The Effect of Locking Screws on Distal Component Fixation in Total Wrist Arthroplasty Using a Cadaver Model

Ryan J. Quigley, MD, PhD,* Catherine Ambrose, PhD,† Brian D. Adams, MD‡

*Department of Orthopedics, Kaiser Permanente, Sacramento, CA
†University of Texas Health Science Center at Houston, Houston, TX
‡Department of Orthopaedics, Baylor College of Medicine, Houston, TX

Purpose: The advent of total wrist arthroplasty has allowed for motion-sparing surgical treatment for wrist arthritis. The Integra Freedom Total Wrist Arthroplasty recently incorporated locking caps into its distal component fixation to minimize implant micromotion and improve osseous integration. The purpose of this study was to assess the kinematic effect of locking caps in a cadaveric model.

Methods: The Integra Freedom was implanted in 4 matched-pair cadavers and tested with and without the use of the locking caps, with the testing order randomized. Each specimen was tested on a custom testing system in a position of 15° of radial deviation, neutral position, and 15° of ulnar deviation with 25 N, 50 N, 75 N, and 100 N of compressive force. The rotation of the capitate, trapezoid, and hamate at all positions was measured using a 3-dimensional digitizer.

Results: Statistical analysis showed no difference in carpal rotation between the nonlocking cap and locking cap groups at all testing loads and wrist positions. The absolute motion of the distal row was minimal. However, of the total 216 loads/positions tested, only 4 (1.8%) showed a rotation of greater than 2° and only 34 (15.7%) showed a rotation of greater than 1°.

Conclusions: This study shows that in a time zero cadaveric model, the initial osseous fixation of the distal component in the Integra Freedom is robust with or without locking caps. The addition of locking caps did not have a kinematic effect on distal carpal row fixation. However, further investigation into its clinical role is necessary.

Clinical Relevance: At time zero, there is minimal carpal motion after implantation of the Integra Freedom Total Wrist with functional loading. The addition of locking caps did not lead to any decrease in carpal motion.

Severe wrist arthritis has historically been treated by arthrodesis, which provides predictable pain relief but sacrifices motion, resulting in reduced function. Total wrist arthroplasty was introduced as an alternative to relieve pain and preserve useful motion. Unfortunately, the clinical outcomes of early total wrist arthroplasty designs were often poor, with distal component loosening being a leading cause of implant failure.1–9 These early clinical failures tempered enthusiasm for the procedure10 but also prompted the development of different implants designed to improve implant fixation, increase joint stability, and expand indications beyond patients with rheumatoid arthritis.

The current total wrist arthroplasty implants, often termed fourth-generation designs, that are currently available in the United States are the Remotion (Stryker) and the Freedom (Smith & Nephew), which are substantially based on the principles of the Universal total wrist (KMI) designed by Menon, which is no longer available. The Universal design included a carpal baseplate with a central post cemented into the capitate and an additional baseplate fixation provided by radial and ulnar screws inserted into the adjacent carpals. An intercarpal arthrodesis to improve carpal component bony support is also recommended. Early clinical
results were promising, with patients showing improved wrist motion and pain scores. However, complications continued, with the Universal total wrist showing radiographic distal component loosening or migration at rates as high as 50% in 1 long-term follow-up study of rheumatoid patients, as well as prosthesis dislocations up to 14%. Given the continued challenges with component loosening and prosthesis dislocations, the next generation designs focused on more anatomical articulations and osseous ingrowth for cementless fixation. A study by Gil et al with a mean follow-up of 9 years showed that cementless TWA [Universal total wrist 2 (KMI)] preserved motion, significantly improved the pain score, and had a 75% estimated 15-year survivorship among patients studied. Although these improved outcomes compared with the outcomes of many older designs, distal component loosening occurred in 7.7% of patients.

The Freedom Total Wrist was designed with improved porous coating for greater osseous ingrowth on the stem and baseplate and the addition of locking caps to create variable angle locking screw fixation for the carpal baseplate to reduce distal component loosening. The concept of locking screw fixation was to minimize component micromotion, thereby improving the conditions for implant osseous ingrowth and intercarpal fusion to reduce late component loosening. Previous finite element modeling studies showed that the highest concentration of stress is found around the carpal screws in a construct with nonlocking screws, suggesting that screw micromotion may develop and lead to implant loosening. Locking screw fixation has been used successfully for the baseplate in reverse total shoulder arthroplasty, with a rare occurrence of baseplate loosening. Similarly, the addition of locking caps to the Freedom wrist has the potential to reduce carpal component loosening. To date, no biomechanical study has evaluated the effect of locking cap screw fixation on the carpal base plate. In this cadaveric study, we hypothesized that the addition of locking caps would decrease the motion of the carpus relative to the carpal base plate under physiologic loading conditions.

