A New Volar Plate DiPhos-RM for Fixation of Distal Radius Fracture: Preliminary Report

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Abstract: We analyzed the efficiency of a new plate DiPhos-RM in CFR-PEEK [carbon-fiber-reinforced poly (etheretherketone)] for the volar fixation of distal radius fractures. The new plate's composition has the advantage of x-ray absolute transparency, therefore allowing to monitor the healing of the fracture. The desired combination of high strength and low rigidity is obtained through the use of the polymer composites CFR-PEEK. In this preliminary study (from March 2012 to June 2012), 10 cases of intra-articular distal radius fractures were treated with DiPhos-RM produced by Lima Corporate (Italy). The fractures were classified according to the AO classification, 4 fractures were type C1, 3 type C2, and 3 were A2. A preoperative computed tomography scan was carried out in all patients. One patient also underwent a postoperative computed tomography scan. Grip strength, range of motion, and DASH score were evaluated at follow-up. There were no cases of hardware failure. Specifically, no loss of position or alignment of fixed-angle locking screws or breakage of the plate were observed. Radiographic union was present at an average of 6 weeks (range, 5 to 8 wk). The overall preliminary experience with this new plate is favorable. The new plate is easy to apply and provides the surgeon dual options of fixed-angle or variable-angle screws. It was rigid enough to maintain the reduction also in AO type C articular fractures.

Key Words: volar plate, distal radius fracture, DiPhos-RM, polymer composites, radiographic translucency

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HISTORICAL PERSPECTIVE

Fractures of the distal radius are among the most common fractures in adults, and their incidence continues to rise as the average age of the population increases.[1,2] Distal radius fractures can be managed successfully with a variety of treatment methods, from closed reduction and splinting to surgical reduction and fixation. Recently, there has been a trend toward open reduction and internal fixation through a volar approach using a precontoured plate with fixed-angle screws.[3,4] The introduction of volar locking plate systems allows the surgeon to easily reduce the fracture anatomically and maintain the reduction effectively until union, even with immediate mobilization.[5] Metal fixation plates have been used successfully for many years, but the stiffness of many metals may shield the underlying bone from stress. As described by Wolff's law, bone grows in response to applied stress and will be reabsorbed if mechanical stimulus is lacking.[6] Alloys with elastic moduli less than stainless steel, such as Ti6A14V, have been successfully used in fracture fixation.[7,8] Plate made of unreinforced plastics such as Teflon, polyacetal, and polyester[9] have moduli lower than that of the bone, but fracture healing has been associated with excessive callus formation, an indication of too much flexibility. The desired combination of high strength and low rigidity can be obtained with polymer composites like CFR-PEEK [carbon-fiber-reinforced poly (etheretherketone)]. The biological response to the PEEK polymer has been evaluated in several in vitro and in vivo studies reported in literature, showing comparable results with the other routinely used materials.[10–13] The DiPhos-RM plate is made of a component that has the advantage of absolute transparency on x-rays allowing monitoring of fracture healing. The aim of this study is to evaluate the efficiency of a new volar plate DiPhos-RM for the treatment of volar distal radius fracture. This plate is made of a new material PEEK, and it has high strength and consists of 2 distal rows for the 2.3 locking screws on the distal part of the plate, and 3 or more different holes for 3.5 locked screws on the diaphysis. This plate is completely transparent on x-rays; a property that allows better evaluation of the state of fracture healing because consolidation and mineralization is not obscured by the plate in both standard views.

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INDICATIONS/CONTRAINDICATIONS

The indications for the use of the volar fixed-angle plating include unstable intra-articular or extra-articular fractures of the distal radius with either an apex dorsal or an apex volar pattern. They can also be used in osteoporotic elderly patients, as the stiffness of the construct provides the necessary subchondral support to maintain fracture reduction. The new DiPhos-RM plate theoretically permits easy removal of the screws, because plate and screws are made of 2 different materials and cold welding does not occur. Another property of the DiPhos-RM plate is its transparency under x-rays. This characteristic allows to monitor the fracture healing through callous osseous visualization and, therefore, this new radiolucent plate can be useful in the treatment of nascent malunion where a distal radius osteotomy with bone grafting is usually performed to correct the wrong angle. Contraindications to the volar plating of the distal radius include fractures in pediatric patients with open physes; open fractures with inadequate soft tissue coverage; and highly comminuted fractures with a metaphyseal defect, when a bone graft is also required; therefore, in this case a dorsal approach is preferable.[14] Unstable, high-energy fractures with considerable comminution (AO C3 fractures) are a relative contraindication to isolated volar plating, and these fractures might require supplemental internal fixation with multiple plates or neutralization with an external fixator.

