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Screw-tip augmentation versus standard locked plating of displaced proximal humeral fractures: a retrospective comparative cohort study

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Background: This study compared the clinical and radiologic outcomes of screw tip–augmented locking plate osteosynthesis vs. standard locked plating in elderly patients with displaced proximal humeral fractures.
Methods: Of the 94 patients older than 65 years with displaced proximal humeral fractures, 55 underwent fixation with a locking plate only whereas 39 underwent fixation using a locking plate with fluoroscopy-controlled polymethyl methacrylate augmentation of screw tips.
Results: At 2 years' follow-up, the locking plate–only group showed a mean Constant score (CS) of 62.6 ± 17.4 points, mean CS as a percentage of the uninjured side of 78.2% ± 18.9%, and mean age- and sex-adjusted CS of 72.4 ± 20.5 points. Among the 39 patients who underwent locked plating with polymethyl methacrylate augmentation of screw tips, the mean CS was 63.7 ± 18.5 points ($P = .28$), the mean CS as a percentage of the uninjured side was 79.5% ± 20.4% ($P = .36$), and the mean age- and sex-adjusted CS was 76.8 ± 26.2 points ($P = .11$). The mean Disabilities of the Arm, Shoulder and Hand score was 26.4 ± 21.3 in the locking plate–only group compared with 23.6 ± 19.2 in the group with screw tip–augmented locking plate osteosynthesis ($P = .41$). The overall complication rate was 16.3% in the locking plate–only group compared with 12.8% in the group with screw tip–augmented osteosynthesis ($P = .86$); loss of fixation occurred in 10.9% vs. 5.1% ($P = .74$). The follow-up rate was 81%.
Conclusions: Loss of fixation was less frequent when augmentation of screw tips was performed; however, at the 2-year follow-up, the clinical and radiologic outcomes were not significantly different compared with standard locked plating without augmentation.
Level of evidence: Level III; Retrospective Cohort Design; Treatment Study

Keywords: Proximal humeral fracture; locked plating; PMMA; augmentation; osteosynthesis; loss of fixation; avascular necrosis

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Fractures of the proximal humerus account for 5% of all fractures, with a high prevalence in elderly patients.[1,7,16] Nondisplaced and stable fractures can be treated nonoperatively with good functional results.[23] In contrast, most authors have suggested operative treatment for displaced and complex fractures. To restore shoulder function, open reduction–internal fixation (ORIF) is performed most often by use of locking plates.[30] However, complications (eg, loss of fixation or screw cutout) are frequently observed in the elderly patient with poor bone quality, and some authors have recommended primary fracture arthroplasty for the treatment of proximal humeral fractures.[7]

Recently, synthetic augmentation of osteosynthesis by use of polymethyl methacrylate (PMMA) bone cement was introduced to increase the fixation strength of the osteosynthesis. PMMA augmentation may be performed through cannulated screws, thereby expanding the interface between the bone and screws, potentially supporting the fixation strength.[25] Although there are several biomechanical studies showing an increase in fixation strength, functional outcomes and complications after screw-tip augmentation of locked plating in displaced proximal humeral fractures are missing.[5,24,25]

The primary objective of the study was to prove the safety of screw tip–augmented locking plate osteosynthesis in displaced proximal humeral fractures. The secondary objective was to compare the clinical and radiographic outcomes of screw tip–augmented locking plate osteosynthesis vs. locked plating only. It was hypothesized that loss of fixation may occur less frequently when the osteosynthesis is augmented compared with osteosynthesis performed without augmentation.

Materials and methods

Study cohort and data collection

This retrospective cohort study enrolled 116 patients with a displaced proximal humeral fracture (>1 cm, 45° angulation) that underwent ORIF by locked plating between January 2014 and August 2016. The inclusion criteria of this review board–approved study were patients older than 65 years with a minimum follow-up period of 2 years. In all cases, true anteroposterior and outlet-view radiographs, as well as computed tomography scans, were obtained, and fractures were classified according to the Neer and Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) classifications.[13,19,20] The exclusion criteria were isolated fractures of the greater or lesser tuberosity, open fractures, pathologic fractures resulting from metastatic or primary neoplasia, and preoperatively diagnosed neurologic deficiency (lesion of the axillary or radial nerve, distinct dementia, condition after apoplectic insults, and consecutive hemiparesis).

