RESEARCH ARTICLE

Fluoroscopic Evaluation of Reduction and Plate Positioning in Proximal Humerus Fractures: A Case-Control Study Comparing CFR-PEEK and Metallic Plates

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Abstract

Objectives: Proximal humeral fractures (PHF) are common upper extremity injuries, particularly in older adults. Recently, carbon fiber-reinforced polyetheretherketone (CFR-PEEK) plates have gained popularity in trauma surgery due to their bone-like elasticity, radiolucency, and reduced risk of stress shielding. However, their impact on intraoperative fracture reduction and implant positioning remains unclear. The aim of our study was to assess CFR-PEEK plates' impact on intraoperative fracture reduction and device positioning.

Methods: This retrospective case-control study evaluated PHFs treated with CFR-PEEK plates versus conventional metallic plates. Radiologic parameters, including plate-tuberosity distance, tuberosity-head distance, neck-shaft angle, neck-shaft distance, head-shaft angle, were assessed postoperatively. Thirty patients with CFR-PEEK plates were matched with a metal plate control group based on age, gender, and fracture type.

Results: The results showed no significant differences in fracture reduction quality between the two groups, suggesting CFR-PEEK plates allow comparable anatomical restoration. However, due to radiolucency and marker positioning, CFR-PEEK plates were more frequently placed too high.

Conclusion: In conclusion, CFR-PEEK plates provide effective fracture fixation comparable to metal plates but require careful positioning to avoid complications. Surgeons should take extra precautions to ensure proper plate positioning, using intraoperative guides rather than freehand techniques.

Level of evidence: IV

Keywords: Carbon fiber-reinforced polyetheretherketone, CFR-PEEK, Fracture reduction, Impingement, Proximal humerus fracture, Radiolucency

Introduction

Proximal Humeral Fractures (PHF) common injuries of the upper extremity, particularly in older adults due to the relationship with osteoporosis.[1] PHF account for six-10% of overall fractures with a bimodal distribution and are the third most common fracture in the elderly,[2–4] after hip and distal radius fractures.[5–8] As well as hip fractures,[9] the incidence of PHF is steadily growing over the years,[10,11] becoming a growing socio-economic challenge for global healthcare systems.[12] Dauwe *et al.* reported more than one million € of one-year economic impact for PHF surgically treated in the University Hospitals of Leuven.[12]

PHFs can be treated nonoperatively with sling immobilization,[13] while selected cases such as multifragmented fractures, fracture-dislocations, or those involving young patients or high functional demands patients, may be addressed to surgery.[14] According to fracture pattern several surgical techniques were reported, including locking plates,[15,16] intramedullary nailing,[17,18] hemiarthroplasty,[19,20] and reverse shoulder arthroplasty.[21–

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[23] Even if locking plates are the most performed procedure worldwide, they carry a significant complication rate of 23.8%,[24] as reported by Oldrini *et al.*,[25] with screw cut-out being most common issue, occupying in up to four% of cases and leading to pain, stiffness, and glenoid erosion.[26]

In the past fifteen years carbon fiber-reinforced polyetheretherketone (CFR-PEEK) implants gained popularity, both for oncology and for traumatology.[27–30] These implants offer an elastic modulus similar to bone, reducing complications associated with stress shielding, promoting faster bone healing, and reducing stress at the screw-tip bone interface lowering the incidence of articular screw perforations.[27–29,31] They are hypoallergenic and they not cause cold welding of the screws on the plates.[32,33] Furthermore, these devices are radiolucent allowing a better control of the fracture healing and/or tumor progression, and enabling for radiotherapy without causing metal backscatter effects or dose amplification in adjacent tissues.[29] Although some studies report that radiolucency aids in fracture reduction,[27,28,34] no authors have evaluated its impact of these devices on the fracture reduction itself. However, Padolino *et al.*,[32] without a statistical significance, reported a lower rate of successful calcar reduction (CFR-PEEK 53% vs metal 62%), possibly due to a lower malleability of the device.[33] Moreover, Rotini *et al.* reported a 11.2% of subacromial impingement due to the contact of the superior edge of the plate and the acromion during abduction.[32]

As a result, the primary aim of our study was to assess CFR-PEEK plates' impact on intraoperative fracture reduction. The secondary aim was to assess the accuracy of device positioning. Our hypothesis is that the plates' radiolucency helps the surgeon in fracture reduction but increase the risk of implant misplacement.