Methods

Specimens

This article does not contain any studies with living human or animal subjects. All institutional policies were followed regarding appropriate use of cadaveric specimens. Informed consent was not required for this study. All institutional policies were followed regarding appropriate use of cadaveric specimens.

Four fresh, frozen matched-pair cadaveric specimens (a total of 8), amputated just distal to the elbow were obtained from the university-willed body program. Two pairs were men and 2 were women, with an average age of 89 years (range, 85 to 94) (Table 1). The institution’s governing policies on storage, usage, and disposal of cadaveric specimens were followed. A power analysis performed before the study showed that 8 specimens in each group would be required to detect 2° of rotational change with 80% power. Before dissection, the specimens were thawed overnight. The specimens were disarticulated at the wrist and metacarpophalangeal joints. All soft tissue (skin, subcutaneous tissue, muscle, and tendons) was removed with care to protect the wrist capsule and ligaments. The wrist was disarticulated through the radiocarpal joint.

Surgical procedure

For this study, the Freedom Total Wrist Arthroplasty system was used (Integra). All implants were placed by the senior author using the technique described in the printed surgical guide. The scaphoid and triquetrum were pinned to the capitate to maintain the positions of the carpal bones and maximize intercarpal contact during implantation. After the lunate was excised, the appropriate implant size was determined using the sizing guide. Using the drill guide, a guide-wire was inserted through the capitate and into the third metacarpal. A cannulated 3.5-mm bit was drilled over the wire to the appropriate depth in the capitate. Using the hamate feeler, the cutting block was applied and pinned at the proper position. The cut was made using a sagittal saw at a level passing through the tip of the proximal pole of the hamate. The hamate bone was disarticulated through the radiocarpal joint. Once the screw was placed through the base plate, the implant size was determined using the sizing guide. Using the drill guide, guide-wires were inserted through the 2 baseplate screw holes. The ulnar-sided pin was inserted into the hamate, and the radial-sided pin passed through the remaining scaphoid, the trapezoid, and into the base of the second metacarpal, approximately 5 mm. A 2.5-mm cannulated bit was drilled to the depth of the guide-wires. Next, 4.5-mm screws of appropriate length were inserted with firm tightness. This was repeated on the ulnar side into the hamate. However, care was taken not to cross the fifth carpometacarpal joint. Once the screw was placed through the base plate, the fifth carpometacarpal joint was shocked to assure the screw had not crossed the joint. If locking caps were to be placed, they were then placed at this point. The locking caps and polyis were all single-use, and all other components were reused. Lastly, the polyethylene liner was impacted in place. The implant sizes for each component are shown in Table 2.

Positioning

The specimens were tested using a custom-built potting jig coupled to an Instron Universal Testing System (Instron, Model 5848) (Fig. 1). To mount the specimens, 1.37 mm (0.054 in) K-wires were inserted transosseous through the metacarpal bases (1 into the thumb and little finger, 2 into each of the others). The ends of the wires were clamped in the jig using corresponding slots on each side of the jig. Bolts at each corner of the clamp were tightened to secure the wires and hold the hand static. The jig was filled with plaster of Paris to impart additional stability. The jig was coupled to the Instron with the long axis of the third metacarpal aligned with the testing cylinder of Instron.

Each radial component was machined along the dorsal and volar sides of its stem to form surfaces for repeated secure clamping in a vice for testing in positions of neutral orientation, 15° of ulnar deviation, and 15° of radial deviation.

Loading

The loading parameters were devised to simulate functional compressive loads with a daily grip. Based on a previous study, the average maximal grip strength for men and women is 40 N, which transmits 106.8 N of force across the radius. Physiologic forces were simulated by testing the specimen with compressive forces of 25 N, 50 N, 75 N, and 100 N, representing a spectrum of physiologic, nondestructive loads. The compressive loads were
applied through the Instron material testing system with a maximum rate of 2 N/S.

