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.

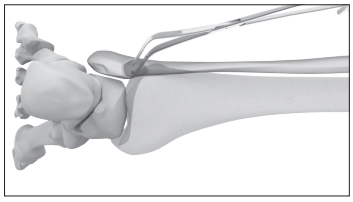
Launched in March 2015, the FibuLock nail (Sonoma Orthopedics) was designed to reduce the complications associated with plates while delivering anatomic reductions and maintaining surgical efficiency. The incisions required for nail implantation are approximately 80% smaller than those for plates and 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.

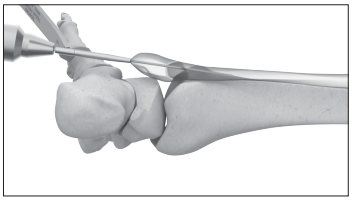
Methods

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).

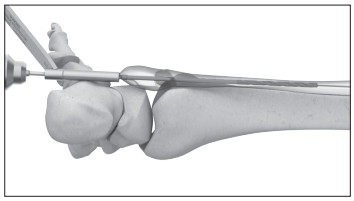
The surgical procedure with the FibuLock nail is similar to that using most long-bone IM devices. However, unlike many nails, when implanting the FibuLock nail, the fracture is first reduced and stabilized with forceps. If possible, this is performed percutaneously. In fractures over 2 weeks old, a small 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.



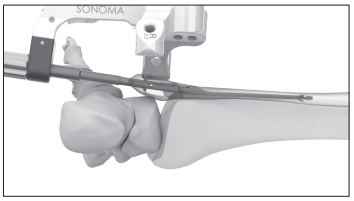
Step 1. *Reduce fracture*



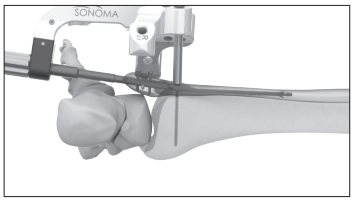
Step 2. *Establish entry point with K-wire*



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.

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.

Table 1

#	Fracture Type	Weber Classificaton	Comorbidities	Male/Female	Age (Years)	Percutaneous or Open Reduction	Syndesmosis Fixation
1	Bimalleolar	B	Healthy	Female	72	Open	No
2	Unimalleolar	B	Healthy	Male	24	Percutaneous	No
3	Trimalleolar	B	Healthy	Female	68	Open	Yes
4	Trimalleolar	B	Diabetes	Female	64	Open	Yes
5	Unimalleolar	B	Healthy	Female	62	Percutaneous	Yes
6	Bimalleolar	B	Healthy	Male	47	Open	Yes
7	Bimalleolar	B	Healthy	Female	84	Open	Yes
8	Trimalleolar	B	Healthy	Female	49	Open	Yes
9	Trimalleolar	B	Lupus	Female	74	Percutaneous	Yes
10	Bimalleolar	B	Healthy	Female	46	Open	Yes
	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%						

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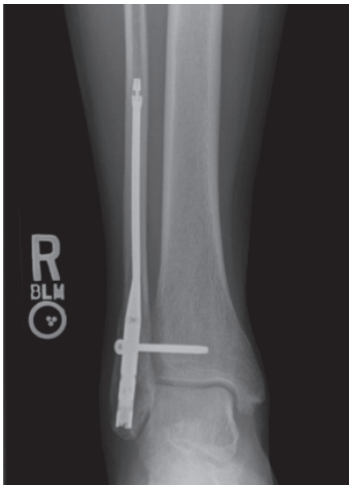
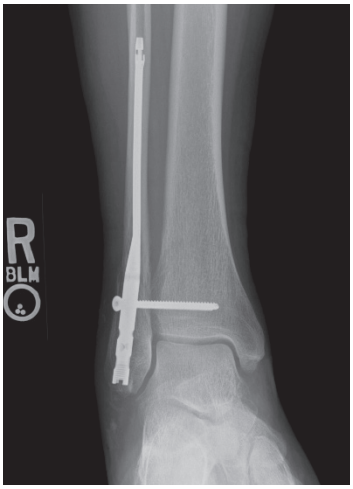
Figure 1

