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Original article

Preliminary experience with triangular CarboFix "Piccolo" Distal Radius Plate in wrist fractures. Clinical and radiological results

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Summary. *Background and aim o the work:* In the recent last years there was a diffusion of new radiolucent plates for the treatment of distal radius fractures. The aim of our study is to evaluate the clinical and radiological outcomes at 12-month-follow-up for the treatment of distal radius fracture with the new triangular CarboFix "Piccolo" Distal Radius Plate. *Methods:* All consecutive patients aged from 18 or over, who were treated for unstable distal radius fracture with a volar CarboFix "Piccolo" Distal Radius Plate with triangular design between September 2015 and May 2016, have been included in the study. From the original 28 patients, 6 patients were lost to the follow up or did not meet the inclusion criteria and 22 were available for the study. The 22 patients were prospectively reviewed with dynamometric, radiographic and clinical evaluations (ROM, VAS, Quick DASH). *Results:* The mean follow-up was 15.7 months. All fractures healed, and radiographic union was observed at an average of 5 weeks. All patients have recovery of R.O.M. comparable to the contralateral at the final follow up; with no significant difference ($p>0.05$) as regards extension, flexion, ulnar deviation, radial deviation, supination and pronation comparing to the unaffected arm. At final follow-up, no patients had a statistically significant difference ($p>0.05$) of grip strength, comparing to the contralateral side. The mean Quick DASH was 9.3 and the mean VAS score was 2.3. *Conclusion:* The most important finding of the present study was that the triangular CarboFix "Piccolo" Distal Radius Plate showed good clinical and radiological results in the treatment of distal radial fractures. These results are comparable to those achieved with conventional plates. (www.actabiomedica.it)

Key words: distal radius fractures, carbon-PEEK, fixation devices

Introduction

Fracture of the distal radius and ulna is the most common fracture encountered by orthopaedic trauma surgeons accounting for 17.5% of all adult fractures with around 120,000 fractures per year in the United Kingdom and 607,000 annually in the United States (1, 2).

It would seem therefore that the incidence of fractures of the distal radius is increasing in men and older women but remains more common in older women (2).

Open reduction and internal fixation with plating is the leading technique for stabilizing fractures of the distal radius. Plating was first popularized for volar displaced distal radial fractures by Ellis in 1965 with a plate which was placed on the volar surface of the radius and acted as a buttress to prevent volar displacement of the distal fragment (3)

Volar locking plates were then introduced to stabilize dorsally displaced fractures. As fixed angle devices, theoretically volar locked plates provide sufficient stability to the dorsally displaced distal fragments (4).

In the few last years some authors described the use of radiolucent plate in the treatment of distal radial fractures surgically treated (5, 6).

These plates are made of 70% of longitudinal and diagonal continuous carbon fibre-reinforced with 30% of polyetheretherketone (CFR - PEEK) (7). This material gives to the osteosynthesis device a radiolucent X-ray property, associated with no artefacts during CT and MRI scans, that enables good visibility through the plate during surgery and follow-up (8). This Composite Material mimics the cortical bone's Modulus of Elasticity (9) with good mechanical properties. As well there are no cold welding events with titanium screws.

Moreover, from their introduction, new designs of carbon plates were introduced to better comply the anatomical reduction and stable fixation and to reduce the hardware complications that represent the majority of complications, ranging from 5.9% to 48% (10-12).

The aim of our study is to evaluate the clinical and radiological outcomes at 12-month-follow-up for the treatment of distal radius fracture with the new triangular CarboFix "Piccolo" Distal Radius Plate.

Methods

All consecutive patients aged from 18 or over, who were treated for unstable distal radius fracture with a volar CarboFix "Piccolo" Distal Radius Plate with triangular design between September 2015 and May 2016, have been included in the study.

The new volar CarboFix "Piccolo" Distal Radius Plates have some advantages: in the smaller size the width is lesser then conventional plate in order to better fit the smaller radius, they are longer than the conventional model with a more anatomical design, all the distal screws are angular stability screws with 10° of poliaxiality and there are more holes for the provisional stabilization with K wires.

Exclusion criteria were: previous fracture of the wrist and carpus, previous local and general infective disease, age <18 years old and previous surgery on the index wrist. The study protocol was approved by the hospital's Ethical Review Board and it was conducted in accordance with the principles of the Declaration of Helsinki and its amendments. We fully informed all the Subjects about the characteristics of the study and they gave their consent.

From the original 28 patients, 6 patients were lost to the follow up or did not meet the inclusion criteria and 22 were available for the study. The 22 patients [8 men and 14 women; mean age (standard deviation, SD)=50.8 (10.34)]; were treated with the triangular carbon plate according to the choice of the surgeon in accordance with all patients.

All patients were prospectively reviewed with radiographic and clinical evaluations.

