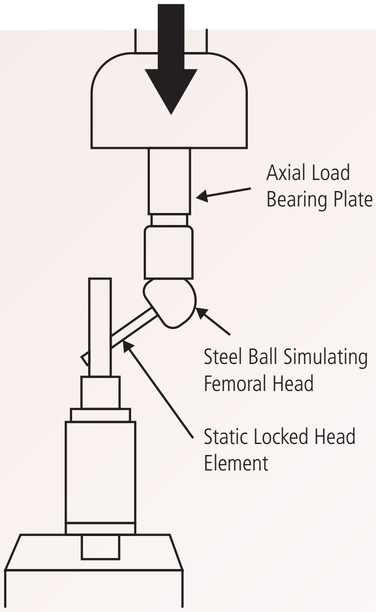
TFN-ADVANCED™ Proximal Femoral Nailing System (TFNA)

Rotational and Static Locking



ABSTRACT

The TFN-ADVANCED™ Proximal Femoral Nailing System (TFNA) features a pre-assembled locking mechanism within the nail to allow the intra-operative decision of rotational locking (control the rotation of the helical blade or lag screw) or statically locking (control the rotation and restrict sliding of the helical blade or lag screw). Static locking is also included in the design of the INTERTAN Nail (Smith & Nephew), and while the Gamma3 Nail (Stryker) was not designed for static locking surgeons have created this by overtightening the set screw.

In order to restrict sliding of the helical blade/lag screw head element (statically lock), a locking mechanism must be tightened down onto the head element. These nail system designs are based on an interference fit where force applied from the tightened locking mechanism creates friction, restricting movement of the head element. However, when the head element is loaded over time this friction may dissipate and sliding may occur.

Mechanical testing evaluated the load each nail system could withstand prior to slippage in two test setups. The first test setup (pre-conditioning) measured the mean slippage load of the head element in nail constructs that were statically locked and had not seen any previous loading. The second test setup (post-conditioning) measured the mean slippage load of the head element in nail constructs that were statically locked and subjected to dynamic loading (conditioning). The conditioning was intended to evaluate the impact dynamic loading had on the nail construct and if there would be loosening of the locking mechanism.

The TFNA Nail mean slippage load in the pre-conditioning test was 15% and 92% greater than the INTERTAN Nail and Gamma3 Nail, respectively; the TFNA Nail mean slippage load in the post-conditioning test was 114% and 109% greater than the INTERTAN Nail and Gamma3 Nail, respectively.[1] These tests demonstrate that the TFNA Nail is superior in static locking performance compared to the INTERTAN Nail and Gamma3 Nail.[1]

Static Locking is Intended to Restrict Collapse

Traditionally, cephalomedullary (CM) nails have been designed to allow the head-neck fragment to collapse, enabled by the head element sliding laterally, as the patient weight bears. Allowing this collapse closes remaining gaps to bring fracture fragments together, which enables closer contact, increased construct stability, and subsequent healing. If there are remaining gaps and the fracture either does not heal or faces delayed healing, this can cause extended loading on the implant which may result in nail breakage or superior cut-out of the head element.

Fig. 1: Illustration of rotational locking (left) and static locking (right). Shown is a TFNA Nail.

Surgeons have identified the need to lock the head element after reduction in an effort to maintain length of the femoral neck to minimize or prevent leg shortening, as studies have shown that greater than 1 cm in leg shortening may lead to discomfort.[2] With this emerging need, CM nails began to include this capability in their device designs and have identified this as “static locking”. With CM nail systems including static locking and its use becoming more prevalent, there are still cases where patients see sliding of the head element and subsequent collapse of the head-neck fragment.

Static Locking Designs Based on Interference Fit Between Locking Mechanism and Head Element

CM nails that are designed for static locking include the TFNA Nail and the INTERTAN Nail (Smith & Nephew); surgeons static lock the Gamma3 Nail (Stryker) by overtightening their set screw, however the system is not designed for this (Figure 2).

In order to restrict sliding of the helical blade/lag screw head element (statically lock), a locking mechanism must be tightened down onto the head element. These nail system designs are based on an interference fit where force applied from the tightened locking mechanism creates friction, restricting movement of the head element. However, when the head element is loaded over time this friction may dissipate and sliding may occur.

TFNA Nail Designed to Restrict Collapse More than the INTERTAN Nail or Gamma3 Nail

Mechanical testing evaluated the load each nail system could withstand prior to slippage in two test setups. The first test setup (pre-conditioning) measured the mean slippage load of the head element in nail constructs that were statically locked and had not seen any previous loading. The second test setup (post-conditioning) measured the mean slippage load of the head element in nail constructs that were statically locked and subjected to dynamic loading (conditioning). The conditioning was intended to evaluate the impact dynamic loading had on the nail construct and if there would be loosening of the locking mechanism.

