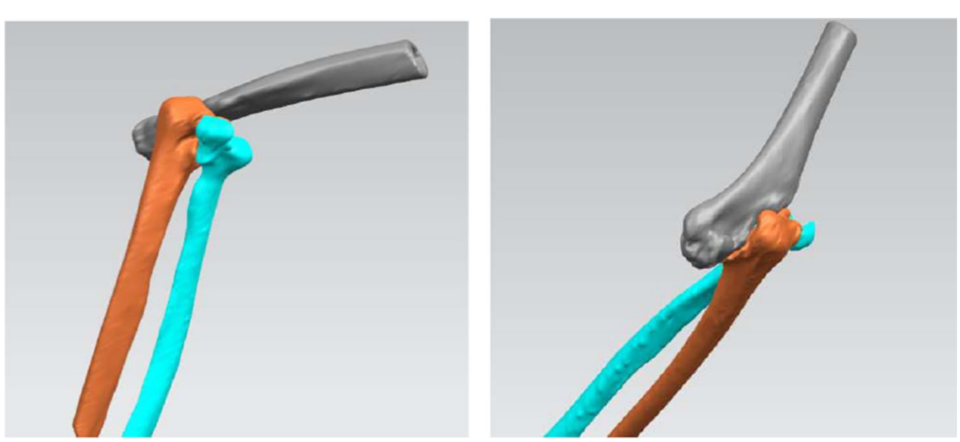

Fig. 1 Preoperative 3D reconstruction of the elbow joint

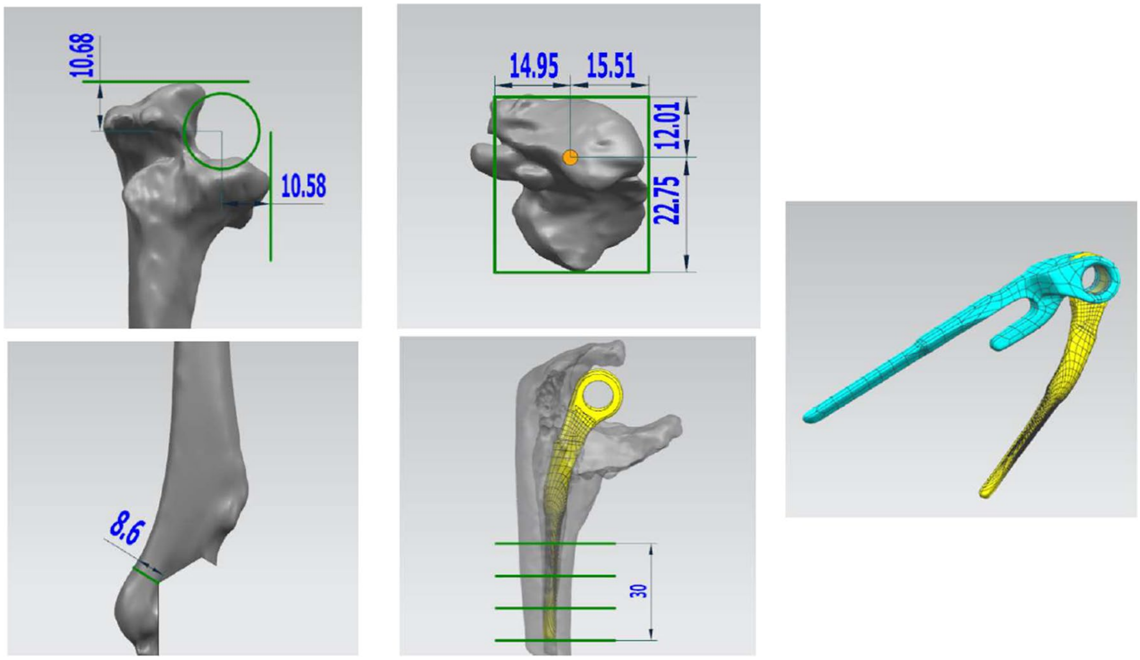

Fig. 2 Preoperative 3D reconstruction and measurement of the elbow joint

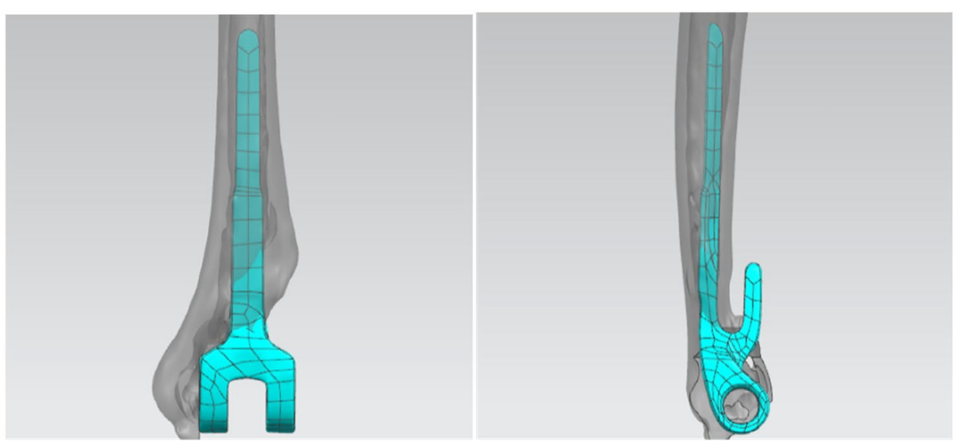

Fig. 3 Preoperative simulation of prosthesis implantation

the guide. The guide and osteotomies were removed, and the distal humerus was reamed using a humeral reamer. A humeral trial prosthesis was inserted, and its position and stability were confirmed to be satisfactory. For the ulnar side, the No. 1 ulnar osteotomy guide was placed on the olecranon fossa. After confirming its proper position, the size of the ulnar prosthesis was determined to be XS. Using the window area defined by guide No. 1, a high-speed burr was used to create the window for the ulnar prosthesis. Then, the No. 2 ulnar osteotomy guide was placed on the proximal ulna, guiding the tunnel for ulnar reaming. After completing the ulnar medullary canal opening, the ulnar reamer was used to ream the canal. The ulnar nerve was anteriorly transposed, and an ulnar trial prosthesis was inserted. The humeral trial prosthesis was also inserted, and the prosthesis was reduced. The position was confirmed to be satisfactory, and the elbow joint was tested for full range of motion (ROM) without impingement, ensuring no tension on the ulnar nerve. The trial prostheses were removed, and the surgical field was irrigated with a pulsatile lavage device until it was clean and dry. The bone surfaces were dried, and bone cement was injected into the medullary canals of the humerus and ulna. The humeral and ulnar prostheses were then inserted. The humeral prosthesis was kept in a semi-dislocated state while reducing the humeroulnar joint prosthesis, and the hinge lock core was secured. Finally, the humeral prosthesis was impacted into place, and the full ROM of the elbow joint was confirmed to be excellent. The ulnar nerve was maintained in an anterior

