MEDCO FORUM®
PRESENTING INNOVATIVE PRODUCTS AND SERVICES TO HEALTHCARE PROFESSIONALS
VOLUME 16 NUMBER 4 FEBRUARY 2009
REPRINT

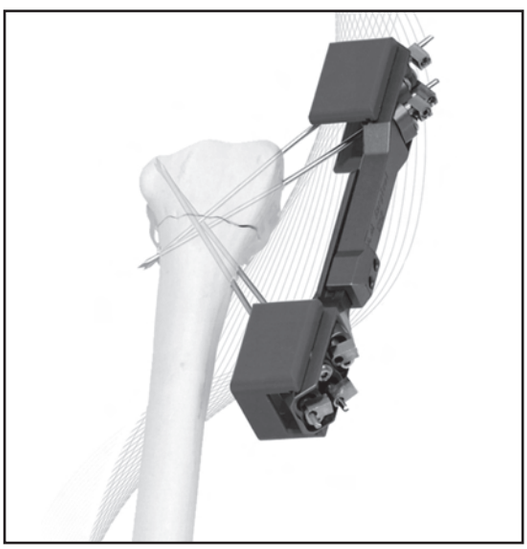
CPX—Non-Spanning, Cross-Pin Distal Radius Fixator

Treatment Pendulum Gains Momentum Toward Less Invasive Devices

Just as Galileo once watched the lamp swing back and forth in the cathedral in Pisa, so too are Ather Mirza, MD and his orthopedic colleagues watching the treatment pendulum swing back toward less invasive treatment options for dealing with distal radius fractures. And this time, a novel non-spanning external fixator is leading the renaissance.

Orthopedists have seen the pendulum swing from numerous treatment options (closed reduction with plaster, percutaneous pinning, external fixators) toward open reduction internal fixation (ORIF). However, several factors have contributed to a recent shift in treatment philosophy: recent literature and lectures describing encouraging outcomes for distal radius fracture patients treated with means other than the plate; and secondly, results are surfacing of long-term sequelae with ORIF.

"Ideally, if a fracture can be held relatively rigid, yet allow for early mobilization and resumption of activities of daily living, with minimal soft-tissue dissection and complications, then that is the best approach," said Dr. Mirza. He believes that the CPX non-spanning, cross-pin distal radius fixator (**A.M. Surgical, Inc., Smithtown, NY**), will help provide the momentum necessary to swing the pendulum away from ORIF toward minimally invasive options.



The CPX from A.M. Surgical, Inc.

Background

In developing the new device, Dr. Mirza evaluated the available treatment options:

Open reduction and internal fixation provides stable anatomic reduction and early mobilization, but requires extensive soft-tissue dissection. There are also potential complications, such as nerve damage, tendon rupture, screw penetration into the articular surface, and plate removal—to name a few. The procedure is often limited to hand surgeons who are most comfortable with the soft-tissue dissection aspect. Dr. Mirza wanted to devise a procedure that would be available to all surgical comfort zones.

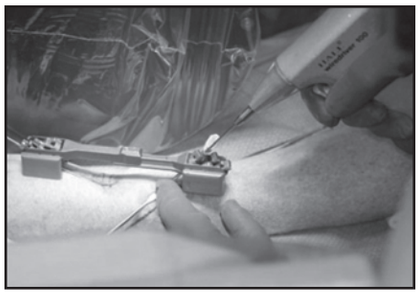
Traditional spanning fixators are another option requiring less surgery, but most devices on the market are bulky and do not necessarily control all parameters of the fracture directly. Other concerns are pin track infection, the fact that the device unloads the fracture and excessive traction can result in a notably stiff wrist and finger joints.

Percutaneous pinning provides a simple and minimally invasive option as well, but alone may not provide enough stabilization to maintain fracture reduction. This, combined with external fixation, provides enhanced rigidity. However, most fixators are unwieldy and rely on ligamentotaxis throughout the healing process, leading to issues previously described.

Origins of CPX

The challenge facing Dr. Mirza was to combine the best of all worlds—to develop a system or device that would stabilize reduction and allow early mobilization of the wrist, all through a less invasive surgery. With these goals in mind, the CPX was conceived as a hybrid of cross k-wire and non-spanning external fixation. This latter component provides stability to the cross-pin construct, holding reduction of the distal radius fracture without compromising wrist mobilization.

