Evaluation of a Novel, Nonspanning External Fixator for Treatment of Unstable Extra-articular Fractures of the Distal Radius: Biomechanical Comparison With a Volar Locking Plate

Eric J. Strauss, MD, Devraj Banerjee, MD, Frederick J. Kummer, PhD, and Nirmal C. Tejwani, MD

Purpose: To compare the stability of a novel, nonspanning external fixator with a standard volar locked plate for treatment of unstable distal radius fractures.

Methods: A simulated, unstable, extra-articular distal radius fracture was created in six matched pairs of fresh frozen human distal radii. One of each pair was treated with a nonspanning external fixator [Mirza Cross Pin Fixator (CPX), A.M. Surgical Inc. Smithtown, NY] and the other was treated with a volar locked plate [Distal Volar Radial Plate (DVR), Hand Innovations, Miami, FL]. Each specimen was axially loaded in central, dorsal, and volar locations, loaded in cantilever bending in volar to dorsal, dorsal to volar, and radial to ulnar directions and loaded in torsion. Load-displacement curves were generated to determine the construct stiffness for each loading schema, with comparisons made between the two treatment groups. Specimens were then cyclically loaded with 50 N axial loads applied for 1,000 and 10,000 cycles. Measurement of construct stiffness was repeated and comparisons made both between the two treatments and within treatments to their precycling stiffness.

Results: There was no significant difference in the mechanical stiffness of the nonspanning external fixator and the volar locking plate after axial loading in any of the loading modalities.

Cyclic loads of 1,000 and 10,000 cycles resulted in no significant difference in construct stiffness between the nonspanning external fixator and volar locked plate. However, the nonspanning external fixator demonstrated decreasing stiffness after cyclic loading with 10,000 cycles ($p < 0.02$).

Conclusion: This study demonstrated no significant difference in the mechanical stiffness of the CPX nonspanning external fixator and volar locked plate in a cadaveric fracture model. Both constructs appear to be biomechanically equivalent in this experimental model; however, this is only one factor in the choice of fixation device for the management of unstable distal radius fractures.

Key Words: Biomechanics, Distal Radius fracture, External fixation, Volar locked Plate.

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Distal radius fractures are common injuries encountered by the orthopedic surgeon. Treatment outcome is dependent on several variables including fracture configuration, the degree of initial displacement, the quality of reduction, maintenance of the reduction through the treatment period, and functional rehabilitation.[1]

The use of nonspanning external fixation for the treatment of distal radius fractures has demonstrated good radiographic and functional outcomes in clinical studies.[2–9] Nonspanning external fixators have the advantage of providing stable fixation without disturbing the biological environment at the fracture site.[10] Additional advantages to this technique include its minimally invasive nature and the ability to start early mobilization of the wrist and forearm. The design of the experimental nonspanning external fixator used in this study allows for stable fracture fixation with a crossed pin configuration, with variable angle inserts allowing the surgeon to adapt the Kirschner wire insertion to each specific fracture. Potential complications associated with the use of external fixation for distal radius fractures include pin tract infections and nerve and tendon injuries.

In recent years, the use of volar, locked plates has gained popularity as a treatment option in the management of distal radius fractures. Volar locked plating constructs have the advantage of providing multiple fixed angle fixation in the distal fracture fragment, providing fracture stability even in osteoporotic bone while allowing early wrist motion.[11,12] Locking plate designs utilizing pegs rely on an interference fit in the distal fragment, obviating the need for threads to obtain bony purchase. Disadvantages of this treatment technique include the disruption of the fracture environment, flexor tendon complications,[13,14] and possible extensor irritation caused by long screws.[14]

Both fixation techniques have been used successfully in clinical settings for unstable intra-articular and extra-articular fracture patterns yet there have been few reports comparing the biomechanical properties of the two treatment options. This investigation performed a biomechanical evaluation and comparison of a novel, experimental, nonspanning external fixation design to a volar, locked plate for fixation stability in a cadaveric unstable, extra-articular distal radius fracture model. We hypothesized that there would be no significant difference between the two fixa-

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From the Department of Orthopedic Surgery, NYU-Hospital for Joint Diseases, New York, New York.
Address for reprints: Eric J. Strauss, MD, Department of Orthopedic Surgery, NYU-Hospital for Joint Diseases, 301 East 17th Street, New York, NY 10003; email: ericstraussmd@gmail.com.
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tion designs with respect to biomechanical stiffness and the resulting fixation stability.

