

Intramedullary Fixation of Distal Radius Fractures Using CAGE-DR Implant

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Abstract

Purpose CAGE-DR implant is a novel Food and Drug Administration approved intramedullary fracture fixation device used for distal radius fractures. We examine a series of 22 patients and report the outcomes with this device.

Materials and Methods A total of 24 patients with distal radius fractures (8 articular AO type C1/C2; 16 extra-articular AO type A2/A3) underwent open reduction and internal fixation (ORIF) using CAGE-DR implant by a single surgeon. Data including fracture type, angle of displacement, radiographic consolidation, grip strength, wrist range of motion (ROM), patient-rated wrist evaluation (PRWE), and Visual Analog Scale (VAS) pain scores were recorded at time of surgery and at standard follow-up.

Results All 24 patients underwent uneventful ORIF. At first follow-up visit (9 days), all patients had full digital ROM (measured as 0 cm tip-to-palm distance). Two patients were lost to follow-up. Eighteen of the remaining 22 patients had sufficient radiographic follow-up and all 18 demonstrated healing. At latest follow-up (mean 9.7 months, range, 3–20), VAS pain scores averaged 0.6 (range, 0–8) and PRWE averaged 12.1 (range, 0–53.5). Grip strength of the operated hand averaged 58 lbs (range, 20–130). ROM included: wrist flexion 73° (50–95), wrist extension 78° (60–110), pronation 77° (60–90), supination 79° (60–90), ulnar deviation 31° (5–45), and radial deviation 17° (10–30). Three patients underwent screw removal to prevent tendon irritation. One patient underwent hardware removal due to prominence on imaging but was asymptomatic. There were otherwise no major complications, including complex regional pain syndrome, in the series to date.

Conclusion The CAGE-DR fracture fixation system is a promising alternative to established methods of distal radius internal fixation. This series has a low reported pain score starting immediately postoperatively and a low complication rate. This novel device is a promising option for internal fixation of displaced distal radius fractures with a low complication profile.

Level of Evidence This is a level IV, therapeutic study.

Keywords

- Conventus
- distal radius fracture
- internal fixation
- intramedullary fixation
- outcomes

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No single method of distal radius fracture fixation has demonstrated superior outcomes, in part related to the variability of fracture types and compounded by a host of patient factors.¹ Factors that contribute to the success of a particular fixation method include the ability of the device to maintain fracture reduction, the degree of additional surgical disruption of the soft tissue envelope, the anticipated frequency of complications, and the relative ease of application. Closed reduction, percutaneous pinning, and external fixation all have a record of surgical success, as do fragment-specific fixation and dorsal plating.² Advent of the fixed angle volar locking plate (VLP) was a substantial turning point in distal radius fracture treatment, as evidenced by a marked increase in frequency of internal fixation over the past two decades.³ Volar plate fixation has its own unique set of complications ranging from 9.7 to 27%.⁴⁻⁶ In a single-center assessment of 206 cases using VLP fixation of distal radius fractures, a 9.7% complication rate was observed, with 3.9% incidence of tendon injuries and 1.9% incidence of tendon rupture.⁶ A review of 665 cases of volar plate distal radius fixation had an overall complication rate of 11.3%, with revision surgery necessary in 10% of patients.⁵

Intramedullary fixation is the preferred method of fixation of many periarticular and long bone fractures, and its use in the distal radius has been described in several forms, including intramedullary nails (IMNs), cannulated pins, and intramedullary implants.⁷⁻¹¹ This technique is attractive, as it employs fixed-angle technology, small incisions, and theoretically should lead to fewer soft tissue complications. Several recent reviews have recommended that current IMN technology is limited to management of displaced extra-articular AO type A fractures and simple AO type C fractures.¹²⁻¹⁴ The overall outcomes are similar to those with VLP with some IMN patients having improved range of motion (ROM) at earlier time points. However, these series have also reported radial sensory neuritis associated with device implantation ranging from 2 to 11%.

