

3D-printed endosteal anatomical support system versus PHILOS plate fixation for severely displaced proximal humeral fractures: protocol for a multicenter randomized controlled trial

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Keywords: proximal humeral fracture, endosteal anatomical support, 3D printing, locking plate, randomized controlled trial, Constant-Murley score, study protocol

Posted Date: September 30th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-11083769/v1>

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Additional Declarations: No competing interests reported.

Abstract

Background

Restoration of the medial calcar is crucial for stable fixation of severely displaced proximal humeral fractures. A patient-specific 3D-printed endosteal anatomical support (EAS) system was developed to provide direct intramedullary medial support while preserving the native shoulder. This study aims to evaluate the superiority of the EAS system versus standard angular stable plate (PHILOS) in the treatment of severely displaced proximal humeral fractures through a prospective randomized controlled trial.

Methods

This is a two-center, parallel-group, assessor-blinded randomized controlled trial in adults aged 45 to 89 years with proximal humeral fractures classified as OTA/AO type B or C and displacement greater than 1 cm or a rotation angle greater than 45°. The registered target sample is 98 participants, with 49 assigned to each group. Participants are allocated 1:1 to the EAS system or locking plate fixation by block randomization with concealed allocation. Surgeons and participants cannot be blinded because the implants differ. Functional outcome assessors are blinded. The registered primary outcome is shoulder function at 24 months after surgery, which is assessed with the Constant-Murley score in this protocol. Registered secondary outcomes include shoulder function, assessed using DASH scores at 3, 6, 12, and 24 months and Constant-Murley scores at 3, 6, and 12 months, as well as fracture healing, loss of reduction, complications, and adverse events. Recruitment was conducted from 14 April 2020 to 13 February 2025 and is now complete, with follow-up scheduled to continue through 28 February 2027.

Discussion

The trial evaluates whether the patient-specific 3D-printed EAS system can improve function and radiographic outcomes while preserving the native humeral head. Key methodological challenges include the inability to blind participants and surgeons, inter-rater variability of the Constant-Murley score, treatment heterogeneity from adjunctive procedures, and the retrospective timing of trial registration. Standardized rehabilitation and blinded outcome assessment are used to reduce bias.

Trial registration:

Chinese Clinical Trial Registry, ChiCTR2000038167.

Background

Proximal humeral fractures are common injuries in older adults and occur after high-energy trauma in younger patients [1, 2]. Stable fixation can be difficult when bone quality is poor, or fracture comminution is substantial [3, 4]. The medial calcar is an important biomechanical structure. Loss of medial support is associated with varus collapse, screw penetration, and fixation failure [5–7].

The optimal treatment of complex displaced fractures remains debated [8–10]. In patients selected for joint-preserving reconstruction, open reduction and internal fixation (ORIF) with an angular-stable proximal humeral plate (PHILOS, Synthes, Switzerland) is widely used. However, loss of reduction, screw penetration, and avascular necrosis remain important complications [4, 11]. Strategies to augment the medial column include calcar screws [7], structural fibular allograft [12–14], autologous iliac crest bone grafting [15, 16], bone substitutes or cement [16, 17], intramedullary cages [18], and supplemental medial plating [19, 20]. These techniques may add donor-site morbidity, implant-related risk, or procedural complexity, and their performance in osteoporotic bone can be variable [12, 13, 16].

To address these limitations, our group developed a three-dimensional (3D)-printed endosteal anatomical support (EAS) system (XIAN WEDO and Tianjin Walkman) [21–23]. The construct combines a patient-specific titanium alloy (Ti-6Al-4V) endosteal prosthesis, a low-profile lateral locking plate, and dedicated targeting instrumentation. Preclinical biomechanical work demonstrated increased construct stability compared with conventional plate fixation [22, 23]. The present randomized trial was designed to determine whether the EAS system improves functional and radiographic outcomes compared with locking-plate fixation while maintaining an acceptable safety profile. We hypothesize that direct endosteal medial support will improve shoulder function and reduce loss of reduction without increasing adverse events.

Methods/Design

Aim, design, and setting

This investigator-initiated study is a two-center, parallel-group randomized controlled trial conducted at the First Medical Center and Fourth Medical Center of Chinese PLA General Hospital in Beijing, China. The registered target sample is 98 participants, with 49 assigned to each treatment group. The General Hospital of the Chinese People's Liberation Army is listed as the primary sponsor. The study compares ORIF using a 3D-printed EAS system with ORIF using a PHILOS locking plate.