MATERIALS AND METHODS

The experimental protocol for the current study was based on a previous experiment comparing different plating devices for distal radius fracture fixation.[15] For this biomechanical evaluation lower loads were applied in an effort to preclude any ordering effect from the multiple tests run on each specimen. To adequately assess the stiffness of each fixation device at the bone-device interface the number of applied cycles was increased to compensate for the lower applied load.

For this biomechanical evaluation, six matched pairs of fresh frozen human cadaveric distal radii were harvested and radiographed to rule out any underlying pathology. The proximal radial shafts of each specimen were potted with acrylic cement in 4.5 cm diameter polyvinyl chloride pipe that was 6 cm long, leaving approximately 8 cm of the radius exposed. Throughout the experiment, each specimen was kept tightly wrapped in airtight double bags to avoid desiccation and by the use of saline soaked gauze during testing.

An experimental unstable, extra-articular distal radius fracture was simulated in each potted cadaveric distal radius. First, an oscillating saw was used to create a transverse osteotomy 2 cm proximal to the articular surface. Next, a 1.5 cm fracture gap was created by making a second transverse osteotomy 1.5 cm proximal to the initial cut with the oscillating saw and this section of bone was removed, simulating the complete lack of cortical contact seen in severely comminuted unstable, extra-articular distal radius fractures. One specimen from each matched pair was randomly selected to undergo fracture fixation using a novel nonspanning external fixation device (Mirza Cross Pin Fixator (CPX), A.M. Surgical Inc., Smithtown, NY), while the other was fixed with a volar locked plate (Distal Volar Radial Plate (DVR), Hand Innovations, Miami, FL). Each fracture was instrumented according to the surgical protocol for each device. A premeasured 1.5-cm piece of rigid foam (Sawbones, Vashon, WA), used as a spacer, was inserted into the fracture gap to facilitate fixation. The fracture in the external fixator group (Mirza CPX) was stabilized using four multi-planar 0.062 inch trans-fragmentary Kirchner wires coupled to the radial external fixator, which was placed 25 mm from the bone. The experimental Mirza CPX design is a variable angle device, allowing the surgeon to choose the Kirschner wire placement angle. This design creates a crossed Kirschner wire configuration, with the wires crossing the fracture site from two directions. Once the Kirschner wire is inserted, tightening of a hex screw locks it in position through a cone locking mechanism. In the volar locked plate group, the distal fragment was fixed using locking screws in every available distal hole (7 screws) and the plate was secured to the diaphysis using two 3.5 mm nonlocking screws placed in buttress mode. Once the specimens were instrumented, the 1.5 cm spacer was removed by carefully tapping it out with a bone tamp and the distal portion of each specimen was potted with acrylic cement in 4.5 cm diameter polyvinyl chloride piping that was 3 cm long (Fig. 1). While potting the distal radius fragments, both the Mirza CPX group and the volar locked plate group, had a layer of clay placed over the fixator's pins or the plate and screws to prevent their engagement with the potting material and ensure that load was only transferred from the fixture to the most distal fracture fragment.