In 2013, the Food and Drug Administration (FDA) approved a novel intramedullary device for distal radius fracture fixation: the CAGE-DR System (Conventus Orthopaedics, Maple Grove, MN). The device utilizes an expandable intramedullary scaffold made of titanium alloy and nitinol (► Fig. 1), and has demonstrated stiffness equivalent to standard VLPs in a previous biomechanical study.¹⁵ The double cage design deploys in the intramedullary space and is locked into place with a small washer device and two bicortical screws. Fragment-specific fixation is realized by two or more percutaneous cannulated titanium screws,

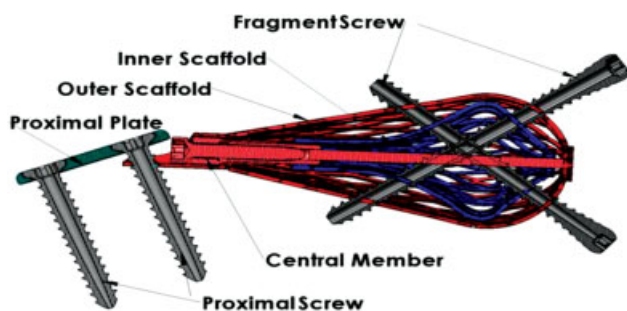


Fig. 1 Diagram of the Conventus Distal Radius System device.

which traverse all four leaves of the cage and achieve locked fixation (► Fig. 2). The device has been in use in Europe for several years. A prospective multicenter series of 100 patients with distal radius fractures treated with the Conventus CAGE-DR System device showed fracture reduction was maintained and all fractures were healed at 3 months; the complication rate was reported as 5%.¹⁶ Adverse events occurred in 5 patients in that series: 2 patients with radial nerve irritation and 3 with tendon irritation involving screws. Three patients underwent screw removal and one underwent neurolysis. Average Disabilities of the Arm, Shoulder, and Hand scores and patient-rated wrist evaluation (PRWE) scores were 9 and 11 at 12 months, respectively.

Our purpose was to study the safety and efficacy of the CAGE-DR intramedullary fixation system for treatment of a wide variety of AO type A and C fractures. We hypothesized that the technique is safe and effective, and has a lower complication profile than that reported for current plate fixation techniques.

Materials and Methods

We obtained Institutional Review Board approval for a retrospective review. This is a single-surgeon (S.W.W.) consecutive case series of patients with eligible fracture types. Indications for the CAGE-DR device include any acute closed fracture of the distal radius, age 18 years or older, with AO fracture classification type A2, A3, B1, C1, or C2. Contraindications included additional ipsilateral upper extremity fractures, inflammatory arthritis, severe osteoporosis, or a medical contraindication to operative treatment.



Fig. 2 Posteroanterior radiograph of the final implant after fracture open reduction and internal fixation.