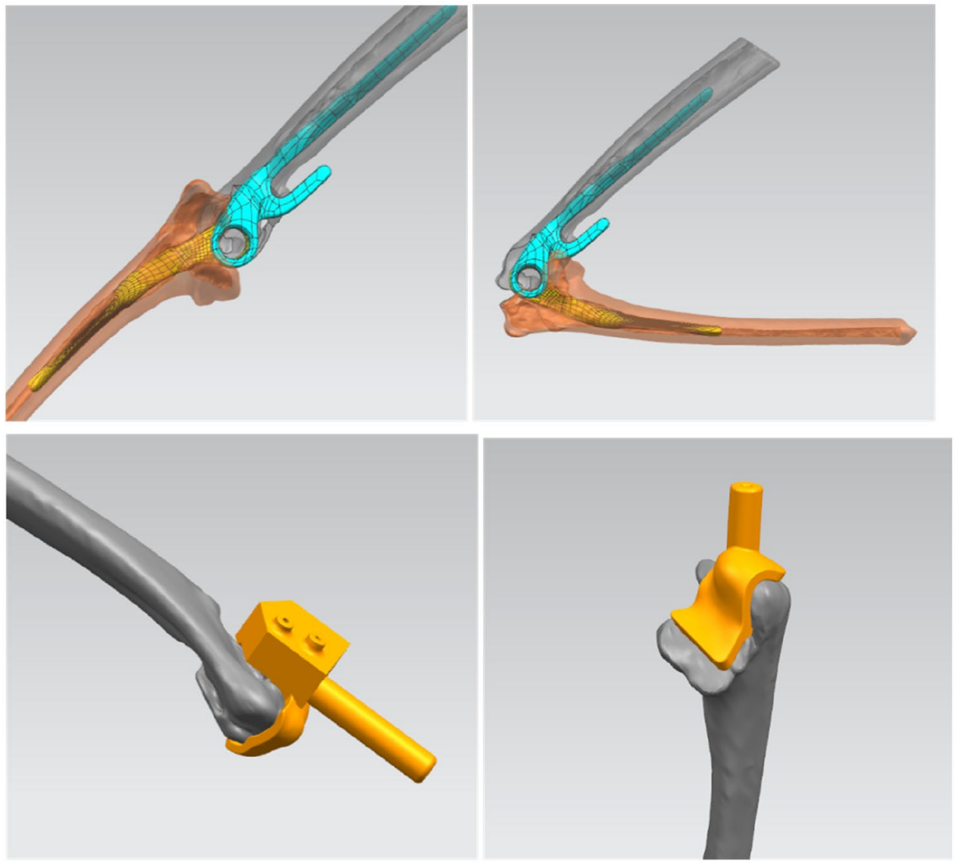

Fig. 4 Design of osteotomy guides based on the specific position of the prosthesis

position, and the triceps tendon was reattached to the dorsal aspect of the olecranon. The wound was meticulously sutured in layers (Figs. 5).

Postoperative management and observation indicators

Finger movement should begin immediately after anesthesia recovery, and patients should be guided to perform functional exercises. Drainage tube was removed 24 h postoperatively. Prophylactic intravenous vancomycin hydrochloride was administered for 48 h perioperatively to prevent infection. Under the guidance of a rehabilitation therapist, patients were instructed to perform daily elbow flexion-extension and forearm rotation exercises. Limb pneumatic compression massage pump was used to improve circulation. Regular outpatient follow-ups were scheduled at 6 weeks, 3 months, 6 months, and 1 year postoperatively. Patients were informed that the weight-bearing limit on the operated limb was 5 kg for life. Perioperative complications were recorded. The number of C-arm fluoroscopies and intraoperative blood loss were recorded. Anteroposterior and lateral radiographs of the elbow joint should be taken preoperatively and at 6 weeks and 1 year postoperatively, respectively measuring and recording the angle between the axis of humerus medullary cavity and the hinge axis of elbow (H-H angle), the angle between the axis of middle ulna medullary cavity and the hinge axis of elbow (MU-H angle), the angle between the axis of proximal ulna medullary cavity and the hinge axis of elbow (PU-H angle), as well as the Mayo elbow performance score (MEPS) and Mayo elbow score at the final follow-up. All radiological measurements were independently completed by two attending physicians; when there were discrepancies in the measurement results, a third associate chief physician made the final judgment.

Statistical analysis

Quantitative indicators were presented as mean ± standard error, and statistical analysis was performed using SPSS 22.0. Paired *t*-tests were conducted, with $P < 0.05$ considered statistically significant.

