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PEEK radiolucent plate for distal radius fractures: multicentre clinical results at 12 months follow up

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KEYWORDS

PEEK reinforced-carbon fiber composite
CFR-PEEK wrist plate
Radiolucent Plate
Complex distal Radial Fractures
bone elasticity modulus

ABSTRACT

Introduction: Open reduction and internal fixation (ORIF) with plate and screws represents the recommended treatment for unstable intra-articular distal radius fractures. Although significant progresses in surgical technique have been made, anatomical reconstruction of radio-carpal articular surface still represent a difficult task, especially in multifragmentary fractures. Available PEEK reinforced-carbon fiber composite radiolucent devices allow both an easier and more careful assessment of intra-operative reduction of the articular surface of distal radius and prompt correction of any residual step deformity.
Materials and Methods: We retrospectively reviewed clinical and radiological multicentre results of 71 consecutive AO B and C fracture pattern of distal radius treated using the same PEEK reinforced-carbon fiber composite radiolucent plate.
Results: Three patients lost at final follow up and 4 cases with incomplete radiological documentations were excluded from the study. 64 patients (38 females, 26 males) were available and formed the basis of this report. Fracture types included 9 patients with 23-B, 13 patients 23-B2, 15 patients with 23-B3, 10 patients with 23-C1, 7 patients with 23-C2 and 10 patients with 23-C3. Mean Modified Mayo wrist Score was on average 38.11 (SD 10.1; range 24–75, 95%CI 34.7–41.4), 67.22 (SD 9.6, range 50–90, 95%CI 64–70.4), 90.54 (SD 6.3, range 75–100, 95%CI 88.4–92.6) at one, two and twelve months of follow-up, respectively. A statistically significant difference was found between mean scores at different follow-up periods ($p = 0.001$). We noted 1 case of distal screw fixation aseptic loosening at 5 months post surgical intervention.
Conclusions: PEEK reinforced-carbon fiber composite radiolucent plate represents a useful device for treatment of complex distal radius fractures in the adult population. It possesses unique biomechanical properties and allows for an easier anatomical reduction during surgical intervention.

Introduction

Population ageing, increase in osteoporosis incidence and physical activities represent the main reasons for distal radius fractures growing incidence [1]. Undisplaced and stable wrist fracture, represent a fracture pattern commonly addressed with conservative treatment, although loss of reduction in such cases is still possible, especially in elderly patients, even after the early weeks of conservative treatment [2]. Open reduction and internal fixation (ORIF) with plate and screws represents the recommended treatment for unstable intra-articular distal radius fractures. [3,4] Improvements in surgical techniques and research on biomaterials, allowed an increase in surgical treatment of displaced and unstable wrist fractures, offering the possibility of a quicker recovery and return to activities of daily living [5,6].

Volar plating allows to perform a satisfactory surgical treatment in almost every kind of wrist fracture [7] with a low complication rate [6,8] providing an immediate stable fixation and distal radius fragment collapse prevention, even in most severe osteoporotic cases [9].

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Although significant progresses in surgical techniques have been made, the anatomical reconstruction of radio-carpal articular surface still remains a difficult task, especially in multifragmentary fractures [10–14], where conventional plates may sometimes hide mal-alignment, preventing a real anatomical reduction. Nowadays, available radiolucent devices allow to both an easier and more careful assessment of intra-operative reduction of the articular surface of distal radius and a prompt correction of a non anatomical reconstruction. Polyetheretherketon (PEEK) polymer radiolucent devices are proposed for its several advantages like radiolucent property, low artifacts on magnetic resonance imaging (MRI) [15–17] and the possibility to be designed with more appropriate strength, toughness, stiffness [18] or to provide better fatigue resistance [19].

Despite numerous studies documenting the successful clinical performance of PEEK devices in orthopedic, trauma and spinal surgery [16,17,19], there are few reports published in literature about its use in distal radius fixation [20–22]. The aim of this study is to describe our preliminary experience with a new CFR-PEEK volar plate in complex wrist fractures and to discuss advantages and disadvantages of these new biomaterials in wrist surgery.

