A Prospective, Randomized Controlled Study To Determine The Radiological And Functional Outcomes Of “IMN” Fixation Of Distal Radius Fractures Using A Novel Device The Sonoma Wrx Distal Radius Nail Compared To Volar Plating

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University of Stellenbosch
Disclosure

• No Personal Financial Conflicts
• Implants And Surgical Supplies Were Purchased Through Sonoma Orthopedics And Acumed.
“One consolation only remains, that the limb will at some remote period again enjoy perfect freedom in all its motions, and be completely exempt from pain; the deformity, however, will remain undiminished throughout life.”

Abraham Colles
1773 – 1843
Goals Of Intramedullary Nail “IMN Fixation”

- Minimally Invasive
- Rotational Stability
- Subchondral Support
- Rigid Construct
- Early Range Of Motion
- Restore Function To Prior Levels
- Early Return To ADLs
- Cosmesis
History of IMN

1986, Street- Closed IM Nail Fixation For Forearm, Extended To Distal Radius Fractures- Rush Rods.


2005, Micronail- Fixed Angle Support Of The Subchondral Bone With Locking Screws,

2005, Orbay et Al- Dorsal Nail Plate, A Hybrid Device That Combines A Dorsal Fixed Angle Screw Plate And A Proximal IM Nail

IMN Advantages

• Quicker Surgery, Minimally Invasive Operative Technique
• Less Chance For Hardware Irritation
• Decreased Postoperative Pain
• Stable Fixation Allowing For Early Range Of Motion
• Faster Return to ADLS

IMN Disadvantages:
- Injury To The Superficial Branch Of The Radial Nerve
- Screw Penetration Into The Distal Radial Ulnar Joint
- Loss Of Reduction

VLP Advantages

• Gold Standard
• Open Procedure
• Templates the Fracture
• Multiple screw options

VLP Disadvantages:
- Big Incision 6 cm Plus
- Rupture of Dorsal Ligaments and Tendons
- Hardware Irritation
- Slower Return To ADLs
- Edema, Pain
Recommendation 3

- We Suggest Operative Fixation For Fractures With Post-reduction Radial Shortening >3mm, Dorsal Tilt >10 Degrees, Or Intra-articular Displacement Or Step-off >2mm As Opposed To Cast Fixation.

- Strength Of Recommendation: Moderate
Recommendation 4

• We Are Unable To Recommend For Or Against Any One Specific Operative Method For Fixation Of Distal Radius Fractures.

• Strength Of Recommendation: Inconclusive

David M. Lichtman, MD, et al. Treatment of Distal Radius Fractures
*J Am Acad Orthop Surg* 2010;18: 180-189
Recommendation 6

• We Are Unable To Recommend For Or Against Locking Plates In Patients Over The Age Of 55 Who Are Treated Operatively.

• Strength Of Recommendation: Inconclusive
Aim

Review The Operative Technique For The Treatment Of Distal Radius Fractures With Sonoma WRx Distal Radius Intramedullary Nail And The Acumed Acu-loc Volar Plate

Assess And Compare The Functional, Radiological, Patient Satisfaction And Cosmetic Results In Patients Treated With The IMN Device Vs Volar Plating

Review The Complications
Sonoma WRx Design Rationale

1. Curved Hub Design With WAVIBODY® Technology 5 mm Or 6 mm Options Use Flexible WAVIBODY Technology To Conform To Patient’s Unique Anatomy.

1. Intramedullary Fixation
Proximal And Distal ACTIVLOC® Grippers Engage Bone Upon Implant Activation To Provide Solid Foundation For Fracture Fixation.

3. Locking Cortical Screws 2.7 Mm Screws Lock into Implant Providing A Solid Fixation Of Fragments And 3-dimensional Subchondral Support, Which Prevents Shortening And Dorsal Tilt.
Method

All Patients Presenting To The Tygerberg Hospital With An Unstable Extra Articular Or Simple Intra Articular Distal Radius Fracture Were Invited To Participate In The Study Based On The Inclusion And Exclusion Criteria.
Inclusion Criteria

Skeletally Mature Patients
Closed Fracture
Isolated Injury
Unstable Extra Articular
Simple Intra Articular and Extrarticular Fracture (AO Classification A2,A3,C1-2)
No Previous Wrist Or Distal Radius Injury Or Deformity
Exclusion Criteria

Skeletally Immature Patients
Open Fractures
Multiple Injury Patients
Complex Intra Articular Fractures Or Stable Fractures Not Requiring Surgical Intervention (Fractures Not In Above Mentioned Classification Group)
Previous Wrist Or Distal Radius Injury Or Deformity
Surgical procedure- VLP

Patients Underwent G/A Or Block
Tourniquet Was Applied
Volar Lock Plating Using A FCR Approach
Back Slab Applied For Two Weeks
Surgical procedure-IMN
Sonoma WRx Distal Radius Nail
GA or Block
Tourniquet applied
Traction for reduction
Entry at radial styloid
Reduction and K-wire Fixation
Surgical procedure-IMN