Results

Preoperative comparisons of the H-H angle, MU-H angle, and PU-H angle showed no statistically significant differences ($P > 0.05$). All 20 patients successfully completed the surgery. All patients were followed for 12 to 36 months (mean 14.8 months) postoperatively. In the

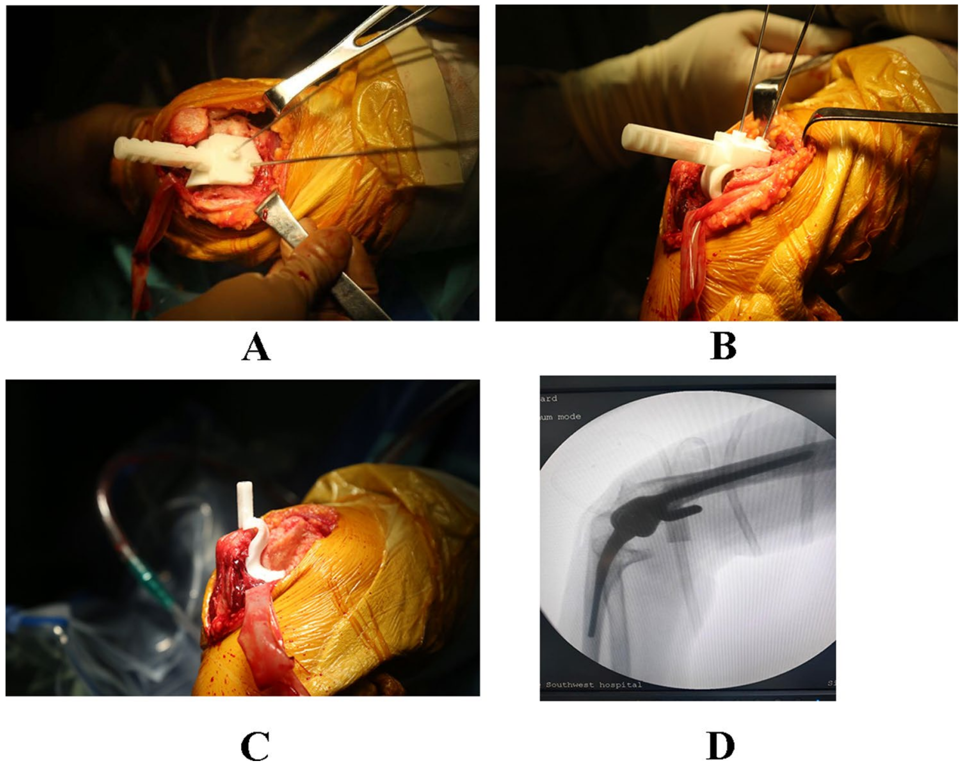

Fig. 5 Radiographic presentation of osteotomy assisted by 3DP guide and prosthetic positioning during total elbow arthroplasty. (**A**-**C**) The osteotomy process assisted by a 3DP guide; (**D**)The fluoroscopic position of the prosthesis during TEA

Table 1 Comparison of intraoperative fluoroscopy times, H-H angle, MU-H angle, and PU-H angle between the two groups ($\bar{x}$ ±s)

Groups	Case no.	Intraoperative fluoroscopy (times)	H-H angle (°)	MU-H angle (°)	PU-H angle (°)
3DP group	9	2.5±0.2	86.3±0. 2	89.5±0. 2	76.0±0. 3
Traditional group	11	5.8±0.2	91.0±0.7	94.0±0. 2	79.5±0.8
t value	-	7.35	6.600	14.959	4.127
P value	-	<0. 001	<0. 001	<0. 001	<0. 001

3DP: three-dimensional printing; H-H angle: the angle between the axis of humerus medullary cavity and the hinge axis of elbow; MU-H angle the angle between the axis of middle ulna medullary cavity and the hinge axis of elbow; PU-H angle: the angle between the axis of proximal ulna medullary cavity and the hinge axis of elbow

Table 2 Comparison of postoperative MEPS and Mayo elbow scores between the two groups ($n=20$)

