INTRODUCTION:
A tibial intramedullary (IM) nail is inserted into the tibial canal to stabilize fractures. Stabilization is achieved by the use of screws which are driven through the bone at the nail ends and pass through transverse or oblique holes in the nail. Such locking screws add torsional stiffness, minimize telescoping of mid-shaft fractures and pull fragments together in cases of comminution. While locked intramedullary nails have a long history of successful clinical use, the presence of nail holes and screws introduces the possibility of complications due to implant breakage [1-4]. In new nail designs, the risk of nail or screw fracture can be mitigated through material selection and biomechanical evaluation of the device subjected to applied forces representing physiological loading. While laboratory fatigue testing is an important part of device safety determination, finite element analysis supports pre-clinical assessment of various design parameters and selection of worst-case implant configurations for testing.

This study introduces a novel biomechanical test method which evaluates the strength of tibial IM nails and locking screws at proximal and distal ends. Polymer fixtures are used to represent the proximal and distal ends of the tibia, and screws transfer loading from fixtures to the nail in a way that mimics load transfer from tibia to nail in-situ. Finite element analysis has been used to study stress in a new nail design with screws, compare results to those from a clinically available predicate and to analyze the effect upon nail and screw stress of various screw combinations.

METHODS:
Proximal and distal epiphyses of a human tibia are represented by fixtures made from acetal copolymer (Delrin®), with shape and size designed to replicate typical bone stiffness properties. Each experimental fixture has pre-drilled holes so that bone screws can be driven through fixture and nail. One end of the fixture has a loading dimple positioned such that a single force applied by a fatigue test machine represents peak joint load applied in a location that produces physiologic bending moments. Figure 1 shows the overall appearance of a proximal test assembly.

Results for various screw combinations in one of the proximal nail models are summarized in Figure 3. In these models, holes are numbered starting from the joint and progressing to the nail midsection. Screw numbers match the hole numbers.

DISCUSSION AND CONCLUSIONS:
Results show that risk of fracture at the holes closest to the tibial mid-shaft may be reduced by placing screws through those holes when a nail is implanted (recommended in the surgical technique). While this method provides an effective way of comparing nail stress for various designs, it does not capture the stress concentration associated with screw threads, or the environmental effects of saline body fluids combined with possible fretting fatigue at screw/nail interfaces. Thus it is not a substitute for laboratory fatigue testing, but can serve to narrow the scope of testing while still ensuring appropriate design validation.

REFERENCES: