Early Clinical Experience with the SHC

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Disclosures

I have no conflicts of interest related to this study
Background
Hip Fracture Epidemiology

- ~352,000 hip fractures occur yearly in the US, 90% of which result from a fall
- 1.66 Million Hip Fxs worldwide in 1990
- 6.26 Million Hip Fxs projected for 2050
Design criteria:
1. Implant can be used in both stable and unstable hip fractures.
2. Insertion can be done without C-arm using a reliable, repeatable technique.
3. The technique is transferable to surgeons in the developing world (i.e., feasible to teach and learn given prior orthopedic training).
4. The device must accommodate variation in the anatomy of the proximal femur.
SIGN Hip Construct Surgical Technique and Early Clinical Experience

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FIGURE 8.  A. Shows the first SHC patient in Afghanistan standing beside the bed with his family the day after surgery. B, 3 month follow-up x-ray on the Afghanistan patient.
Where are we at 7 years later?
Total # of SHC’s Placed Worldwide:

400 Standard SHC
52 Fin SHC
Total: 452 SHCs in 47 Hospitals (as of 9/20/16)
Study Purpose

To report the safety profile and complication rate for an early consecutive series of patients with hip fractures managed using the SHC
Hypothesis

We hypothesized that the SHC would provide stable fixation of proximal femur fractures with acceptable union and complication rates similar to published literature.
Methods

• Retrospective review of the prospective SIGN Online Surgical Database (SOSD) from 2009 to 2014.
• Inclusion criteria:
  • Standard hip construct nail
  • Fracture radiographs available
  • Follow-up radiographs available
• Exclusion criteria:
  • Follow-up ≥ 12 weeks
  • Inadequate radiographs
  • Primary diagnosis of non-union (surgeon defined)
  • Non-standard technique (ex. use of compression screws or IM nail only)
Variables Collected

- Patient demographics (age, M/F, WHO region)
- Time to surgery
- Follow-up (weeks)
- Fracture type (open/closed, location, AO/OTA classification)
- Implant specifics (lateral wall plate, compression screws, distal fixation)
- Complications (varus collapse >15°, delayed/non-union, intra-articular screw penetration, and infection)
- Neck-shaft angle (post-op and follow-up)
- Clinical outcomes (painless full weight bearing and knee flexion >90°)
Statistical Analysis

• Data collected in Microsoft Excel (Redmond, WA) and transferred to Stata 13.0 (College Station, TX) for analysis.

• Descriptive statistics were calculated for demographic data, injury characteristics, and complications.
  
  • Univariate analysis was conducted to assess for risk factors for complications using Fischer’s exact test.

  • Findings statistically significant if p<0.05.

• Student’s paired t-test was used to compare changes in neck-shaft angle from baseline to follow up.
RESULTS
# Patient Demographics

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (range)</td>
<td>49.5 (12-91)</td>
</tr>
<tr>
<td>Gender, no. (%)</td>
<td>Male 48 (67.6)</td>
</tr>
<tr>
<td></td>
<td>Female 23 (32.4)</td>
</tr>
<tr>
<td>WHO Region, no. (%)</td>
<td>Africa 27 (38)</td>
</tr>
<tr>
<td></td>
<td>Eastern Mediterranean 21 (29.6)</td>
</tr>
<tr>
<td></td>
<td>Western Pacific 17 (23.9)</td>
</tr>
<tr>
<td></td>
<td>Americas 3 (4.2)</td>
</tr>
<tr>
<td></td>
<td>South-East Asia 3 (4.2)</td>
</tr>
<tr>
<td>Follow up in weeks, mean (range)</td>
<td>39 (21-64)</td>
</tr>
<tr>
<td>Country</td>
<td>Number</td>
</tr>
<tr>
<td>-------------</td>
<td>--------</td>
</tr>
<tr>
<td>Pakistan</td>
<td>21</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>15</td>
</tr>
<tr>
<td>Mongolia</td>
<td>10</td>
</tr>
<tr>
<td>Tanzania</td>
<td>8</td>
</tr>
<tr>
<td>Philippines</td>
<td>4</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>3</td>
</tr>
<tr>
<td>Cambodia</td>
<td>3</td>
</tr>
<tr>
<td>Cameroon</td>
<td>2</td>
</tr>
<tr>
<td>Kenya</td>
<td>1</td>
</tr>
<tr>
<td>Dominican</td>
<td>1</td>
</tr>
<tr>
<td>Haiti</td>
<td>1</td>
</tr>
<tr>
<td>Nicaragua</td>
<td>1</td>
</tr>
<tr>
<td>Somaliland</td>
<td>1</td>
</tr>
</tbody>
</table>

*All countries classified as Low or middle income by WHO*
# Injury Characteristics

<table>
<thead>
<tr>
<th>Fracture</th>
<th>Location</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Intertrochanteric</td>
<td>55</td>
<td>77.5%</td>
</tr>
<tr>
<td></td>
<td>Subtrochanteric</td>
<td>7</td>
<td>9.9%</td>
</tr>
<tr>
<td></td>
<td>Intertrochanteric + Subtrochanteric</td>
<td>4</td>
<td>5.6%</td>
</tr>
<tr>
<td></td>
<td>Femoral neck</td>
<td>4</td>
<td>5.6%</td>
</tr>
<tr>
<td>Yes</td>
<td>Intertrochanteric + Subtrochanteric</td>
<td>1</td>
<td>1.4%</td>
</tr>
<tr>
<td></td>
<td>Femoral neck + Intertrochanteric</td>
<td>1</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

% open fractures were 70 (98.6%) and 1 (1.4%) respectively.
# Treatment Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Union at final follow-up</td>
<td>68 (95.8%)</td>
</tr>
<tr>
<td>Days from injury to surgery, median (IQ range)</td>
<td>10 (5-21)</td>
</tr>
<tr>
<td>Lateral Wall Plate</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>29 (41%)</td>
</tr>
<tr>
<td>No</td>
<td>42 (59%)</td>
</tr>
<tr>
<td>Distal fixation</td>
<td></td>
</tr>
<tr>
<td>Screw</td>
<td>66 (93%)</td>
</tr>
<tr>
<td>Fin</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>None</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>3 (4.2%)</td>
</tr>
</tbody>
</table>
Neck-shaft Angle

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate post-op**</td>
<td>126° (7.3)</td>
</tr>
<tr>
<td>Final follow-up</td>
<td>119.3° (11)</td>
</tr>
<tr>
<td>Difference</td>
<td>-6.9° (8.2)*</td>
</tr>
</tbody>
</table>

* p<0.0001

- Immediate post-op neck-shaft angle did not correlate with delay to surgery or subsequent varus collapse
- Compare with a mean difference of -2° found by Mereddy et al for the AO/ASIF proximal femoral nail antirotation (PFNA)
## Reduction Quality*

<table>
<thead>
<tr>
<th>Quality Description</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good (&lt;5° varus/valgus)</td>
<td>35 (49%)</td>
</tr>
<tr>
<td>Acceptable (5-10° varus/valgus)</td>
<td>19 (27%)</td>
</tr>
<tr>
<td>Poor (&gt;10° varus/valgus)</td>
<td>17 (24%)</td>
</tr>
</tbody>
</table>

* Based on normal neck shaft angle of 130°

Compare with 97% good/acceptable rate shown by Merredy et al for the AO/ASIF PFNA inserted under fluoroscopic guidance.
# Subjective Surgeon Assessments

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Painless weight bearing at final follow-up</td>
<td>90.1% (64)</td>
</tr>
<tr>
<td>Knee flexion $&gt;90^\circ$ at final follow-up</td>
<td>98.6% (70)</td>
</tr>
</tbody>
</table>
## Major Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varus collapse (&gt;15°)</td>
<td>6</td>
<td>8.5%</td>
</tr>
<tr>
<td>Nonunion</td>
<td>3</td>
<td>4.2%</td>
</tr>
<tr>
<td>Intra-articular screw</td>
<td>5</td>
<td>7%</td>
</tr>
<tr>
<td>Infection</td>
<td>3</td>
<td>4.2%</td>
</tr>
</tbody>
</table>
Varus Collapse

