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Clinical and radiographic outcomes of distal radius fracture treatment with Carbon-Fiber-Reinforced-Polymer Volar Plates (CFR-PEEK): analysis of 40 cases

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Summary

Introduction. To optimize fracture healing, Carbon- Fiber-Reinforced-Polyetheretherketon Polymer (CFR-PEED) implants have been developed as an alternative to metal plating. Material-specific advantages include X-ray radiolucency, better bone-like elastic modulus, lower bending stiffness and avoidance of the "cold welding" phenomenon.
The purpose of this study was to evaluate the clinical and radiographic results after distal radius fracture fixation with Carbon-Fiber-Reinforced-Polymer Volar Plates at 12 months follow-up.
Materials and methods. We included 40 patients with AO type 23-B and 23-C radius fractures who were treated with CFR-PEEK volar plate fixation. Clinical and radiographical evaluation were scheduled up to 12 months after surgery.
Results. At 12-month follow-up no adverse events were reported. All fractures had healed, and radiographic union was observed at 3 months. The final Quick-DASH average score diminished of 75% and the active ROM almost doubled.
Discussion. The X-ray transparency of the device allows easier and truthful intra-operative assessment of the articular surface and facilitates its anatomical reduction, which is harder to achieve with standard metal plates, improving the functional recovery of the wrist.
Conclusions. Anatomical design, radiolucency and the presence of polyaxial locking screws orientation make the CFR-PEEK volar plate a suitable device for the treatment of both old and young patients, with simple and complex wrist fracture patterns.

Key words: radius, wrist, fracture, plate, PEEK, carbon-fibre, radiolucent

Introduction

The ORIF (Open Reduction and Internal Fixation) technique has become the primary surgical treatment for displaced and unstable wrist fractures, permitting quick recovery and return to everyday activities.
Volar plating combined with locking-screw technology allows managing complex periarticular distal radius fractures with a low complication rate, providing

an immediate stable fixation and preventing distal radius articular surface collapse even in the most severe osteoporotic cases through direct support of subchondral bone with distal screws [1-3].

Along the years, these internal fixation devices have been constructed with different materials, from metal to stainless steel to titanium alloys, but in the last decade a polymer reinforced with radiolucent carbon fibers has been introduced, namely Carbon- Fiber-Reinforced-Polyetheretherketon (CFR-PEEK) [4,5].

CFR-PEEK radiolucent Volar Plates provide several advantages over the use of conventional orthopedic materials, such as radiolucency, low artifacts on magnetic resonance imaging (MRI) and the possibility to be designed with appropriate strength and stiffness or to provide better fatigue resistance [6].

The aim of this study is to describe our preliminary experience with CFR-PEEK volar plates in simple and complex wrist fractures, by analyzing the reliability and functionality of the new system and discussing the advantages and disadvantages of these new biomaterials in wrist surgery.

Materials and methods

We performed a retrospective study by recording clinical and radiological results of 40 patients treated for unstable distal radius fractures from January 2019 to November 2020 at the Orthopedics and Traumatology Unit of "Moscati" Hospital in Aversa (CE). We included all consecutive displaced distal radius fractures that extended to the articular surface and classified as 23-A2, 23-A3, 23-B and 23-C according to Muller's AO classification [7]. Exclusion criteria were: 23-A1 and stable 23-A2 fractures, since they were treated non-surgically, open wrist fractures, previous traumatic and non-traumatic wrist deformities, rheumatoid arthritis, surgeries performed more than 2 weeks after trauma, carpal instability requiring additional implants (wires or screws), patients with genetic disorders affecting the musculoskeletal system, oncological patients and cognitive impairment affecting the appropriate compliance to physical therapy

All the patients underwent surgical fixation, within 2 weeks from the original trauma, using CFR-PEEK radiolucent volar plates (Unimedical Biomedical Technologies, Turin – Italy). The CFR-PEEK volar plate is characterized by a 2.4 mm thickness, polyaxial locking screws and both standard and triangular designs.

Common recommendations were explained to patients to prevent edema and thrombosis and informed consent was collected. When necessary, due to complex distal radius fracture patterns, a CT scan was performed to aid the surgeon in pre-operative planning. Surgery was undertaken under regional anesthesia with axillary plexus block. The surgical procedure was performed by an experienced orthopedic hand surgeon, constantly choosing Henry's modified volar approach to the distal radius. The plate was placed directly on the radius after obtaining reduction of the fracture, and the adequate positioning of plate and screws was confirmed by intra-operative fluoroscopy. A below-elbow wrist splint was used for 1 week in all cases. All patients were discharged one or two days after surgery. The first clinical and radiographic evaluation with AP and lateral view was performed at one week after surgery. Patients then started a rehabilitation protocol, and the cast was replaced with a removable wrist splint to be kept for 4 weeks in total [8,9] (Fig. 1).