Materials and methods

We retrospectively recorded clinical and radiological results of 71 consecutive patients treated for distal radius fractures from July 2013 to April 2014 in different Trauma Centers. Inclusion criteria were: patients with displaced distal radius fracture extended to articular line classified as 23-B and 23-C according to Muller's AO classification [4]; ORIF with the same CFR-PEEK volar wrist plate; minimum 12 months of clinical and radiological post-operative follow-up; age between eighteen to ninety years old; trauma to surgery time less than 2 weeks; surgical exposure with Henry's volar access to distal radius; availability of adequate series of radiographs, including at least 1 pre-operative postero anterior (PA) and lateral radiograph (an injury film, post reduction film or both) and 3 post operative PA and lateral radiographs (one taken at the first post-operative follow-up visit, one at 8 weeks after surgery and one at 12 months follow-up). Exclusion criteria were: 23 A distal radius fracture pattern, according to Muller's AO classification; open wrist fractures; previous traumatic and non-traumatic wrist deformities; rheumatoid arthritis, trauma to surgery time more than 2 weeks; bad cognitive and responsive ability to physical therapy; incomplete clinical or radiographic data; incomplete follow-up at 12 months.

All fractures underwent fixation using the Piccolo Composite™ CFR-PEEK radiolucent volar plate (Unimedical Biomedical Technologies, Torino – Italy, Figure 1). Piccolo Composite™ CFR-PEEK volar plate is characterized by a 2,4 mm thickness, polyaxial locking screws, and both standard and narrow designs. A pre-operative wrist half-cast was made to prevent pain, further fracture dislocation and to protect the median nerve. Common recommendations were explained to patients to prevent edema and thrombosis. When necessary, due to complex distal radius fracture pattern, a CT examination was performed to aid surgeon in pre operative planning. Informed consent was obtained from all patients. Regional anesthesia with axillary plexus block using peripheral nerve stimulator was performed for all patients of our series. Surgical interventions were performed at each Department by an experienced orthopedic hand surgeon. Plates used had 3 or 4 holes. Distal row of the plate was filled entirely or one