- Comparable to rate of 11.8% shown by Haonga et al
- 4 of 6 achieved painless weight bearing and 2 were lost to follow-up
- 5 of 6 had significant displacement preoperatively and were unstable patterns (31A2.2(3), 31A3.3(1) and 31-B2(1))
  - Single stable pattern (A1.1) was a IIIb open injury with infection superficially and eventually delayed union.
- 2 of 6 constructs were placed higher on the trochanter with fixation crossing the superior 3rd of the femoral neck only
Risk Factors for Varus Collapse

Advanced age (p=0.027)

- ≥ 50yo: 6/38 (15.8%)
- < 50yo: 0/33 (0%)

Gender, fracture location, delay to surgery, open fracture, immediate post-op neck-shaft angle and type of SHC (lateral plate, distal fixation) were NOT associated with varus collapse
80yo F with varus collapse but painless full weight bearing at 8 weeks

Was a lateral wall HV plate indicated based on fracture pattern?
Would the lateral wall plate have prevented or lessened varus collapse?
Risk Factors for Intra-articular Screw Placement

- 4 of 5 cases from single center (p<0.0001)
- If single outlying center eliminated, rate of intra-articular screw penetration 1/67 (1.5%)
- Patients with intra-articular screw tended to be older (mean age 65 vs. 48.3, p=0.08) suggesting poor bone quality may be risk for screw mal-positioning
We would recommend a single AP radiograph (if available) and/or taking the hip through gentle ROM prior to closing the wound.
Infection

• 3 patients (4.2%) with 2 being superficial and 1 being deep.
• All patients were treated with intravenous antibiotics and went on to eventual union.
• Infection rate compares to Haonga et al whom found a 1.5% infection rate in 68 patients treated with the SHC in Tanzania.

Risk factors for infection
• Open fracture (p=0.04)
  • Closed 2/70 (2.8%)
  • Open 1/1 (100%)
Case Example

80yo F with uneventful healing

Note use of the lateral plate based on the indication of the fracture line exiting below the proximal interlock.
Unrecognized lateral wall fracture…iatrogenic or new injury?
?? lost to follow-up
Non/Delayed Union

- Non-union noted in 2 patients (2.8%) and delayed in union in 1 patient (1.4%) with their last radiographs recorded at weeks 62, 40 and 19 respectively.

- Comparable to published non-union rates for intertrochanteric fractures that range from 1-2% for operative treatment.
30yo M with delayed union at 33 weeks but painless full weight bearing at 9 weeks
Limitations

- X-Ray quality
  - Unavailable contralateral hip imaging
- Irregular patient follow-up intervals
  - Time to union data meaningless
- Subjective outcome data based on individual SIGN surgeon’s assessment
  - Lack of case specific details (i.e. mechanism, extent of infection etc.)
- 42.8% loss to follow-up
Conclusions

- Preliminary data suggest the SHC can be safely inserted in the absence of fluoroscopy with a reasonable complication rate.
- The SHC facilitates early mobilization while maintaining acceptable fracture reduction until union.
- Room for improvement exists with regard to quality of reduction.
Technical Observations

• Compression screws should go through the inferior half of the femoral neck and abut the calcar

• Lateral wall plate is indicated for lateral trochanteric fracture lines exiting below the proximal interlocking screw

• Take the hip through a range of motion and/or get an x-ray prior to wound closure if any concern for an intra-articular screw.

• If significant initial displacement and/or unstable pattern then err on the side of caution with more rigid fixation

• Caution should be exercised in older patients with poor bone quality

• A lateral decubitus position with a pillow between legs may help avoid varus fracture fixation.
Thank-you
References


27. Roth JS, D; Zirkle, LG; Johnson, A; LaBarre, P. Development and Biomechanical testing of the SIGN Hip Construct. Techniques in Orthopaedics. 2009;24 265-272.