Groups	MEPS	Mayo elbow score
3DP group	90. 6±0. 5	90. 7±0.6
Traditional group	88.3±1. 4	90. 2±0. 7
t value	1.239	0.783
P value	>0. 05	>0. 05

MEPS: Mayo Elbow Performance Score

traditional group, the number of intraoperative fluoroscopies was 4 to 8 times. In the 3DP group, the number of intraoperative fluoroscopies was 1 to 2 times. The differences between the two groups were statistically significant ($P<0.01$, Table 1). Compared with the traditional group, the postoperative imaging indicators of the H-H angle, MU-H angle, and PU-H angle in the 3DP group had statistical significance ($P<0.01$, Table 1). There was an improvement postoperatively and the differences were not statistically significant ($P>0.05$, Table 2). No complications such as loosening or displacement of the elbow prosthesis fixation or wound infection occurred in the 20 patients during the follow-up period (Figs. 6).

Discussion

TEA is a surgical option for patients with end-stage elbow arthritis [1–6]. Although initially used for advanced RA, the indications for TEA have since broadened to include osteoarthritis (OA), post-traumatic arthritis, irreparable distal humeral fractures, and poor outcomes from trauma. Less common indications include juvenile idiopathic arthritis, hemophilic arthropathy, and elbow reconstruction following the resection of primary or metastatic tumors, as well as congenital elbow deformities and elbow ankylosis. Non-surgical treatments, interposition arthroplasty, resection arthroplasty, or arthrodesis