Preoperative



6 week

Preoperative



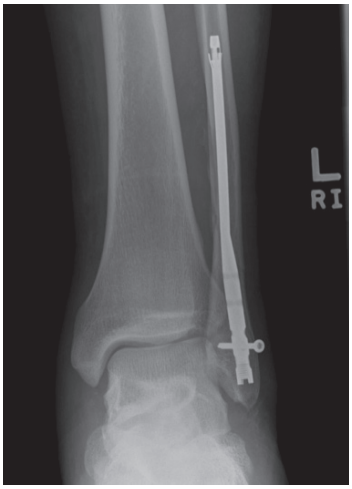
6 week

Preoperative

6 week

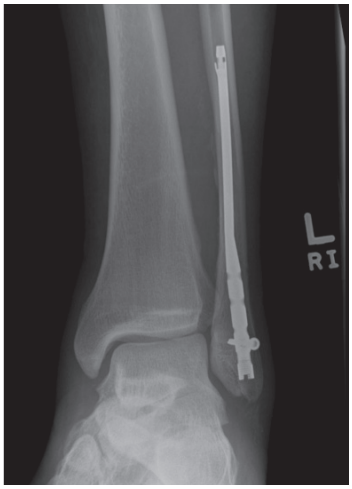
Figure 2

Preoperative



6 week

Preoperative



6 week

Preoperative

6 week

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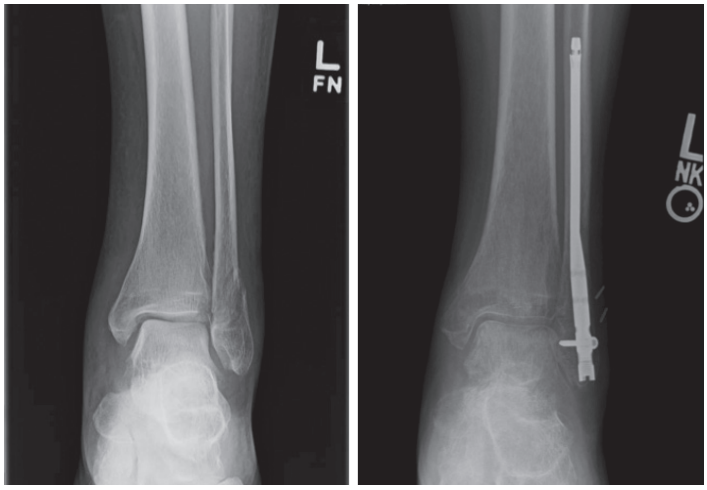
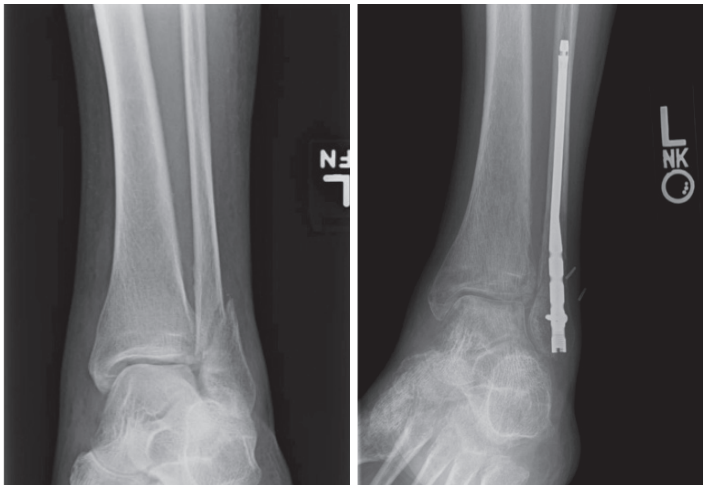
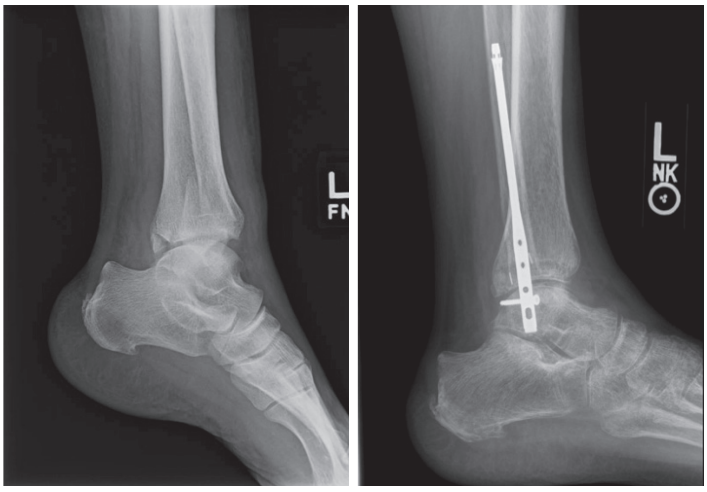
Figure 3