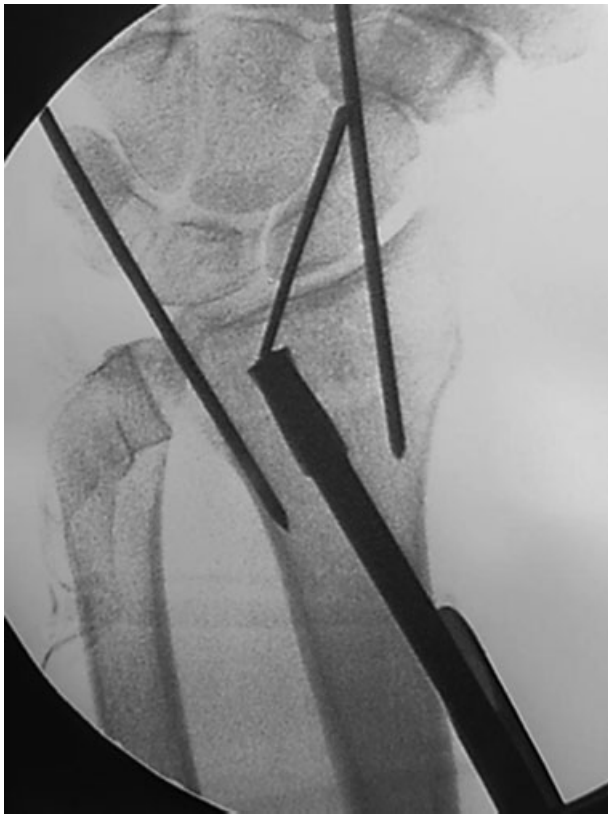


Fig. 3 Fluoroscopic image depicting the two provisional fixation Kirschner wires (the ulnarly and radially positioned Kirschner wires), the target Kirschner wire (central wire), and the drill in place.

Technique

The procedure is performed with the patient in a supine position on a hand table. A tourniquet was used in the first 4 of 24 patients in this series. The fracture is reduced with a

closed traction maneuver or with a percutaneous Kapandji reduction technique.¹⁷ Provisional fixation is achieved using Kirschner wires in the dorsoradial and dorsoulnar positions, leaving the center of the distal radius free for the implant. The reduction is confirmed with fluoroscopy. A target Kirschner wire is placed in an anterior–posterior direction near Lister’s tubercle at the planned apex of the implant beneath the subchondral bone (►Fig. 3). The implant is sized, and the implant incision is marked using a targeting guide approximately 4 to 5 cm proximal to the radial styloid. The first 15 implants were placed using a 2.5-cm incision in the radial midaxial line, and the next 9 implants were placed through a straight 2.5-cm dorsal incision. One percent lidocaine with epinephrine (1 g/100,000 mL) was infiltrated in the planned incision and the subcutaneous tissues are dissected down to bone using blunt dissection, with care to identify and retract subcutaneous nerves.

A custom self-retaining soft tissue retractor enables unrestricted access to the radial insertion site, and a side cutting 2.5-mm drill is used to perforate the radial cortex and is directed distally toward the target Kirschner wire. A guidewire is inserted and then overdrilled with a 5.0-mm drill (►Fig. 3). Each step is confirmed in two planes with fluoroscopy. A cavity for the cage is then prepared using a collapsible cannulated reamer; care is taken to preserve the cortical bone (►Fig. 4). The cavity prep tool is then collapsed and removed, and the implant is placed, expanded, and locked. A two-hole washer is attached to the implant and fastened with two bicortical screws across the radial shaft (►Fig. 5).

Articular fragments are then secured using cannulated 2.7-mm screws which pass through all four leaves of the cage, gaining unicortical or bicortical fixation at the surgeon’s discretion. The screws can be placed in a 270 degree arc around the distal radius margin. Note that 2- to 3-mm



Fig. 4 Anteroposterior (A) and lateral (B) fluoroscopic images depicting the fixation and target Kirschner wires and the intramedullary reamer in place.



Fig. 5 Anteroposterior intraoperative fluoroscopic image depicting the proximal plate fixation with two bicortical screws across the radial shaft.

incisions are recommended to safely place a percutaneous wire, measure, overdrill, and insert the cannulated screw. Each wire and screw position is confirmed fluoroscopically (► **Fig. 6**).

Postoperatively, the patients were placed in a volar splint for 7 to 10 days; following this, active and active-assisted ROM exercises were begun and a removable volar resting

wrist splint was used. Patients were assessed at each follow-up visit with radiographs taken at the first postoperative visit, 4 to 6 weeks, subsequent visits, and at final follow-up.

All five outcome parameters as recommended by Waljee et al were recorded at each postoperative visit, including performance (ROM and grip strength), PRWE assessment, Visual Analog Scale (VAS) pain score, radiographic evaluation, and complications.¹⁸ Recorded radiographic parameters included volar tilt, ulnar variance, radial inclination, coronal shift, and distance from the CAGE-DR axle distally to the subchondral plate.^{19,20} Radiographic healing was assessed by a single radiologist (E.A.B.) and determined by > 50% cancellous bridging across the fracture lucency. As radiographic intervals were variable, time to healing could not be accurately calculated. ROM, grip strength, PRWE, and VAS data were stratified by follow-up group and further analyzed to determine if scores were affected by follow-up length. We performed unpaired Student's *t*-test analysis on all ROM and strength parameters as a percent of the contralateral wrist and on raw radiographic, PRWE, and VAS data. A *p*-value of less than 0.05 indicated significance.