The registered study framework and target allocation are summarized in Fig. 1. The figure therefore shows the registered sample size and planned allocation only.

Trial registration and status

Ethics approval was obtained on 5 March 2020. Recruitment started on 14 April 2020 and ended on 13 February 2025. The registry currently lists recruitment as completed. The registered study period extends to 28 February 2027, allowing completion of the 24-month follow-up for the last recruited

participants. The trial was registered in the Chinese Clinical Trial Registry as ChiCTR2000038167 on 11 September 2020 and is therefore retrospectively registered. At the time of preparation of this manuscript, recruitment is complete, and follow-up is ongoing.

Participants

Potentially eligible patients were screened at the two participating centers. Fracture classification and eligibility were confirmed by senior orthopaedic surgeons before written informed consent and randomization.

Inclusion criteria

1. Age 45–89 years.
2. Proximal humeral fracture classified as OTA/AO type B or type C [24].
3. Fracture displacement greater than 1 cm or a rotation angle greater than 45°.

Exclusion criteria

1. History of shoulder joint trauma, shoulder surgery, or bone nonunion.
2. Severe osteoarthritis, rheumatoid arthritis, pathological fracture, or open fracture.
3. Systemic disease that precludes anesthesia or surgery, including severe hemorrhagic disease, serious cardiac disease, severe respiratory disease, or other major medical illness.
4. Coagulation dysfunction.
5. Inability to accept intraoperative radiation exposure.
6. Inability to tolerate the required operative position.
7. Known allergy to implant materials.
8. Local or systemic active infection.
9. Mental illness, drug abuse, or alcoholism.
10. Pregnancy, lactation, or planned pregnancy during the clinical study period.
11. Inability to understand the study requirements or to cooperate with study procedures.
12. Participation in another clinical study of drugs, biologics, or medical devices within the preceding 3 months.

13. Other disease or circumstance that limits participation or follow-up and could compromise the scientific integrity of the study.
14. Inability or unwillingness to cooperate with treatment or postoperative rehabilitation.

Interventions

Intervention group: EAS system

Participants assigned to the experimental group undergo ORIF using a patient-specific 3D-printed EAS system. The EAS prosthesis is manufactured from medical-grade Ti-6Al-4V using selective laser melting. Implant planning is based on preoperative CT imaging, with a mirrored model of the contralateral humerus used to guide patient-specific endosteal geometry. Through a deltoid-splitting approach, the prosthesis is introduced through the lateral fracture window, positioned adjacent to the medial calcar, and secured using the dedicated targeting system and locking components. Tuberosity reduction and rotator-cuff repair are completed using the lateral plate and sutures. The operative objective is to restore alignment and provide direct medial endosteal support while permitting postoperative rehabilitation [21–23]. The principal components and implantation concept are shown in Fig. 2.

Control group: locking-plate fixation

Patients assigned to the control group undergo ORIF using an angular-stable PHILOS locking plate. Plate position, calcar screw placement, tuberosity repair, and screw length are controlled fluoroscopically. Bone graft or a bone substitute may be used when judged necessary by the operating surgeon and is recorded as an adjunctive procedure. This pragmatic allowance reflects standard fixation practice but introduces potential treatment heterogeneity that will be considered when interpreting the results.

Perioperative standardization and rehabilitation

Participating surgeons and physiotherapists completed standardized training before study participation. Preoperative preparation, fracture reduction principles, wound closure, and postoperative rehabilitation are standardized as far as feasible across groups. A sling is used after surgery, anti-edema exercises begin immediately, and supported shoulder mobilization starts within the first three postoperative days. Resisted exercises are avoided during the first 6 weeks. The physical-therapy schedule is summarized in Table 1.

Table 1 Timeline for physical therapy guideline

Elements of physical therapy	
Anti edema elbow, hand, fingers	Day 1
Pendula exercises, passive assisted exercises in forward elevation, extension, and abduction	Day 1
Active assisted exercises, Stability exercises, and positioning of the scapula	Day 5
Active assisted Internal + External Rotation	Day 5
Active exercises. Functional exercises	8 weeks
Isometric resistance	8 weeks
Active strengthening exercises	8 weeks
Functional strengthening exercises and proprioceptive exercises-restore dynamic stability	8 weeks

Randomization and allocation

The trial uses randomized block allocation with a 1:1 treatment ratio. The randomization sequence was generated using SAS software in accordance with the trial registration record. Allocation concealment is achieved using sequentially numbered, opaque, sealed envelopes. Envelopes are opened only after eligibility has been confirmed, written informed consent has been obtained, and the participant has been enrolled. This sequence is intended to prevent foreknowledge of the next treatment assignment by recruiting clinicians.