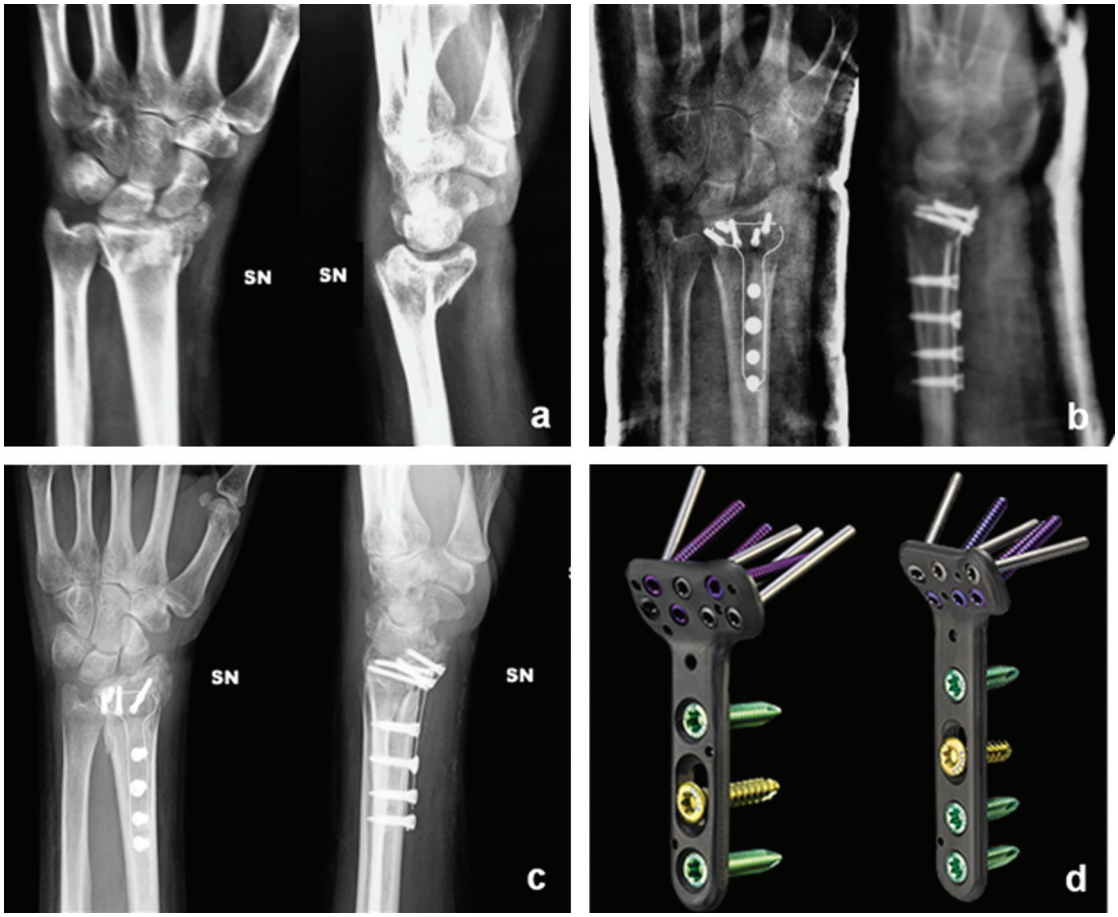

Fig. 1. (a) Pre operative fracture pattern AO 23-B3 of a left distal radius in a 51 years old woman; (b) Immediate post operative RX examination with wrist splint; (c) 1 months post operative follow up: Rx examination in standard projection showing callus formation. (d) Piccolo Composite™ distal radius plate: on the left standard plate; on the right narrow version of volar wrist plate.

hole was left empty. All patients were discharged the day after the surgical intervention except in eight patients because of wrist edema and pain. A post-operative half-cast splint was recommended for 12–14 days. The first clinical and radiographic evaluation with AP and lateral view was performed in the 15th day after surgical intervention; the half-cast was removed and patients begun assisted physiotherapy. Subsequent follow up visits were scheduled at 1, 2 and 12 months after surgical intervention.

Primary efficacy outcome was the progression of the fracture to osseous healing. Secondary efficacy outcomes were the improvements of wrist function based on Modified Mayo Wrist Score [23]. Safety outcome was no loss of radiological reduction at any follow-up control.

Statistics

The Lilliefors (Kolmogorov–Smirnov) normality test was performed for all the assessed variables. Mean, 95% confidence intervals (CI) and standard deviation (SD) were computed for all measurement sets. Paired t-tests were performed to test differences between means at different time endpoint within subjects.

The reliability of wrist fracture classification using the AO classification system between the four different orthopaedic hand surgeons performing surgical interventions was tested (inter-observer reliability) using the intraclass correlation coefficient (ICC). A test–retest was conducted for intra-observer variability 4 weeks after the first assessment. The Kaplan-Meier product limit estimates of implant survival at 12 months was calculated in our patient cohort. The level of significance was set at 0.05 for all tests. SPSS for Windows (version 17.0, SPSS, Chicago, IL) was used for the statistical analysis.

Results

We retrospectively identified 71 patients who underwent CFR-PEEK radiolucent volar plate fixation; 3 patients lost at final follow up and 4 cases with incomplete radiological documentations were excluded from the study. Overall 64 patients formed the basis of this study (38 females, 26 males). Mean age was 56.8 years (min 23-max 84). The mechanisms of injury were: 42 falls on hands, 9 sport injuries and 13 road accidents. Fracture types included 9 patients 23-B1, 13 patients 23-B2, 15 patients 23-B3, 10 patients with 23-C1, 7 patients with 23-C2 and 10 patients with 23-C3. A computer tomography (CT) examination was performed in 4 cases of 23-B1, in 5 cases of 23-B2, in 4 cases of 23-B3 and in all cases of C-type fractures.