Subsequent follow-up visits were scheduled at 1, 3, 6 and 12 months after surgery and were performed exclusively by the treating surgeons. Clinical examination included the recording of the Range of motion (ROM), pain and grip strength. Radi-

Figure 1. A) Pre-operative fracture pattern AO 23-A2.2 of left distal radius in a 47 yo woman; B) 1 week post-operative X-ray examination in standard projection, with wrist splint, showing stable fixation.

ographic evaluation was obtained by standard postero-anterior and lateral projections for fracture pattern, assessing the reduction of the bone cortices, restoration of the volar tilt and radial length (Figs. 2-3).

The primary endpoint was the progression of the fracture healing, assessing the disappearance of the fracture edges in at least three of the four cortices by formation of bridging callus or remodeled bridging callus, according to the Litrenta scoring system [10,11]. Secondary endpoints were the improvement of wrist function, based on clinical parameters such as the Visual Analogue Scale (VAS) for pain, Active Range of Motion, Grip strength evaluated using a Jamar Hand Dynamometer and Quick-Disabilities of the Arm, Shoulder and Hand Score (Quick-DASH). Safety outcome was the absence of secondary displacement seen on X-rays at any time during the follow-up [12-14].

Figure 2. A) Pre-operative fracture pattern AO 23-C1 of right distal radius in a 71 yo woman; B) 1 month post-operative X-ray examination in standard projection, showing stable fixation and initial bone healing.

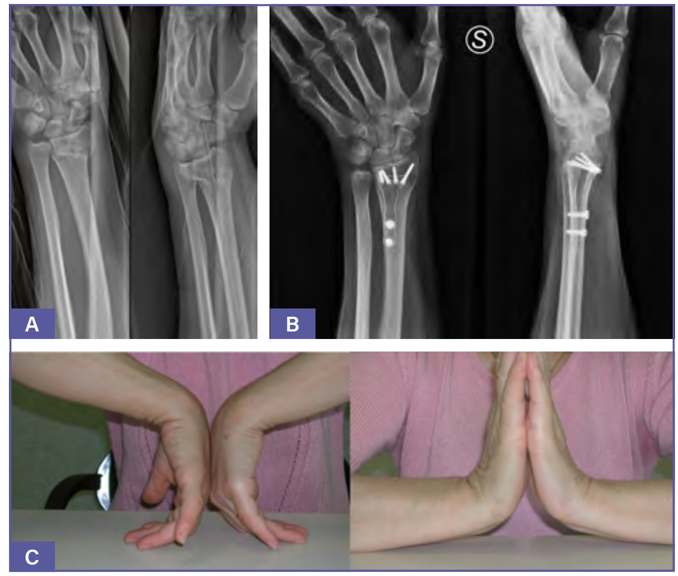

Figure 3. A) Pre-operative fracture pattern AO 23-A2.2 distal radius fracture in a 54 yo woman; B) 12 months post-operative X-ray in standard projection, showing fracture complete fracture healing; C) AROM evaluation at 12 months follow-up.

VAS, AROM in flexion-extension, Grip (Jamar) and DASH-score scales were evaluated: the 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 level of significance was set at 0.01 for all tests. STATA for Windows data processing was used for the statistical analysis.

Results

There were 18 men and 22 women, with an average age of 62 years at the time of injury (range 45-83) in the cohort. Radiographic progressive healing of fractures was confirmed at 1 month after surgery and was complete at 3 months post-operatively in all patients in our cohort. At 6 and 12 months there was no loss of reduction and no implant loosening or failure. No adverse events (secondary displacement, malunion, non-union or superficial/deep infections at surgical site) were reported.

Mean VAS was on average 6.67 ± 2.0 and 1.62 ± 0.74 at the first week and at 12 months of follow-up, respectively, and a significant difference ($p < 0.01$) was found between mean scores (Tab. I). A significant difference was found between mean Quick-Dash scores, with a mean of 49.17 ± 12.6 and 28.14 ± 9.68 at first post-operative week and 12 months. This

Table I. Comparison of functional parameters at 1° week and 12° month post-operative.