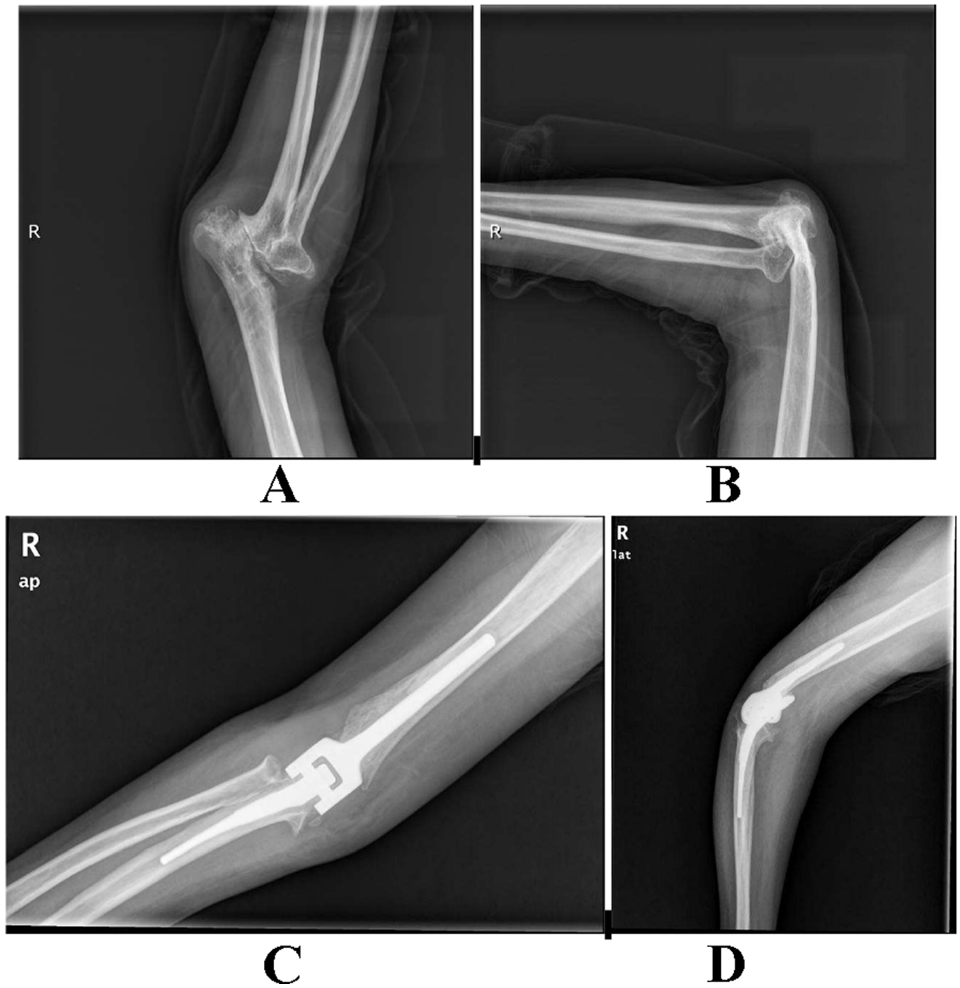

Fig. 6 Female patient, 55, deformity after surgery for right elbow fracture for 52 years, pain worsened over the past half year. **A**) Preoperative anteroposterior radiograph of the elbow joint; **B**) Preoperative lateral radiograph of the elbow joint; **C**) Anteroposterior and lateral radiographs of the elbow joint 1 year after TEA; **D**) Lateral radiograph of the elbow joint 1 year after TEA

are typically considered first in treating end-stage elbow arthritis.

Over time, it has been found that resection arthroplasty or arthrodesis can result in the loss of joint function and numerous complications. In 1947, Mellen et al. [10] performed the first partial elbow arthroplasty on patients suffering from severe pain and degenerative diseases, using implants made of simple acrylic materials to replace the distal humerus or proximal ulna. Prior to the 1970s, there were no prostheses available for elbow instability due to end-stage degeneration [11]. As a result, simple, customized, fully-constrained hinged ulnohumeral implants were developed. These cementless devices were designed to achieve biological fixation through intramedullary bone in-growth in both the humerus and ulna, with metal-on-metal articulations. By the late 1970s, Morrey introduced two major innovations: semi-constrained hinges and anterior flanges. Data from the Norwegian Arthroplasty Register show survival rates of 92%, 81%, 71%, and 61% at 5, 10, 15, and 20 years, respectively, for TEA between 1994 and 2016. Historically, complication rates for elbow arthroplasty have been reported to range from 14 to 80%, while recent literature on modern prostheses suggests complication rates between 20% and 40%. Common complications of TEA include aseptic loosening, instability, and infection, with periprosthetic fractures occurring intraoperatively and postoperatively. Postoperative triceps tendon rupture or insufficiency and ulnar nerve complications are also frequent [12].

The goal of TEA is to relieve elbow pain while maintaining a functional ROM. A recent study in the United States confirmed the predictive value of radiographic measurements for postoperative pain, complications, and revision after TEA [13, 14]. Radiographs is still a crucial tool for follow-up after TEA. In 2018, Pham et al. [13]. reported on their 7-year average follow-up of 46 patients who received Coonrad-Morrey elbow arthroplasty between 1997 and 2012; 29% of patients experienced implant stem wear, 26% had complications related to arthroplasty, and 7 required revisions. 3DP is a revolutionary technology that has been widely applied in orthopedics, including the construction of complex 3D anatomical models for better doctor-patient communication, preoperative planning, and surgical simulation, which contributes significantly to the training of young surgeons. It can also be used to make personalized osteotomy guides and custom-made prostheses based on patient's specific bone defects. This study allows surgical simulation by applying preoperative 3D reconstruction of elbow joint data and lesion model printed out for surgical design and planning, achieving personalized and precise treatment.

Compared with traditional radiographs, 3D models are more concrete, vivid, and accurate. We previously applied 3DP technology for the world's first radial head and carpal bone replacement, resulting in good functional recovery and avoiding complications associated with lunate necrosis resection, paving the way for personalized orthopedic treatment [15, 16]. Traditional TEA often relies heavily on the surgeon's clinical experience, requiring multiple osteotomies and fluoroscopic adjustments to achieve satisfactory results, leading to increased radiation exposure, intraoperative blood loss, and postoperative complications, thus reducing the efficacy of the surgery. Additionally, the angle of the replaced elbow joint in patients often differs from that of normal adults. By simulating the surgical process and determining the osteotomy position preoperatively, surgeons can achieve precise replacement. Tanji et al. [17] verified in cadavers that AR technology and 3D reconstruction could improve the accuracy of placing humeral and ulnar prostheses.