Before testing, each mounted specimen was preconditioned to reduce creep, which naturally occurs during the testing of viscoelastic tissues. Preconditioning was done using 25 cycles of loading from 10 to 25 N, holding at 25 N for 30 seconds for each cycle.

Kinematic measurements

Three bony indentations, arranged to form a 90° angle, were made in each capitae, trapezoid, and hamate using an awl on the exposed dorsal surface of each bone (Fig. 1). These 3 indentations created points to form an angle on the carpus with 1 limb pointing distal and the other pointing radial. Three points were also made using a similar technique on the polycomponent of the implant. The 3-dimensional coordinates of the 3 points on each poly and carpus were measured for each testing condition using the vectors formed by the 3 points on the bone and the arc sine function.

Testing

The specimens were randomized to be tested with or without locking caps first (Table 2). After preconditioning, testing began with the radial component in the neutral position. Each specimen was loaded to 10 N, 25 N, 50 N, 75 N, and 100 N. The 3-dimensional coordinates of the points on the poly, capitae, trapezoid, and hamate were recorded for each load. The 10 N condition served as the nominal or control load, against which other loading conditions were compared. The second trial of all loading and measurements was made to assess repeatability. In this study, acceptable repeatability was subjectively set at <0.5 mm based on previous studies, which occurred for every specimen and condition. The average of the measurements from the 2 trials was used for the final result. The same method was repeated for 15° of radial deviation and 15° of ulnar deviation. Once testing was complete for all conditions, the poly was removed, and the locking caps were either added or removed depending on the first condition tested. A new poly was then placed, and testing was repeated. All testing was performed by the lead author.

Data analysis

All reported data are the change in rotation of each carpal bone compared with the 10 N testing condition. Statistical comparison was performed between the locking cap and no locking cap groups at each load and position using a 2-tailed paired student t test. Statistical comparisons between individual loads within each condition (locking cap or no locking cap) were performed using analysis of variance. Additionally, we evaluated if there was any difference between specimens dependent upon which condition was tested first, eg, specimens in which the locking cap was tested first compared with specimens in which the locking cap was tested second. This comparison was made using a 2-tailed unpaired student t test. All statistical analyses were performed using SPSS Software (Tibco).

Results

The results are shown in Figures 3 to 5. Overall, there was minimal motion of the distal carpal row throughout all loads, with or without locking caps. Of the 216 total combinations of position, load, and the presence of locking caps, only 4 testing conditions (1.8%) showed a change of more than 2° from the 10 N loading condition. In addition, only 34 (15.7%) conditions showed a change greater than 1° compared with the 10 N loading condition. There was no statistical difference in rotation in any plane between the locking cap and no locking cap groups at any load or position. Similarly, when comparing loads within the groups of locking caps

| Specimen | Lunate Type | Implant Size | Radial Screw | Ulnar Screw | First Condition |
|----------|-------------|--------------|--------------|-------------|----------------|
| 1 - Left | II          | Size 1       | 30 mm        | 20 mm       | Locking caps   |
| 1 - Right| II          | Size 1       | 30 mm        | 17.5 mm     | No locking caps|
| 2 - Left | II          | Size 2       | 30 mm        | 20 mm       | No locking caps|
| 2 - Right| II          | Size 2       | 35 mm        | 25 mm       | Locking caps   |
| 3 - Left | II          | Size 1       | 30 mm        | 17.5 mm     | No locking caps|
| 3 - Right| II          | Size 1       | 30 mm        | 17.5 mm     | No locking caps|
| 4 - Left | II          | Size 2       | 30 mm        | 17.5 mm     | Locking caps   |
| 4 - Right| II          | Size 2       | 30 mm        | 17.5 mm     | Locking caps   |

Figure 1. A custom testing system with the 3 markers measured at all testing positions to measure carpal rotation. The carpal bones with markers are from left to right: trapezoid, capitae, hamate.
and no locking caps, there was no significant difference ($P > .05$) in rotation between loading conditions (10 N, 25 N, 50 N, 75 N, 100 N) at any position.

