Innovation in Proximal Humerus Fixation

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Disclosure Information
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Conflicts of Commitment/Effort
- Editorial Board: JBJS Essential Surgical Techniques, J Knee Surgery, J Orthopaedic Trauma
- Chief, Dept. of Orthopedic Surgery: Hennepin County Med Ctr.

Disclosures of Financial Relationships
- Royalties: Thieme, Inc.; Smith and Nephew.
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Disclosure of Off-Label and/or investigative Uses
I will not discuss off label use and/or investigational use in my presentation.

Current PH Treatment Options

- Non-Operative/Sling
- Flexible Nails
- Locked Rigid Nails

Locked Plates and Screws
Hemi
Reverse TSA

Many Options – None work in every situation
Are any of these patients back to normal?

Mean OSS in recreational athletes over 40 years old is 97.4% (58.4 out of 60)

*van Kampen et al. J Orthop Surg Res 2013; 8:40
Surgical Management of Complex Proximal Humerus Fractures—A Systematic Review of 92 Studies Including 4500 Patients

- 92 studies, just 1 RCT
- 5219 patients, but 4500 had a final follow-up, 4300 had x-rays at final follow-up
- 70% women
- ORIF / Pinning 62 yrs, HA 70 yrs, RTSA 75 yrs

All outcome measures favor ORIF

But....

Locking Plate Literature

28 Articles: 2294 patients, 1147 Complications
Current Surgical Options Have High Complications

<table>
<thead>
<tr>
<th>Technology</th>
<th>Pros</th>
<th>Cons</th>
<th>Complication Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closed Reduction and Percutaneous Pinning (CRPP)</td>
<td>Minimize soft tissue trauma, Reduce risk of AVN, Conservation of vascular supply, Less surgical trauma &amp; healing</td>
<td>Poor stability, particularly in comminuted fractures and osteoporotic bone, Risk of injury to neurovascular structures, Loss of reduction, Pin site pain and/or infection</td>
<td>~ 25%</td>
</tr>
<tr>
<td>Plates</td>
<td>Can be used to aid in reduction, Familiar technique, Early ROM</td>
<td>Extensive dissection - risk of AVN, Early loosening/ malposition, Screw perforation of articular surface, Varus malalignment, Malposition, entrapment of neurovascular structures</td>
<td>~ 40%</td>
</tr>
<tr>
<td>Intramedullary Rods</td>
<td>Less invasive than plates, High primary stability</td>
<td>Violates rotator cuff - source of pain &amp; dysfunction, Rod migration, Screw perforation</td>
<td>~ 20-30%</td>
</tr>
<tr>
<td>Hemiarthroplasty</td>
<td>Implantation cost, Increase in pain &amp; dysfunction, Subsidence</td>
<td>Acetabular loosening, Subsidence of implant, Collapse, Malunion, Nonunion of tuberosities, Post-implant options</td>
<td>~ 35%</td>
</tr>
<tr>
<td>Total Shoulder Arthroplasty - Reverse or Conventional</td>
<td>Satisfactory mobility, Predictable</td>
<td>ROM limitations, Scapular notching, Limited longevity of implant, Options post-implant</td>
<td>~ 35%</td>
</tr>
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Outcomes remain substandard with both operative and nonoperative management of proximal humeral fractures.

Surgical methods all have high complications.

There is still room for improvement!

Predictors of PH Repair Failure

Predicting failure after surgical fixation of proximal humerus fractures

Dietmar Krappinger, Nicola Bizzotto, Stephan Riedmann, Christian Kammerlander, Clemens Hengg, Franz Sebastian Kralinger

Department of Trauma Surgery and Sports Medicine, Innsbruck Medical University, Anichstraße 35, A-6020 Innsbruck, Austria

Results: The following parameters were found to have a significant influence on the failure rate:
- Age, local BMD, anatomic reduction, and restoration of the medial cortical support.
- The failure rate significantly increased with the number of risk factors.
Unmet Clinical Need

Peer reviewed literature suggests that factors of critical importance in successful ORIF are:

1. Compensating for poor bone mineral density and bone loss
2. Achieving and maintaining anatomical reduction of the head and the tuberosities
3. Restoration of medial column support
4. Managing rotator cuff forces
Genesis of a New Approach

- Local group of business people/engineers with significant experience designing expandable nitinol medical devices
- Wondered about orthopedic applications... especially for metaphyseal fracture patterns

Ideal Technology Intersection

- Minimally Invasive Intramedullary Scaffold
  1. Fragment specific reduction
  2. Interfragmentary compression
  3. Subchondral support