Results

There were 24 patients in the series (18 female and 6 male) with AO classification type A2 ($n = 7$), A3 ($n = 9$), C1 ($n = 6$), and C2 ($n = 2$) distal radius fractures. The average age was 49 years (range, 18–74 years). Two patients with A2 type fractures were lost to follow-up after 1 month and their data were consequently excluded from the analysis. Clinical and radiographic follow-up ranged from 3 to 20 months (average 9.7 months) for the remaining 22 patients. Five patients not available for clinical follow-up after their early postoperative visit were reached by telephone for PRWE and VAS, while the two lost to follow-up declined further visits when contacted. All patients had full digital motion at their first follow-up visit. At final follow-up, PRWE averaged 12.1 (range, 0–53.5).

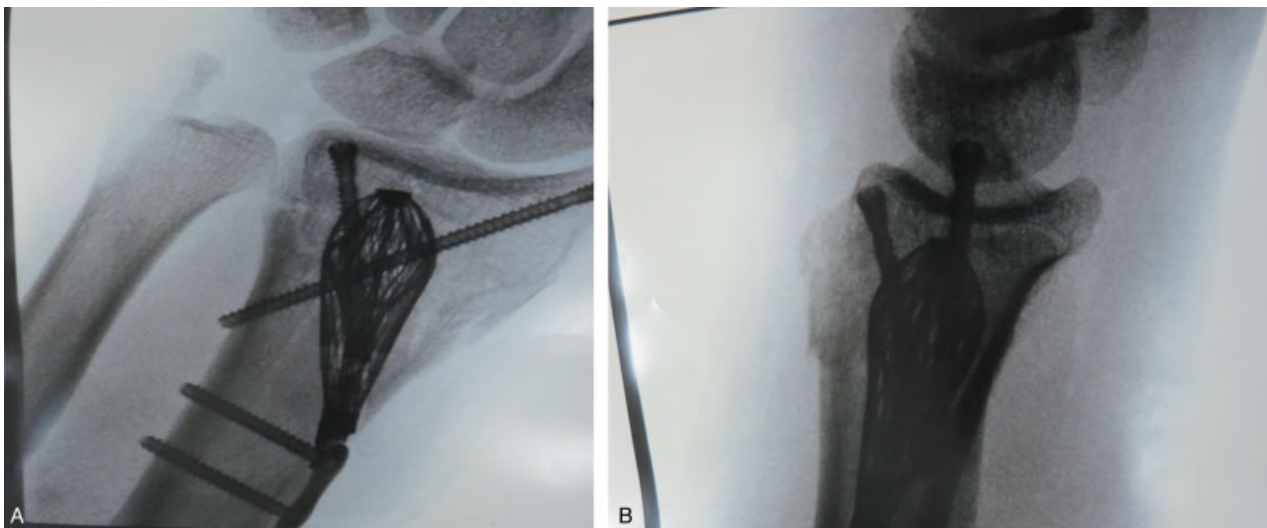


Fig. 6 Anteroposterior (A) and lateral (B) fluoroscopic images depicting the final hardware after open reduction and internal fixation distal radius.

Table 1 Subjective outcomes: PRWE scores and VAS pain scores

Parameter	Average score of patients with < 6 month follow-up (N = 5)	Average score of patients with 6–12 month follow-up (N = 7)	p-Value (comparing < 6 and 6–12 groups)	Average score of patients with ≥ 12 month follow-up (N = 10)	p-Value (comparing 6–12 and > 12 groups)
PRWE	7.7	9.4	> 0.05	18.0 ^a	> 0.05
VAS	0.2	0	> 0.05	1.2	> 0.05

Abbreviations: OA, osteoarthritis; PRWE, patient-rated wrist evaluation; STT, scaphotrapezotrapezoid; VAS, Visual Analog Scale.

^aTwo outliers: 1 with opioid addiction, 1 with concomitant STT OA

VAS pain score was assessed at every visit postoperatively as well, with average final score of 0.6 (range, 0–8; median, 0). No significant difference in PRWE and VAS scores between follow-up groups was detected (►Table 1). No patient required additional narcotics after the initial postoperative prescription.

The average ROM and grip strength measurements of the operated wrist are reported as well as the percentage when compared with the nonoperated contralateral wrist (►Table 2). All 22 patients in the cohort had sufficient radiographic evidence of healing by their 2-week visit to begin ROM exercises and progressive strengthening. Of those with images at 6 to 8 weeks, 6 had healed. All 18 patients with sufficient radiographic follow-up were healed at long-term assessment and there were no instances of delayed union. At last assessment, the two patients lost to follow-up presented with stable radiographs, had already begun using their hand, and were doing well.

The average radiographic parameters are reported as measured from the trauma (n = 15), the 2-week postop (n = 22), and the final follow-up radiographs (n = 22) (►Table 3). For 7 patients, only the postreduction films were available and therefore radiographic measurements from trauma films were not possible. The measurement of the distance from the CAGE-DR axle to the subchondral line was performed only in the postoperative radiographs. Com-

parison of the measurements from the 2-week postop and final follow-up radiographs shows no significant difference in volar tilt, radial inclination, ulnar variance, or distance from the CAGE-DR axle to the subchondral plate.

There were four hardware-related complications (18.1%). Two patients demonstrated screw prominence when the screw was judged to be just above the dorsoulnar cortex on an oblique radiograph. One of these patients was asymptomatic; the other had symptoms of dorsal tendinopathy. Both screws were removed as a precaution. A third patient sustained a second wrist injury at 4 months postoperatively, and complained of new pain at the radial styloid. Her history was complicated by narcotic abuse controlled by Narcan, and this patient was the single outlier of the VAS pain outcome analysis (VAS = 8). Radiographs demonstrated no new injury and no change in position or alignment of the hardware or fracture. An ultrasound of the wrist showed no tendon fraying, rupture, or tendinitis. Despite a lack of objective findings, the patient ultimately underwent first dorsal tenolysis and removal of the radial screw with marginal improvement in her symptoms.

The fourth patient's healing was complicated by 1 to 2 mm of settling of the articular fracture fragments at 4 weeks, raising concerns for prominence of the tip of the cage within the wrist joint. She was osteoporotic but otherwise healthy, and had no clinical symptoms consistent with hardware

Table 2 Objective outcomes: ROM and grip strength

Parameter	Average postoperative measurement of operated wrist (range)	% of contralateral wrist				
		< 6 month follow-up (N = 5)	6–12 month follow-up (N = 7)	p-Value (comparing < 6 and 6–12 groups)	≥ 12 month follow-up (N = 10)	p-Value (comparing 6–12 and > 12 groups)
Wrist extension (°)	78 (60–110)	94	97	> 0.05	94	> 0.05
Wrist flexion (°)	73 (50–95)	88	97	> 0.05	87	> 0.05
Radial deviation (°)	17 (10–30)	86	107	< 0.05	78	< 0.05
Ulnar deviation (°)	31 (5–45)	88	96	> 0.05	84	> 0.05
Supination (°)	79 (60–90)	92	106	< 0.05	98	< 0.05
Pronation (°)	77 (60–90)	96	100	> 0.05	99	> 0.05
Grip strength (lbs)	58 (20–130)	80	89	> 0.05	83	> 0.05
Digital flexion (cm from DPC)	0 (0)	100	100	> 0.05	100	> 0.05

Abbreviations: DPC, distal palmar crease; ROM, range of motion.

