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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Disclosure

- No Personal Financial Conflicts
- Implants And Surgical Supplies Were Purchased Through Sonoma Orthopedics And Acumed.

On the Fracture of the Carpal Extremity of the Radius*

ABRAHAM COLLES, M.D.

"*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

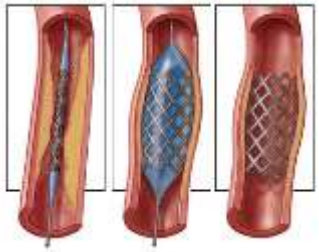
Goals Of Intramedullary Nail “IMN Fixation”

- 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.

2002, C. Nelson & H. Saravia "The Bone Stent Concept "



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

2006, C. Nelson & H. Saravia, WRx Novel Intramedullary Fracture Fixation Device, Patent Issued March 2011

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 Disadvatages:

- 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

AAOS Clinical Practice Guideline Summary

Treatment of Distal Radius Fractures

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

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

AAOS Clinical Practice Guideline Summary

Treatment of Distal Radius Fractures

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

AAOS Clinical Practice Guideline Summary

Treatment of Distal Radius Fractures

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

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

Aim

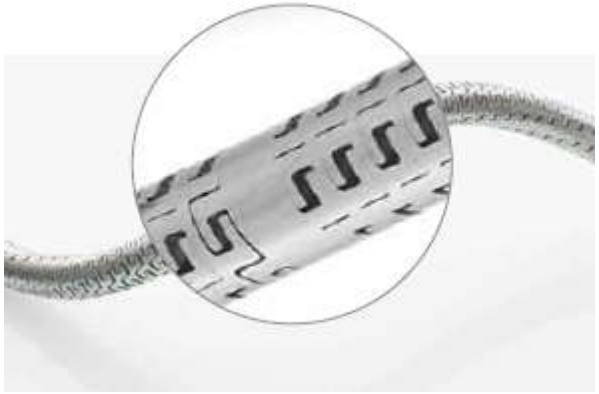
Review The Operative Technique For The Treatment Of Distal Radius Fractures With *Sonoma WRx Distal Radius Intramedullary Nail And The Acumed Acu-loc Volar Plate*

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

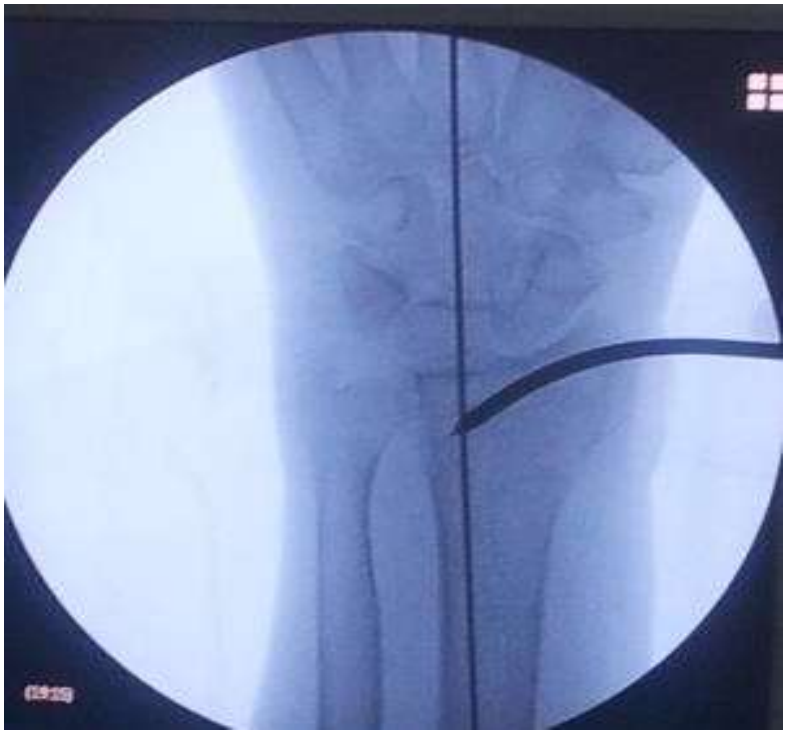
- Incision at radius styloid between 1-2 Comp

- 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

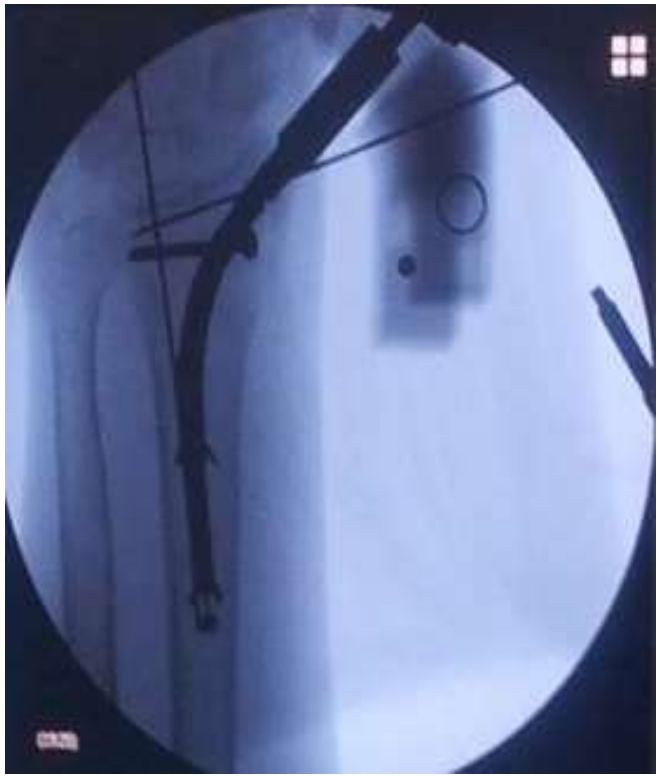
- K-wires to hold reduction and orientation of nail

