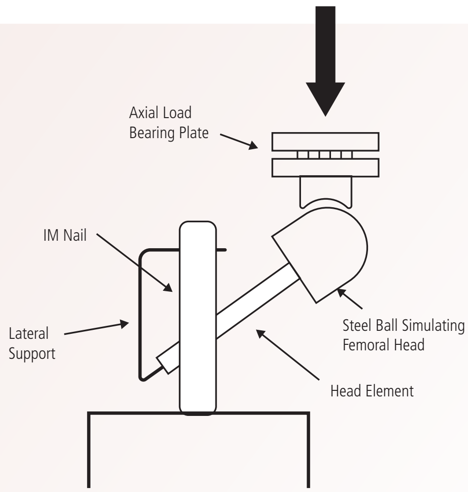
TFN-ADVANCED™ Proximal Femoral Nailing System (TFNA)

Nail Strength Analysis

ABSTRACT

The TFN-ADVANCED™ Proximal Femoral Nailing System (TFNA) is designed to be a better fitting implant such that the fit to the anatomic bow of the femur is superior to previous cephalomedullary (CM) nails, and the proximal body of the nail better fits patient anatomy.[1]

Given clinical feedback supporting the need for a reduced proximal diameter from the Titanium Trochanteric Fixation Nail System (TFN), the TFNA Nail was designed to have a proximal diameter of 15.66 mm, comparable to the Gamma3 Nail (Stryker) and the INTERTAN Nail (Smith & Nephew). A critical benefit of the TFNA Nail is even with a comparable proximal diameter, the nail has superior strength relative to the Gamma3 Nail and INTERTAN Nail, which is created by a unique combination of material selection and implant geometry.[2,3]



The TFNA Nail is made from a high strength Ti-15Mo (TiMo) titanum alloy, due to its combination of high strength and fatigue resistance, and has unique features such as the LATERAL RELIEF CUT® Design and BUMP CUT® Design.

Finite Element Analysis was performed throughout the design process to optimize the design of the TFNA Nail, with extensive biomechanical testing completed in a laboratory to verify implant strength. Through a series of fatigue tests, the TFNA Nail was proven to be 24% stronger than the Gamma3 Nail and 47% stronger than the INTERTAN Nail.[2,3]

Cephalomedullary Nail Strength Determined by Material & Geometry

Cephalomedullary (CM) nails are intended to be load sharing, not load bearing, devices however they must withstand loads for a period of time to allow the fracture to heal. There are multiple factors that influence fracture healing, and if healing is compromised the implant may withstand excessive cyclic loading. While the strength of the nail is critical in these cases, if faced with excessive loads all CM nails will fatigue and eventually break. The weakest part of a CM nail is at the proximal aperture, where the head element is inserted, which is the most common location of breakage.

There is a tradeoff between nail strength (i.e. larger diameter) and minimizing disruption to the patient anatomy (i.e. minimally invasive). Considerations for reducing the proximal geometry include: compromised reduction with larger diameter nails due to medialization of the head-neck fragment (i.e. wedging) creating a varus deformity during nail insertion, impingement of the lateral cortex of the shaft fragment with larger nails, and bone removal during drilling/reaming to create an opening for the nail compromising osteoporotic patients.

Through a combination of geometrical dimensions, material selection, and material finishing processes during manufacturing, the strength of an implant can be affected.

TFNA Nail Proximal Geometry Designed to Address Clinical Needs

The TFNA Nail is designed to be a better fitting implant such that the fit to the anatomic bow of the femur is superior to previous CM nails, and the proximal body of the nail better fits patient anatomy.[1]

The proximal diameter of the TFNA Nail was reduced from its prior generation TFN Nail (17 mm) to 15.66 mm to address clinical needs while being comparable to other nails on the market (Figure 1).

CM nails tend to most frequently break at the oblique hole as this area contains the highest stress concentration. The BUMP CUT Design featured on the TFNA Nail was developed to distribute the high stress concentration at the proximal hole into two valleys on either side of the "bump", moving the stress away from the edge of the oblique hole and into the body of the nail. A Finite Element Analysis (FEA) was performed to evaluate the impact of this feature, which showed improvement in the distribution of stress (Figure 2).

The LATERAL RELIEF CUT Design was included in the TFNA Nail design to further minimize the proximal diameter, reducing lateral impingement. This was achieved by contouring the lateral aspect of the implant, creating a "flattened" effect. The LATERAL RELIEF CUT Design was specifically designed such that material at the edge of the oblique hole (area of highest stress concentration) was not removed.

High Strength Material (Ti-15Mo) Used to Increase Nail Strength

Reducing the proximal diameter has an impact on nail strength, therefore alternative materials were considered to compensate. A high strength Ti-15Mo (TiMo) Titanium Alloy was selected because of its similar modulus and significantly improved smoothed and notched fatigue strength compared to TAV (Gamma3 Nail and INTERTAN Nail) and TAN (TFN Nail).

The smoothed fatigue strength of TiMo is 15% higher than TAV/TAN (Figure 3), indicating fatigue performance purely based on material properties.[4,5] The notched fatigue strength of TiMo is 100% higher than TAV/TAN (Figure 3), indicating fatigue performance when a stress riser is introduced (in the form of a notch).[4,5]

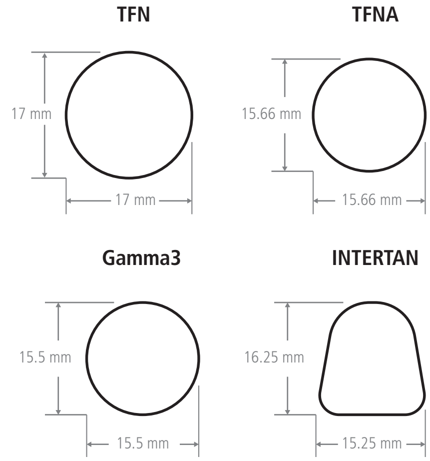


Fig 1: TFNA Nail Proximal Diameter Comparable to Gamma3 Nail and INTERTAN Nail

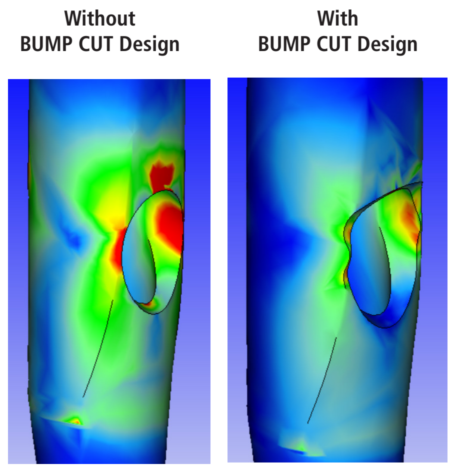


Fig 2: FEA analysis comparing TFNA Nail without and with BUMP CUT Design

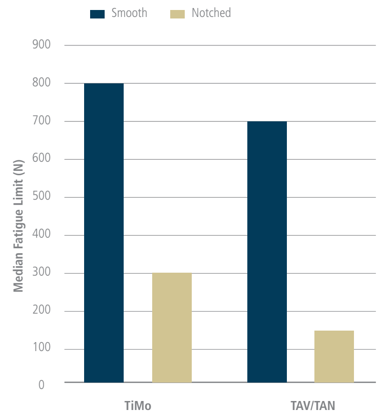


Fig 3: Smoothed and Notched Fatigue Strength of TiMo vs TAV/TAN [4,5]

TFNA Nail Designed to be Stronger than the Gamma3 Nail and INTERTAN Nail

Biomechanical testing was conducted to evaluate and compare the construct fatigue strength of the TFNA Nail, Gamma3 Nail, and INTERTAN Nail to validate the design modeling and computer simulations. All testing was performed using nails with a 130º caput-collum-diaphyseal (CCD) angle. Six (6) constructs of each system were evaluated for median fatigue limit and all testing was run in ambient laboratory conditions.

Implants were assembled and loaded into a test fixture where the head element was cyclically loaded (Figure 4). All testing was done using a compressive sine wave cycle, with a load ratio of 10 where the peak was 10 times the valley (i.e. 1,700 – 170 N). This was performed at a rate of 5 Hz for a total of 2,500,000 cycles unless a failure of the construct occurred first.

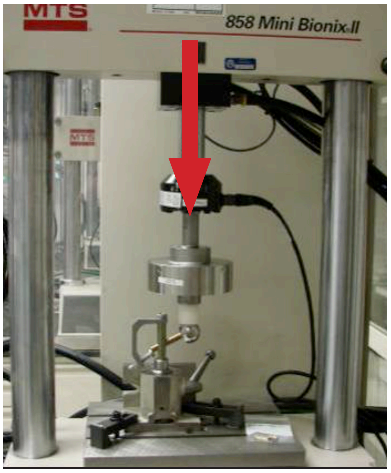


Fig 4: Implant fatigue test setup with nail construct sample (ex. TFNA Nail) mounted for mechanical testing. Red arrow denotes loading direction.

RESULTS:

Testing was completed and median fatigue limits were calculated using ASTM STP 731 Method. Results of the testing are summarized below, and comparison of the nail fatigue limits are displayed in Figure 5.

- The TFNA Nail is 24% stronger than the Gamma3 Nail.[2,3]
- The TFNA Nail is 47% stronger than the INTERTAN Nail.[2,3]

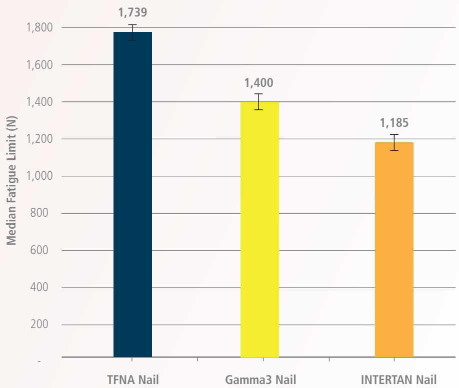


Fig 5: TFNA Nail Median Fatigue Limit Greater than Gamma3 Nail and INTERTAN Nail

Discussion:

Nail breakages typically occur at the intersection of the proximal oblique hole and the lateral aspect of the nail, as this location is exposed to a high concentration of stress as a result from the load placed on the head element.

Strength of the nail can be modified through a unique combination of implant geometry and material to minimize the risk of nail breakage. Surgeon feedback desired a smaller proximal diameter than the TFN Nail given clinical considerations for inserting the implant and preserving native bone. By reducing the proximal diameter of the TFNA Nail and compensating with a high strength alternative material, the nail could be made stronger than nails of comparable size to minimize the risk of implant breakage. Based off the testing completed, TFNA Nails are 24% and 47% stronger than both the Gamma3 Nail and INTERTAN Nail, respectively.[2,3]

References
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