Fig. 1. *Cadaveric distal radius fracture model in which the fractures were treated with either a CPX nonspanning external fixator (*right*) or a volar locking plate (*left*).*

Biomechanical evaluation was performed using an Instron 2000 Universal Material Testing Machine (Instron, Canton, MA) for axial compressive loading at central, dorsal and volar locations, cantilever bending in volar to dorsal, dorsal to volar and radial to ulnar directions, and in torsion (Fig. 2). Five minutes were taken between testing phases to allow specimens to reach equilibrium. Each specimen was loaded at a rate of 1 N/s to a maximum load of 50 N (25 N with a 2 cm moment arm in torsion). Load-displacement curves were generated for each specimen for each mode of loading, and the slope of the curve was determined. Construct stiffness was calculated in Newtons/millimeter for axial and cantilever bending and Newton-meters/degree for torsional loading.

Next, each specimen was cyclically loaded with 50 N central, axial compressive loads applied at a rate of 3 Hz for 1,000 cycles. The specimens were allowed to reach equilibrium (120 seconds) after the cyclic loading, and then retested to determine construct stiffness. This process was repeated after an additional 10,000 cycles.

Paired Student T-Tests were used for statistical comparisons. A p value of <0.05 was considered to be statistically significant. Based on the lack of a significant difference between the two treatment groups, a post hoc power analysis was performed.

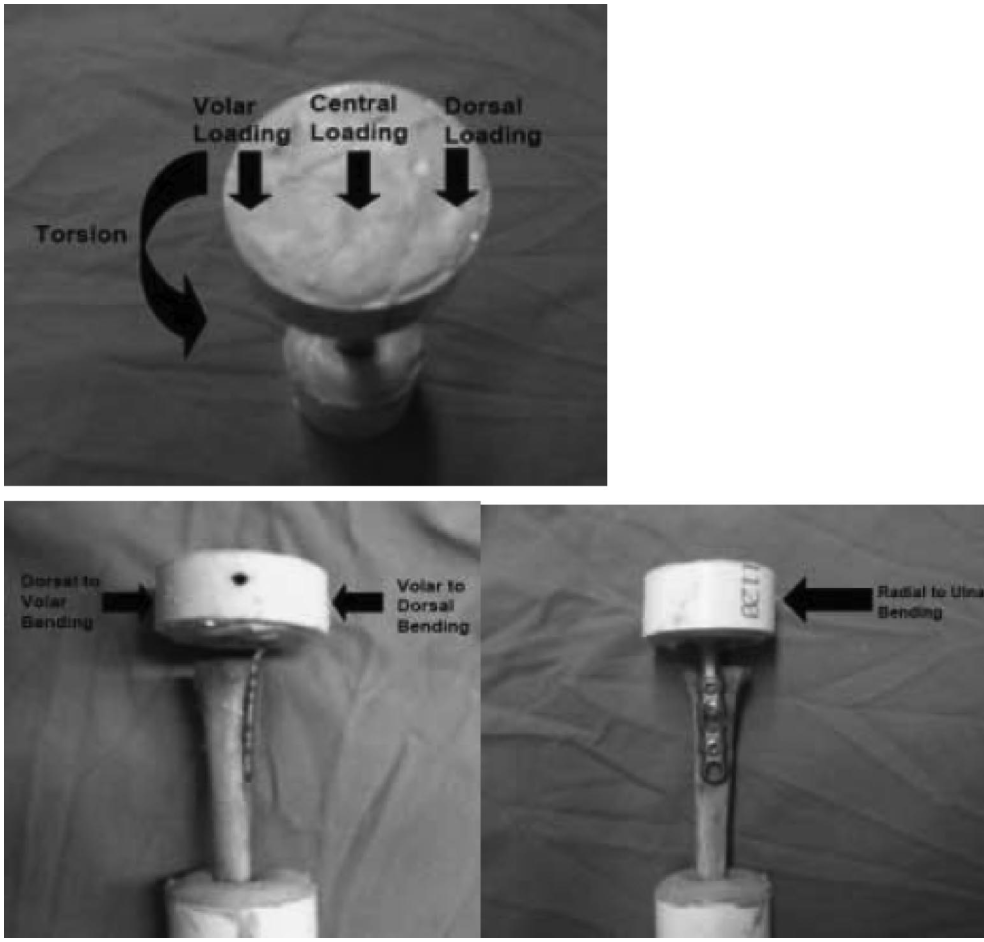

Fig. 2. *Loading schema for potted bone/implant constructs utilized for biomechanical evaluation.*