Blinding

Blinding of surgeons and participants is not feasible because the experimental and control implants are visibly and procedurally different. Outcome assessment is therefore assessor blinded. Independent physiotherapists who are not involved in the operative care perform the functional assessments. Participants are asked not to reveal their treatment group during assessment, and scars are covered when practical.

Outcome measures

Primary outcome

The registered primary outcome is shoulder joint function at 24 months after surgery. In this protocol, shoulder function is assessed using the Constant-Murley score [25, 26], which ranges from 0 to 100 with higher scores indicating better shoulder function. The 24-month Constant-Murley score is the primary analysis variable used to operationalize the registered primary outcome. This wording distinguishes the registry's outcome domain from the instrument specified in the protocol.

Secondary outcomes

1. Shoulder function at 3, 6, and 12 months measured with the Constant-Murley score [25, 26].
2. Upper-extremity disability at 3, 6, 12, and 24 months measured with the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire [27, 28]. These functional measurements operationalize the registered shoulder-function secondary outcome domains.
4. Fracture-healing rate at 3, 6, 12, and 24 months, assessed radiographically.
5. Loss of reduction at 3, 6, 12, and 24 months, including changes in neck-shaft angle and humeral-head or tuberosity position.
6. Adverse events throughout the study period, including clinically important implant-related, wound, infectious, neurovascular, healing, and reoperation events.

Operative variables such as operation time, incision length, blood loss, and adjunctive graft use may be recorded as exploratory process measures. They are not labeled as registered secondary outcomes in this protocol.

Radiographic evaluation

Preoperative imaging includes standardized shoulder radiographs and CT with 3D reconstruction for fracture classification [24]. Follow-up radiographs are obtained at prespecified postoperative visits. Radiographic assessment includes neck-shaft angle, medial metaphyseal comminution, medial hinge characteristics [29, 30], tuberosity position and healing, implant position and integrity, humeral-head alignment, screw penetration or cut-out, avascular necrosis, and nonunion. Change in neck-shaft angle and humeral-head height or position are used to characterize maintenance of reduction [14]. Representative measurement methods are shown in Fig. 3.

Sample-size calculation

The planned sample size was based on the Constant-Murley score. Assuming mean scores of 74.0 in the EAS group and 67.0 in the locking-plate group, a common standard deviation of 10.0, a two-sided alpha of 0.05, and 90% power, 44 participants per group were required. Allowing for approximately 10% loss to follow-up increased the registered target to 49 participants per group (98 total). The assumed between-group values were informed by prior clinical data from a closely related endosteal-support construct [21].

Statistical analysis

The primary analysis will follow the intention-to-treat principle. Continuous outcomes will be summarized using means with standard deviations or medians with interquartile ranges, as appropriate, and treatment effects will be presented with 95% confidence intervals. The primary comparison will

evaluate the 24-month Constant-Murley score between treatment groups using an independent-samples t test or a Mann-Whitney U test if distributional assumptions are not met. Secondary outcomes will be analyzed at their prespecified assessment times. Categorical outcomes, including fracture healing and adverse-event components, will be compared using chi-square or Fisher's exact tests as appropriate. Center-specific estimates may be described in addition to pooled analyses. Missing primary outcome data will be handled according to a prespecified approach based on the amount and pattern of missingness. Multiple imputation will be considered when its assumptions are reasonable. Two-sided P values below 0.05 will be considered statistically significant for the primary comparison, while secondary analyses will be interpreted as supportive.

Safety monitoring and adverse events

Adverse events are a registered secondary outcome and are recorded throughout follow-up. Events of clinical interest include infection, neurovascular complications, implant failure, screw penetration, loss of reduction, avascular necrosis, nonunion, and reoperation.

Data collection, confidentiality, and sharing

Study data are collected using case-report forms and an electronic data-capture system. Participants are identified in the study database by coded study numbers, and direct identifiers are stored separately from analytic data. The trial registry states that individual participant data will be shared. De-identified individual-level data, associated metadata, and the protocol are planned for release through the ResMan platform in January 2028, subject to applicable ethical, institutional, and privacy requirements.

Patient and public involvement

Patients and members of the public were not involved in the design, conduct, reporting, or dissemination planning of this protocol.