Surgical procedure

Fracture treatment was performed within 8 days of the traumatic incident as first-line therapy by ORIF. Surgery was conducted by 1 of 2 senior trauma surgeons (F.H. and B.O.) with the patient placed in the beach-chair position on a radiolucent table as previously reported.[21,22] Under general anesthesia in combination with an interscalene block for perioperative pain management, every patient received prophylactic intravenous antibiotics as a single shot at the beginning of the surgical procedure. Via a standardized deltopectoral approach, surgical reconstruction was conducted by ORIF. Fracture fixation was achieved by a proximal humeral interlocking plate system (PHILOS; DePuy Synthes, Zuchwil, Switzerland). The rotator cuff was evaluated for rotator cuff tears, and tuberosity sutures (No. 5 FiberWire; Arthrex, Naples, FL, USA) were used when necessary. After accurate fracture reduction, 6 locking screws were carefully driven in until 5 mm from the subchondral layer under fluoroscopic evaluation to ensure that the screw length was correct and that the articular surface of the humeral head was not penetrated. Screws were repositioned to obtain the intended distance and location of the screw tip relative to the subchondral bone layer when necessary. Three bicortical locking screws were inserted to fix the plate against the humeral shaft.

Screw-tip augmentation

Screw-tip augmentation was performed based on preoperative and intraoperative signs of poor bone quality (T-score < -2.5 from previously performed dual-energy x-ray absorptiometry, Fracture Risk Assessment [FRAX] without bone density measurement, or deltoid tuberosity index < 1.4).[10,27] Intraoperatively, poor bone quality was assessed by advancing the drill bit in the humeral head under fluoroscopic control. After penetrating the lateral cortex, the drill bit was advanced carefully without drilling up to 5 mm from the subchondral layer. If drilling was not necessary to advance the drill bit up to 5 mm from the subchondral layer, the bone quality was rated poor and screw-tip augmentation was performed.

After a careful evaluation of the intended screw position, 3 or 4 screws were changed to cannulated screws with identical screw lengths. In all cases, the screws of the top row (line A) were changed to cannulated screws; in addition, either both screws of the third row (line C) or the center screw (No. 7, line D) was exchanged. Before screw-tip augmentation was begun, 0.5 to 1 mL of radiographic contrast agent was injected through the cannulated screws under image intensifier control to identify potential leakage into the fracture or glenohumeral joint. If the contrast agent could not be injected, the screw cannulation was cleared by probing a 1.6-mm K-wire via the cannulated screw. If the contrast agent led to inappropriate visualization, saline solution was injected to wash out the agent of the humeral head. In the case of positive contrast agent leakage ($n = 4$), augmentation of screw tips was not performed. When evaluation confirmed the absence of leakage, augmentation was performed using PMMA (Trauma Cem V+; DePuy Synthes) through the cannulated screws under image intensifier control. The cement was applied via 1-mL syringes connected to a Luer-lock adapter. After the prefilled syringes were attached, the tip of the adapter was inserted into the perforated screws and 0.5 to 1 mL of cement was applied per screw; the surgeon did not inject more than 4 mL of cement in total. In accordance with the manufacturer's recommended technique, a setting time of 15 minutes was respected while any motion at the fractured arm of the patient was avoided. Any spilled cement was removed from the screw heads, plate, and soft

tissue afterward. It was confirmed that at least 6 screws secured the humeral head and at least 3 of them were augmented. After setting of the cement, a final evaluation of screw-tip augmentation was performed under an image intensifier in full range of glenohumeral motion.

Rehabilitation protocol

The standardized postsurgical protocol allowed passive- and active-assisted rehabilitation exercises immediately on day 1 after surgery under the supervision of a physiotherapist. All patients received a shoulder sling in the operating room. For the first 6 weeks, abduction and elevation up to 60° without forced external rotation were allowed. Before active exercises with full range of motion and increasing force were allowed, radiographs in the true anteroposterior and outlet views were obtained to confirm the correct implant position without loss of fixation.

Follow-up and outcome measures

Locking plate procedures were performed in 116 patients within the study period who matched the study criteria. After giving their informed consent, consistent with the Declaration of Helsinki, all 116 patients were longitudinally followed up from the time of the operation until 2 years of follow-up. A total of 22 patients were lost to follow-up, leaving a study cohort of 94 patients (mean age, 77.5 ± 10.1 years; 79.8% women). Of the patients, 55 underwent fixation with only a locking plate (mean age, 76.6 ± 11.1 years; 78.1% women) and 39 underwent screw tip–augmented locking plate osteosynthesis (mean age, 78.2 ± 10.2 years; 82.1% women) (Fig. 1). Every patient was both examined and interviewed according to a standardized protocol at every follow-up examination.

