

433 Excluded:

- 103 Fracture extended into the joint
- 99 Non-intramedullary nail operative treatment or conservative treatment
- 59 Less than 18 years of age
- 47 Patient could not comply with protocol
- 32 Concomitant injury which was likely to impair function for as long as or longer than the subject's tibial fracture
- 20 Problems anticipated with follow-up
- 19 Treating surgeon refused to randomize patient
- 15 Approached for consent >14 days from operative treatment
- 11 Patient already in a competing study
- 9 Pathological fracture
- 6 Bilateral tibial fractures
- 6 Circumferential, open wound that precludes placement of ultrasound at the fracture site
- 4 Grade IIIb or IIIc fracture
- 3 Surgical delay of >14 days

51 Randomized*

28 Assigned to Control
(Sham LIPUS)

6 Lost prior to 1 year

22 Available for Analysis
at 1 year23 Assigned to Treatment
(Active LIPUS)

2 Lost prior to 1 year

21 Available for Analysis
at 1 year

* There was one stratification error, when a patient with an open fracture received an ultrasound unit designated for the next patient with a closed fracture