Early Experience with the FibuLock® Nail
Single surgeon results with first 10 patients

Robert Tonks, MD

**Background**

Intramedullary (IM) fixation of tibia and femur fractures became the standard of care in the 1970s. Paradoxically, during this time distal fibula fractures continued to be predominantly treated with plate osteosynthesis. Plating the lateral malleolus has yielded predictable patient outcomes and is perceived to routinely result in anatomic reductions through an efficient surgical procedure. However, the large incisions required for plating and the prominence of the plates have been surmised to result in wound complications in 5% to 16% of patients and a secondary removal rate of 2% to 23%\(^1^4\). The higher rates are generally attributed to patient comorbidities and noncompliance.

Launched in March 2015, the FibuLock nail (Sonoma Orthopedics) was designed to reduce the complications associated with plates while delivering anatomic reductions and maintaining surgical efficiency. The incisions required for nail implantation are approximately 80% smaller than those for plates and the nail exhibits minimal prominence under the skin. Proximal incisions for screw placement are negated by proprietary fixation talons. These talons are actuated to secure the nail proximally and may be deactuated in the event of removal. Similar to plates, the FibuLock nail features syndesmosis fixation and compression.

This data captures a single surgeon’s initial experience with this Intramedullary treatment option. The author is an orthopedic traumatologist who predominantly receives patients through calls at multiple hospitals. This data represents real-world orthopedics typified by a patient population interspersed with noncompliance, difficult fractures, and other considerations experienced by many practices. The FibuLock nail is the primary treatment for these patients due to its potential to provide excellent outcomes and anatomic reductions with fewer complications than plating.

**Methods**

The FibuLock nail was used to treat fibula fractures in 10 patients (8 women and 2 men). Patients had a mean age of 59 years (range, 24 to 84). The patient population was predominantly healthy (80%). Two patients had comorbidities that would endanger wound healing. During surgery, the author rarely used a tourniquet to manage blood flow. X-rays were obtained 6 weeks postsurgery and evaluated for fracture reduction and bone healing. Any postoperative complications were noted (see Table 1).

The surgical procedure with the FibuLock nail is similar to that using most long-bone IM devices. However, unlike many nails, when implanting the FibuLock nail, the fracture is first reduced and stabilized with forceps. If possible, this is performed percutaneously. In fractures over 2 weeks old, a small incision may be made over the fracture to allow direct visualization and removal of fibrous tissue before reducing the fracture. A small incision is then made distal to the lateral malleolus, and a 1.6 mm K-wire is driven into the center of the canal. Distal and proximal reamers are driven over the wire, and the nail is inserted with a screw-targeting outrigger. Proximal talons are then actuated with a torque-limiting driver. The outrigger allows preparation for distal 2.7 mm screws and 3.5 mm screws or TightRope® sutures if warranted. After the procedure, patients are generally splinted and allowed to bear weight as tolerated after 2 weeks.

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**Step 1. Reduce fracture**

**Step 2. Establish entry point with K-wire**

**Step 3. Ream canal**

**Step 4. Insert nail and release proximal talons**

**Step 5. Insert screws or TightRope suture**
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Results
Ninety percent (90%) of fractures were Weber B, with 10% being Weber C. Additionally, 40% of fractures were trimalleolar, 40% were bimalleolar and 20% were unimalleolar. All reductions were anatomic and were equivalent to what would be accepted with plate treatment. Eighty percent (80%) of patients received syndesmosis screws which were radiographically parallel to the plafond. No wound infections were observed and no nails were removed.

Although surgeries were efficient, it was difficult to isolate the FibuLock nail surgical time because most fractures involved more than the lateral malleolus. Additionally, tourniquet time was unavailable due to the lack of tourniquet use. Seventy percent (70%) of reductions were made through a small incision or an already present wound.

Table 1

<table>
<thead>
<tr>
<th>#</th>
<th>Fracture Type</th>
<th>Weber Classification</th>
<th>Comorbidities</th>
<th>Male/Female</th>
<th>Age (Years)</th>
<th>Percutaneous or Open Reduction</th>
<th>Syndesmosis Fixation</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Bimalleolar</td>
<td>B</td>
<td>Healthy</td>
<td>Female</td>
<td>72</td>
<td>Open</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>Unimalleolar</td>
<td>B</td>
<td>Healthy</td>
<td>Male</td>
<td>24</td>
<td>Percutaneous</td>
<td>No</td>
</tr>
<tr>
<td>3</td>
<td>Trimalleolar</td>
<td>B</td>
<td>Healthy</td>
<td>Female</td>
<td>68</td>
<td>Open</td>
<td>Yes</td>
</tr>
<tr>
<td>4</td>
<td>Trimalleolar</td>
<td>B</td>
<td>Diabetes</td>
<td>Female</td>
<td>64</td>
<td>Open</td>
<td>Yes</td>
</tr>
<tr>
<td>5</td>
<td>Unimalleolar</td>
<td>B</td>
<td>Healthy</td>
<td>Female</td>
<td>62</td>
<td>Percutaneous</td>
<td>Yes</td>
</tr>
<tr>
<td>6</td>
<td>Bimalleolar</td>
<td>B</td>
<td>Healthy</td>
<td>Male</td>
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<td>Open</td>
<td>Yes</td>
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<tr>
<td>7</td>
<td>Bimalleolar</td>
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<td>Healthy</td>
<td>Female</td>
<td>84</td>
<td>Open</td>
<td>Yes</td>
</tr>
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<td>8</td>
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<td>B</td>
<td>Healthy</td>
<td>Female</td>
<td>49</td>
<td>Open</td>
<td>Yes</td>
</tr>
<tr>
<td>9</td>
<td>Trimalleolar</td>
<td>B</td>
<td>Lupus</td>
<td>Female</td>
<td>74</td>
<td>Percutaneous</td>
<td>Yes</td>
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<tr>
<td>10</td>
<td>Bimalleolar</td>
<td>B</td>
<td>Healthy</td>
<td>Female</td>
<td>46</td>
<td>Open</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Bimalleolar 40% B 90% 80% healthy 80% female Open = 70% 80% syndesmosis fixation
Trimalleolar 40% C 10% 20% comorbidities 20% male Average 59 years Closed = 30% 20% no fixation

Unimalleolar 20%

Conclusions
The author allows patients with repaired unimalleolar and bimalleolar fractures to bear weight quickly due to the load-sharing qualities of this intramedullary device. This early return to mobility is catalyzed by the small incision size of the nail and the reduced pain experienced by the patients. Additionally, hardware removals were unnecessary and wound infections did not occur due to the reduced incision size and the tissue-sparing procedure. Reductions were as anatomic as what would have been expected had plates been used in the same indications.

As evident in Figures 1-10, the FibuLock nail provides anatomic reductions with an efficient procedure for Weber B and C fractures.
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This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature and the product’s Directions For Use. Postoperative management is patient specific and dependent on the treating professional’s assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes.

References