A New Intramedullary Device for Distal Radius Fracture Fixation
Biomechanical Comparison to Volar Plating

Robert van Kampen, M.D., Andrew Thoreson, M.S., Nathan Knutson, M.S., Joseph Hale, Ph.D., Steven Moran, M.D.

Department of Plastic Surgery, Mayo Clinic, Rochester, MN USA
Biomechanics Laboratory, Division of Orthopedic Research, Mayo Clinic, Rochester, MN USA
Conventus Orthopaedics Inc., Maple Grove, MN USA

Summary
A nitinol intramedullary scaffold exhibited similar axial stiffness to a commonly-used titanium volar locking plate and was significantly stiffer than a non-locking stainless steel T-plate before and after cyclic loading. A similar trend was observed for bending stiffness.

Introduction
Open reduction distal fracture fixation with volar plating has several disadvantages including soft tissue irritation and tendon rupture. Intramedullary (IM) fixation has been proposed to prevent secondary tissue damage while maintaining construct stability. A novel nitinol IM scaffold (Fig. 1) has been designed to provide distal fixation with a minimally invasive procedure.

Hypothesis
The stiffness of the novel IM scaffold will be similar to both a titanium volar locking plate and a stainless steel T-plate before and after cyclic loading when evaluated using a previously reported wedge fracture model (Fig. 2).

Methods
Specimen Preparation
Dorsal wedge fractures were created in 18 radius bone models (Sawbones1005) divided into 3 groups, each repaired with a different distal fracture fixation device: 1) stainless steel non-locking T-plate (Syntec Scientific); 2) titanium DVRA locking plate (Hand Innovations); 3) nitinol Fracture Fixation System (Conventus Orthopaedics, Inc.). Fractures were repaired per respective instructions for use (Fig. 3).

Mechanical Testing
Specimens were placed into a chamber maintained at 37.8°C on mechanical test systems (Fig. 4). Specimens were pre-heated and load was applied as follows:

1) Axial pre-load and loading, 0 N to 100 N
2) Off-axis bending pre-load and loading, 0 N•m to 1.5 N•m
3) Cyclic axial loading, 100 N magnitude at 2 Hz for 10⁶ cycles
4) Repeat axial pre-load and loading, 0 N to 250 N

Stiffness was calculated with linear regression of load-displacement curves (Fig. 5). Data was analyzed using a one-factor ANOVA with a post-hoc test. P-values less than 0.05 indicated significance.

Results
Test results are shown in Table 1. The following was observed:

- There was no significant difference in stiffness between the IM scaffold and the DVRA plate at any condition
- The SST construct was significantly less stiff than at least one of the other constructs at all conditions
- 10,000 cycles of loading did not cause observable damage

Discussion
For each load case, the IM scaffold stiffness was not significantly different than that of the DVRA plate. The stiffness of the novel IM scaffold was higher than the SST plate before and after 10,000 cycles. The variation was always largest for the IM scaffold, possibly due to more variable contact between the device and the bone analog. The Fracture Fixation System was shown to be as stiff or stiffer than devices currently used for distal radius fracture fixation when subjected to anticipated physiological loading conditions.

References

Table 1. Biomechanical property summary of the fracture fixation constructs.

<table>
<thead>
<tr>
<th>Design</th>
<th>Axial (0-100N)</th>
<th>Bending (0-1.5 N•m)</th>
<th>Axial* (0-250 N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SST Plate</td>
<td>235 (69) N ¹</td>
<td>22 (6) N•m</td>
<td>187 (53) N</td>
</tr>
<tr>
<td>DVRA plate</td>
<td>427 (43) N ²</td>
<td>66 (5) N•m</td>
<td>392 (67) N ²</td>
</tr>
<tr>
<td>IM Scaffold</td>
<td>370 (149) N ³</td>
<td>67 (14) N•m</td>
<td>405 (108) N ³</td>
</tr>
</tbody>
</table>

¹,² Indicate groups that are not significantly different (P>0.05)

* CE mark Pending
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Steven L. Moran, M.D.
Department of Plastic Surgery
Mayo Clinic, Rochester
St. SW, Rochester, MN 55905

http://mayoresearch.mayo.edu/mayo/research/biomechanics
Phone: (507) 538-1717
Fax: (507) 284-5392
200 1st St. SW, Rochester, MN 55905

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