	1° week			12° month			
	Mean ± SD°	Range	95% CI°°	Mean ± SD	Range	95% CI	P-value**
Pain (VAS*)	6.67 ± 2.0	4-10	6.03-7.31	1.62 ± 0.74	1-3	1.38-1.86	< 0.01
QUICK DASH** score	49.17 ± 12.6	25-70	45.1-53.22	28.14 ± 9.68	15-45	25.04-31.23	< 0.01
Wrist joint extension (degree)	26.0 ± 7.52	10-40	23.59-28.4	58.72 ± 6.39	40-70	56.68-60.76	< 0.01
Wrist joint flexion (degree)	31.62 ± 9.22	20-50	28.67-34.57	62.57 ± 0.94	55-70	60.67-64.47	< 0.01
Grip strenght (Jamar scale)	12.8 ± 4.7	8-23	11.29-14.3	21.72 ± 5.37	12-30	20-23.44	< 0.01

SD°: standard deviation; CI°°: Confidence Interval VAS*: Visual Analogue Scale for pain; DASH**: Disability of the Arm, Shoulder and Hand

indicated that both pain and functional limitation decreased within 12 months.

Mean Flexion and Extension were, after the first week, were 31.62 ± 9.22 and 26 ± 7.52, respectively, and at 12 months were 62.57 ± 0.94 and 58.72 ± 6.39. Paired T-Student showed a statistically significant increase ($p < 0.01$) at 12 months, similar to Grip Strength (Jamar), with a mean of 12.8 ± 4.7 and 21.72 ± 5.37 at the first week and after 12 months of follow-up, respectively.

All the analyzed variables demonstrated significant validity ($p < 0.01$) in terms of wrist and hand motion and functional recovery without major personal and work disabilities.

All patients in working age fully returned to their previous employment without significant limitations; wrist range of movement was restored to a satisfactory functional level as reported by the ROM Score and Quick-DASH Score. No patient complaints due to hardware prominence or wrist pain were recorded. None of the patients asked for removal of the plate during follow-up and no allergic reactions were reported.

Discussion

Our results at 12 months are largely in line with those reported in literature concerning clinical and radiological outcomes using traditional metal implants and other carbon fiber PEEK reinforced implants. Carbon fiber material is radiolucent on X-ray. This provides a suitable direct intra-operative assessment of the fracture throughout the surgical procedure and good visualization of the fracture site on follow-up X-ray, allowing better radiological surveillance of healing. Furthermore, the implant does not interfere with MRI and CT of the soft tissues.

CFR-PEEK is an inert material, with a low incidence of tissue reaction and need for hardware removal, and suitable to use for patients who are allergic to nickel and heavy metals.

CFR-PEEK might better mimic the mechanical properties of bone, allowing osteogenesis. Even though it is stronger than steel, it is less rigid and has a more suitable modulus of elasticity, permitting micro-movements of bone, which improve fracture healing. These plates provide a unique combination of biomechanical characteristics with bone-like elastic modulus, high strength, and superior fatigue strength [15-20].

CFR-PEEK implants have shown excellent biocompatibility with a minimal cellular elicitation response both in vitro and in vivo. Compared to titanium and other metal devices, they have a low rate of debris release, and show superior results in biomechanical analysis for both bending and fatigue stress. Composite plates present an elasticity modulus closer to that of bone, and therefore modulus mismatch related problems between bone and plate, which cause stress shielding and bone resorption, are avoided. This possibility is offered by the unique characteristic of composite implants of being engineered such as to have a varying degree of strength and stiffness on the base of the orientation and number of carbon fiber layers to better match the modulus of elasticity of the bone.

The carbon fiber implants do not cause cold-related pain and do not trigger inflammatory reactions, and are free of the metal-metal cold fusion phenomena risk.

Among all fixation devices, CFR-PEEK radiolucent volar plates represent a valid tool in the surgical management of distal radius fractures, benefiting from the above mentioned advantages. Radiolucency allows easier and truthful intra-operative assessment of the articular surface reduction and prompt correction of a non-anatomical reconstruction, which would be difficult to achieve with a standard metal plate, unless with the aid of an arthroscope. A cortex-similar modulus of elasticity promotes the bone healing process. A low rate of artifacts are also present in wrist MRI and CT, which allows secondary investigations in the suspect of carpal ligament lesions, tendon injuries or infectious processes, and responsible for unexplained wrist pain [21-26].

The disadvantages are comparable to those of all internal wrist fixation devices, with the addition of a lower tolerance to plastic deformity, affecting the risk of intra-operative implant rupture (an event that did not occur in the sample under examination) [27]. The overall costs for the implant are around € 1300 compared to slightly lower average costs of metal plates available on the market, although they are covered by the national health system in Italy.