Clinical evaluation

All patients were evaluated at a minimum follow up of 12 months with: active and passive ranges of wrist motion (ROM), Quick Shoulder and Hand score (Quick-DASH) and the Visual Analog Scale (VAS). Grip strength was measured with a Jamar® dynamometer evaluating Hand Grip and Key Pinch. Grip strength, Hand Grip (HG) and Key Pinch (KP) of the uninjured side was used as control.

In addition, the patients were asked to state at which post-operative time they were able to return to their normal daily activities.

Radiographic evaluation

We performed posterior-anterior (PA) and lateral (LL) x-ray at time of injury and postoperatively (Figure 1). A standardized radiological assessment was performed postoperatively at one month, three months, six months and 12 months after surgery. The evaluation was made by the same expert observer. We recorded: radial height, radial inclination, volar tilt and ulnar variance both preoperatively and postoperatively in order to estimate correction values. We also considered postoperative articular step-off persistence.

Surgical Technique

The surgical technique was the same for all patients.

The patient is placed supine and the arm abducted to 90 degrees, supinated, and placed on an arm

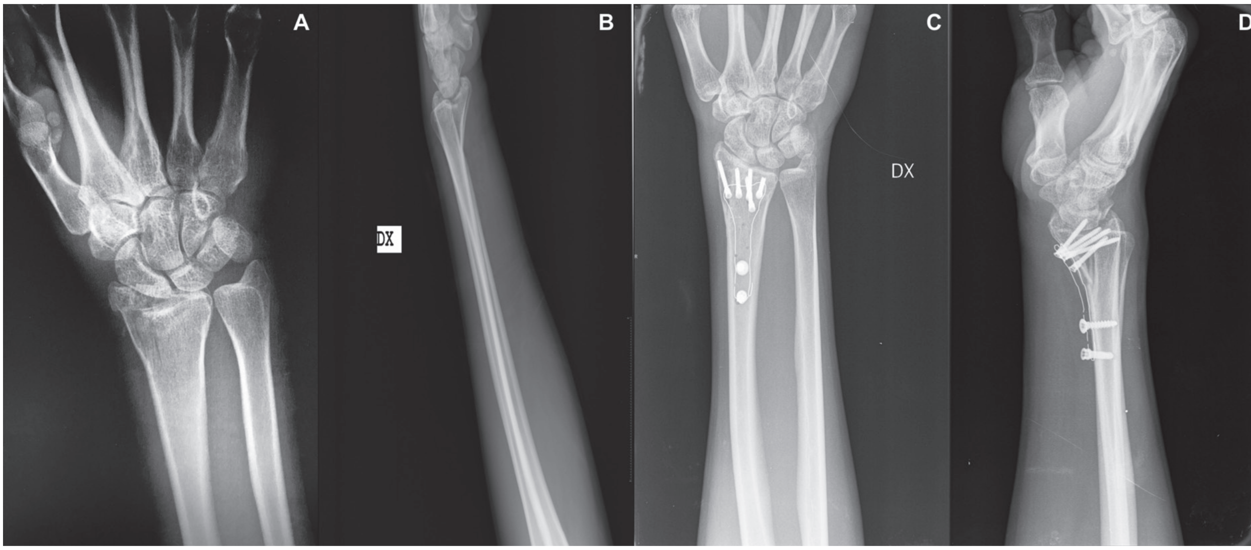

Figure 1. A, B: Pre operative trauma series of a distal radius fracture. **C, D:** Post operative X-ray of a distal radius fracture treated with a radiolucent triangular plate

table. A tourniquet is applied to the upper arm. The surgeon sits in the axilla and the C-arm is positioned diagonally from the opposite side of the arm table. The approach is the modified Henry's approach. A longitudinal skin incision is used in line with the flexor carpi radialis (FCR) tendon. The fascia is released to expose the FCR tendon, which is mobilized by incising the sheath. The tendon is then retracted in an ulnar direction and an incision made in the floor of the tendons heath. This exposes the flexor pollicis longus (FPL) muscle belly, which is swept to the ulnar side by blunt dissection. The transverse muscle fibers of pronator quadratus are then evident and should be released from the radial side of the radius and elevated subperiosteally from the radius in a volar direction to expose the fracture. Reduction is achieved with pointed reduction clamps. Plate is selected of sufficient length and fixed with screws.

Postoperative Rehabilitation

Immediately after surgery, the patient was encouraged to elevate the hand and begin early finger motion. A short arm plaster splinting was maintained for 2 weeks until the first follow-up visit. At that visit, the dressings and sutures were removed, radiographs were taken, and therapy was started under the supervision of a certified physiotherapist. A prefabricated orthosis was also applied for comfort and protection for further 2 weeks. During weeks 2 through 6, an anti-edema protocol was started along with tendon gliding and range of motion exercises.

Statistical Analysis

Statistical Package for social Sciences (SPSS) version 22 was used for calculations. All the data were analyzed by a single blinded researcher. Computed *P* values were two-sided, and $P<0.05$ was used to determine statistical significance. The Wilcoxon-Mann-Whitney test for two independent samples was performed in order to evaluate differences for numerical variables.