Trial registration and protocol amendments

The trial is registered in the Chinese Clinical Trial Registry (ChiCTR2000038167; registration date 11 September 2020). The registry is treated as the authoritative source for the registered eligibility criteria, target sample, intervention groups, primary and secondary outcome domains, funding status, ethics approval date, enrollment start date, registration date, and recruitment status. Any protocol amendment that changes these elements should be documented in the trial records and, when applicable, updated in the registry. The final trial report should distinguish registered outcomes from post-registration exploratory analyses.

Discussion

This randomized trial addresses the challenge of restoring reliable medial support in displaced proximal humeral fractures while preserving the native humeral head. The EAS system is intended to provide

patient-specific endosteal support while permitting lateral fixation and tuberosity repair [21–23]. The trial compares this construct with conventional locking-plate fixation using a registered target sample of 98 participants.

The design has several strengths, including randomized allocation, a standardized rehabilitation pathway, blinded functional assessment, prespecified radiographic follow-up, and use of validated Constant-Murley and DASH instruments [25–28]. Radiographic assessment addresses clinically important failure mechanisms such as varus collapse, loss of reduction, screw penetration, avascular necrosis, and nonunion [5–7, 24, 29, 30].

The study also has practical limitations. First, surgeons and participants cannot be blinded, so knowledge of treatment may affect rehabilitation behavior or symptoms reported by participants. Second, the Constant-Murley measurements can vary between assessors, which makes standardized training and blinded assessment important. Third, surgeon-directed adjunctive bone grafting or substitute use in the control group may introduce treatment heterogeneity. Fourth, enrollment began before registration. The trial is therefore retrospectively registered. Finally, the registry currently lists recruitment as completed, while actual enrollment and participant-flow results are not populated in the exported record. For that reason, this protocol reports only registered target numbers and contains no trial outcome results.

Transparent linkage between the registered outcome domains and the protocol's measurement instruments is particularly important. The registry specifies shoulder function at 24 months as the primary outcome, and this protocol measures that outcome with the Constant-Murley score. Similarly, the protocol's Constant-Murley and DASH follow-up assessments are presented as measurement instruments within the registered shoulder-function secondary outcome domains rather than as newly registered outcomes.

Abbreviations

AO/OTA

Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association

DASH

Disabilities of the Arm, Shoulder and Hand

EAS

Endosteal anatomical support

EDC

Electronic data capture

ORIF

Open reduction and internal fixation

RCT

Randomized controlled trial

Declarations

Ethics approval and consent to participate

The design and conduction of this study complied with Declaration of Helsinki. It has been reviewed and approved by our Medical Ethics Committee (S2020-011-01, V2.0). The Chinese Clinical Trial Registry records the study's ethics review as approved on 5 March 2020. Written informed consent for participation is obtained from all participants before study-specific procedures and randomization.

Consent for publication

Written informed consent was obtained for publication of the anonymized radiographic images used in Fig. 3. The figure is adapted from the authors' previously published work [14], which is available under the Creative Commons Attribution License (CC BY). The source is cited and the adaptation is identified in the figure legend. The figure is used only to illustrate the measurement methods and does not contain outcome data from the present trial.

Availability of data and materials

No trial outcome dataset is reported in this protocol manuscript. The trial registry indicates that individual participant data are planned to be shared, but the exported record does not specify the sharing platform, timing, scope, or access conditions. Any future sharing of de-identified data will be subject to the ethics approval, institutional requirements, participant consent, and applicable privacy protections.

Competing interests

The authors declare that they have no competing interests.

Funding

The National Natural Science Foundation of China (No. 81772336, 82272455) supported this work.

Authors' contributions

HC, PFT, HYL, NZZ, LQ, ML, and ZXC contributed to conception and design of the trial and coordination between study centers. HYL, NZZ, and ZXZ contributed to pilot work and study implementation. HC, HYL, ZXC, and ML contributed to manuscript drafting and methodological revision. PFT, HC, and ML supervised the study. All authors critically reviewed the manuscript, approved the final version, and accept accountability for the work.

Acknowledgements

The authors thank the orthopaedic and rehabilitation teams at the participating centers for their contributions to standardized perioperative care and follow-up.

Authors' information

Not applicable.

