



WHITE PAPER

Conventus Cage™ Distal Radius – A Preliminary Report

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ABSTRACT

A prospective study of intra- and extra-articular distal radial fractures was undertaken in 60 patients using an expandable, intramedullary implant and percutaneous screws at six European centers [Conventus Cage™ - DR, Conventus Orthopaedics, Maple Grove, MN]. Patient outcomes were assessed based on DASH scores, serial radiographs, and adverse events. Fifty-seven patients were available for follow-up at twelve weeks, and at the time of data collection for this report, 38 patients were available for one year follow-up. The mean DASH score was 22.3 at 12 weeks and 11.1 at one year. Radiographs revealed healing present for all fractures by 12 weeks. There were five patient-related adverse events (8.3%), all of which resolved.

This preliminary report demonstrates that simple and complex distal radial fractures can be successfully and safely treated with the Conventus Cage™ - DR intramedullary device.

Introduction

Fractures of the distal radius are one of the most common injuries of the skeletal system with a reported incidence of 195.2 per 100,000.^{3,8,9} Although approximately 60% of distal radial fractures are managed nonoperatively, there is an increasing trend toward surgical management.^{2,6,4} The introduction of volar locking plating in the early 2000's represented a major improvement in treatment of such fractures.⁷ Today, volar locking plates have arguably become the standard of care. However, the procedure is invasive and hardware-related complications are relatively common (16-27%).^{1,5} The Conventus Cage™ -DR offers an alternative to the extensile exposure needed to insert volar or dorsal plates and the Conventus hardware is all within the bone, with the exception of a small radial plate.

Device Description and Surgical Technique:

The Conventus Cage™ - DR is intended for the fixation of distal radius fractures. It is composed of a self-expanding, Nitinol scaffold, a central member with locking screw, cannulated 2.7 mm titanium alloy fragment screws, a proximal plate and proximal screws (Figure 1).

Reduction of the distal radial fracture is obtained and stabilized with temporary Kirschner wires. A radial skin incision is made, the radial nerve protected, and the medullary canal of the distal radial metaphysis entered with a drill. The drill is advanced to the subcortical area of the distal radius. The metaphyseal area is prepared under fluoroscopic control and the Conventus Cage™ - DR implant inserted and deployed in its subcortical location. A side-plate and screws are attached to the proximal aspect of the implant and through small stab wounds, one to three cannulated screws are inserted through the fracture fragments into the implant, stabilizing the reduction.

Methods and Materials

An international, multi-center, prospective study was performed in 60 patients undergoing closed reduction and internal fixation of a distal radius fracture using an expandable, intramedullary implant. Patients ranged in age from 19 to 87 years with a mean age of 66. There were 52 men and 8 women. 71% of fractures were AO class A2 or A3, 2% were B2 and 26% were C1 or C2. 83% of patients were right-handed yet 37% fractured the right wrist and 63% the left wrist. Fifty-seven patients were available for follow-up at 12 weeks. At the time of data collection for this preliminary report, 38 patients were available for one year follow-up. Patients were evaluated utilizing the Disability Arm Shoulder Hand (DASH) score, radiographic parameters, and adverse events (both patient and device-related).

Results

The baseline DASH score for all patients was 70.7. Follow-up DASH scores on 57 patients at three months averaged 22.3 and improved in the one year follow-up to 11.1 in 38 patients.

Radiographically, all fractures had healing present by three months. (Figure 2) One fracture was noted to have loss of reduction at eight weeks and required re-operation as a result of a failure to fix an unrecognized large volar ulnar fracture fragment. This situation is recorded as a complication in this preliminary study.

There were five patient-related adverse events. The first involved the unrecognized fracture fragment that led to repeat surgery as outlined above. There were four injuries to the radial nerve. Three resolved within twelve weeks and the fourth at slightly over one year.

There were four intraoperative device-related events which were easily corrected during the surgical procedure and resulted in no adverse patient sequelae.

Discussion

Over the past decade, the operative management of distal radial fractures has evolved from dorsal plating and fragment specific fixation to the widespread use of volar plates for both simple and complex fractures. Volar plating offers several advantages over other techniques, including visualization of the volar fracture fragments; however, with increasing follow-up, more publications have focused on the complications associated with hardware placement, screw placement, and extensive periosteal stripping. Tendon rupture, nerve injury, and soft tissue impingement on the hardware have all been reported with the volar approach.

The Conventus Cage™ - DR and technique of insertion offer many advantages over volar or dorsal plating for the management of simple and complex distal radial fractures including:

1. Minimal incisions
2. No violation of the flexor or extensor tendon compartments
3. The ability to customize screw placement in the optimal direction to provide maximum purchase of the fracture fragment to the internal implant

In this prospective study, DASH scores were found to continue to improve from 12 weeks to one year. There was no loss of reduction seen during the entire follow-up, with the exception of one patient who required reoperation. There were no device-related events or additional patient-related complications noted during the follow-up period.

There were four intraoperative device-related events that were easily corrected at the time of surgery. Three involved bending of a drill (the drill has since been modified) and one involved damage to the cavity prep tool by a k wire. In this instance, the cavity prep tool was exchanged and the procedure proceeded without delay.

The four nerve injuries reported in this study are all resolved. One resulted from an attempt to insert the implant and side-plate through a 1 cm long incision. A 2-3 cm radial incision with visualization and protection of the radial nerve is now a recommended part of the surgical technique. Three nerve injuries occurred about the radial screw placement site and were related to traction of the cutaneous branches of the radial nerve that occurred at the time of drilling for or insertion of the radial cannulated screw. In these three instances, an attempt was made to insert the screws percutaneously. A small cutdown incision, exposure of the cutaneous nerves, and tissue protection are now recommended for K-wire insertion and screw placement.