Materials and Methods

Study Design and Patient Selection

We retrospectively performed a case-control study in a first level trauma center on PHF treated with open reduction and internal fixation (ORIF) using a CFR-PEEK (DIPHOS H plate, Lima Corporate, San Daniele del Friuli, Italy) plate between first October 2021 and 30th June 2024.

The control group included PHF treated with conventional metallic plates (stainless steel PHILOS plate, DePuy Synthes, Oberdorf, Switzerland), identified starting from the general database of our department, through a propensity score matching based on age, gender, and fracture type according to the Neer classification.

Only PHF treated by the same senior surgeon (R.T.) were included in the study, while cases treated with different plates, and those with poor intraoperative fluoroscopic images, were excluded.

Starting from 32 cases of PHF treated with CFR-PEEK plate, 2 were excluded for low quality images, so 30 cases were included. Nineteen were women and 11 men with a mean age of 54± 16 years old (range 21-76). According to the Neer classification eight fractures were classified as two parts, 10 fractures as three parts, eight fractures as four parts, and four fractures as fracture dislocation with four parts.

The Metal group was extracted from the archive of our Institute of patients operated between 1st January 2019 and 30th June 2024, using the propensity score matching according to gender, age, and fracture type. It included 20 women and 10 men, p=0.79 with a mean age of 57± 15 years old (range 27-77), p=0,09. In eight cases we found a two parts fracture according to Neer classification, 10 cases of three parts, eight fractures as four parts, and four fracture dislocations with four parts, p=1.

Preoperative Evaluation

All patients were evaluated preoperatively with both X-rays and CT scans. Fracture patterns were classified according to the Neer classification for proximal humeral fractures.

Surgical Technique

All surgeries (CFR-PEEK and Metal plates) were performed using the beach chair position and the arm placed on an arm holder. Trans-deltoid, deltopectoral, or anterolateral approach were employed, based on the fracture pattern. The surgeries were conducted with the aim of intraoperative fluoroscopy. Various techniques were employed to achieve fracture reduction. First, the reduction was attempted by using nonabsorbable FiberWire sutures (Arthrex, Naples, FL, USA) placed on the rotator cuff tendons. Additionally, K-wires were utilized to manipulate fragments like joysticks and temporarily secure the reduction. In case of impacted head fragments, they were reduced by placing a periosteal elevator under the humeral head.[35,36]

Fluoroscopic Measurements

Fractures' reduction and plate positioning were analyzed using fluoroscopic (Cios Connect, Siemens Healthineers, Erlangen, Germany) anterior-posterior (AP) images taken at the end of surgery. Given the aim of the study to assess the impact of a radiolucent plate in plate positioning and fracture reduction, we decided to analyze fluoroscopic images as they are the ones the surgeon relies on intraoperatively.[37] The fluoroscopic image was taken with the arm in neutral rotation and with the X-ray beam tilted to be perpendicular to the glenoid, like a Grashey view.[38] An adequate view requires the beam to be perpendicular to the axis of the humerus, a superior-to-inferior view or inferior-to-superior view of the humerus were considered as low quality images and excluded from the study.

The images were independently measured by two orthopedic surgeons (G.G. and J.C.) using the online tool Tyche.[39,40] Each image was calibrated based on the screw diameter to ensure accuracy (3.5 mm screws for Philos plate, 4.0 mm screws for Diphos plate). The following parameters were measured:

Plate-Tuberosity distance (PTD): The measurement refers to the distance between two parallel lines. One line passes tangent to the apex of the greater tuberosity, while the other passes through the highest point of the plate. For metal plates, this line is drawn from the actual highest point of the plate. In the case of CFR-PEEK plates, the line passes through the upper radiopaque marker. According to the literature the plate has to be roughly eight-10 mm inferior to the greater tuberosity apex.[15,41,42] [Figure 1a]