Trauma to surgery time was on average 2.41 days (SD 1.64; range, 0–7; 95%CI 1.86–2.95). The mean surgical time was 47.7 ± 3.4 min. No intra-operative complications were recorded.

Mean Modified Mayo wrist Score was on average 38.11 (SD 10.1; range 24–75; 95%CI 34.7–41.4), 67.22 (SD 9.6; range 50–90; 95%CI 64–70.4), 90.54 (SD 6.3; range 75–100; 95%CI 88.4–92.6) at one, two and twelve months of follow-up, respectively (Table 1). A significant difference ($p = 0.001$) was found between mean scores of Modified Mayo Wrist Score at one, two and twelve months of follow up (Figure 2). The inter and intra-observer reliability in classification of distal radius fractures according to AO classification was, on average, 0.88 (95%CI, 0.84–0.93) and 0.94 (95%CI, 0.90–0.97) respectively. The overall implant survivorship at 12-months follow-up was 98.59%, according to Kaplan-Meier estimator analysis.

Table 1
Modified Mayo Wrist Score for specific fracture pattern at different follow up time.

AO fracture pattern	Number of cases	Age (mean)	1 months (mean)	2 months (mean)	12 months (mean)
B1	9	59.6	31.6	63.3	95.3
B2	13	52.3	40.7	66.8	90.8
B3	15	56	39.3	68.5	90.25
C1	10	52.25	34.87	69	91.12
C2	7	69	36.3	57	88.3
C3	10	52	41	71.6	88
TOT	**64**	**56.8**	**38.11**	**67.22**	**90.54**

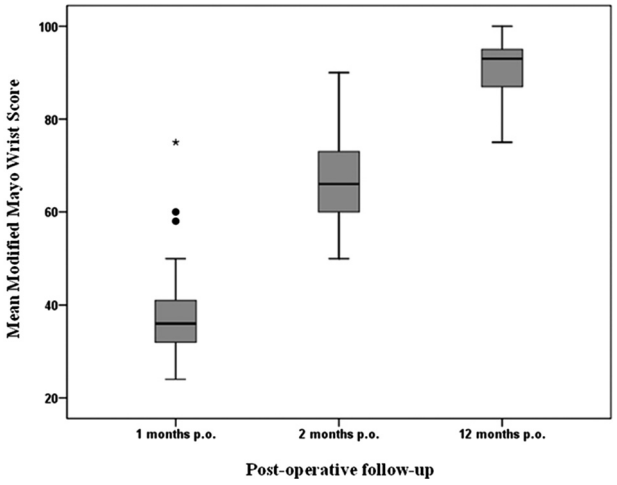

Fig. 2. Box plots indicate mean Modified Mayo Wrist Score at 1, 2, and 12 months follow-up post surgery. A significant statistical difference was found between mean score values at different follow-up times. The p value is 0.001.

One case of aseptic loosening of a plate screw was observed in a heavy hand worker and this led to plate removal after 5 months from primary surgical intervention (Figure 3). No further hardware failures were observed. All fractures healed without problems, with an average of 5.8 weeks (range 4.8–7.8 weeks) and patients in working age fully returned to their previous employments without significant limitations. No patient complaints due to hardware prominence or wrist pain were recorded. We had no cases of flexor longus pollicis rupture, secondary displacement of synthesis, malunion, non-union or superficial/deep infections at surgical site.

Discussion

Fixation and outcomes related to distal radius fractures continues to be a topic of great interest to clinicians [24–29].

On the light of recent availability of radiolucent devices for wrist fracture fixation, we retrospectively reviewed clinical and radiological multicentre results of 71 consecutive AO B and C fracture patterns of distal radius treated using the same radiolucent plate.