PRELIMINARY EXPERIENCE AND CASE EXAMPLE

In a preliminary study from March 2012 to June 2012, 10 cases of intra-articular distal radius fractures were treated with

DiPhos-RM produced by Lima Corporate (San Daniele Del Friuli, Udine, Italy). Patients were 6 men and 4 women with a mean age of 57 years at the time of injury (range, 35 to 70). The mechanisms of injury were simple falls on outstretched hand in 4 cases, motor vehicle accidents in 3 cases, and sports injury in another 3 cases. The mean follow-up was 2 months (range, 8 to 15 wk). The fractures were classified according to the AO classification: 4 fractures were type C1, 3 type C2, and 3 were A2. A preoperative computed tomography scan was carried out in all patients and in 1 patient a postoperative computed tomography scan was also obtained (Figs. 1, 2). Clinical results were assessed with physician-directed outcome tools and with subjective questionnaires after surgery. Preoperative radiographs were evaluated to identify the type of fracture using the AO classification. Grip strength and range of movement were evaluated and recorded by the same surgeon. The subjective outcome tool used was the Disabilities of Arm, Shoulder and Hand (DASH) questionnaire. This instrument quantifies disabilities related to the upper extremity with a score ranging from 0 point (no disability) to 100 points (maximum disability). At the time of follow-up visit, we reviewed the final radiographic and functional results. The surgeons measured wrist and forearm motion with a goniometer. Grip strength was measured with a Jamar dynamometer (Asimov Engineering Corp., Santa Monica, CA) and compared with the controlateral side.

Surgical Technique

In all cases, a Henry volar approach between flexor carpi radialis and the radial artery was performed. After identification and retraction of the flexor pollicis longus, the pronator quadratus muscle was identified and elevated after making an "L" incision.[15] The distal radius fracture was reduced by using a standard intra-articular reduction technique under fluoroscopic imaging and temporary K-wire reduction, and a volar DiPhos-RM plate was subsequently applied. The correct application of the plate on the volar surface of the radius proximally to the watershed line is the key to achieving a good

FIGURE 1. A, Wrist fracture type C2 according with the AO classification. B, Preoperative computed tomography (CT) scan in 2 and 3 dimension shows the articular fracture of the distal radius. C, Postoperative x-ray with reduction of the wrist fracture: only the screws are visible. D, CT scan after 10 days shows the subchondral support of the distal screws under the articular joint.

FIGURE 2. A, X-ray with articular fracture type A2. B, Intraoperative view of the implant DiPhos-RM on the volar facet of the distal radius. C, Postoperative x-ray with reduction of the fracture.

result.[16,17] In fact after reduction of the fracture and temporary stabilization with K-wire, the plate must be applied in the correct place to avoid joint penetration by the fixed-angle distal locking screws. A metallic guide (Fig. 3A) can be applied on the distal plate allowing the application of distal locking screws using fixed angle. The guide also facilitates the correct sitting of the plate as the distal edge of the guide conforms to the watershed line that is visible on fluoroscopy. The insertion of a single 3.5-mm cortical screw first in the elliptical diaphyseal hole on the plate allows for final adjustment of the plate in a proximal-distal and radio-ulnar direction. The operator then introduces a K-wire in the hole of the proximal row of the distal plate (accepts a K-wire of 1.2 mm) that has the same angle as the proximal row (Fig. 3B). Then, a fluoroscopy in lateral view of 25 degrees is performed to verify that the K-wire lies under the articular surface. The next step consists of inserting locking screws in the holes through the guide using a marked drill that, in addiction, allows the measurement of screw length (Fig. 3C). Once all the distal screws are inserted on the 2 rows, the surgeon removes the guide and proceeds with the insertion of the last distal screw. That one must be inserted on the proximal row in the same hole of the first K-wire, in fact the guide not permits to introduce the screw in the same time of the K-wire. After that, using the screwdriver all the distal screws are tightened by the operator. In case of necessity, after guide removal, the change of fixed angle of the distal screws is allowed for no more than 3 times. The hole of the plate, in fact, does not have the thread. When the screw penetrates the hole of the plate, the head of the screw performs the filets on the hole allowing locking the screws.