RESULTS

Specimen loading for each loading scenario resulted in linear load-displacement curves without appreciable toe regions. (Fig. 3) This allowed for the calculation of construct fixation stiffness as the slope of the linear stiffness portion of each curve (Fig. 4).

No significant difference was noted in construct stiffness between specimens treated with the nonspanning external fixator and those treated with the volar locked plate with axial loading in the central, dorsal or volar positions ($p = 0.40$, $p = 0.16$, and $p = 0.84$ respectively). Similarly, there was no difference found in construct stiffness between the two treatment groups with volar-to-dorsal, dorsal-to-volar and radial-to-ulnar cantilever bending ($p = 0.38$, $p = 0.84$, and $p = 0.33$ respectively) and with torsional loading ($p = 0.34$).

Comparison of the two treatments did not demonstrate any significant differences after cyclic loading with 50 N central compressive loads after 1,000 and 10,000 cycles ($p = 0.20$ and $p = 0.07$ respectively). (Table 1) Compressive stiffness of the volar locked plate construct did not demonstrate significant change after cyclic loading with 1,000 and 10,000 cycles ($p = 0.19$ and $p = 0.32$ respectively) compared with precycling stiffness. Compressive stiffness of the nonspanning external fixator construct demonstrated no significant change after cyclic loading with 1,000 cycles ($p = 0.15$). External fixator stiffness was significantly lower after 10,000 cycles compared with precycling stiffness ($p < 0.02$), although the absolute difference between pre- and postloading was only 3.4 N/mm.

Based on the number of samples tested in our study and the mean mechanical stiffness determined during specimen loading, a post hoc power analysis determined that for 80% power, the minimum significant difference that could be detected was 9.2 Newton-millimeters/degree for torsional stiffness and the minimum significant difference that could be detected was 34.3 N/millimeter for central compressive stiffness.

DISCUSSION

Currently there is no consensus within the orthopedic community with respect to the ideal method of operative fixation in cases of unstable distal radius fractures. Surgical techniques using both external fixation and volar plating have been well documented in their ability to restore distal radial anatomy and allow for excellent functional outcomes. The application of external fixation in the treatment of an unstable distal radius fracture relies on soft tissue ligamentotaxis to