Tuberosity-head distance (THD): The measurement refers to the distance between two parallel lines. One line passes tangent the apex of the head, while the other passes

through the tip of the greater tuberosity. According to Sheng *et al.*, a THD between 5 and 10 mm is a predictor of good postoperative outcome.[43] [Figure 1b]

Neck-shaft angle (NSA): The angle between the shaft axis and the neck axis. The neck axis was identified as the line between the tip of the head and the midpoint of the anatomical neck. According to Greinier *et al.*,[44] NSA has to be between 120° and 150°. [Figure 1c]

Neck-Shaft Distance (NSD): The distance between the medial cortex of the shaft and the most inferior portion of the head. It corresponds to the calcar reduction. According to Dheenadhayalan *et al.*,[45] NSD has to be inferior to four mm. [Figure 1d]

Head-shaft angle (HSA): The angle between the shaft axis and the anatomical neck line. A lower HSA is predictive of poor postoperative outcome, as reported in literature.[35,46] [Figure 1e]

True Plate-Tuberosity Distance (TPTD): Given that the radiopaque marker of DIPHOS H CFR-PEEK plate is four mm from the plate apex [Figure 2], this distance is also calculated as: PTD - four mm. Since for metallic plate PTD and TPTD are equivalent, CFR-PEEK TPTD was compared to Metal PTD.

The differences in these measurements between the CFR-PEEK plate group and the metallic plate group were analyzed. The study was conducted in accordance with the principles of the Declaration of Helsinki.

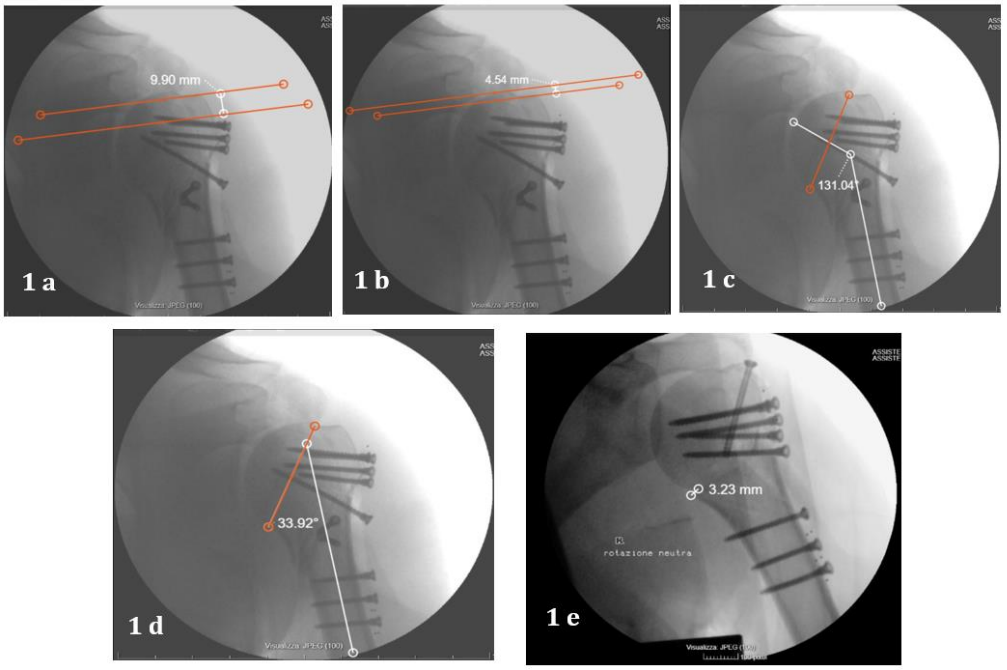

Figure 1. a: Plate-Tuberosity Distance; b: Tuberosity-Head Distance; c: Neck-Shaft Angle; d: Neck-Shaft Distance; e: Head-Shaft Angle

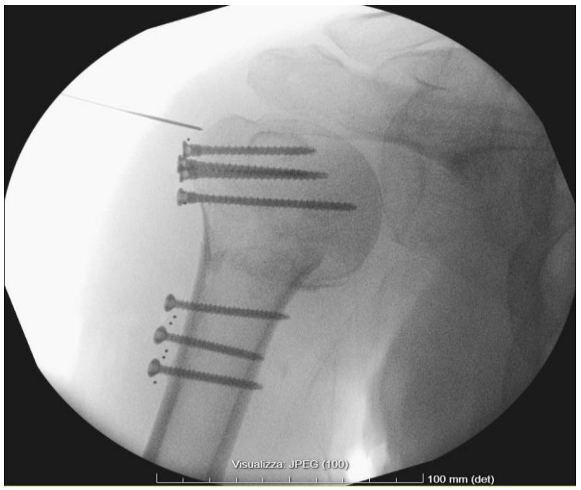

Figure 2. A K wire is placed on top of the plate so the distance (four mm) between the radiopaque marker and the plate edge is well identifiable

Statistical Analysis

A total of 157 PHF were treated with plating during the study period by the single surgeon (R.T.). The patients treated with CFR-PEEK plate were matched according to age, gender, and fracture type according to the Neer classification using a one: one propensity score matching. The interobserver and intraobserver reliability of the measurements were assessed using the Intraclass Correlation Coefficient (ICC), with 0.8 as minimum acceptable value.[17] The normality of the data distribution was evaluated using the Shapiro-Wilk test. For normally distributed data, Student's T test was used for comparisons between groups, while the Mann-Whitney U test was applied for non-normally distributed data. P value <0.05 was established as threshold for significance. Additionally, descriptive statistics, including mean, standard deviation (SD), and range, were reported for continuous variables. Statistical analysis was conducted using Prism 9.5 (GraphPad Software, Boston, MA, USA) and SPSS version 21 (IBM, Armonk, NY, USA).

Results

At the radiologic analysis we registered no differences between CFR-PEEK group and Metal group for PTD, THD, NSA, NSD and HSA. The TPTD was the only measurement which showed a statistically significant difference (p< .00001) between CFR-PEEK group (5.4± 2.4 mm), and Metal group (9.2 ± 2.5mm). [Table 1, Chart a-f]

The Inter-observer reliability showed an average ICC of 0.82 (0.80-0.86) across all measurements. We observed an Intra-observer reliability for Observer one with an ICC of 0.88 (0.84-0.92), and for Observer two with an ICC of 0.85 (0.81-0.88).

Table 1 . Table summarizing the results

Parameter	CFR-PEEK	Metal	p value
PTD (mm)	9.4 ± 2.4	9.2 ± 2.5	0.7
THD (mm)	5.9 ± 2.5	6.1 ± 2.2	0.6
NSA (°)	131.5 ± 5.4	130.5 ± 4.5	0.4
NSD (mm)	3.6 ± 3.9	3.5 ± 3.8	0.8
HSA (°)	40.9 ± 5.4	39.7 ± 4.7	0.5
TPTD (mm)	5.4 ± 2.4	9.2 ± 2.5	< .00001 *

PTD= Plate-Tuberosity distance; THD= Tuberosity-head distance; NSA= Neck-shaft angle; NSD= Neck-Shaft Distance; HSA= Head-shaft angle; TPTD= True Plate-Tuberosity Distance; (mm) = millimeters; (°) =degrees; *=significative.

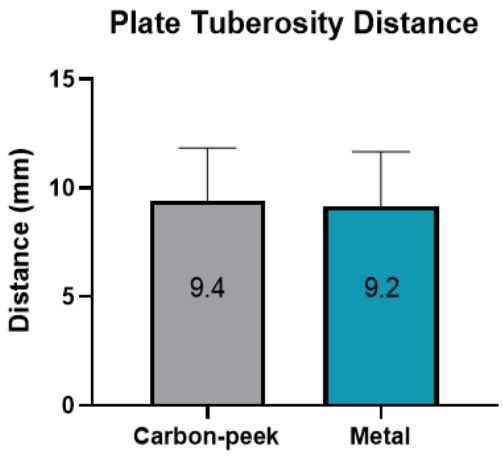

Chart a. Differences in Plate-Tuberosity Distance, assessed with Student's T test

