DVR® Crosslock Wrist Spanning Plate In-Vivo Model Axial Fatigue

March 23, 2022

Key Findings

The purpose of this test setup was to replicate the anatomical loading of an implanted wrist spanning plate using fixtures which simulate the distal radius, metacarpal, and distance to the thumb pivot location which is utilized during patient task completion. The results showed the DVR® Crosslock Wrist Spanning Plate replicated geometric and forces generally seen under 4-months of normal healing conditions with an established maximum runout force of 120,000 cycles.

Introduction

Wrist Spanning Plates are designed for temporary fixation to aid in the stabilization and fixation of fractures of the distal radius, which require prolonged fixation. They are implanted on the dorsal aspect of the wrist, then removed after fracture healing.

Standardized testing is used to directly compare two wrist spanning plates to each other but may not directly replicate the exact force vectors generated by the human body. Post implantation and during rehabilitation, the patient will slowly increase their activity level when using their hand/wrist to complete daily activities. Daily activities can involve gripping and pushing/pulling using the entire hand and thumb. The intent of this test setup was to replicate the anatomical loading of an implanted wrist spanning plate using fixtures which simulate the distal radius, metacarpal, and distance to the thumb pivot location which is utilized during patient task completion.

Methods

The Zimmer Biomet DVR® Crosslock Wrist Spanning Plate is a single-use, titanium (Ti-6Al-4V) plate indicated for skeletally mature patients for fixation of fractures, osteotomies, and non-unions of the distal radius. The plate spans the patient's wrist and is placed from the radial shaft to the second or third metacarpal, depending on fracture pattern and patient anatomy. The plate provides ligamentotaxis on a temporary basis while the distal radius heals.

The plate consists of a single, 180mm long, sterile-packed plate designed to be used with DVR® 2.7mm locking, non-locking and multi-directional screws. The mid-section of the plate was designed with increased width and concave contouring in the center for added strength.[1] There is a dorsal bend at the distal end of the plate to accommodate patient anatomy.

This benchtop test was a flexion test utilizing 3 pivot points to simulate the simulate the hand and thumb relative to the wrist, in which two outer pivot points are offset from the central slotted pivot point creating a moment about the central pivot point. To provide an accurate test setup for an axial test, a measurement method was created and conducted on seven adult male and seven adult female volunteers, to determine the average distance from the middle of the radius to the center point of the thumb pivot point (**Figure 1-7**).

