

A Prospective, Randomized, Clinical Trial of a Novel Radial Plating System for Unstable Fractures of the Distal Radius

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A. Study Purpose and Rationale

The purpose of the study is to evaluate the open reduction and internal fixation of complex, unstable distal radius fractures using a novel, radial plating system. Patients with distal radius fractures that require surgical intervention presenting to one attending will be randomized to treatment with either radial or volar plate; patients presenting to a second attending will receive external fixation, with or without augmentation as deemed necessary by the surgeon. Patients will be followed longitudinally and outcome measures will include radiographic evidence of fracture healing, residual deformity, and arthrosis; clinical assessment of range of motion and grip strength; and patient self-assessment of functional status using well-validated questionnaires. Our hypothesis is that internal fixation with the EBI plating system will provide better functional, clinical, and radiographic outcomes than either volar plating or external fixation while maintaining a low rate of complications.

a. Background

Fractures of the distal radius are among the most common traumatic injuries, representing nearly 20% of all fractures seen in emergency departments and occurring in a bimodal age distribution, being most common among both adolescents and the elderly.⁴⁸ The lifetime prevalence. While many of these fractures are simple metaphyseal fractures that can be managed through closed reduction and immobilization, approximately 50% involve the articular surface or distal radioulnar joint, necessitating more intensive treatment.¹⁹ Management of these injuries can be problematic, associated with a high prevalence of complications including stiffness, loss of reduction, malunion, instability, loss of radial length, infection, tendon rupture, sensory neuritis, degenerative arthritis, eventual arthrosis, and a resultant decrease in motion, strength, and ultimately function of the wrist^{1,35,10,16,23,32,35,53}. The incidence of complications has been reported to be as high as 31%.¹⁰

Unstable fractures of the distal radius have been approached using a variety of treatment options. These include closed reduction and cast immobilization^{34,66}, pinning^{8,17,23,36,42,51,55}, external fixation^{9,12,13,22,25,26,38,50,59,61,63-65}, internal fixation^{2,6,14,20,21,30,33,36,47,52}, and various combinations of the above techniques^{13,23,53,59,65}. Although unstable fractures generally require one of the latter, more aggressive treatments⁶⁶, the ideal fixation solution for the distal radius does not yet exist.^{13,21}

Restoration of normal anatomy of the articular surface is the most critical factor for a good functional result^{1,2,7,11,13,15,27,28,30,34,36,39,40,53}, as failure to achieve and maintain nearly anatomic restoration can lead to some of the complications previously listed. Knirk and Jupiter showed that >2.0mm of displacement of the distal radial articular surface resulted in traumatic osteoarthritis,³⁵ and other studies have confirmed both radiographic evidence of radiocarpal arthrosis and poor functional outcome with an even a lower threshold for articular displacement.^{16,62} Yet maintaining a reduction throughout healing is made more difficult by the desire to initiate early active motion.¹³ Early joint motion after fracture treatment is important as it may facilitate repair of articular cartilage and could reduce some of the complications of joint immobilization.^{15,41,43,47,56-58,65}

External fixation, with or without percutaneous pinning, is a commonly used modality for treating fractures of the distal radius and has been shown to be effective for maintaining radial length in the setting of the defomuing force of the brachioradialis muscle⁶⁰. External fixators are easy to

apply, can be adjusted in the office, require minimal exposure and thus avoid operative complications, and leave no internal hardware to be dealt with.⁶⁴ Disadvantages include an inability to visualize and manually reduce intrarticular fracture fragments, inability to visualize concomitant ligamentous damage, and reduced early mobilization of the radiocarpal joint. While external fixation utilizes ligamentotaxis to maintain reduction of displaced fracture fragments and is very useful for several types of fractures, it may not provide adequate reduction for more severely comminuted or displaced intraarticular fractures, though the subject is highly controversial.^{29,64}

Open reduction and internal fixation provides direct visualization and manipulation of fracture fragments, and early mobilization, and clinical series have documented generally good results with plate fixation.^{6,20,27,52} Various plating systems for treatment of unstable fractures have been designed and proposed^{16,20,21,27,33,47,49,52}, with the primary goals of anatomic reduction and early motion. While clinical outcomes have generally been good, the efficacy of the dorsal plate fixation has been tempered by a number of sub-optimal results.^{2,6,18,20,21,24,31,37,43,52} These include implant failure, poor adaptation to the pathologic anatomy of the distal radius, limited and difficult contouring or trimming of the plate, difficulty securely fixing small articular fracture fragments to the hardware, and most notably, complications involving extensor tendons such as irritation, tenosynovitis, adhesion formation, and tendon rupture. Internal fixation is more invasive, and the insertion of the volar plate, in particular, requires extensive soft-tissue dissection. Both low-profile dorsal plates⁵⁴ and volar plates^{43,44-46} have been shown to provide stable fixation in biomechanical studies and good functional outcomes in vivo but there is no direct evidence comparing plating techniques to external fixation.