Table 3 Radiographic outcomes

Parameter	Trauma films (N = 16)	1–2 wk postop (N = 22)	p-Value	Final follow-up (N = 22)	p-Value
Ulnar variance (mm)	1.5	–0.4	< 0.05	–0.3	> 0.05
Radial inclination (°)	13.6	26.1	< 0.05	26.6	> 0.05
Volar tilt (°)	–22.5	–1.9	< 0.05	0.8	> 0.05
Coronal shift (mm)	3.6	0.7	< 0.05	0.1	< 0.05
Distance from DRS axle to subchondral plate (mm)	N/A	1.7	N/A	1.6	> 0.05

Abbreviations: DRS, Distal Radius System; N/A, not applicable.

irritation. Computed tomography scan demonstrated the hardware was flush with the subchondral bone (►Fig. 7). We recommended arthroscopic inspection and removal of the cage if indicated by visual confirmation of prominence. The hardware was demonstrated to be just beneath the articular cartilage on arthroscopy and there was no articular damage on the opposing lunate surface. We elected to remove the implant as a precaution to prevent long-term articular damage; the implant was removed without difficulty. Demineralized bone matrix putty (Grafton, BioHorizons, Birmingham, AL) was placed into the resultant metaphyseal cavity. The patient has mild pain related to 3 mm of ulnar positive variance; she has returned to her occupation as a makeup artist.

There were three cases of transient radial sensory neuritis (13.6%), two of which resolved completely by 4 weeks. The third patient demonstrated improved radial sensory irritability compared with prior exams at 5 months and is expected to recover uneventfully. There were no infections, tendon ruptures, or diagnoses of chronic regional pain syndrome.

The tourniquet was inflated during the operation for only the first 4 cases (average 76.5 minutes; range, 65–110) in the series; there was no tourniquet use in the subsequent 18 cases.

Discussion

VLP prominence is well known to be associated with flexor tendon attritional injury and rupture.^{21–23} An intramedullary cage is a unique approach to address distal radius fracture fixation, and its percutaneous implantation should theoretically minimize soft tissue complications. In this case series, we documented a low VAS pain score, minimal soft tissue swelling, early and full digital ROM, as well as a minimal need for postoperative pain medication (►Fig. 8). At an average of 9.7 months postoperatively, there was no significant difference between wrist and forearm ROM of the injured versus uninjured sides. Grip strength achieved 85.2% of the contralateral wrist by final follow-up, comparable to other studies of distal radius fracture fixation.^{24,25} The average PRWE was 12.1 at 9.7 months postoperatively,