The standardized physical examination included assessment of the Constant score (CS),[3,4] by measurement of strength with a digital spring balance (76000 Tara PS; Burg-Wächter, Wetter-Volmarstein, Germany) and range of motion; the CS as a percentage of the uninjured contralateral shoulder; and the age- and sex-normalized CS according to Katolik et al.[12] The Disabilities of the Arm, Shoulder and Hand score was assessed as previously published.[9] Furthermore, medical records comprising demographic information, trauma mechanism, surgical time, surgical protocols, and radiographs were collected in a digital database. The standardized follow-up comprised clinical and radiographic examinations of the affected shoulder after 6 weeks; after 3, 6, and 12 months; and at 2 years' follow-up.

Radiographic evaluation

In all patients, true anteroposterior and outlet-view radiographs were assessed within 3 days after surgery and at every follow-up. Quality of fracture reduction was evaluated in accordance with Schnetzke et al.[26] Radiographs were further evaluated for radiographic signs of secondary displacement, loss of fixation, screw cutout, avascular necrosis of the humeral head, nonunion, malunion, or failure of the implant (loosening or breakage). Avascular necrosis was evaluated according to Hattrup and Cofield.[8] Apart from this, partial avascular necrosis around screw tips was assessed in cases of minor humeral head settling (<10°) without secondary displacement or functional impairment. Loss of fixation was defined as a change in the humeral head-shaft angle of more than 10°.[21]

Statistical evaluation

A sample size calculation indicated that 36 patients were needed in each group to detect a minimal clinically important difference of 10 points for the CS. Statistical analysis was performed using SPSS software (IBM SPSS Statistics for Windows, version 24.0 [released 2016]; IBM, Armonk, NY, USA). Demographic data and functional outcomes were described by means and standard deviations and were compared with an independent-samples t test. Radiographic characteristics and all categorical variables were analyzed with the χ^2 test. The level of significance for all testing was set at $P < .05$.

Results

In the 55 patients who underwent fixation with only a locking plate (mean age, 76.6 ± 11.1 years; 78.1% women; 82.0% follow-up rate), the fracture patterns according to the Neer classification were as follows: 2-part fracture in 20 cases (36.4%), 3-part fracture in 22 (40.0%), and 4-part fracture in 13 (23.6%). According to the AO/OTA classification, fracture diversification was as follows: A2 in 6 cases (10.9%), A3 in 12 (21.8%), B1 in 9 (16.4%), B2 in 15 (27.3%), C1 in 4 (7.3%), and C2 in 9 (16.4%). In comparison, in the 39 patients who underwent screw tip–augmented locking plate osteosynthesis (mean age, 78.2 ± 10.2 years [$P = .24$]; 82.1% women [$P = .84$]; 79.5% follow-up rate), the fracture patterns according to the Neer classification were as follows: 2-part fracture in 16 cases (41%), 3-part fracture in 15 (38.5%), and 4-part fracture in 8 (20.5%, $P = .46$). According to the AO/OTA classification, fracture diversification was as follows: A2 in 3 cases (7.7%), A3 in 10 (25.6%), B1 in 6 (15.4%), B2 in 12 (30.8%), C1 in 2 (5.1%), and C2 in 6 (15.4%, $P = .53$). In 4 cases, chondral penetration was noted before augmentation (positive dye leak test), resulting in aborting the augmentation procedure.

At 2 years' follow-up, patients in the locking plate–only group showed a mean CS of 62.6 ± 17.4 points, mean CS as a percentage of the uninjured side of 78.2% ± 18.9%, and mean age- and sex-adjusted CS of 72.4 ± 20.5 points. Among the 39 patients who received a locking plate with PMMA augmentation of screw tips, the mean CS was 63.7 ± 18.5 points ($P = .28$), the mean CS as a percentage of the uninjured side was 79.5% ± 20.4% ($P = .36$), and the mean age- and sex-adjusted CS was 76.8 ± 26.2 points ($P = .11$). The mean Disabilities of the Arm, Shoulder and Hand score was 26.4 ± 21.3 in the locking plate–only group compared with 23.6 ± 19.2 in the group with screw tip–augmented locking plate osteosynthesis ($P = .41$) (Table I).

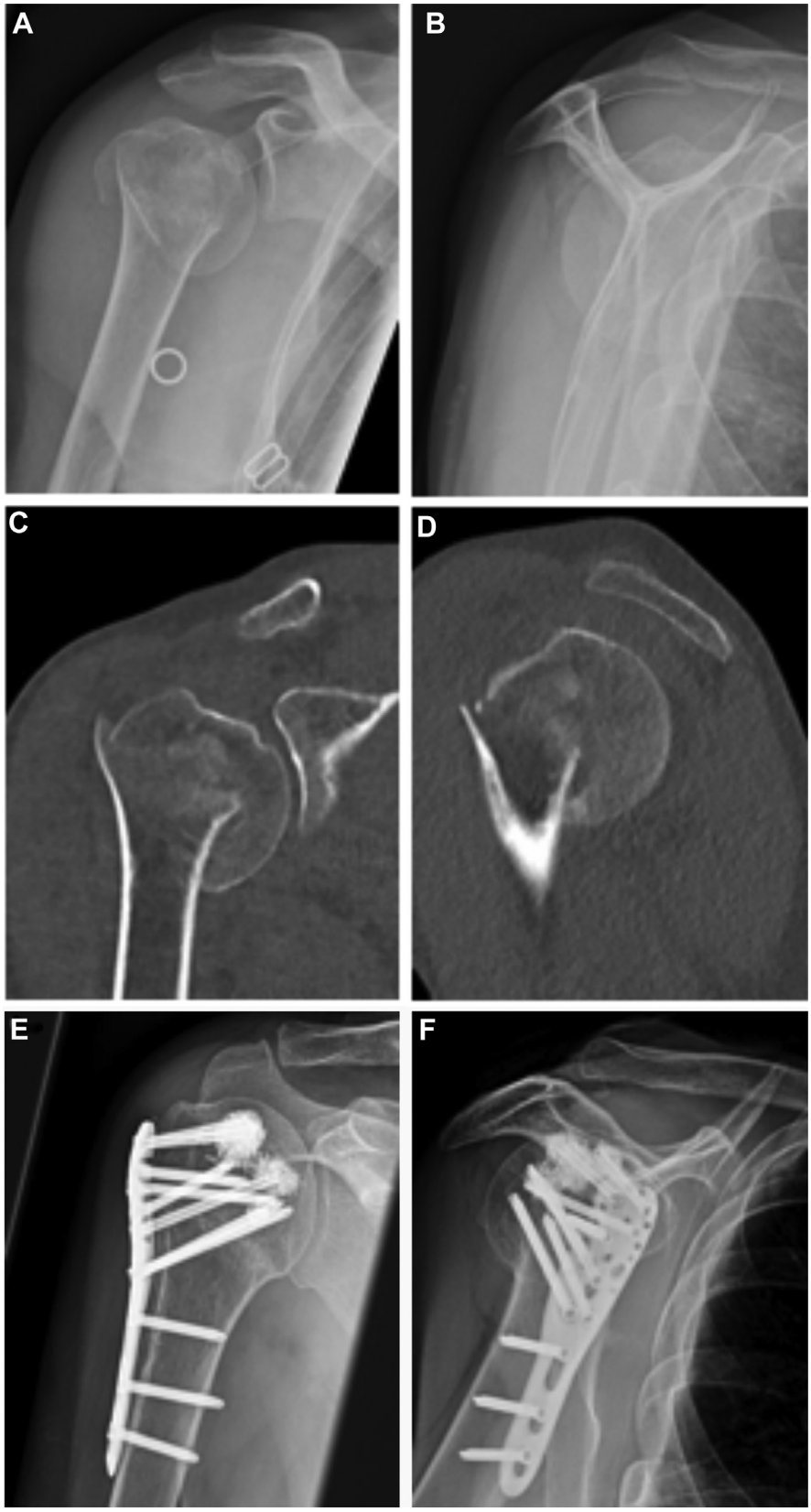

Figure 1 True anteroposterior (**A**) and outlet-view (**B**) radiographs and coronal (**C**) and sagittal (**D**) computed tomography reconstructions of a right shoulder in a 78-year-old female patient with a Neer type III 2-part fracture. (**E**, **F**) Radiographic outcome after locking plate osteosynthesis and screw-tip augmentation with polymethyl methacrylate.

Table I Descriptive data for patient characteristics, functional outcomes, complications, and revision rates

	Locking plate only (n = 55) (%)	Screw tip–augmented locking plate (n = 39) (%)	*P* value
Age, mean ± SD, yr	76.6 ± 11.1	78.2 ± 10.2	.24
Female, n	43 (78.1)	32 (82.1)	.84
Fracture pattern, n			
2-part fracture	20 (36.4)	16 (41.0)	.46
3-part fracture	22 (40.0)	15 (38.5)	.88
4-part fracture	13 (23.6)	8 (20.5)	.72
CS, mean ± SD, points	62.6 ± 17.4	63.7 ± 18.5	.28
CS %, mean ± SD	78.2 ± 18.9	79.5 ± 20.4	.36
Age- and sex-normalized CS, mean ± SD, points	72.4 ± 20.5	76.8 ± 26.2	.11
DASH score, mean ± SD	26.4 ± 21.3	23.6 ± 19.2	.41
Complication rate total, n	9 (16.3)	5 (12.8)	.86
Loss of fixation, n	6 (10.9)	2 (5.1)	.74
AVN, n	3 (5.5)	3 (7.7)	.99
Revision rate, n	4 (7.3)	2 (5.1)	.68

SD, standard deviation; *CS*, Constant score; *CS%*, Constant score as percentage of uninjured side; DASH, Disabilities of the Arm, Shoulder and Hand; *AVN*, avascular necrosis.

Overall, complications were observed in 14 cases (14.9%) distributed between the group with only a locking plate (9 cases, 16.3%) and the group with a screw tip–augmented locking plate (5 cases, 12.8%; $P = .86$). Loss of fixation was observed in 8 cases (8.5%), of which 6 (10.9%) occurred in the group with only a locking plate and 2 (5.1%) occurred in the group with a screw tip–augmented locking plate ($P = .74$). Avascular necrosis of the humeral head despite stable fixation was seen in 6 cases (6.4%), of which 3 were seen in each group (5.5% vs. 7.7%, $P = .99$). In relation to the fracture pattern, all cases of loss of fixation and avascular necrosis within the group with screw-tip augmentation occurred in 4-part fractures. In contrast, loss of fixation was observed in the group with only a locking plate in 2-part fractures (n = 2), 3-part fractures (n = 2), and 4-part fractures (n = 2), whereas all cases of avascular necrosis occurred in 4-part fractures ($P = .64$). Screw cutout accompanying loss of fixation was seen in 2 cases in the standard locking plate–only group and was not seen in the group with a screw tip–augmented locking plate ($P = .43$). No cases of postoperative infection or hematoma and no cases of implant failure occurred.

The overall revision rate was 6.4% (n = 6); of these cases, 4 (7.3%) were in the group with only a locking plate and 2 (5.1%) were in the group with a screw tip–augmented locking plate ($P = .68$). Revision surgery included 2 cases (2.1%) of revision osteosynthesis and 4 cases (4.3%) of conversion to reverse shoulder arthroplasty.

Discussion

The main finding of this study is that screw-tip augmentation with the use of PMMA can be safely performed and shows comparable functional outcomes to standard locking plate osteosynthesis without augmentation in a selective cohort of predominantly elderly and female patients. Although many studies have shown good results of open reduction and locked plating in younger patients, several studies reported complication rates of 20% to 46% in patients older than 60 years, such as loss of fixation and screw cutout.[7,15,18,22,30]

Recently, fracture fixation by use of PMMA bone cement augmentation of screw tips in locked plating of proximal humeral fractures was introduced to increase the fixation strength. Several biomechanical studies reported less movement at the interface between the bone and implant in PMMA-augmented locking plate osteosynthesis.[5,11,14,24,25] In a biomechanical study, Schliemann et al[25] reported that the addition of bone cement to augment head screws reduced motion at the bone-implant interface, thus potentially reducing the risk of secondary displacement. However, until now, there have been no data reporting on the clinical outcomes and complications of PMMA-augmented locking plate osteosynthesis.