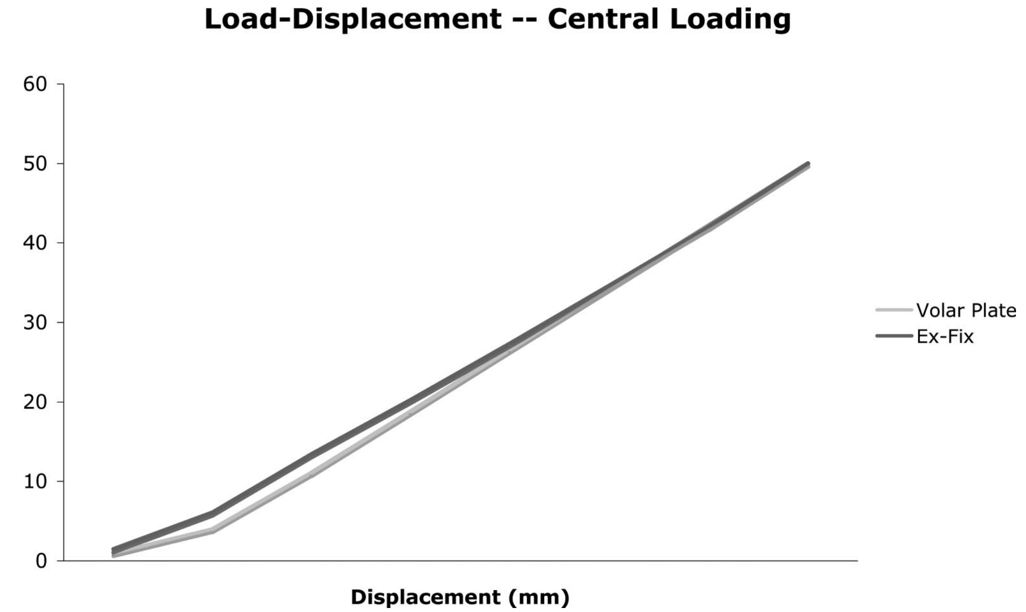

Fig. 3. *Representative load-displacement curve generated during central loading of the two treatment constructs. The calculated stiffness shown was 459.1 N/mm for the volar locking plate and 450.6 N/mm for the external fixator.*

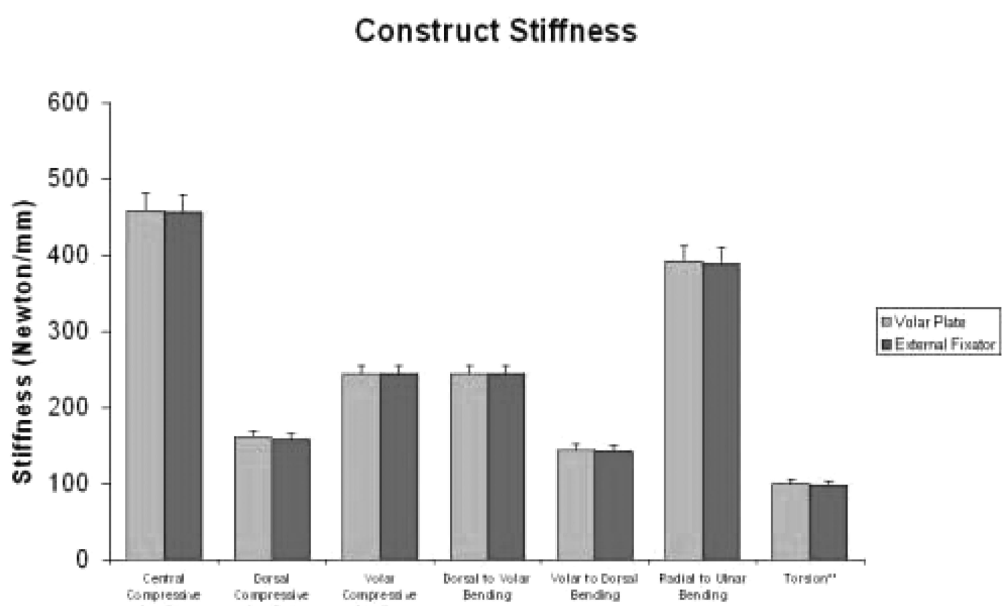

Fig. 4. *Mechanical stiffness of volar plate and external fixator constructs during seven different modes of loading. **Torsional stiffness as measured in Newton-millimeters/degree.*

achieve fracture fragment reduction. Indications for the use of external fixation include open fractures, bilateral distal radius fractures, and unstable distal radius fractures in young manual laborers. The advantages of the nonspanning type of external fixation include maintaining the biological environment at the fracture site while providing stable fixation and allowing for early mobilization of the wrist and forearm. Recently, volar locked plates have gained popularity among orthopedic trauma surgeons and hand surgeons treating distal radius fractures. Volar locked plating is indicated in patients with osteoporotic bone, in cases of failed closed treatment and in fractures with significant comminution that are at high risk for loss of reduction. Advantages of volar locked plating include providing stable subchondral fracture fixation in osteoporotic bone, precise restoration of distal radial anatomy and the ability for early active wrist ROM.