Surgical procedure-IMN

- Grippers activation

Surgical procedure-IMN

- Interlocking screws insertion



Surgical procedure-IMN

- Final position after insertion of all screws

Results

	Nail	Plate
Total	22	21
Age (Yrs)	49.6 (17 - 73)	37.6 (23 - 45)
Dominant hand	R= 21 L=1	R=21 L=0
Injured hand	R=12 L=10	R=14 L=7
Classification AO	22 23-A1	20 23-A1, 1 23-A2

Results:
Mechanism of Injury- Nail

Fall from height	4
Fall (ground level)	10
Motor Vehicle Accident: Car Motorcycle/cycle	 2 3
Other: Assault	 3

Results:
Mechanism of Injury- Plate

Fall from height	3
Fall (ground level)	10
Motor Vehicle Accident:	
Car	2
Motorcycle/cycle	3
Other:	
Assault	2
Mountain bike	1

Results

Average Tourniquet Time:

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

Complications:

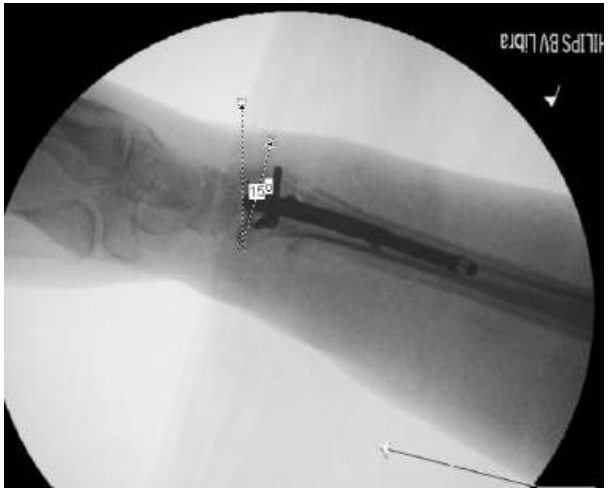
- 1 Patient in Plate Group had an infection for which debridement was done
- No complications were experienced in the Nailing Group

Early Clinical Results

	IMN (9pts>3/12)	VLP (7 pts>3/12)
Scar size	2.5 cm ave	6.7cm ave
Wrist Flexion	40º	40º
Wrist extension	45º	40º
Supination	80º	75º
Pronation	85º	80º
Radial Deviation	15º	15º
Ulnar Deviation	15º	20º
Dash	13.9	18.2

Early Results

	Pre-op		Post-op	
	IMN	VLP	IMN	VLP
Radial height	9.7	9.9	12.2	12.1
Radial Inclination	20.1	17.1	23.7	20.3
Palmer Tilt	-22.9	-22.9	-6.8	-0.6



Case 1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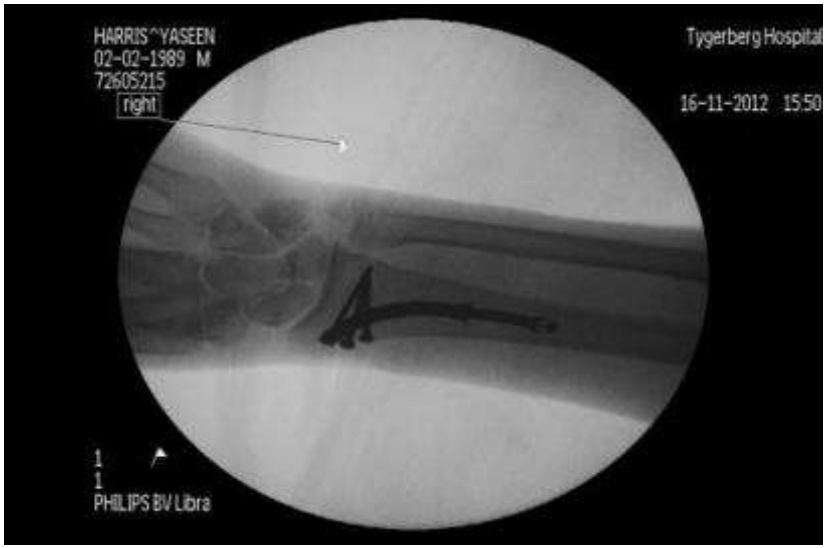
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Case 2


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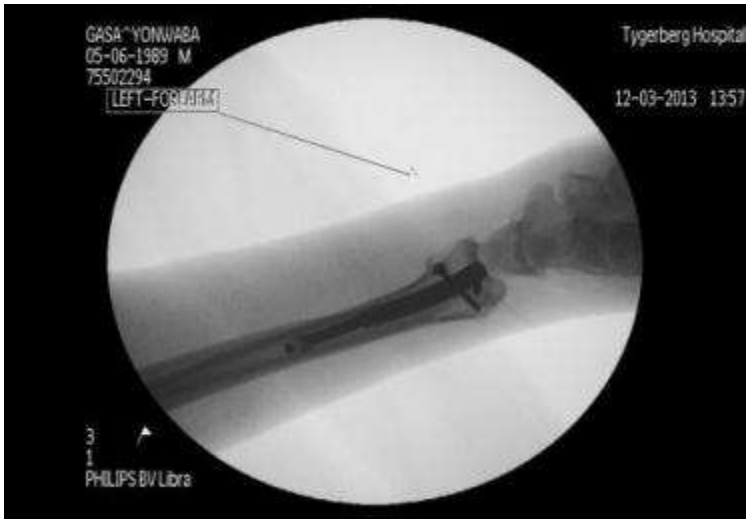
Case 3

Case 4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Case 5


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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