This study included patients older than 65 years. Among patients who underwent screw-tip augmentation, the mean age was 78 years and 82% of the patients were women. This study cohort thus well represents a typical patient with a displaced proximal humeral fracture that may be treated by ORIF.[15,17,18,31] In this comparative study, the rate of loss of fixation was 5.1% in patients treated by a screw tip–augmented locking plate and 10.9% in patients treated by only a locking plate; however, this difference was not statistically significant. In the study by Südkamp et al,[29] the rate of secondary displacement was 7%, without augmentation. One reason for a lower rate of secondary displacement in patients who underwent screw-tip augmentation may be related to the effect of screw-tip augmentation. However, in comparison to patients who received only a

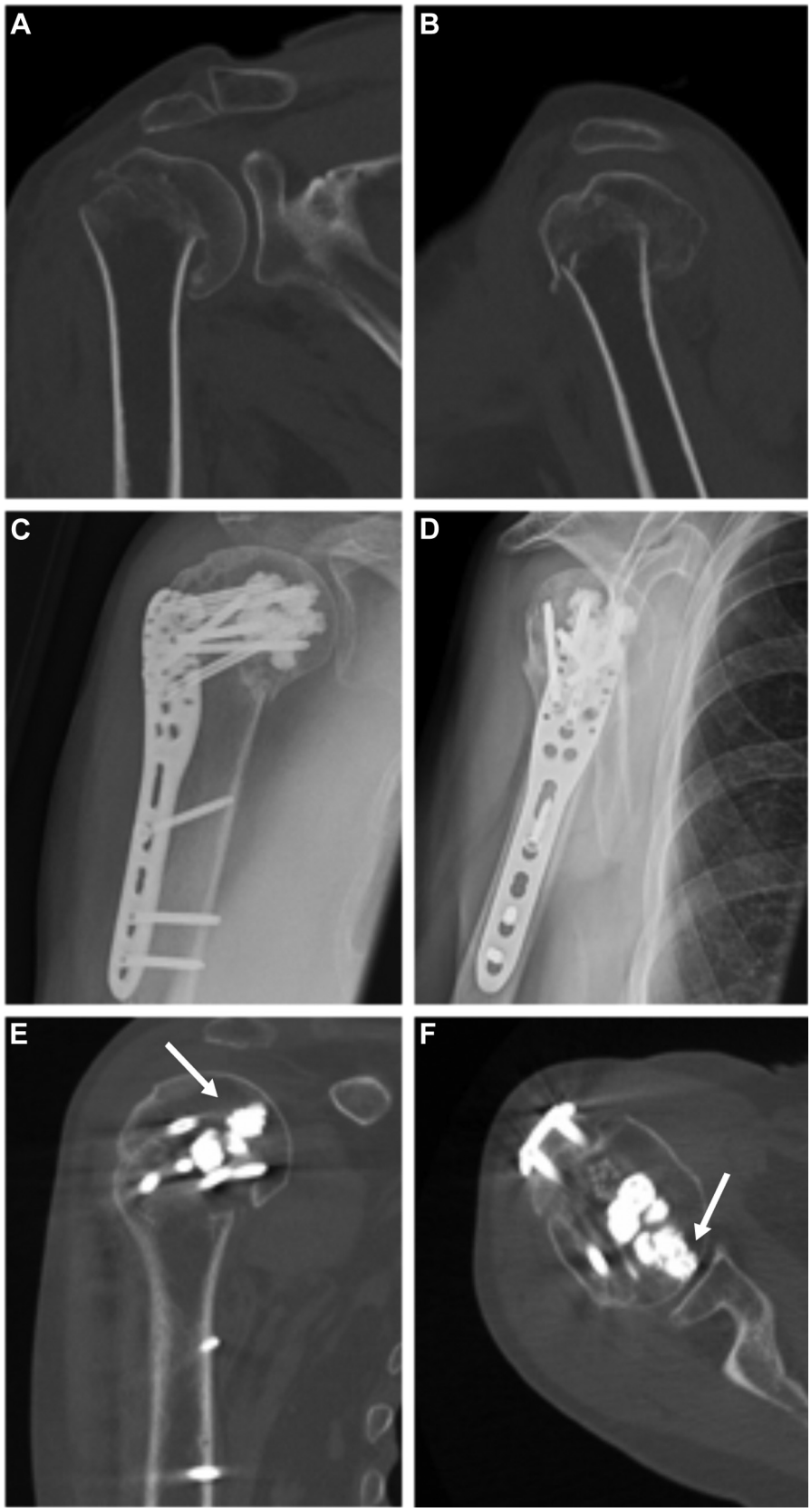

Figure 2 Coronal (**A**) and sagittal (**B**) computed tomography reconstructions in a 72-year-old female patient with a Neer type III 2-part fracture. The mean T-score was –3.6. True anteroposterior (**C**) and outlet-view (**D**) radiographs 1 day after surgical treatment with locking plate osteosynthesis and polymethyl methacrylate augmentation of screw tips. Coronal (**E**) and axial (**F**) computed tomography reconstructions 6 months after surgery, showing partial avascular necrosis (*arrows*) surrounding augmented humeral head screws.