In a recent clinical study, Wright et al. retrospectively compared functional outcomes following the operative treatment of unstable distal radius fractures with either external fixation or fixed angle volar plating.[16] At a mean follow up of

Table 1 Mean Mechanical Stiffness of Volar Plate and CPX External Fixator Constructs After Cyclic Compressive Loading at 1, 1,000, and 10,000 Cycles

	Mean Volar Plate Stiffness (SD), N/mm	Mean CPX External Fixator Stiffness (SD), N/mm
After 1 cycle of 50 N central compressive loading	458.6 (20.6)	457.1 (17.4)
After 1,000 cycles of 50 N central compressive loading	457.6 (18.8)	455.9 (16.2)
After 10,000 cycles of 50 N central compressive loading	457.8 (22.7)	453.7 (20.3)*

* Statistically significant difference between the stiffness of the external fixator after 1 cycle and the stiffness after 10,000 cycles.

47 months for the 11 patients treated with external fixation and 17 months for the 21 patients managed with ORIF the authors found similar wrist and forearm range of motion between the 2 patient cohorts. Functional outcome as measured by the Disability of the Arm, Shoulder, and Hand Questionnaire and Patient Rated Wrist Evaluation was also similar between the two treatment groups. Although evaluation of follow up radiographs demonstrated better restoration of radial length, volar tilt and articular reduction with volar plating, grip strength was significantly better in the patients managed with external fixation.[16]

Margaliot et al. performed a meta-analysis including 46 studies comparing outcomes between external fixation and plate fixation in the management of unstable distal radius fractures.[17] Based on the pooled data, the authors found higher rates of infection, neuritis and hardware failure with external fixation while higher rates of tendon complications and the need for early hardware removal were seen with plate osteosynthesis. Overall, there was no significant difference in wrist range of motion, grip strength, postoperative pain or radiographic alignment found between the two treatment options. Based on these findings the authors concluded that both external fixation and volar plating are viable treatment options in the management of unstable distal radius fractures.[17]

At the present time there have been few reports in the orthopedic literature comparing the biomechanical properties of volar locked plating and nonspanning external fixation. In the current study, we found no significant difference in the biomechanical stiffness of volar locked plates compared with the CPX nonspanning external fixation device during initial cantilever bending, axial and torsional loading. After 10,000 cycles of central compressive loading, we found that the axial stiffness of the nonspanning external fixator significantly decreased compared with its precycling stiffness, although the absolute difference in stiffness between pre- and postloading was only 3.4 Newtons/millimeter. Where this change was not grossly visible, this decrease in stiffness may be caused by loosening at the pin coupling with the fixator as a result of the vibrational effect of the axial loading protocol. Clinically, this highlights the potential importance of assessing the fixator tightness in the early follow-up period.

The optimal size, number, and configuration of K wires for the stabilization of the distal radius fractures have been evaluated biomechanically by Naidu et al.[18] Using a fresh-frozen cadaveric extra-articular distal radius fracture model, the authors found that percutaneous pinning with a crossed configuration having two 0.062-inch pins introduced from the radial side and one from the ulnar side created the most rigid construct in both torsion and cantilever bending. Crossed Kirschner wire configurations have demonstrated better bending and torsional stiffness and a more normal distribution of bone stresses in validated finite element analysis.[19] However, it is important to acknowledge that wire configurations that cross the fracture site are accompanied by their own potential risks. Pin tract infections, which have been reported to occur in up to 21% of distal radius cases managed with external fixation, may extend to the fracture site potentially leading to an infected nonunion, significantly complicating the treatment course.[20]

Dunning et al., in a biomechanical study, compared the fragment stability achieved with a 3.5 mm dorsal AO plate, a Hoffman external fixator, and a Hoffman external fixator supplemented with two 0.062 inch parallel trans-styloid Kirschner wires, in a sophisticated cadaver fracture model.[21] The authors found that fracture fragment stability in the augmented external fixator group approached that of AO dorsal plate in nearly all modes of testing. The only significant difference reported was in rotation, where the dorsal AO plate was significantly more stable than the external fixation constructs. The authors postulated that a crossed Kirschner wire configuration would have added more rotational stability to the augmented external fixator construct. In the present study, we used four 0.62-inch crossed Kirschner wires inserted with a wide angle of crossing and locked to a nonspanning external fixation device. This crossed Kirschner wire configuration created a construct with no significant difference in mechanical stiffness compared with volar locked plates.