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Figures

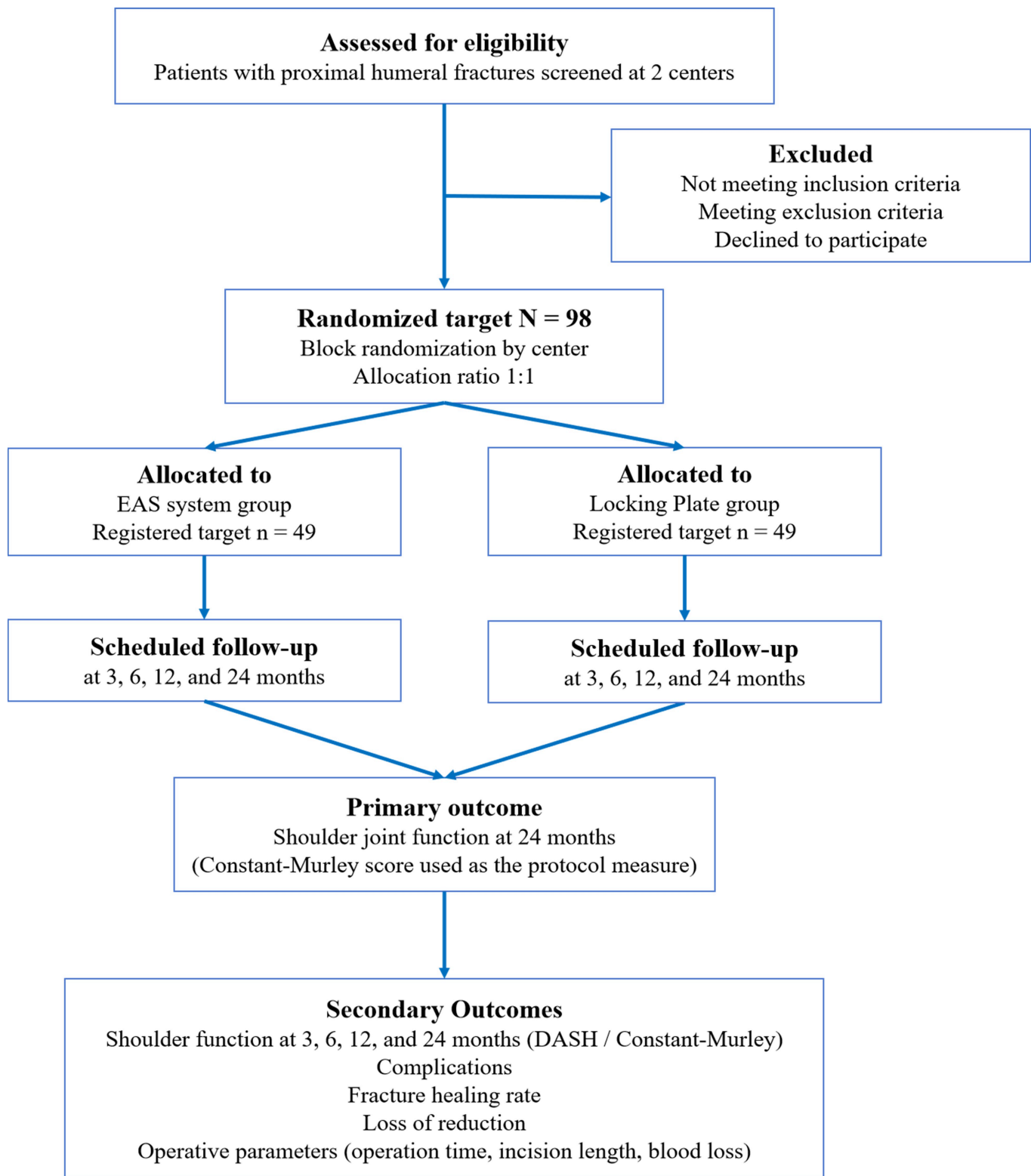


Figure 1

Trial flow and registered outcome framework. The registered target sample is 98 participants with a 1:1 allocation target (49 per group). Completed treatment and analyzed participant counts are not yet available because the trial remains in the follow-up phase.



Figure 2

Schematic of the 3D-printed Endosteal Anatomical Support (EAS) System (1, 2, 3) for proximal humeral fracture fixation (A). The system (B) consists of: (1) a patient-specific EAS prosthesis fabricated from Ti-6Al-4V via Selective Laser Melting (SLM), designed from a mirrored CT scan of the contralateral humerus with a 135° support plane for anatomical endosteal head support; (2) a low-profile lateral locking plate featuring suture holes (*) for rotator cuff repair and three screw types—proximal locking screws (\$) to stabilize tuberosities, a central cannulated screw (*) connecting the head, prosthesis, and plate, and distal screws (#) anchoring the plate to the shaft via the prosthesis; and (3) a dedicated targeting guide ensuring precise prosthesis implantation and distal screw insertion.