In case of multi-fragmentary volar rim articular fractures, due to the conformation of the device, it is nearly impossible to sufficiently control the key-fragments, unlike other devices that are currently on the market. It would be desirable that the manufacturing company develops new models that are suitable for the management of these complex fractures.

In our opinion, wrist and hand functional scores achieved in the sample under examination primarily depended on the easy anatomical reduction of even complex distal radius fractures. By exploiting the radiolucency of the plate, it was possible to promptly correct any interfragmentary step-off more easily than with common titanium alloy plates.

This study has several limitations. First, its retrospective nature. We did not use questionnaires assessing patient's global health and could not ascertain the quality of the physiotherapy path followed by the patients, because of the lack of a rehabilitation unit in our orthopedics department. Another limitation is the inclusion of patients with a follow-up limited to 12 months. The difficulty in recruiting patients over 12 months after treatment was due to the organizational difficulties encountered during the midst of the COVID-19 pandemic.

Conclusions

The results of the present study may provide useful information for physicians when choosing among different plate materials for the treatment of distal radius fractures. CFR-PEEK yields material-specific advantages, including X-ray radiolucency, better bone-like elastic modulus that improves fracture healing, lower bending stiffness and the avoidance of the "cold welding" phenomenon. However, the major disadvantage of this plate is represented by the scarce tolerance to plastic strain, with the risk of implant breakage.

The plate anatomical design and the presence of poly axial locking screws orientation makes it a suitable device for treatment complex wrist fracture patterns, in both elderly and young patients.

Future studies are required to fully understand the pros and cons of carbon fiber radius volar plates. It would be useful to evaluate and compare the biomechanical properties, including volar/dorsal bending and torsional loadings of different plate materials (stainless steel, titanium alloys) used for fixation of distal radius fractures.

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Conflict of interest statement

The Authors declare no conflict of interest.

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Authors' contributions

MP (first author) mainly wrote this manuscript and performed the acquisition, analysis and interpretation of data.

AVC, AC, GP and AP (corresponding authors) mainly performed the conception and design of this study. All Authors read and approved the final manuscript.

Ethical consideration

The research was conducted ethically, with all study procedures being performed in accordance with the requirements of the World Medical Association's Declaration of Helsinki. Written informed consent was obtained from each patient for study participation and data publication.

References

1 Fok MW, Klausmeyer MA, Fernandez DL, et al. Volar plate fixation of intra-articular distal radius fractures: a retrospective study. J Wrist Surg 2013;2:247-254. https://doi.org/10.1055/s-0033-1350086

2 Orbay J. Volar plate fixation of distal radius fractures. Hand Clin 2005;21:347-354. https://doi.org/10.1016/j.hcl.2005.02.003

3 Soong M, van Leerdam R, Guitton TG, et al. Fracture of the distal radius: risk factors for complications after locked volar plate fixation. J Hand Surg Am 2011;36:3-9. https://doi.org/10.1016/j.jhsa.2010.09.033

4 Allemann F, Halvachizadeh S, Rauer T, et al. Clinical outcomes after carbon-plate osteosynthesis in patients with distal radius