Intramedullary Design

- Minimally Invasive Intramedullary Scaffold
- Expandable Nitinol Scaffold
Distal radius fractures — A solved problem, or can we do better?
Return to Normal Daily Activities

DASH Score (0-100)

High Score = More Symptoms

Follow-up Timepoint

External Fixation
Volar Plate
Conventus

DRS clinical results vs. Egol et al., JBJS 2008

DASH Comparison

Fewer Complications

Systematic Review of 56 Published Studies (2004-2012), Majority < 100 pts

Complications include:
- Loosening/Failure
- Loss of Reduction
- Irritation/Discomfort
- Infection
- Tendon Rupture
- Tenosynovitis/Tendonitis
- Median Nerve Injury
- Radial Nerve Injury
- Compartment Syndrome
- Carpal Tunnel
- Wound Infection
- Skin/Wound Healing
- Malunion/Delayed Union
- Nonunion
- Stiffness
- CRPS
- RSD
- Sudek's
- Joint Instability/Impingement

Sources available upon request
Bone Density Augmentation Strategy
Engineered Augmentation with Multiple Fixation Opportunities

The Importance of Medial Support in Locked Plating of Proximal Humerus Fractures

Medial Support
Engineered Support with Multiple Fixation Opportunities
The PH CAGE Solution

Bone Density Augmentation
- Distributes load over large surface area
- Support articular surface

Manage隧道ity & Cuff Forces
- Tunneling specific to approximation
- Optional suture washer for cuff force management

Maintain Reduction
- 3-dimensional support prevents collapse and loss of alignment during the healing phase
- Cage helps maintain reduction during the surgical procedure

Polyaxial Screw Placement & Locking Capabilities
- Screw cage interface provides locking capabilities
- Place screws in any orientation necessary

Medial Column Support
- Sub-chondral buttress limits head collapse and thus limits collapsing forces across calcar and medial cortical area
- Torsional stability and medial support provided by construct

Polyaxial Screw Placement & Locking Capabilities
- Screw cage interface provides locking capabilities
- Place screws in any orientation necessary

Biomechanical Test Setup

- Fracture (gap ostectomy) represents a worst case comminuted model
- 5mm gap model used for all testing

Biomechanical Tests - Quasistatic

<table>
<thead>
<tr>
<th>Mode</th>
<th>Maximum Load</th>
<th>Failure Criteria</th>
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<tbody>
<tr>
<td>Axial Compression</td>
<td>1500 N</td>
<td>Gap closure, hardware failure, screw pull out</td>
</tr>
<tr>
<td>Torsion</td>
<td>9 Nm</td>
<td>Rotation &gt; 30°</td>
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Axial Stiffness of Constructs

- Sample size for axial loading:
  - PH Cage, PH Cage w/Plate \( N = 5 \)
  - PHILOS \( N = 3 \)
- Axial stiffness, PHILOS < PH Cage < PH Cage w/Plate (statistically significant)
- No deviations from test protocol & setup

Schmidt A et al., "Biomechanical performance of a proximal humeral Cage (PH Cage) in comparison to a locking plate technology"

Axial Failure Loads

- PH Cage w/Plate
  - Only 1/5 failed. The remaining 4/5 reached a maximum load of 1900N without failure.
  - Failure load, PHILOS < PH Cage < PH Cage w/Plate (statistically significant)
  - No deviations from test protocol & setup

Schmidt A et al., "Biomechanical performance of a proximal humeral Cage (PH Cage) in comparison to a locking plate technology"
### PH Cage - Patient Demographics

**Age Distribution**
- [Histogram showing age distribution]

**Gender**
- Female: 20.4%
- Male: 79.6%

**Fracture Type**
- [Pie chart showing fracture type]
  - 2-Part: 38.4%
  - 3-Part: 38.4%
  - 4-Part: 18.6%
  - Other: 4.6%
PH Cage – Surgical Technique

- Minimally Invasive
  - Deltopectoral
  - Deltoid Split
  - Minimally Invasive

PH Cage – Procedural Data

- Retrograde
  - Retrograde
- Antegrade (Drop In)

- PH Cage implantation with & without a plate can be completed using both procedures
  - PH Cage Only = 31% of procedures
  - PH Cage + Plate = 69% of procedures

PH Cage vs. Locking Plates

- Locking plate complications is obtained from literature review meta-analysis (~2300 Pts)

- PH Cage complication rate is approximately 1/5th as compared to locking plates
Surgical Technique

- Similar to current plating procedures
- Angled bushing for consistent access
- Poly-axial screw placement
- Screws lock into Cage

CASE EXAMPLES

Case Example

56 year old male in MVA
Is this the answer?

Clinical studies are the next step…