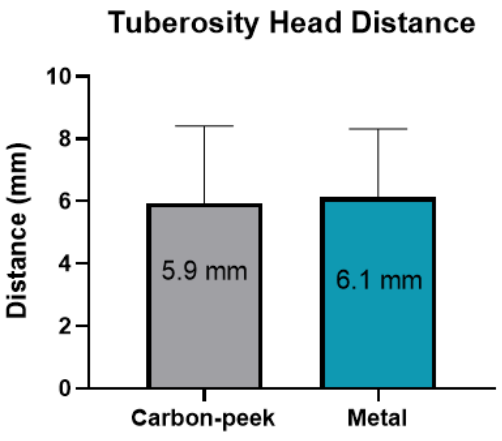

Chart b. Differences in Tuberosity-Head Distance, assessed with Mann- Whitney U test

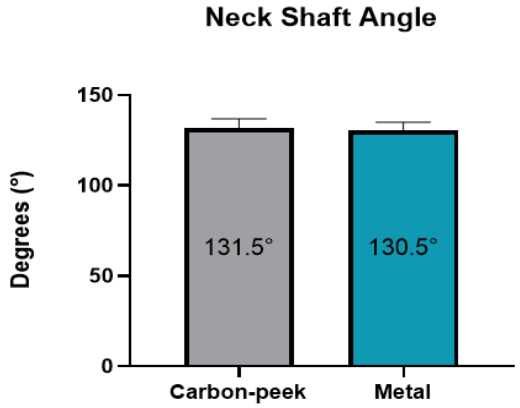

Chart c. Differences in Neck-Shaft Angle, assessed with Whitney U test

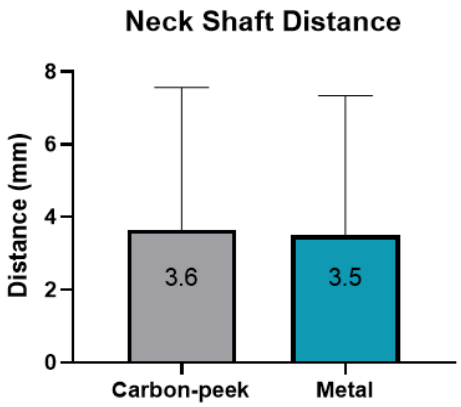

Chart d. Differences in Neck-Shaft Distance, assessed with Mann- Whitney U test

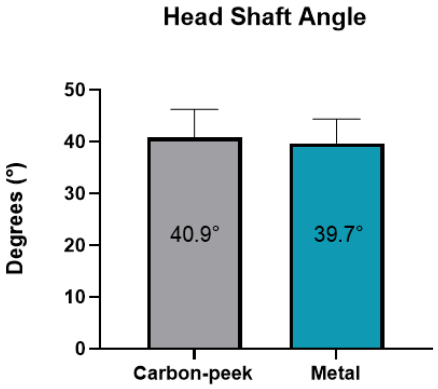

Chart e. Differences in Head-Shaft Angle, assessed with Student's T test

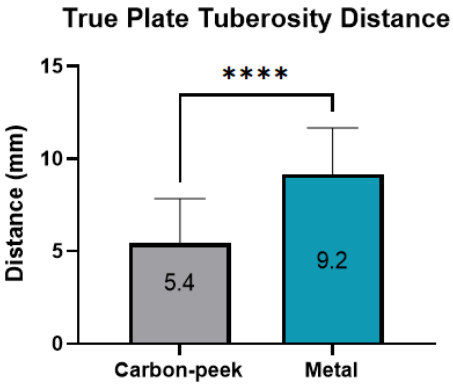

Chart f. Differences in True Plate-Tuberosity Distance assessed with Student's T test (p<0.0001)

Discussion

The main finding of this article is that, due to the CFR-PEEK plate's radiolucency and the radiopaque marker is not precisely on the edge of the plate, there is an increased risk of the hardware being positioned too high. As a result, surgeons must exercise greater caution when positioning the plate. We recommend avoiding freehand placement of the plate and always using the guide or checking the height with a K wire positioned at the upper edge of the plate [Figure 2]. Furthermore, in relation to fracture' reduction, the literature reports both positive aspects of CFR-PEEK plates, such as their radiolucency,[27] and criticisms, particularly regarding their lower malleability,[33] while our results show that CFR-PEEK plates lead to comparable results to traditional plates.