Preoperative *6 week*

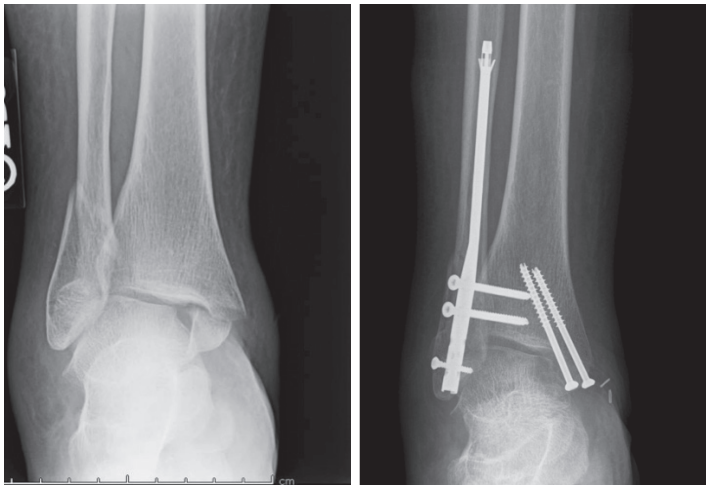


Preoperative *6 week*

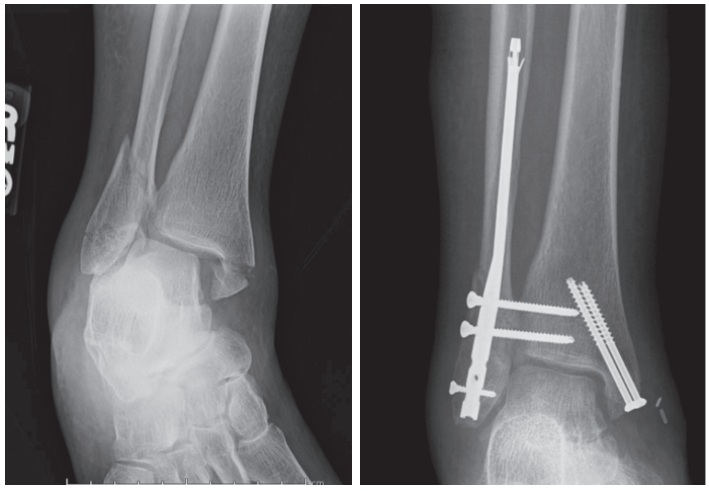


Preoperative *6 week*

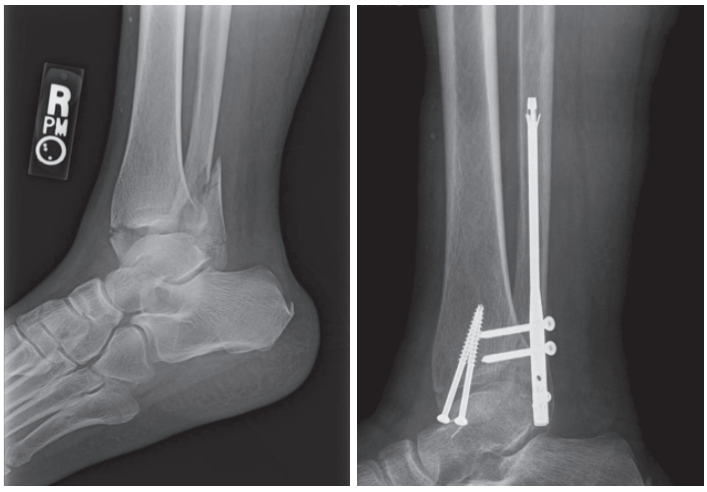
Figure 4



Preoperative *6 week*



Preoperative *6 week*



Preoperative *6 week*

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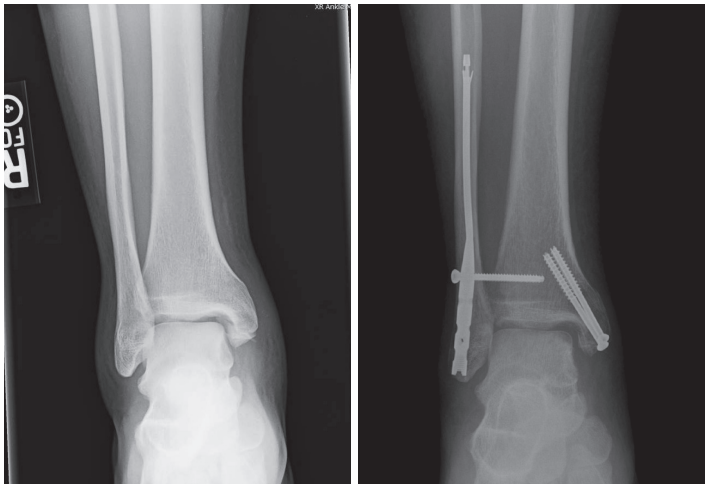
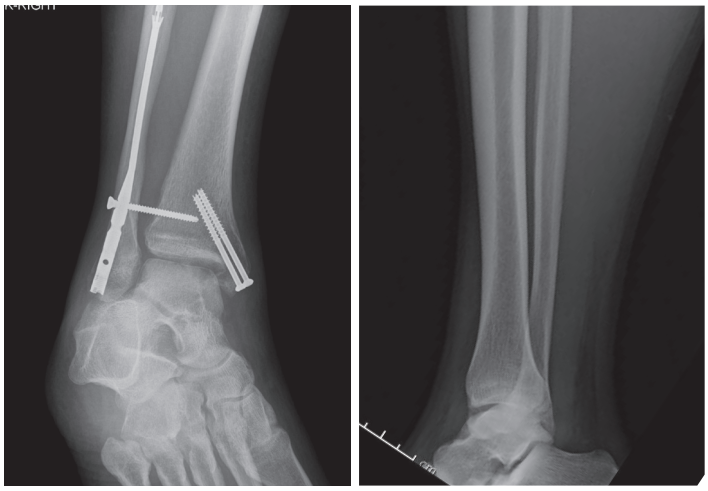
Figure 5