Figure 1: Wrist Measurement Setup

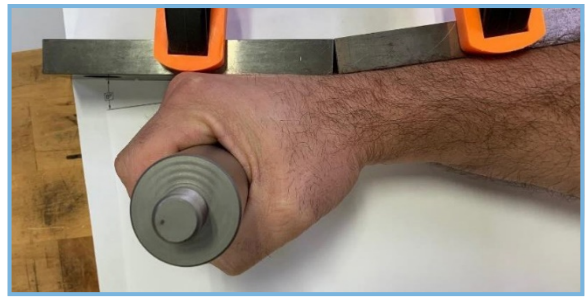

Figure 2: Wrist Measuring

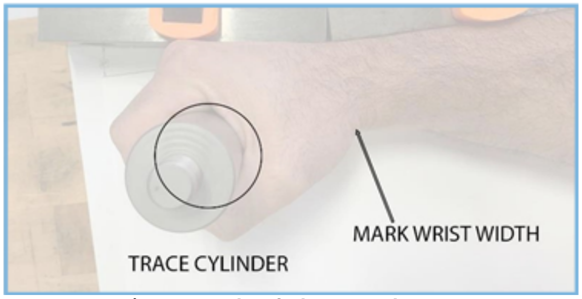

Figure 3: Overlay of Where to Mark Paper

Figure 4: Tracing the Cylinder

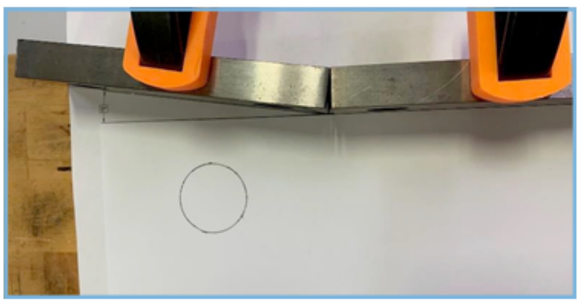

Figure 5: Traced Cylinder

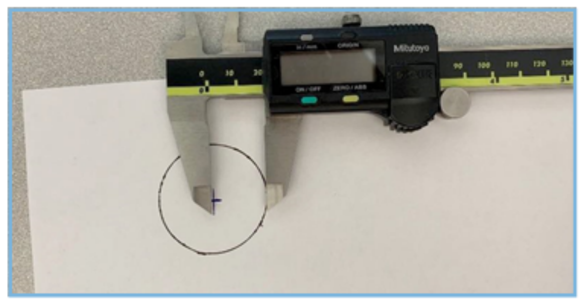

Figure 5: Measure and Mark Center

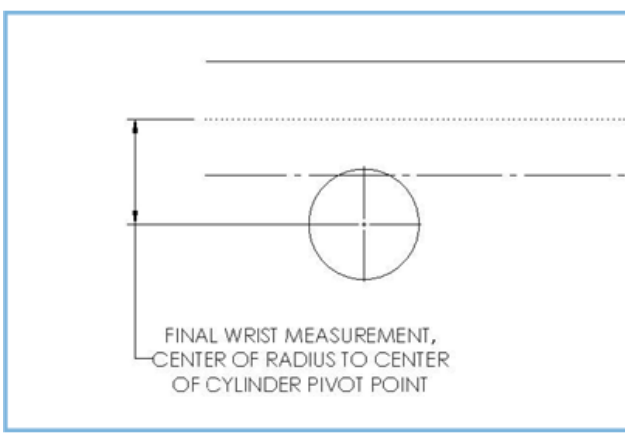

Figure 7: Measurement Marking Setup

According to the article *"A Guide to Selecting Non-Powered Hand Tools"* and as defined by the Center for Disease Control (CDC) and Operational Safety and Health Administration (OSHA), the average handle diameter for power tasks is 1.625".[2] This was utilized when the volunteer's hand/wrist was held at 8° per the geometry of this wrist spanning plate. This dimension of 19.8mm as seen in **Table 1**, along with the distance between the center of the radius to the dorsal surface of 12mm was utilized when designing the two fixtures.

Table 1: Wrist of Measurements

Final Wrist Measurement (in.)		
Volunteer	Male	Female
1	0.671	0.916
2	0.904	0.657
3	0.825	0.635
4	0.755	0.649
5	1.015	0.742
6	0.780	0.785
7	0.810	0.755
Average	**0.823**	**0.734**
Combined Average	0.779 (19.8mm)	

To calculate how many cycles the wrist may experience during normal use, the article *"Wear Characterization of a Total Wrist Replacement Prosthesis"* is referenced. This reported one million cycles per year, or 333,332 for four months for a healthy wrist.[3] It is logical that a patient would limit wrist use post-surgery. The article *"Mechanical Fatigue Analysis Comparing Two Locking Plates in a Metaphyseal Fracture Model of the Distal Ulna"* reported 500 to 1,000 load cycles per day for a recuperating person, or a total of 120,000 cycles for a period of four months.[3] Analysis of the two studies supports the rates as a recovering wrist is roughly 1/3 functional compared to that of a healthy wrist. Therefore, the load cycle of 120,000 cycles for 4 months was utilized, as these rates are seen for wrist spanning plates before removal. **Figures 8-10** illustrates the test fixture set up.

It is the surgeon's discretion during surgery which screw locations to utilize based on numerous factors including but not limited to anatomy, placement, desired outcome, and personal choice. It is common practice for some surgeons to leave the distal radius screw cluster (centrally located 2 holes) empty, in fact, some wrist spanning plates currently on the market are not designed with screw holes in the central aspect of the plate. Leaving these holes empty in this test will decrease the support and is considered worst-case for testing which was utilized in this test setup. 9 specimens were tested, to include 3 with both center screw holes filled and 6 without the center screw holes filled. **Figure 11** shows the test fixture set up with and without distal radius screws.