locking plate, the fracture pattern was different. In the group of patients who underwent screw tip–augmented locking plate osteosynthesis, 41% of fractures were 2-part surgical neck–type fractures and 38% were 3-part fractures. In turn, 4-part fractures were represented less frequently than in the locking plate–only group and other studies. One might argue that PMMA augmentation of locking plate osteosynthesis may not be of benefit in 2-part fractures. However, in comparison to other studies, the rate of secondary displacement was lower.

In 7.7% of patients who underwent PMMA augmentation of screw tips, avascular necrosis was observed. After screw-tip augmentation, avascular necrosis may be related to the temperature and pressure reaction associated with PMMA augmentation. Although in vitro studies have suggested no harmful effects, in vivo studies of the proximal humerus have not been performed.[2,31] We have seen avascular necrosis in cases in which the cement was filled into the subchondral layer. We therefore suggest that drilling into the subchondral layer of the humeral head should not be conducted and the screws' lengths of at least 1 cm of the apex should be chosen. In accordance with the surgical technique, we believe that care must also be taken not to exceed 1 mL of PMMA around each screw tip. In 1 case, we observed prolonged fracture consolidation after screw-tip augmentation and partial necrosis around the screw tips in the humeral head (Fig. 2). Although the rates of avascular necrosis were similar between the study groups and comparable to those in other studies investigating avascular necrosis after proximal humeral fractures,[28,29] avascular necrosis after PMMA augmentation of screw tips needs further critical observation from studies with longer follow-up.

If revision surgery was necessary, we observed that removal of PMMA-augmented screws was technically undemanding, as screw heads were cleaned of PMMA after insertion in the index surgical procedure. We therefore recommend cleaning screw heads of PMMA by either a 1.6-mm K-wire or a depth gauge.

The major strengths of this study are the cohort size and close follow-up. The patient selection criteria were strict, with exclusion of patients aged 65 years or younger. There are several limitations to this study, however. First, this was a retrospective cohort study, and the groups were not identical in terms of age and fracture pattern. Second, although the indication for screw-tip augmentation was based on preoperative evaluation of poor bone quality, the surgeons intraoperatively rejected augmentation of screw tips if the radiographic contrast agent showed potential leakage into the fracture or the glenohumeral joint during image intensifier control, before augmentation (n = 4). Thus, augmentation of screw tips may have been biased by the surgeon for more simple fractures that had otherwise healed well without augmentation; however, fracture patterns were evenly distributed between groups. This study may not reach conclusions on the effect of screw-tip augmentation in all fracture patterns. In fact, PMMA-augmented locking plate osteosynthesis may not be a good indication in elderly patients with 4-part or head-splitting–type fractures owing to the risk of cement leakage and an otherwise complicated outcome with severe rates of avascular necrosis. In turn, for younger patients with good bone quality, we do not see an indication for augmentation of screw tips. However, this study shows that screw-tip augmentation may be safely performed and result in good functional outcomes and low complication rates in 2- and 3-part fractures of the proximal humerus in a rather elderly cohort of patients.

Another limitation is the follow-up period of 2 years, which may be too short to judge the long-term outcomes and complications, specifically regarding the presence of avascular necrosis. Avascular necrosis may occur up to 5 years after fracture treatment.[6] Although this is the first study on the subject, further studies with longer follow-up periods are necessary to evaluate a potential influence of screw-tip augmentation by PMMA on avascular necrosis.

Conclusion

Loss of fixation was less frequent when augmentation of screw tips was performed; however, clinical and radiographic outcomes after 2 years' follow-up were not significantly different in comparison to patients who underwent standard locking plate fixation only. Partial avascular necrosis around augmented screw tips needs further critical evaluation in studies with longer follow-up periods (>24 months) and larger numbers of cases.

Disclaimer

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