Once all the distal screws are inserted, the surgeon completes the internal fixation by inserting the remaining diaphyseal screws (3.5 mm) (Figs. 3D, E).

RESULTS

The average follow-up time was 2 months (range, 8 to 15 wk). All fractures healed uneventfully and were included in the study. There were 5 men and 3 women with an average age of 57 years. The radiographic reduction achieved surgically was maintained during healing in all 8 cases (100%). Upon comparison of final follow-up x-rays with the initial postoperative images from day of surgery, no loss of reduction was identified in any case. Radiographic union was present at an average of 6 weeks (range, 5 to 8 wk). On final physical examination, the average wrist flexion was 70 degrees (range, 60 to 90 degrees), extension 65 degrees (range, 55 to 75 degrees), radial deviation 16.5 degrees (range, 5 to 35 degrees), ulnar deviation 33.4 degrees (range, 30 to 45 degrees), supination 80 degrees (range, 45 to 90 degrees), and pronation 80 degrees (range, 45 to 90 degrees). The final DASH score

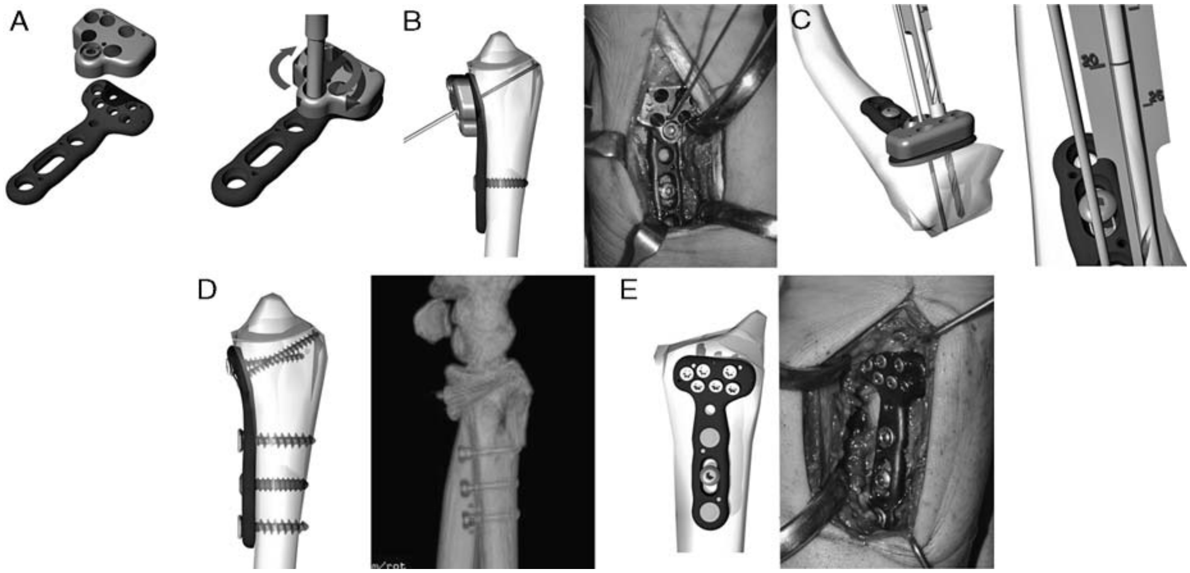

FIGURE 3. A, DiPhos-RM plate with mask applied on the distal part. B, Right position of the plate with the K-wire under the articular surface. C, The guide allows the measurement of the length of the screws. D, Final implant on the distal radius with the computed tomography scan. E, Intraoperative view of distal radius fracture with the DiPhos-RM implanted.