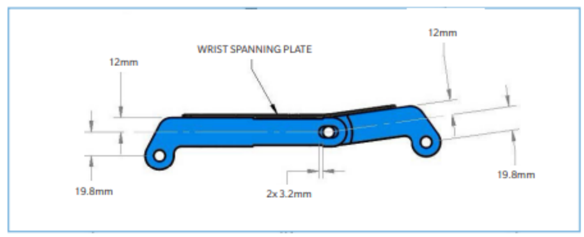

Figure 8: Fixture Design

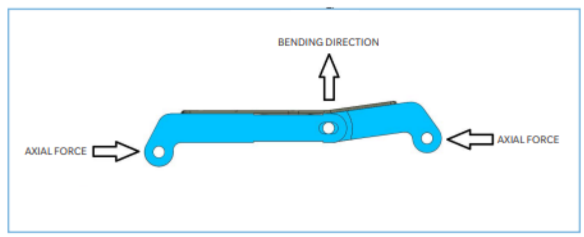

Figure 9: Force Direction

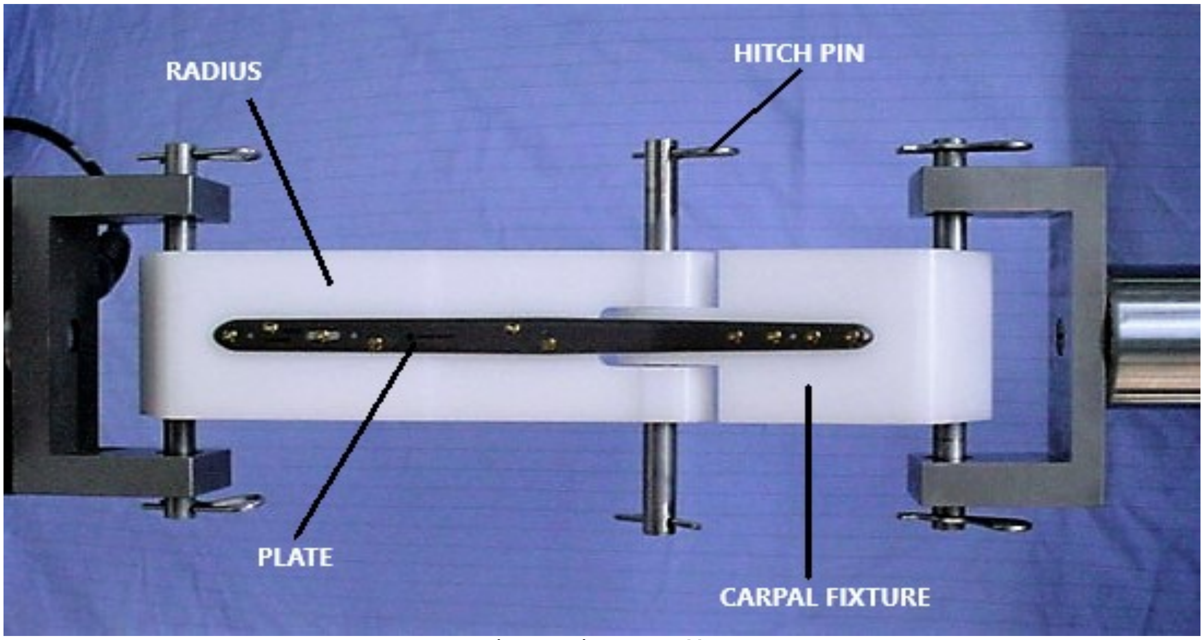

Figure 10: Fixture Assembly

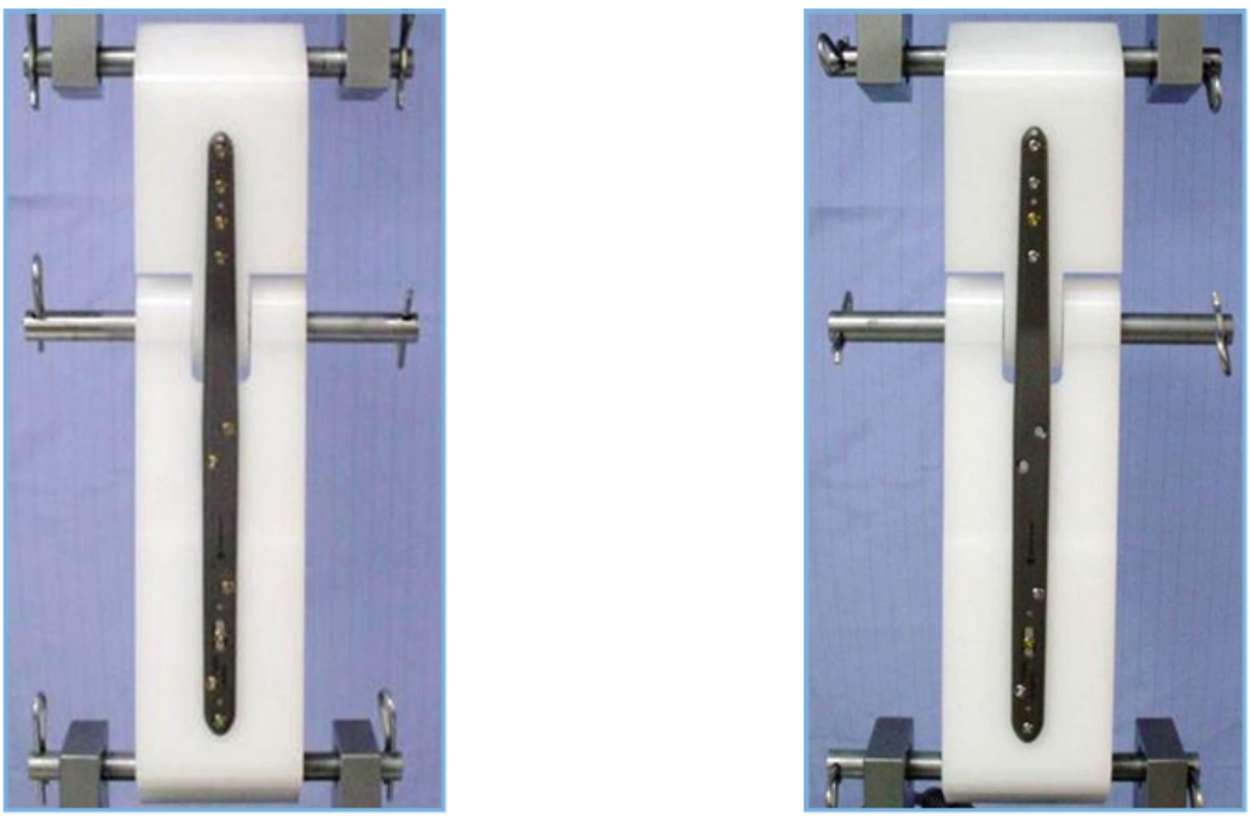

Figure 11: Wrist Plate Setup with and without Distal Radius Screws

Results

The in-vivo model of the wrist spanning plate was cyclic tested in axial fatigue flexion to characterize runout at 120,000 cycles. Two plate sample groups were tested; one group with distal radius screws inserted in the plate and the other without. Results of the two samples are summarized in **Table 2**. The first sample includes two screws in distal radius holes of the wrist plate. Specimens 10-12 are included in this sample and reached runout at 344.4 N load. The second sample excludes the two distal radius screws and is the worst-case construct. Sample two comprises of specimens 14-18 and established runout at 172.2 N load.[5]

Table 2: Wrist Spanning Plate Axial Fatigue Test Results

Specimen	Load (N)	Center Screws	Cycles	Comments
2666-10	344.4	With	120,000	End of Test, No plate fracture
2666-11	401.8	With	8,793	Plate fracture across pivot
2666-12	344.4	With	120,000	End of Test, No plate fracture
2666-13	401.8	Without	45,471	Plate fracture across most distal central hole
2666-14	344.4	Without	46,995	Plate fracture across most distal central hole
2666-15	287.0	Without	42,701	Plate fracture across most distal central hole
2666-16	229.6	Without	111,302	Plate fracture across most distal central hole
2666-17	172.2	Without	120,000	End of Test, No plate fracture
2666-18	172.2	Without	120,000	End of Test, No plate fracture

Discussion

Standardized testing is used to directly compare two wrist spanning plates to each other but may not directly replicate the exact force vectors generated by the human body. The intent of this test setup was to simulate the loading experienced by a hand and wrist in direct flexion for the expected duration of implantation of a wrist spanning plate. The testing was run at a