In the surgical treatment of PHF, the anatomic reduction is critical.[35,46,47] Inadequate head position relative to the tuberosities and shaft, particularly in osteopenic bone, can lead to loss of fixation,[47] as reported by Hertel as the "egg-shell method".[48] This concept in clinical practice is confirmed by Mathur et al.,[46] who demonstrated that postoperative radiological parameters for reduction such as NSA, HAS, THD, and NSD, are predictors of the outcome of a PHF treated using a locking plate. In our cohort, fracture reduction, defined as the restoration of proper radiological parameters, appeared to be in line with literature,[35,41–46,49] and without differences between CFR-PEEK and metal devices. Both systems allow the surgeon to achieve an optimal reduction.

Plate positioning in the treatment of PHF is crucial to achieving a good result, in fact a plate misplacement led to several complications such as subacromial impingement, biceps tendon entrapment, and lower strength of the construct with an increased risk of loss of reduction.[15,41] Especially in case of too high plate positioning, as already highlighted, there is a high risk of impingement between the

plate and the acromion during abduction; furthermore it cause a misplacement of the calcar screw, which is one of the key point of the success of the plating of the PHF in case of medial hinge disruption.[15,50] Calcar screw should be located within the medial quarter of the proximal humerus, close to the calcar area.[51,52] Additionally, it is essential to ensure the screw is long enough for its tip to reach the subchondral region.[52] Kimmeyer et al. demonstrated that the calcar screw has to be placed less than 12 mm from the calcar, to avoid loss of reduction, implant failure, and unsatisfactory outcome.[52] On the other hand, even if in our cohort there was the tendency to high positioning of CFR-PEEK plate, we didn't observe an increased risk of unsatisfactory calcar reduction at the end of the surgery. We believe that it was possible due to the polyaxiality of the screws allowed by the implant.[52] This is an advantage to allow the surgeon to place the screw in the best position of the humeral head regarding the biomechanic configuration or the bone density.[53,54]

Rotini et al. reported 18 cases (11.2%) of symptomatic subacromial impingement.[32] This evidence strengthens the validity of our results, as we show an increased risk of high positioning of the CFR-PEEK plate. It is related to the position of the radiopaque marker, so each radiolucent plate from different manufacturers has a different configuration of the marker. On the other hand, considering that most of the complications of the PHF plating require plate removal, it is crucial to use a device that could be removed with minimal effort. In fact, as highlighted by Rotini et al.,[32] the CFR-PEEK plate didn't cause cold fusion of the screws, guaranteeing lower complications during the removal. In our cohort we registered a similar symptomatic subacromial impingement rate (3 out of 32, 9.3%), treated with hardware removal.

The study has some limitations. First, the limited number of cases included; second, only AP projection was evaluated, lastly, as this is a purely radiological study, clinical outcomes were not reported. On the other hand, the study has notable strengths, such as the case-control design, and the fact that all patients were operated on by the same surgeon.

Conclusion

In conclusion, both CFR-PEEK and metal plates enable surgeons to achieve an optimal reduction of PHF. However, when utilizing a radiolucent CFR-PEEK plate, special care should be taken to ensure proper placement and height. This is crucial to avoid complications, such as impingement between the plate and the acromion, which could jeopardize the patient's postoperative recovery and range of motion.

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Authors Contribution: All authors contributed to the study conception and design. The first draft of the manuscript was written by Gregorio Secci and all authors commented on previous versions of the manuscript. Measurements were performed by Giovanni Galardi and Jacopo Corti. Matteo Innocenti contributed to data collection and spreadsheet management. Luigi Zanna performed the statistical analysis. Raffaele Tucci supervised the work. All authors read and approved the final manuscript.

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Declaration of Ethical Approval for Study: The study and follow-up, respecting the criteria of the Declaration of Helsinki, have been approved by Institutional Review Board (IRB) of Azienda Ospedaliera Universitaria Careggi (AOUC) but due to its retrospective design, no Ethical Approval Code was required.

Declaration of Informed Consent: We declare that there is no information in the submitted manuscript that can be used to identify patients.

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