fractures. Patient Saf Surg 2019;13:30. https://doi.org/10.1186/s13037-019-0210-8
5 Tarallo L, Mugnai R, Adani R, et al. A new volar plate made of carbon-fiber-reinforced polyetheretherketon for distal radius fracture: analysis of 40 cases. J Orthop Traumatol 2014;15:277-283. https://doi.org/10.1007/s10195-014-0311-1
6 Petersen R. Carbon Fiber Biocompatibility for implants. Fibers (Basel) 2016;4:1. https://doi.org/10.3390/fib4010001
7 Ruedi T, Buckley R, Moran C. AO principles of fracture management. 3rd Eds. New York: Thieme 2018.
8 Ruckenstuhl P, Bernhardt GA, Sadoghi P, et al. Quality of life after volar locked plating: a 10-year follow-up study of patients with intra-articular distal radius fractures. BMC Musculoskelet Disord 2014;15:250. https://doi.org/10.1186/1471-2474-15-250
9 Giannotti S, Alfieri P, Magistrelli L, et al. Volar fixation of distal radial fracture using compression plate: clinical and radiographic evaluation of 20 patients. Musculoskelet Surg 2013;97:61-5. https://doi.org/10.1007/s12306-012-0238-8
10 Litrenta J, Tornetta P, Mehta S, et al. Determination of radiographic healing: an assessment of consistency using RUST and modified RUST in metadiaphyseal fractures. Orthop Trauma 2015;29:516-520. https://doi.org/10.1097/BOT.0000000000000390
11 Goldhahn J, Mitlak B, Aspenberg P, et al. Critical issues in translational and clinical research for the study of new technologies to enhance bone repair. J Bone Joint Surg Am 2008;90(Suppl 1):43-47. https://doi.org/10.2106/JBJS.G.01090
12 Bohannon RW, Peolsson A, Massy-Westropp N, et al. Reference values for adult grip strength measured with Jamar dynamometer: a descriptive meta-analysis. Physiotherapy 2006;92:11-15.
13 Delheimer S, Focht D, Schapmire D, et al. Simultaneous bilateral testing: validation of a new protocol to detect insincere effort during grip and pinch strenght testing. J Hand Therapy 2002;15:242-250.
14 Phadnis J, Trompeter A, Gallagher K, et al. Mid-term functional outcome after the internal fixation of distal radius fractures. J Orthop Surg Res 2012;7:4. https://doi.org/10.1186/1749-799X-7-4
15 Kurtz S, Devine J. PEEK biomaterials in trauma, orthopedic, and spinal implants. Biomaterials 2007;28:4845-4869. https://doi.org/10.1016/j.biomaterials.2007.07.013
16 Fujihara K, Huang Z-M, Ramakrishna S, et al. Feasibility of knitted carbon/PEEK composites for orthopedic bone plates. Biomaterials 2004;25:3877-3885. https://doi.org/10.1016/j.biomaterials.2003.10.050
17 Steinberg EL, Rath E, Shlaifer A, et al. Carbon fiber reinforced PEEK Optima – a composite material biomechanical properties and wear/debris characteristics of CF-PEEK composites for orthopedic trauma implants. J Mech Behav Biomed Mater 2013;17:221-228. https://doi.org/10.1016/j.jmbbm.2012.09.013
18 Li CS, Vannabouathong C, Sprague S, et al. The use of Carbon-Fiber-Reinforced (CFR) PEEK material in orthopedic implants: a systematic review. Clin Med Insights Arthritis Musculoskelet Disord 2015;8:33-45. https://doi.org/10.4137/CMAMD.S20354
19 Hak DJ, Mauffrey C, Seligson D, et al. Use of carbon-fiber-reinforced composite implants in orthopedic surgery. Orthopedics 2014;37:825-830. https://doi.org/10.3928/01477447-20141124-05
20 Behrendt P, Kruse E, Kluter T, et al. Fixed angle carbon fiber reinforced polymer composite plate for treatment of distal radius fractures: pilot study on clinical applications. FitAllemann Unfallchirurg 2017;120:139-146. https://doi.org/10.1007/s00113-015-0088-6
21 Mugnai R, Tarallo L, Capra F, et al. Biomechanical comparison between stainless steel, titanium and carbon-fiber reinforced polyetheretherketone volar locking plates for distal radius fractures. Orthop Traumatol Surg Res 2018;104:877-882. https://doi.org/10.1016/j.otsr.2018.05.002
22 Morrow T. Material gain: CarboFix's carbon fiber hardware better than metal implants. Manag Care 2016;25:34-35.
23 De Jong JJ, Lataster A, van Rietbergen B, et al. Distal radius plate of CFR-PEEK has minimal effect compared to titanium plates on bone parameters in high-resolution peripheral quantitative computed tomography: a pilot study. BMC Med Imaging 2017;17:18. https://doi.org/10.1186/s12880-017-0190-z
24 Osada D, Fujita S, Tamai K, et al. Biomechanics in uniaxial compression of three distal radius volar plates. J Hand Surg Am 2004;29:446-451. https://doi.org/10.1016/j.jhsa.2003.12.010
25 Perugia D, Guzzini M, Mazza D, et al. Comparison between Carbon-Peek volar locking plates and titanium volar locking plates in the treatment of distal radius fractures. Injury 2017;48(Suppl 3):S24-S29. https://doi.org/10.1016/S0020-1383(17)30653-8
26 Di Maggio B, Sessa P, Mantelli P, et al. PEEK radiolucent plate for distal radius fractures: multicentre clinical results at 12 months follow up. Injury 2017;48(Suppl 3):S34-S38. https://doi.org/10.1016/S0020-1383(17)30655-1
27 Tarallo L, Giorgini A, Novi M, et al. Volar PEEK plate for distal radius fracture: analysis of adverse events. Eur J Orthop Surg Traumatol 2020;30:1293-1298. https://doi.org/10.1007/s00590-020-02701-7