A third possibility for stable internal fixation exists, which involves a plating system along the lateral side of the radius as opposed to the dorsal or volar cortices. Aside from its use as a small part of a more complex fixation system,³⁶ this concept of radial plating has been unexplored in the literature. Radial plating offers many theoretical advantages to both dorsal and volar plating techniques. Because it is positioned perpendicular to the major flexion-extension loading axis of the wrist, it should effectively offer increased plate strength and stiffness while reducing screw pull-out forces under normal loading patterns. In addition, a radial plate will eliminate the complications associated with the extensor tendons, while permitting less soft tissue disruption than is required by the volar approach. Furthermore, the radial plate allows direct stabilization of both dorsal and volar metaphyseal fragments without interrupting their vascular supply. The addition of fixed-angle, locking screws should allow efficient fixation of metaphyseal fragments with increased stiffness.

The present study will incorporate a new radial (lateral) plate, and prospectively investigate its efficacy versus both external fixation and internal fixation with a volar plate.

b. Hypothesis

We believe that patients receiving radial plates will have better clinical and subjective outcomes at one year than patients receiving either external fixation or internal fixation with a volar plate.

B. Study Design and Statistical Analysis

a. Study Design:

This study has both a cohort study aspect and a controlled, randomized, prospective aspect to evaluate the functional outcome of distal radius fractures treated with a new system of internal fixation devices. As one hand attending (Dr. Rosenwasser) performs only plating procedures and one (Dr. Strauch) only external fixation, only the comparison of the two plating methods will be randomized. In this arm, patients will be randomized, by computer, to either volar or radial plating.

Patients of Dr. Strauch will receive bridging external fixation with or without augmentation. Appropriate augmentation strategies include filling of metaphyseal void with bone graft and use of extrafocal or intrafocal (Kapandji) pinning. Due to the obvious nature of the intervention and residual scars, the study can be only partially blinded. The co-investigator processing functional data will be blinded to the treatment group of the patients; radiographic angles and range of motion data will be

assessed by a trained co-investigator with no financial or other ties to the makers of either set of fixation devices.

b. Endpoints

The primary endpoint will be the overall subjective outcome at one year, as measured by the Michigan I-land Questionnaire, a validated instrument that specifically assesses functional outcome after hand surgery. We will also employ the clinical scales of Green and O'Brien and Gartland and Werley, both of which are standard reporting measures in the orthopedic literature. These measuring tools assign points or demerits on the basis of patient self-assessment of pain and function, clinical assessment of range of motion, and radiographic assessment of healing and angulation. The resulting number is applied to a scale that categorizes results as "excellent," "good," "fair," or "poor." The Gartland and Werley scale is considered less rigorous but is still the standard; the Green and O'Brien scale is being used more frequently now and takes greater account of patient self-assessment.

Secondary endpoints will include interim assessments of functional outcome using the same scale at earlier and later timepoints; DASH (Disabilities of the Arm, Shoulder, and Hand) questionnaire scores; and direct evaluation of range of motion and radiographic angles.

Complication rates will also be recorded and analyzed.

c. Statistical Analysis

The categorical endpoints will be assessed with chi-square analysis or the Fisher Exact Test. Those endpoints which function as continuous variables (MHQ, DASH, angles, ROM) will be analyzed by two-tailed t-testing. The level of significance will be set at .05 and corrected using the Bonferroni method for any interim analyses that are performed.

Power was calculated for the Michigan I-land Questionnaire, the primary outcome measure, using previously reported standard deviations in the 8- 18 point range and a minimally significant clinical effect of approximately 15 points. The data is extrapolated from studies of other wrist injuries, including CMC arthritis and toe-to-thumb transfer, as there is no previously published study using the MHQ to evaluate wrist fractures; nevertheless, we believe it is the most useful instrument for assessing outcome.

With a power of .80, it would require 17 subjects per group to detect this approximately 1 standard deviation difference; with a power of .90, it would require 23 subjects per group. We hope to enroll upwards of 60 patients, which is approximately the number of patients who present to our service with distal radius fractures necessitating operative treatment in a given year.