CFR-PEEK implants, though not new in orthopedic surgery, are recently gaining more attention in literature, as highlighted by more clinical articles describing routinely experience with such implants especially in trauma surgery theatre [20,21]. The reason for this trend, lies on the increased availability of implant design options for fracture patterns in different anatomical districts, and especially on encouraging laboratory data on the biomechanical properties of these implants [30–36]. CFR-PEEK implants have shown excellent biocompatibility with minimal cellular elicitation response when studied both in vitro and in vivo due to the very low debris release when compared to titanium [31,34,36–37] and superior results in biomechanical analysis for both bending and fatigue stress compared to traditional titanium and other metal devices [31–32,35]. Composite plates present an elasticity modulus closer to that of bone, when compared to titanium [31], so modulus mismatch related problems between bone and plate, causing stress shielding and bone resorption, are avoided [31]. This possibility is offered by the unique characteristic of composite implants to be engineered to have a varying degree of strength and stiffness on the base of orientation and number of carbon fiber layers to better match the modulus of elasticity of bone [31,33–35]. Clinical advantages are: an easier implant/plate removal because of absence of cold-welding phenomenon and corrosion; the possibility

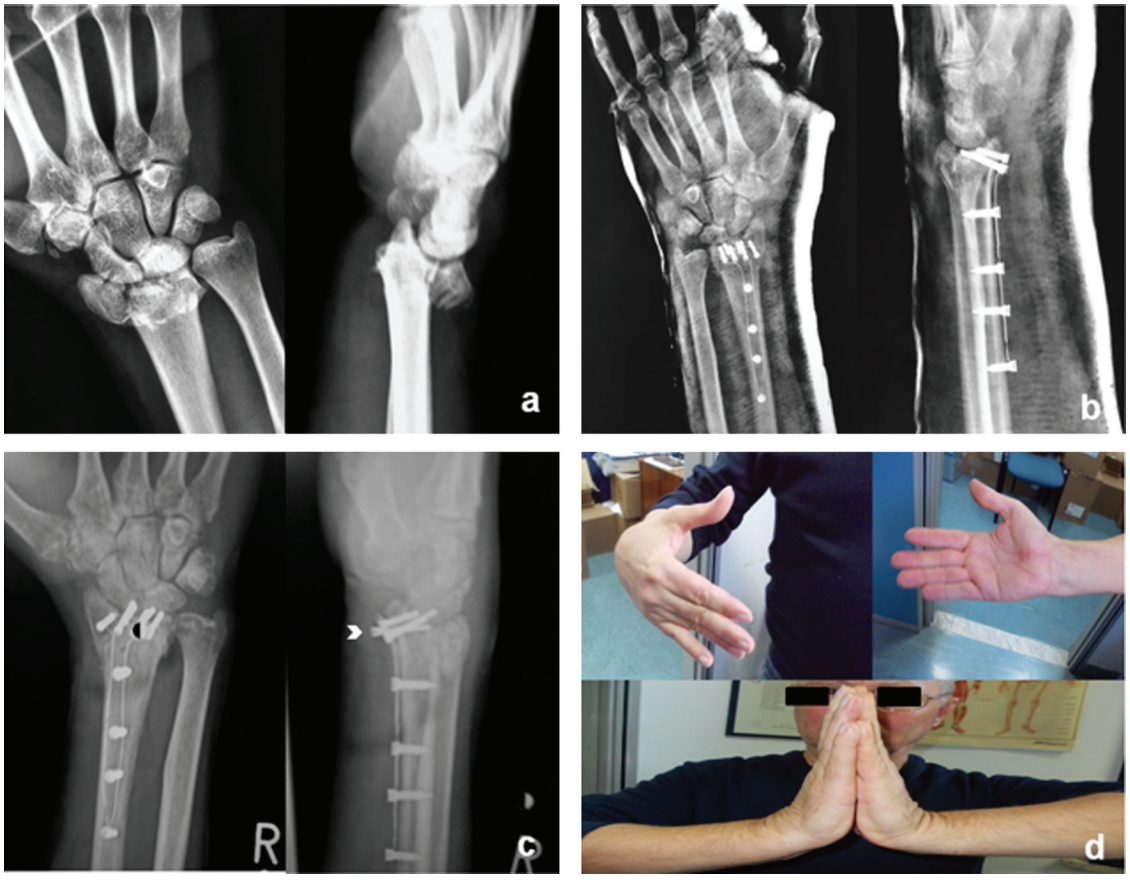

Fig. 3. (a) Pre operative fracture pattern AO 23-C2 of a right distal radius in a 57 years old heavy hand worker; (b) Immediate post operative RX examination with wrist splint; (c) Aseptical loosening of a distal fixation locking compression screw at 5 months post surgical intervention: arrowhead indicates screw loosening; (d) 12 months clinical follow up, 7 months after wrist plate removal, shows satisfactory articular range of movement.