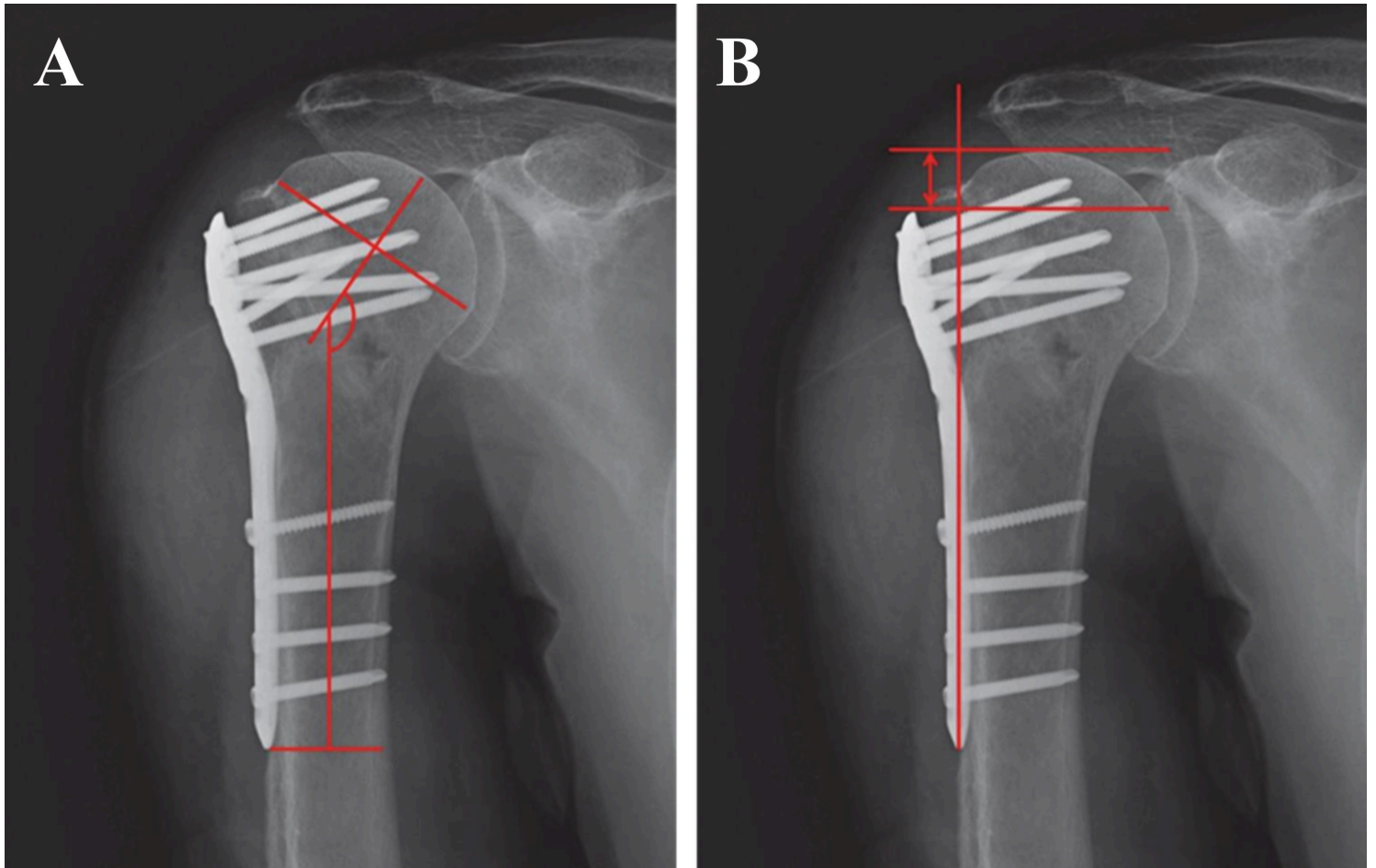


Figure 3

Radiographic measurements used to assess maintenance of reduction. (A) Measurement of the humeral neck-shaft angle. (B) Measurement of humeral head height, defined as the distance from the superior edge of the humeral head to the proximal edge of the locking plate. Red lines show the measurement axes. Adapted from Chen et al. [14] under the Creative Commons Attribution License (CC BY). The two previously published illustrations were combined into one figure. This figure illustrates the measurement methods and does not show outcome data from the present trial.