Although not specifically measured in this prospective study and therefore not included in our results, patient postoperative pain, swelling and use of narcotics was reported by all investigators to be minimal. We believe these improvements result from the fact that the Conventus Cage™ -DR does not violate the flexor and/or extensor compartments of the wrist or require periosteal stripping. Ongoing studies utilizing the Conventus Cage™ - DR are further evaluating postoperative pain, swelling, wrist motion, return to activities of daily living, and patient satisfaction as well as DASH scores, radiographic measurements, and adverse events.

Conclusion

This report confirms that the Conventus Cage™ - DR provides excellent fracture fixation through minimal incisions that results in rapid bony union and a reduction in operative complications when compared with published reports of dorsal and volar plating systems.

This White Paper describes data taken from a clinical investigation of the Conventus Cage™ - DR which was conducted with the financial support and sponsorship of Conventus. For the Full *Instructions For Use* for the Conventus Cage™ - DR, please go to www.conventusortho.com/products/resources-products.

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Notes:

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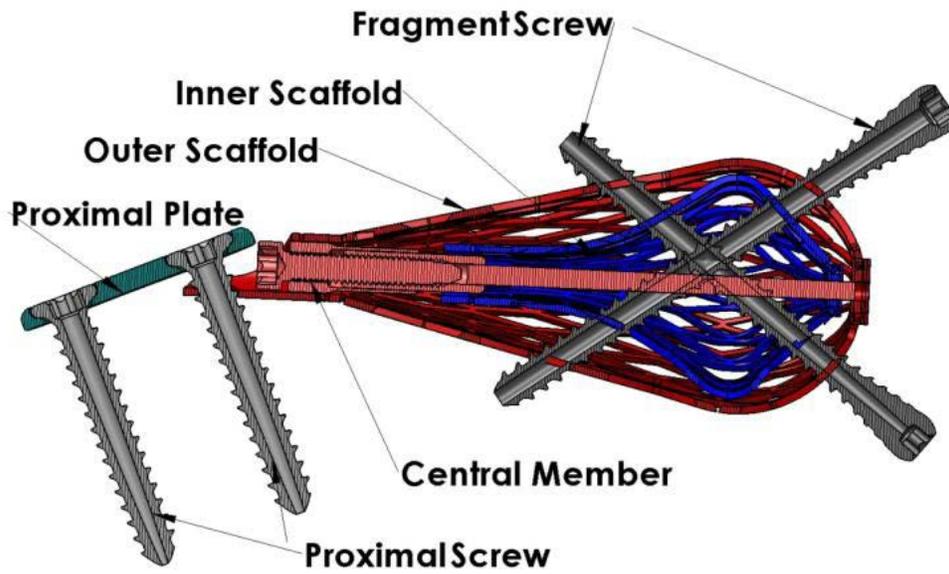


Figure 1 – Conventus Cage™ - DR Schematic Cross-Section

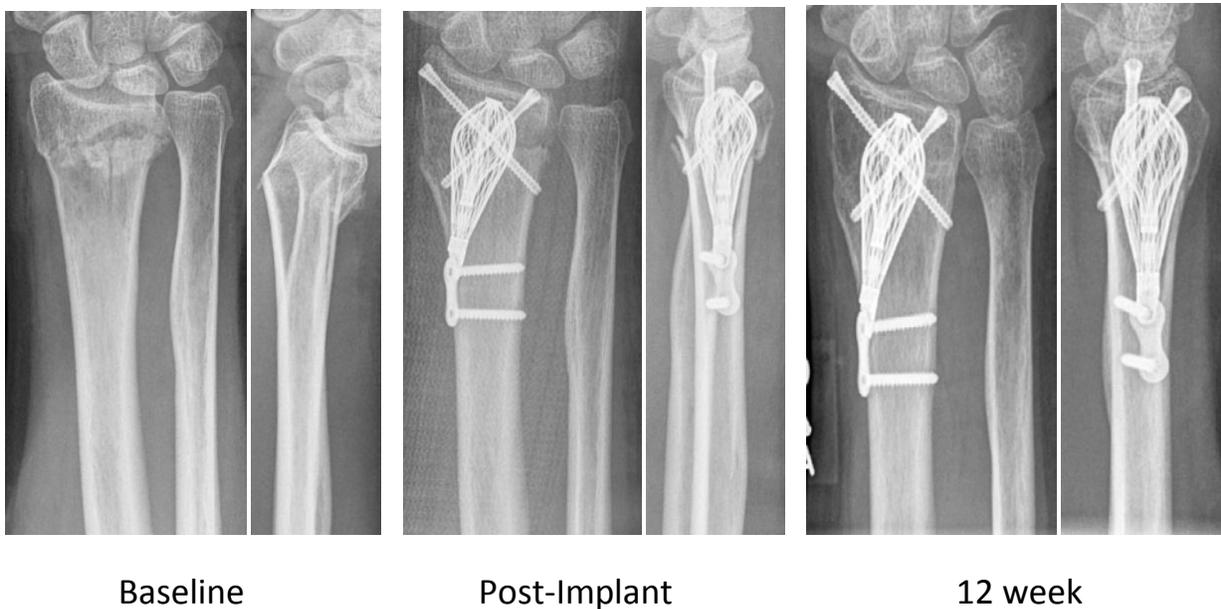


Figure 2 – Sample Radiographs

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