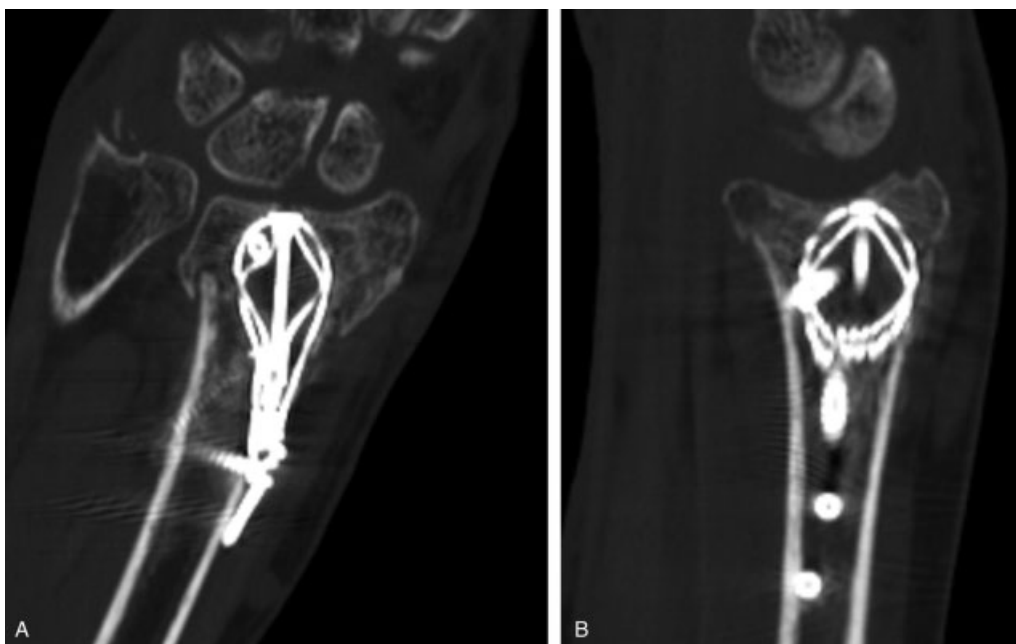


Fig. 7 Coronal (A) and sagittal (B) computed tomography cuts demonstrate fracture settling about the hardware, which is flush with the distal radius articular surface in both planes.



Fig. 8 Postoperative photographs depicting full wrist flexion and extension, full and equal pronosupination, and full radioulnar deviation.

which compares favorably to several recent series of plate fixation.^{26–28} Excluding the one outlier with VAS pain score of 8, our VAS pain scores ranged between 0 and 3, indicating a nil- to low-intensity of pain experienced by all patients except one, suggesting the procedure is quite well tolerated.

Major complications (reoperation, hardware removal) were documented in four (18.1%) of the patients in this series, only two of which were symptomatic. The three screw removal procedures were performed using only local anesthetic and fluoroscopy, while complete device removal required regional anesthesia. Minor complications included three cases (13.6%) of radial sensory neuritis, two of which resolved spontaneously by 4 weeks, and one that is expected to resolve as well. These findings concur with those observed by Duncan and Trzeciak, who reported frank contact between the CAGE-DR guide and the superficial radial nerve in 4 of 10 cadaveric specimens and an average 1.7-mm proximity to the nerve in 6 of 10 specimens when there was no direct contact with a radial-based approach.²⁹ In our series, the incidence of radial sensory neuritis has decreased since the device insertion site was moved dorsally. The device has a relatively steep learning

curve and this technical modification as well as others in the placement of the distal screws has helped to minimize hardware-related complications.

Removal of the device was performed without difficulty in less than 20 minutes, using a set of instruments specifically designed for this purpose. Demonstration of the removability of the device 2 years after implantation in a dog model was one of the criteria for FDA approval of the CAGE-DR implant.

One reason for the relative lack of swelling, rapid return of motion, and minimal pain postoperatively may be because the procedure can be performed without a tourniquet. The last 18 of the 22 cases were performed without tourniquet in this series. Controlled studies would be necessary to more definitively address this observation.

The CAGE-DR intramedullary implant was demonstrated to be safe and effective for a wide variety of fracture configurations. Screws can be placed at variable angles to secure the articular fragments, including the volar ulnar corner fragment, which can be approached through a 2-cm incision for safe wire/screw placement. As long as an adequate closed reduction is obtained, this implant can be safely used for

internal fixation of distal radius fractures. Relative contraindications include severe osteoporosis, volar shear fractures, and exceedingly comminuted fractures (e.g., AO fracture classification C3), the latter of which should likely be managed with a fragment-specific approach.

The complication rate in this series is at least comparable to the rate for other types of distal radius fracture fixation, which ranges between 3 and 37%. The hardware complication rate in this series was 18.1%, with three screw removals and one complete hardware removal. When performed, the screw removal with the CAGE-DR system is fast and well tolerated. We noted a steep and quick learning curve with the system as well and, combined with proper patient selection, would anticipate this to be a steady if not declining rate of complication. Additionally, with the modification of the dorsal approach, the likelihood of radial sensory neuritis diminishes considerably.

Based on the results of this case series, we believe CAGE-DR is a promising alternative to established methods of distal radius fracture fixation. A controlled clinical trial comparing this device to volar plate fixation for similar fractures is ongoing.

Ethical Approval

This study was approved by the Hospital for Special Surgery's Institutional Review Board (#2016-476) on April 29, 2016.

Conflict of Interest

Scott W. Wolfe, MD declares receipt of consulting fees and an industry research grant from Conventus Orthopaedics, Inc. The remaining authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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