was of 20.8 points (range, 18 to 22). The average grip strength at final follow-up, expressed as percentage of respective controlateral limb, was 83%. There were no cases of hardware failure; in particular, no loss of position or alignment of fixed-angle locking screws or breakage of the plate were seen. There were no cases of soft tissue injuries, including nerve or tendon injuries, and no cases of infections or allergy to the plate.

DISCUSSION

Locking plate fixation for the distal radius and for other fractures has become increasingly popular across the developed world over the past 5 years.[18–20] The benefits of this method include early return of function, improved final motion, virtual elimination of extensors' tendon problems, and lack of routine plate removal.[21,22] The new DiPhos-RM plate theoretically permits easy removal of the screws, as plate and screws are made of 2 different materials and cold welding does not occur. The plate has a guide that allows the use of fixed-angle screws in the distal part of the plate. Removal of the guide allows the insertion of the distally locked screws in a variable-angle manner and with an angular range of 15 degrees that reliably avoids intra-articular screw penetration. The angle of the screw can be selected by the surgeon and is not determined by the implant. Following its anatomic reconstruction, the articular surface is supported by the proximal row of screws in the dorsal subchondral portion (seeing the radius in lateral view), whereas the distal rows can support the volar subchondral portion of the articular surface. We believe that the first step to approaching a distal radius fracture is obtaining an anatomic reduction of the fracture, and only after that, proceeding to the application of plate and screws. Plate positioning can be optimized by correct balancing between dorsal subchondral bone support, buttressing of the volar cortex, and watershed line respect. Adequate reduction must be achieved before plate application to prevent dislocation of screws and peg from their intended position on the distal fracture fragments.[23,24] The plate must be positioned in the correct place, not too much distally and not too proximally, and most of all, in perfect alignment with the major axis of the radius. This is key to a good outcome of the implant. If the first K-wire inserted in the proximal row is placed under the articular surface in lateral view, then the screw inserted on the first row will be also under the articular surface. The K-wire fit snuggly through the plate without toggling and maintain reduction during the process of screw insertion. A reduced amount of fluoroscopic investigation would also be needed. The following step is that of inserting all distal screws without the need of fluoroscopy, because if the fracture is well reduced, no distal screw should be found inside the radio-carpal joint. A major property of the DiPhos-RM plate is its transparency under x-rays. This characteristic allows to monitor the fracture healing through callous osseous visualization. It will also allow the early identification of a suboptimal reduction as performed by the surgeon. The identification of new stronger, safer, better tolerated, and longer-lasting materials, for fracture reduction, represent one of the most important goals of orthopedic research in the upcoming years. We suppose that there are no complications related to the new material of the implant. The only important thing is that particular attention is needed while inserting the screws as the hole of the plate does not has the thread. When the screw penetrates the hole of the plate, the head of the screw performs the filets on the hole allowing locking the screws, and, therefore, the changing of fixed angle of the distal screws is allowed for no more than 3 times. An advantage related to the new material is represented by the theoretically easy removal of the screws, because plate and screws are made of 2 different materials and cold welding does not occur. We believe that potential complications related to this implant are similar for typology and occurrence to that reported in literature for the other new-generation plates, including: tendinitis or tendon rupture, loss of reduction, loss of fixation, hardware failure, symptoms of carpal tunnel syndrome, other nervous complications, compartment syndrome, and infection. Compared with stainless steel or titanium plates the cost of production of this implant is higher but the commercial price is in line with that of the other metal systems. The overall preliminary experience with the new DiPhos-RM plate seems favorable, although the short follow-up does not provide yet substantial information with regard to fracture stabilization as well as hardware's safety and durability. Moreover, we will be able to compare the clinical outcomes and complications of the 2 types of plate PEEK and metal in the next future with more data, larger sample size, and a longer follow-up.

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