to assess intra operative reduction with fluoroscopy, allowing the surgeon to perform on going corrections of fragments' position during open reduction and fixation. Moreover, radio-transparency allows for easier assessment of bone healing and detection of late union or non union, fragment dislocation or malunion during follow-up [20–22]. The absence of artifacts on both computed tomography (CT) and magnetic resonance imaging (MRI) has applications for assessment of infectious processes or unexplained wrist pain after surgery.

Biomechanical and design characteristics of Piccolo Composite™ CFR-PEEK radiolucent volar plate were previously assessed by several studies in literature [30–31]. The low profile of Piccolo™ CFR-PEEK reinforced wrist plate and the minor radial extension where watershed lies more proximal [8], avoids flexor pollicis longus tendon irritation or rupture (3% of cases), [8,38].

Our 12 months follow up results reported in the present study are in line with that reported in literature for clinical and radiological outcomes when considering traditional metal implants [37,39–41] and other carbon fiber PEEK reinforced implants commercially available [20]. We observed no cases of secondary disruption, fracture reduction loss or fatigue implant failure. No patient asked for plate removal during the follow up period and no allergic cases were reported. Wrist range of movement was restored to a satisfactory functional level as reported by the Modified Mayo Wrist Score. We had one case of aseptic screw loosening in a manual heavy worker, incidentally found at follow-up without symptoms. A preventive plate removal at 5 months from primary surgical intervention was performed after assessing complete bone healing. No difficulties were encountered in plate removal. There were no complications after plate removal and a satisfactory clinical and radiological result was achieved. No disadvantages to PEEK plate fixation were observed. To our knowledge, this is the largest case series of radiolucent CFR-PEEK reinforced wrist plates reported in literature, with minimum 12 months follow up. Besides, this is, to our knowledge, the first time a case of aseptic screw loosening in a CFR-PEEK reinforced wrist plate is reported in literature. We are not sure if the aseptic loosening was a consequence of patient's behavior (patient's independent decision to early remove post operative casts and coming back to manual heavy work against medical prescription) or of a technical error in screw locking.

Our study has several limitations. First of all its retrospective nature. Furthermore, we only used one evaluation tool, the Modified Mayo Wrist Score, to assess functional results of surgical interventions; in our clinical evaluation we didn't use questionnaires assessing patient's global health and mental status. Another limitation is the inclusion of patients with a follow-up limited to 12 months, due to the need to align clinical follow-up of different Trauma Departments that began using the Piccolo Composite™ CFR-PEEK reinforced wrist plate in different periods. Clinical advantages towards titanium plate, due to radio-transparency of PEEK plates need to be confirmed by case control studies.

Our preliminary experience with Piccolo Composite™ CFR-PEEK reinforced wrist plates is satisfactory when considering clinical and radiological results at a minimum of 12-months follow-up. The presence of radiopaque tantalum marker was, in our experience, useful to decide plate positioning during surgical intervention and to assess potential plate position migration during follow-up. Besides, in addition to material unique biomechanical characteristics, the presence of additional plate screw holes (7 holes) in respect to other

commercially available plates (4 holes) allowed to gain a more stable fixation when surgically needed. The narrow proximal design allows to better fit radius in smaller bone epiphysis cases, avoiding overhang complications. The plate anatomical design and the presence of poly axial locking screw orientation made it a suitable device for treatment both in older and young patients and for complex wrist fracture pattern. Further studies with larger case series and longer follow-up may be useful to increase clinical experience with such device.

Conflict of interest

The authors declare no conflict of interest.

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