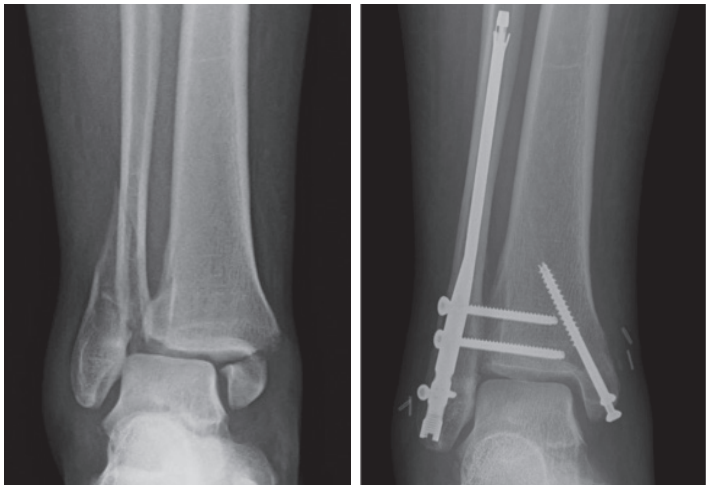
Preoperative *6 week*



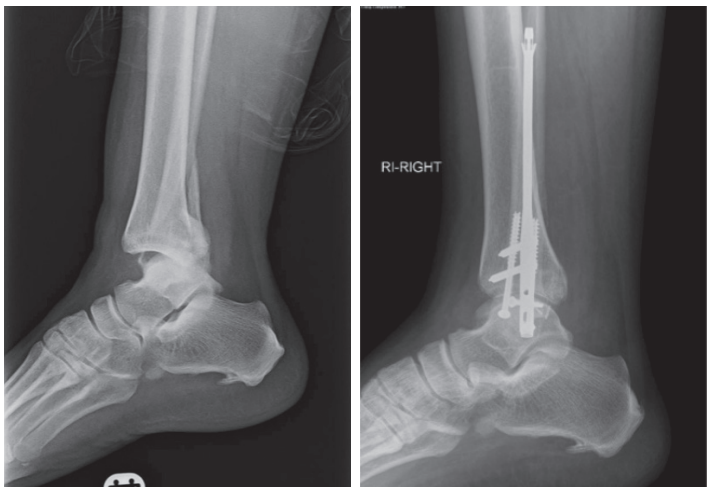
6 week *Preoperative*

6 week

Figure 6



Preoperative *6 week*



Preoperative *6 week*

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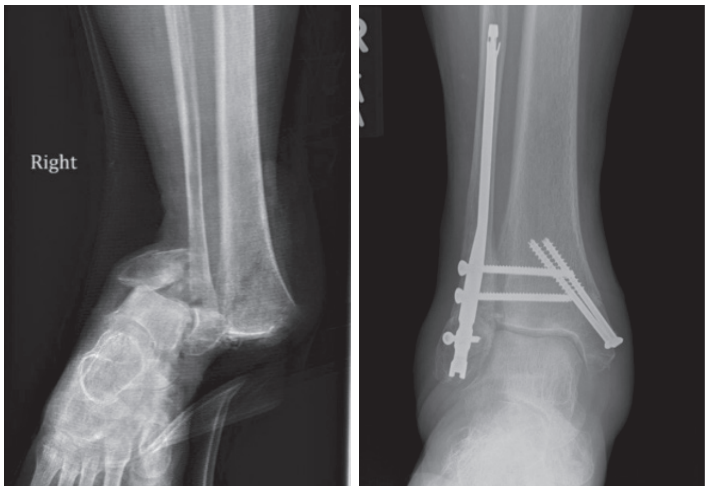
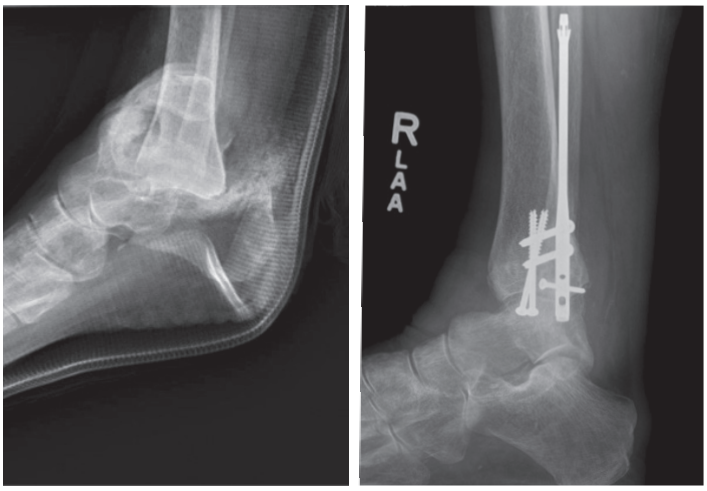
Figure 7