3DP surgical guides and models play a crucial role in achieving precise osteotomies during TEA. These customized preoperative tools are specifically designed to meet the unique needs of each patient, effectively bridging the gap between preoperative planning and actual surgical execution. By leveraging 3D technology for precise osteotomies, TEA can achieve higher precision, improved surgical efficiency, and reduced fluoroscopy time. Compared with knee and hip arthroplasty, elbow arthroplasty is more complex and demands higher precision. PSI technology has greater technical challenges and higher costs. Compared with the hip or knee joints, the ulnar component of the elbow prosthesis is anatomically designed, which is similar to the proximal ulna's anatomical shape. The medullary cavity is not a standard cylindrical tunnel but rather a curved path slightly biased towards the radial side. Therefore, the entry point depth determined by the ulnar guide is limited. If there is a long segment of the proximal ulna's medullary cavity that is completely sealed off, it might be impossible to fully enter the medullary cavity guided solely by the osteotomy guide. In such cases, a safer approach would be to extend the incision and fully expose the proximal ulna to locate the medullary cavity. Similarly, for ankylosed elbows with bony fusion, there is no usable surface on the ulnar side for the guide. Our approach is to make an oblique cut at an appropriate position between the humerus and ulna. The sigmoid notch of the ulna would be an artificially created oblique plane, and the ulnar guide can be designed accordingly.

Postoperatively, the HEW angle and intramedullary offset in TEA patients are typically less than those in a normal elbow, while the H-H angle, MU-H angle, and PU-H angle are greater. In Chinese patients, the postoperative elbow joint exhibits less valgus and lateral displacement of the forearm compared with a normal elbow. Preoperative planning using 3DP technology allows for the simulation of prosthesis implantation, making osteotomies and prosthesis placement more accurate and enabling better correction of the elbow angles, thereby reducing postoperative valgus. Furthermore, 3DP preoperative planning and customized osteotomy guides significantly shorten the learning curve for surgeons. They eliminate the need for repeated intraoperative fluoroscopies, reduce intraoperative trauma and blood loss, and mark a transition from traditional empirical medicine to precision medicine. This approach not only enhances surgical outcomes but also improves patient safety and satisfaction.

Our study found that using preoperative 3D reconstruction, along with 3DP surgical guides and models for TEA, can significantly reduce the need for intraoperative fluoroscopy and improve the precision of osteotomies. This approach makes preoperative planning more intuitive, enhancing both safety and efficiency during surgery. As a result, we were able to achieve more personalized and precise treatments for our patients. However, it's important to note that our study still has some limitations. For instance, we only had a relatively small number of cases, which limits the generalizability of our findings. Additionally, we lacked long-term follow-up data, so we couldn't fully assess the long-term outcomes of using 3DP technology in TEA. We believe that future research should focus on conducting longer-term studies with larger patient groups, which will help us better understand the sustained benefits of 3DP in TEA and address any potential long-term complications.

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Author contributions
CGZ analyzed and interpreted the patient data, and wrote the manuscript draft. HQH performed the surgeries and collected the data. SD analyzed and interpreted the patient data. XC collected the data and revised the manuscript. GXC designed and supervised the study, and revised the manuscript. HC designed the study, performed the surgeries and revised the manuscript. All authors read and approved the final manuscript.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study has been approved by the Ethics Committee of the First Affiliated Hospital of Army Medical University (No. KY2024098). Informed consent was obtained from all participants.

Consent for publication
Consent is waived by the Ethics committee of the First Affiliated Hospital of Army Medical University (No. KY2024098).

Competing interests
The authors declare no competing interests.

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