The CPX system is unique in its approach in that it is an external fixator that directly controls



Insertion of k-wire though the CPX. A tissue protector is used.

the fracture without ligamentotaxis. It does so by taking a multi-planar (variable angle) cross-pinning approach coupled with an external buttress, which provides greater rigidity and superior fixation. Compared with existing external fixators, the pins of the CPX system are more longitudinally oriented and do not unload the fracture. The CPX uses small-diameter k-wires (0.062 in; 1.6 mm) that flex when the construct is put in place, allowing for load-sharing across the fracture fragments. A detailed theoretical explanation is provided by Mirza & Reinhart.[1]

Biomechanical Study

To validate the mechanical strength of the CPX device, Strauss *et al.*[2] compared the stability of the CPX with a standard volar locking plate for the treatment of unstable distal radius fractures. Replicating the deforming forces associated with fracture management, the authors concluded that there is no significant difference in the mechanical stiffness between the CPX and the volar plate in a cadaveric fracture model and both constructs appear to be biomechanically equivalent.

"This was fantastic evidence," Dr. Mirza commented. "If the CPX construct is as biomechanically rigid as the plate for treating unstable extra-articular fractures, then the CPX will maintain the reduction just as well, obviating the need for extensive soft tissue dissection."

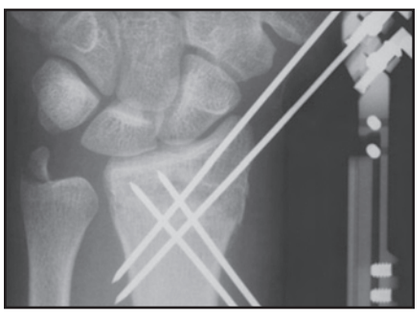
Clinical Study

Having established the biomechanical properties, the next step was to subject the CPX to a clinical study. Dr. Mirza is publishing a paper on 21 patients who received treatment with the CPX—13 females and eight males, with a mean age of 54 years and with a minimum one-year follow-up.[3]

The study found that there was no loss of reduction; and at final follow-up, mean grip and lateral pinch strength recovered 86 percent and 94 percent respectively. There were no pin track infections, non-unions, or tendon injuries. All patients returned to their prior employment and activities.

Dr. Mirza points out that the CPX is not indicated for all distal radius fracture patterns. "The prerequisite is quite simple," he said. "If you can close reduce the fracture then the CPX is applicable for treatment." He recommends that you attempt the reduction, and if you cannot restore the fracture to your standards, then move to ORIF.

Dr. Mirza also comments on pin track infection, which is a common concern. Through his clinical experience he has not seen any infections in more than 60 CPX patients. His explanation is that since the pins are inserted on the mid-lateral plane of the radius, there is little movement of the skin around them, limiting irritation and infection throughout the course of treatment. He adds that the pins are smooth and are not the larger-diameter threaded screws that are more commonly associated with pin track infection. He also promotes the use of Hibiclens,® gauze, and pin site care by the therapist during routine patient visits.



Fluoroscan of anteroposterior view showing four k-wires buttressed by the CPX.

Practical Application

In other hands, the CPX has been well received. Anthony Viola, MD is an orthopedic surgeon with New Milford Orthopedic Associates, PC in Connecticut. He feels that Dr. Mirza has indeed capitalized on the simplicity of percutaneous pinning with the added rigidity of the non-spanning external fixator. He adds, "If you can obtain comparable results with the CPX, it is difficult to justify ORIF." And he comments that his patients are often relieved when they are told that they do not have to endure invasive surgery.

William Terrell, MD is an orthopedic surgeon at Pinnacle Orthopaedics (Marietta, GA) who is equally enthusiastic. He was amazed at the strength of the device and immediately saw the potential as an alternative to the plate where appropriate. He further makes the wry observation that ORIF can be as traumatic as the original injury itself, adding "there has been a trend towards minimally invasive surgery in the last 10 years and the CPX meshes perfectly with this philosophy."

The clinical and anecdotal evidence supporting the CPX, together with the positive surgeon and patient response, indicates that the CPX is destined to become the fixator of choice for the treatment of reducible distal radius fractures. The pendulum has indeed started to swing the other way.

To Learn More

For more information about the **CPX,** including improved reimbursement information compared to ORIF, and references to the published literature, please call **A.M. Surgical, Inc.** at 1-800-437-9653, or email to cpx@amsurgical.com.

References:

1. Mirza, A. & Reinhart. M.K. In: Fractures and Injuries of the Distal Radius and Carpus. Ed. D. Slutsky & A.L. Osterman 2008 63-74.
2. Strauss, E.J., Banerjee, D., Kummer, F.J. & Tejwani, N.C. *J of Trauma Injury, Infection, and Critical Care* 2008 64 (4) 975-981.
3. Mirza *et al. J Hand Surgery* (in press).