Liporace et al., in a biomechanical comparison of a dorsal T plate and a volar fixed angle plate, reported that the volar locked plate was stiffer than the dorsal plate in both volar and ulnar loading.[15] The authors found that the volar locked plate was stiffer than the dorsal plate in all modes of axial loading with the exception of dorsal loading. They noted a trend for increased axial stiffness of the volar locked plate after cyclic loading presumably caused by compression of the locking screw against the subchondral bone.[15] In the current study, there was no difference in the stiffness of the two constructs after single cycle multi-axial loading to 50 N, nor after central compressive loading with 50 N for 1,000 and 10,000 cycles. We did not detect the trend toward increased axial stiffness of the volar locked plate potentially caused by the smaller applied load in our study (50 N vs. 80 N).

In a similar biomechanical study, Trease et al. compared dorsal and volar locked and nonlocking plates in a cadaveric distal radius fracture model with dorsal comminution.[22] The authors found no significant differences in stiffness or failure strength between volar locked and nonlocked plates. Axial loading demonstrated that the stiffness of dorsal locked plates was 50% greater than that of nonlocked plates, but this difference failed to reach statistical significance. Load to failure testing showed that the failure strength of dorsal constructs (locked and nonlocked) was 53% higher ($p < 0.02$) than that seen with volar constructs (locked and nonlocked).

The biomechanical stiffness values of the volar locked plates in our investigation are comparable to that seen in other biomechanical studies. After central loading, we found a mean stiffness of 459 N/mm, which was very similar to the 457 N/mm in the study by Trease et al.[22] and slightly higher than the 430 N/mm found by Liporace et al.[15] The stiffness of the volar locked plate after dorsal and volar off-center loading was 160 N/mm and 244 N/mm, respectively, which agrees with the 150 N/mm for dorsal loading and 250 N/mm for volar bending in Liporace's investigation.[15] The stiffness values found for the CPX nonspanning external fixator were significantly higher than that shown with percutaneous pinning in the study by Naidu et al.[18] This is likely secondary to the rigidity provided by the external fixator component with its locked pin coupling.

There are a few limitations to our investigation. They include the use of cadaveric specimens with their inherent variability and the use of isolated radii stripped of all soft tissue to assess the stiffness of the two constructs. Although this method has been used in various studies, a model with intact soft tissue may have been more clinically relevant. Our evaluation of construct stiffness used applied loads that were approximately 50% lower than the maximum loads normally seen physiologically.[15] Differences between the tested constructs may be found with higher applied loads and testing each construct to failure. Finally, the biomechanical evaluation performed in this study utilized separate axial loading, cantilever bending and torsional loading to simulate the multidirectional physiologic loads experienced by the fracture fixation techniques in vivo. We acknowledge that physiologic loading during activity is more complex.

This study performed a biomechanical evaluation and comparison of the CPX nonspanning external fixator and the volar locked plate for treatment of an unstable, extra-articular distal radius fracture. In this experimental model, we found no significant differences in the fixation stiffness of the two tested devices initially or after cyclic loading. After 10,000 cycles of axial loading the compressive stiffness of the CPX external fixator was lower than its precycling stiffness; however, there was still no statistically significant difference in the postcycling stiffness of the CPX fixator and the volar locked plate. The results of this biomechanical study suggest that a nonspanning external fixator may be a viable alternative for treatment of unstable distal radius fractures with equivalent rigidity to volar locked plates.

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