range of repeated cyclic loading to characterize the plate construct performance using a simulated convalescence period of four months. The central pivot point has been created as a slotted joint which will allow for translation to prevent the screws being placed directly in shear and to simulate the multi-bone wrist joint which allows for some compression during flexion.

Conclusion

For a healthy individual four months would equate to 333,332 cycles[3], while for an individual recuperating from a wrist injury the expected cycle count would be about one-third of that, or 120,000 cycles[4].

To conclude, the in-vivo model showed the DVR® Crosslock Wrist Spanning Plate runout at 120,000 cycles was established at 344.4 N for wrist plates with distal radius screws and 172.2 N for wrist plates without distal radius screws.

References

1. Zimmer Biomet Wrist Spanning Plate, Summary of Contour FEA and Plate Length Claims Technical Report #22006, 26 April 2022
2. A Guide to Selecting Non-Powered Hand Tools; CDC, OSHA, NIOSH, DHHS Publication No. 2004-164. (2022)
3. Qingshan Chen, William P Cooney III, Fredrick M Schultz, Dave Leibel, Ronald Linsheid, Kai-Nan An – Mayo Clinic Rochester MN, AVANTA Orthopedics Sand Diego CA., Wear Characterization of a Total Wrist Replacement Prosthesis Orthopedic Biomechanics Laboratory (2022)
4. M Brodbeck, A Spiegel, J Hunt, J Gruenert – Department of Hand, Plastic and Reconstructive Surgery, Kantonsspital St. Gallen, Switzerland, Mechanical Fatigue Analysis Comparing Two Locking Plates in a Metaphyseal Fracture Model of the Distal Ulna (2022)
5. Zimmer Biomet Wrist Plate Setup In Vivo Model Axial Fatigue Test Report #2259, 29 March 2022

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Laboratory testing is not necessarily indicative of clinical results. No partial weight bearing or non-weight bearing device can be expected to withstand the unsupported stresses of full weight bearing or sudden dynamic loads, such as falls or other accidents.

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