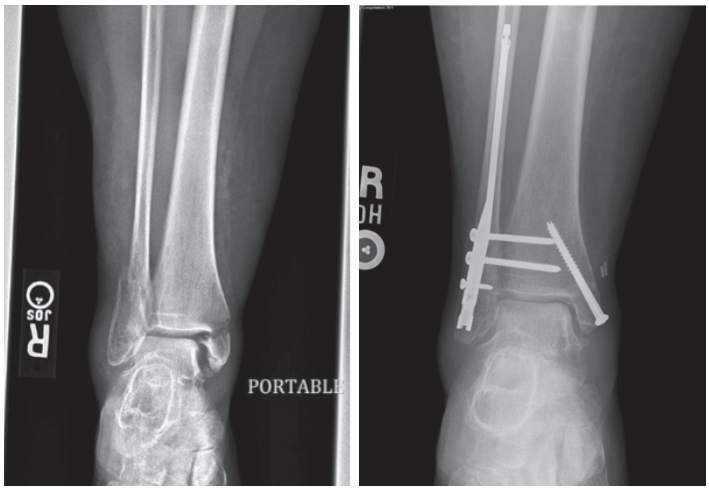


Preoperative *6 week*

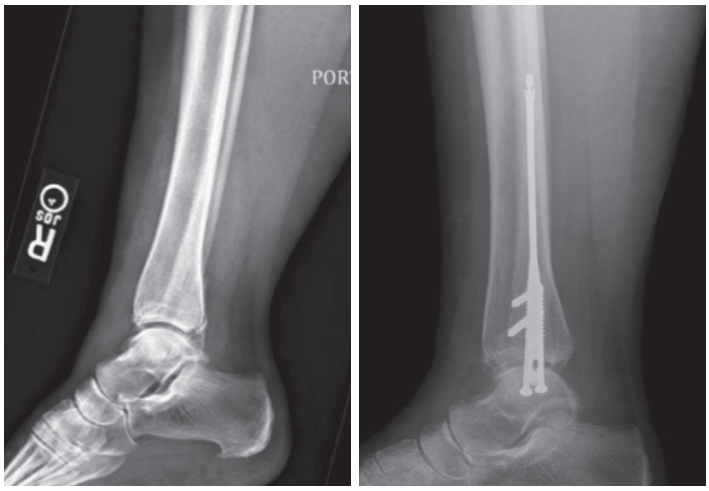


Preoperative *6 week*

Figure 8



Preoperative *6 week*



Preoperative *6 week*

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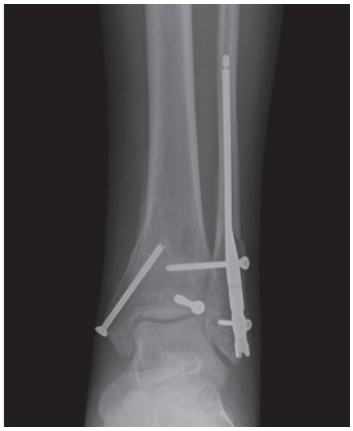
Figure 9

Preoperative



6 week

Preoperative

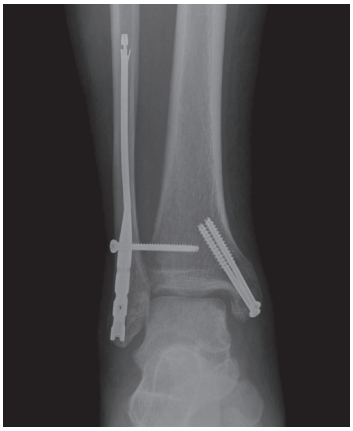
6 week

Preoperative

6 week

Figure 10

Preoperative



6 week

Preoperative

6 week

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