Last, our subgroup analysis showed there was no effect on whether locking caps were placed first or second in each specimen. The group in which the locking cap was placed first was not

$$\begin{align*} 
(P_x, P_y, P_z)_{X_b} &= \text{coordinates of point in the new baseplate coordinate system, } X_b \\
[R_{\text{base}}]_{\text{exp}}^{-1} &= \text{inverse of rotation matrix for baseplate coordinate system} \\
(P_x, P_y, P_z)_{X_{MS}} &= \text{coordinates of any point in the Microscribe coordinate system, } X_{MS} \\
(O_x^B, O_y^B, O_z^B)_{X_{MS}} &= \text{coordinates of origin point on the Baseplate in } X_{MS} 
\end{align*}$$

Figure 2. The coordinate transformation equation for the creation of a specimen-specific 3-dimensional coordinate system

Figure 3. Kinematic measurements in the flexion/extension plane for each wrist position (neutral, radial deviation, ulnar deviation), without locking caps (left column) and with locking caps (right column). All measurements are reported as the change from the 10 N condition.
Discussion

Our study assesses the effect of variable angle locking screw fixation on the Integra Freedom Total Wrist. Despite the theoretical benefit of adding variable angle locking screw fixation, our study found that adding locking caps to the carpal screws had no significant effect on carpal component motion relative to the carpus immediately following implantation. However, the results demonstrated that the construct is rigid at the time of initial fixation, both with and without locking caps. A change in rotation of more than 2° occurred in only 1.8% of the testing conditions, and rotation greater than 1° occurred in only 15.7%.

Distal component loosening with total wrist arthroplasty has been recognized since the second-generation cemented implants, including the Volz (Howmedica) implant, with a distal component loosening rate of 24%. The Universal Total Wrist, a third-generation implant and prototype for current generation implants, introduced the concept of a central carpal component cemented stem combined with radial and ulnar screws for carpal fixation. Although the design was considered an advancement, the radiographic loosening rates of the cemented distal component reached upward of 50% (10/20), and loosening was the indication for 90% of the revisions (9/10) at a mean follow-up of 7.3 years. With progression to cementless distal components, the revision rate for loosening decreased significantly. One study showed 7.7% loosening at a mean follow-up of 9 years, but another showed 45% loosening at a mean of 7 years.

Although cementless fixation through osseous ingrowth may have improved loosening rates, distal component migration and loosening remain challenging clinical problems. The locking caps added to the Freedom Total Wrist create variable angle locking screw fixation for the distal component, which is intended to decrease carpal micromotion and promote osseous ingrowth.

statistically significant from the group in which it was placed second.
Pronation/Supination

Figure 5. Kinematic measurements in the pronation/supination plane for each wrist position (neutral, radial deviation, ulnar deviation), without locking caps (left column) and with locking caps (right column). All measurements are reported as the change from the 10 N condition.

thereby decreasing distal component loosening. The concept is supported by biomechanical studies showing that the highest concentration of stress is located around the 2 carpal screws. Given the success, both clinically and biomechanically, of glenoid baseplate fixation in reverse total shoulder arthroplasty that uses locking screw fixation, there is reason to be optimistic in applying the same concept to carpal component fixation.

This study has several limitations. The testing was performed at time zero after implantation in a cadaveric study, which does not account for short-term and long-term bone remodeling that naturally occurs, including osseous integration. Although cyclic loading was applied, the number of cycles and range of loads did not replicate the cumulative stresses applied to the implant over years of functional loading. The construct was loaded only in axial compression, which may be its most stable position; off-axis loading, such as lateral bending, may have demonstrated the benefit of locking screws. Testing to failure may have also shown an effect of locking screws. However, we believe that loading to failure in axial compression had minimal clinical relevance since the typical wrist injury occurs with the wrist extended. We did not simulate an intercarpal arthrodesis recommended in clinical practice to improve carpal fusion and long-term implant durability. A simulated arthrodesis preparation could have reduced the initial construct rigidity and shown the benefit of locking screw fixation. Although our power analysis showed that we used a sufficient number of specimens, a larger sample size may have shown more subtle differences from the addition of locking caps.

Initial rigid fixation is considered highly beneficial for osseous integration of the porous implant coating and successful intercarpal arthrodesis. Our study has shown that the initial fixation of the carpal baseplate in the carpus is rigid, with minimal motion between the carpus and the implant or between the carpal bones. Although locking screws did not show a mechanical benefit in this time zero cadaveric model, locking fixation may show clinical significance, as seen in reverse total shoulder arthroplasty.
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