Results

All fractures healed, and radiographic union was observed at an average of 5 weeks (range 4-8 weeks). No cases of loss of the surgically achieved fracture reduction were documented.

The mean follow-up was 15.7 months (range 12-19 months). Mean wrist range of motion, assessed with a goniometer, resulted as follows: 65° of extension (range 54°-76°), 78° of flexion (range 72°-80°), 18° of radial deviation (range 15°-20°), 39° of ulnar deviation (range 35°-45°), 87° of supination (range 82°-90°) and no patients showed loss of pronation at follow-up (80°).

All patients have recovery of R.O.M. comparable to the contralateral at the final follow up; with no significant difference (p>0.05) as regards extension, flexion, ulnar deviation, radial deviation, supination and pronation comparing to the unaffected arm.

At final follow-up, no patients had a statistically significant difference (p>0.05) of grip strength, evaluating Hand Grip (HG) and Key Pinch (KP) comparing to the contralateral side. On average, the HG was 92.3% (mean value 19.5 Kg, range 11.2-33.6 Kg) and KP was 90.4% (mean value 8.1 Kg, range 2.3-16.7 Kg) of the unaffected extremity.

The mean score on the Quick DASH was 9.3 (range 2.5-15.9). Patients were able to return to their normal activities of daily living at an average of 4.2 weeks (range 3-8.4 weeks) post-op. Finally, mean VAS score was 2.3 (range 0-3.5).

Articular step-off persistence was assessed in 18.3% of patients. Normal radial inclination (21°-25°) was restored in 78.5% of patients (range 15°-27.5°). Normal radial height (10 mm-13 mm) was restored in 70.6% of patients (range 6.8 mm-7.3 mm). Normal volar tilt (7°-15°) was achieved in 93.2% of patients (range 3°-187°). Normal ulnar variance (0.7 mm-1.5 mm) was restored in 89.5% of patients (range 0.7 mm-4.1 mm). The statistical analysis has shown a significant difference between the pre-operative and post-operative radiographic values (p value <0.01).

No cases of hardware failure, loss of position or alignment of locking screws, nervous complications, infection or allergy to the plate were observed in our cohort of patients.

Complications

In one case, a 43-year-old male, clinical signs of extensor tendons synovitis were reported 6 months after surgery. Radiographs revealed an excessive length of one screw of the distal branch of the plate, after which the plate and the screws were removed. Intraoperative hardware integration was found to be limited, facilitating, therefore, removal of the plate.

Discussion

The most important finding of the present study was that the triangular CarboFix "Piccolo" Distal Radius Plate showed good clinical and radiological results in the treatment of distal radial fractures.

Comparing our results with literature, the overall clinical results obtained with the use of the new triangular carbon plates at 12-month follow-up are consistent with the recent findings using conventional metal plates (13-18).

Despite data showed a substantial equivalence, the triangular CFR-PEEK plates have some potential advantages that may support their introduction into clinical practice (19). In fact, this material gives to the fixation device a radiolucent X-ray property, with no artifacts during CT and MRI scans, and enables good visibility through the plate during surgery and follow-up (8, 20, 21).

In fact, the authors of a recent study (20) showed that a volar distal radius plate made from CFR-PEEK has minimal effect on bone parameters obtained at the distal radius with high-resolution peripheral quantitative computed tomography. So they recommend the use of CFR-PEEK plates instead of conventional titanium plates to monitor the healing process of distal radius fractures.

This composite material mimics the cortical bone's Modulus of Elasticity (9) with good mechanical properties. As well there are no cold welding events with titanium screws (6).

These advantages are well described by Tarallo at al. (6) in a recent publication.

The authors showed the results of 12 months follow up of carbon-PEEK plates for the treatment of distal radius fracture.

Also in this paper, the Authors reported good clinical and radiological outcomes without any significant complication in a cohort of 40 patients treated with carbon-PEEK plates.

In our experience, the triangular CarboFix "Piccolo" Distal Radius Plate helps surgeons in their work by enabling good observation of the fracture during reduction and healing and it is associated with rapid fracture healing. This was emphasized by the current study in which all patients showed radiographic healing at an average of 5 weeks follow-up.

In only one case the triangular CarboFix "Piccolo" Distal Radius Plate was removed without complications.

However, this study has some limitations. The number of patients is small and the follow-up period was short, however it is a preliminary report from a single center.

Finally, the present study is a case series without a control group, but to our knowledge, this is the first study to report prospective clinical and radiographic outcomes after fixation of a distal radius fracture with a CFR-PEEK triangular plate and future case control studies should be performed to compare these new CFR-PEEK triangular plates with the conventional titanium plates.

Conclusion

Fixation of the distal radius fractures with a triangular CarboFix "Piccolo" plate provides satisfying clinical and radiographic results after 1 year of follow-up.

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