- Incision at radius styloid between 1-2 Comp
- Reduction and temp K-wire Fixation
Surgical procedure-IMN

• Entry with drill

• Intramedullary awl
Surgical procedure-IMN

- Intramedullary awl
Surgical procedure-IMN

• Intramedullary reaming and insertion of nail
Surgical procedure-IMN

- K-wires to hold reduction and orientation of nail
Surgical procedure-IMN

- Grippers activation
Surgical procedure-IMN

- Interlocking screws insertion
Surgical procedure-IMN

• Final position after insertion of all screws
## Results

<table>
<thead>
<tr>
<th></th>
<th>Nail</th>
<th>Plate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>22</td>
<td>21</td>
</tr>
<tr>
<td><strong>Age (Yrs)</strong></td>
<td>49.6 (17 - 73)</td>
<td>37.6 (23 - 45)</td>
</tr>
<tr>
<td><strong>Dominant hand</strong></td>
<td>R= 21</td>
<td>R=21</td>
</tr>
<tr>
<td></td>
<td>L=1</td>
<td>L=0</td>
</tr>
<tr>
<td><strong>Injured hand</strong></td>
<td>R=12</td>
<td>R=14</td>
</tr>
<tr>
<td></td>
<td>L=10</td>
<td>L=7</td>
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<tr>
<td><strong>Classification</strong></td>
<td>22 23-A1</td>
<td>20 23-A1, 1 23-A2</td>
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# Results: Mechanism of Injury - Nail

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
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<tbody>
<tr>
<td>Fall from height</td>
<td>4</td>
</tr>
<tr>
<td>Fall (ground level)</td>
<td>10</td>
</tr>
<tr>
<td>Motor Vehicle Accident:</td>
<td></td>
</tr>
<tr>
<td>Car</td>
<td>2</td>
</tr>
<tr>
<td>Motorcycle/cycle</td>
<td>3</td>
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<tr>
<td>Other:</td>
<td></td>
</tr>
<tr>
<td>Assault</td>
<td>3</td>
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## Results:
### Mechanism of Injury - Plate

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
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<tbody>
<tr>
<td>Fall from height</td>
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<tr>
<td>Fall (ground level)</td>
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<tr>
<td>Motor Vehicle Accident:</td>
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<td>Car</td>
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<td>Motorcycle/cycle</td>
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<tr>
<td>Other</td>
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</tr>
<tr>
<td>Assault</td>
<td>2</td>
</tr>
<tr>
<td>Mountain bike</td>
<td>1</td>
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</tbody>
</table>
Results

Average Tourniquet Time:
- IMN: 29.5 Min (23 - 36)
- VLP: 37.8 Min (29 - 43)

Complications:
- 1 Patient in Plate Group had an infection for which debridement was done
- No complications were experienced in the Nailing Group
## Early Clinical Results

<table>
<thead>
<tr>
<th></th>
<th>IMN (9pts&gt;3/12)</th>
<th>VLP (7 pts&gt;3/12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scar size</td>
<td>2.5 cm ave</td>
<td>6.7 cm ave</td>
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<tr>
<td>Wrist Flexion</td>
<td>40°</td>
<td>40°</td>
</tr>
<tr>
<td>Wrist extension</td>
<td>45°</td>
<td>40°</td>
</tr>
<tr>
<td>Supination</td>
<td>80°</td>
<td>75°</td>
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<tr>
<td>Pronation</td>
<td>85°</td>
<td>80°</td>
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<tr>
<td>Radial Deviation</td>
<td>15°</td>
<td>15°</td>
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<tr>
<td>Ulnar Deviation</td>
<td>15°</td>
<td>20°</td>
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<tr>
<td>Dash</td>
<td>13.9</td>
<td>18.2</td>
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Early Results

<table>
<thead>
<tr>
<th></th>
<th>Pre-op</th>
<th></th>
<th>Post-op</th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>IMN</td>
<td>VLP</td>
<td>IMN</td>
<td>VLP</td>
</tr>
<tr>
<td>Radial height</td>
<td>9.7</td>
<td>9.9</td>
<td>12.2</td>
<td>12.1</td>
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<tr>
<td>Radial Inclination</td>
<td>20.1</td>
<td>17.1</td>
<td>23.7</td>
<td>20.3</td>
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<tr>
<td>Palmer Tilt</td>
<td>-22.9</td>
<td>-22.9</td>
<td>-6.8</td>
<td>-0.6</td>
</tr>
</tbody>
</table>
Case 1
Case 2
Case 3
Case 4
Conclusions
IMN compared to VLP

• Least Invasive
• Less Soft Tissue Stripping
• Equivalent Rotational Stability
• Non Invasive Subchondral Support
• Decreased Operating Times
Conclusions
IMN compared to VLP

- Decreased Postoperative Pain
- Earlier Range Of Motion
- More Cosmetic Incision
- Higher Patient Satisfaction
- Less Soft Tissue (Tendon) Irritation
Note

- This Presentation Reports On The Early Findings In Regards To This Study, And Therefore, Definitive Conclusions Can Not Be Drawn Until The Study Is Completed.
Thank you