C. Study Procedure

a. Enrolment

Patients will be enrolled in the study during their pre-operative visit. They will be walked through HIPAA regulations and the consent form; it will be explained to them that, if they are patients of Dr. Strauch, no change from his usual treatment will be performed and, if they are patients of Dr. Rosenwasser, they will be randomized to either a standard treatment or a new treatment. The patients will be given the opportunity to decline participation. Dr. Rosenwasser will be notified of the treatment group the morning of the operative case.

b. Surgical Procedure

All procedures will be conducted in the Milstein OR under standard conditions and with either general or MAC anesthesia. The volar plating procedure will be conducted as described by Orbay, the external fixation is a standard orthopedic procedure. The lateral plating procedure involves an incision into the first dorsal compartment followed by isolation of the lateral sensory branches of the radial nerve and the dorsal branch of the radial artery. The APL and EPB tendons will be retracted and dissection will be carried down to the lateral aspect of the radius. The pronator quadratus muscle will be divided under fluoroscopic guidance, the fracture will be reduced so that there is less than 1mm of measurable articular step-off or gap, and so that proper radiocarpal alignment is restored. The lateral plate will be applied and

secured preliminarily with Kirschner wires. Reduction, fixation of fracture fragments, and plate placement will be confirmed with fluoroscopy and the plate will then be secured with locking screws. If there is a significant metaphyseal void, it will at this time be filled with bone graft or filler.

c. Post-operative care

Following the operation, the patients will be placed in a plaster or fiberglass sugar tong splint ending below the distal palmar crease. Early and active motion of the digits will be recommended. Patients receiving ORIF will be encouraged to move their wrists to obtain full range of motion as tolerated but will be discouraged from lifting objects with the affected hand for 6 weeks or until osseous union is documented radiographically.

D. Assessment

All patients will receive a baseline orthopedic history and physical examination including standard preoperative radiographs. Patients Will receive standard radiographs at 2,6,12, and 52 weeks of follow-up, at which time they will also have a co-investigator administer the DASH and NIHQ and test range of motion with a goniometer and grip strength with a device designed for that purpose.

For this study, we will use the Michigan Hand Questionnaire as well as the Disabilities of the Arm, Shoulder, and Hand PAS" Survey as a means to measure functional outcome. DASH was created as a joint effort by the American Academy of Orthopedic Surgeons (AAOS), the Council of Musculoskeletal Specialty Societies, and the Institute for Work and Health. The survey contains 30 questions on activities of daily living and pain and is intended to be used to evaluate disability and symptoms in single or multiple disorders of the upper limb at one point or at many points in time. A higher score reflects greater disability. Preliminary work on the DASH showed that it was both reliable and valid. The Michigan Hand Questionnaire is a validated, hand-specific functional outcome questionnaire that was developed by Kevin Chung at the University of Michigan and that has been used increasingly in the plastic and orthopedic literature.

E. Medical Device

The EBI Opti-Lock plating system is an FDA-approved medical device, and contains both stainless steel radial and volar plates using a fixed-angle, locking screw design.

F. Study Subjects

Subjects can be male or female, of any race, at least 18 years old, with an intra-articular fracture of the distal radius of one hand of AO/ASIF class C1, C2 or 0 (simple articular, simple articular with comminution of metaphysis, or multifragmentary articular cortex, respectively); or an extra-articular fracture with comminution (AO/ASIF class A3) that was deemed primarily unstable or else collapsed following closed reduction. Exclusion criteria include open fractures, AO/ASIF class B fractures (Barton's or Reverse Barton's), pregnancy, diabetes mellitus, autoimmune disorders, documented acquired immunodeficiency complex (AIDS), chronic immunosuppressive medications or other conditions that could affect postoperative wound healing. To minimize confounding outcome measures, subjects with a lack of adequate cutaneous coverage at repair site, concomitant fractures, amputated digits, arthritis of hand, prior hand injury or trauma, congenital hand defects, or other condition(s) that will impair comparative, measurements in the treated hand or the contralateral, control hand, will be excluded.

G. Study Recruitment

Subjects will be identified and referred by the patient's primary orthopedic surgeon, either Dr. Rosenwasser or Dr. Strauch, after confirmation that the patient meets inclusion criteria.

H. Confidentiality of Study Data

Study data will be coded and a unique identifier will be assigned to each subject. All study data will be stored in a locked cabinet in the Department of Orthopedics Trauma Training Center, accessible only to the investigators of the study.

I. Potential Conflict of Interest

None

J. Location

Dept. of Orthopaedic Surgery at CUMC

K. Potential Risks

The lateral plating system confers some risk of damage to the radial sensory nerve when achieving operative exposure as well as potential irritation of the first dorsal compartment. In addition, the lateral plating technique may provide poor clinical results compared to other treatments, with limitation of grip strength, range of motion, and function, as well as persistent wrist pain and the development of arthritis. Other risks are standard orthopaedic surgical risks and are not specifically related to the present study.

L. Potential Benefits

Patients may benefit from the operative treatment.

M. Alternative Therapies

Treatment of unstable distal radius fractures is highly controversial. Several plating systems, external fixation systems, and methods of percutaneous pinning exist. All of these techniques have been proven effective, but none has been shown to have a clinical advantage over another.

N. Compensation

none.

O. Costs to Subjects

Patients will not incur any additional costs due to their participation in the study.

P. Minors as Research Subjects

Not applicable.

Q. Radiation or Radioactive Substances

Radiography and fluoroscopy are part of standard treatment and follow-up of distal radius fractures. This study will not involve any additional radiation risks.

R. References

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