All testing was performed using nails with a 130° caput-collum-diaphyseal (CCD) angle. Five (5) constructs of each system were tested and all testing was run in ambient laboratory conditions. The TFNA Nail was assembled and the locking mechanism was tightened to a torque of 5.4 +0.06/-0 Nm per the surgical technique; the INTERTAN Nail was assembled and tightened to a torque of 5.4 +0.15/-0 Nm; the Gamma3 Nail was also assembled and tightened to 5.4 +0.15/-0 Nm for the first test and 6.0 +0.15/-0 Nm for the second test.

Fig. 2: Nail designs demonstrating locking mechanism surface contact area on respective head element

The pre-conditioning test was performed prior to inducing any loads on the nail constructs. Nails were assembled and mounted in a test fixture and an axial load was applied along the axis of the head element. All testing was run at a rate of 2 mm per minute until 2 mm of displacement occurred; load and displacement data were collected in real-time (Figure 3).

Data was evaluated to determine the slippage load which was defined as an initial abrupt change in slope, indicating the initiation of slippage (Figure 4).

The post-conditioning test required nail construct conditioning prior to measuring the slippage load. Conditioning was applied to the nail constructs using a dynamic compressive load, between 20 and 200 N (Figure 5). This was performed at a rate of 5 Hz for a total of 1,000,000 cycles unless a failure of the construct occurred first. Failure was defined as a maximum of 1 mm of displacement of the loading actuator.

Following conditioning, the nail constructs were tested using the same method as for the pre-conditioning test (Figure 3). Data was evaluated to determine the slippage load again.

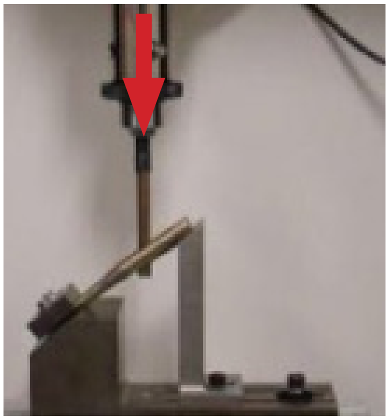


Fig. 3: Test setup with nail construct sample (ex. TFNA Nail) mounted for mechanical testing. Arrow denotes loading direction.

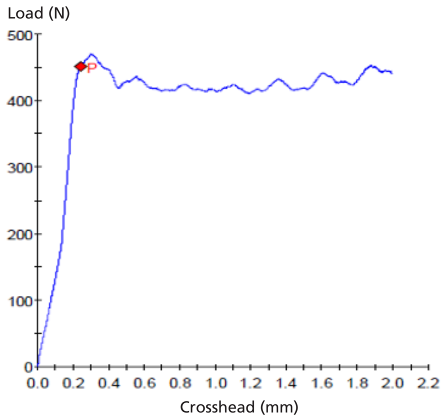


Fig. 4: Representative load displacement curve showing determination of slippage load (P). Shown is a pre-conditioning data set for the TFNA Nail.

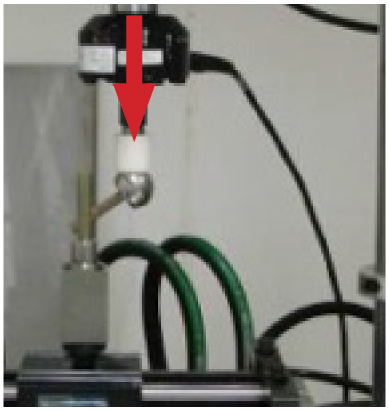


Fig. 5: Implant conditioning test setup with nail construct sample (ex. TFNA Nail) mounted for mechanical testing. Arrow denotes loading direction.

Results:

Results of the testing are summarized below, and comparison of the nailing systems are displayed in Figure 6.

- The TFNA Nail mean slippage load in the pre-conditioning test was 15% and 92% greater than the INTERTAN Nail and Gamma3 Nail, respectively; the TFNA Nail mean slippage load in the post-conditioning test was 114% and 109% greater than the INTERTAN Nail and Gamma3 Nail, respectively.[1]
- Comparison of the pre-conditioning slippage loads demonstrate that the TFNA Nail mean is non-inferior to the slippage loads of the INTERTAN Nail ($p = 0.008$) and Gamma3 Nail ($p < 0.001$). When further tested for superiority, the TFNA Nail also demonstrated superiority to the Gamma3 Nail.[1]
- Comparison of the post-conditioning slippage loads demonstrate that the TFNA Nail is superior to both the INTERTAN Nail ($p<0.001$) and the Gamma3 Nail ($p<0.001$).[1]

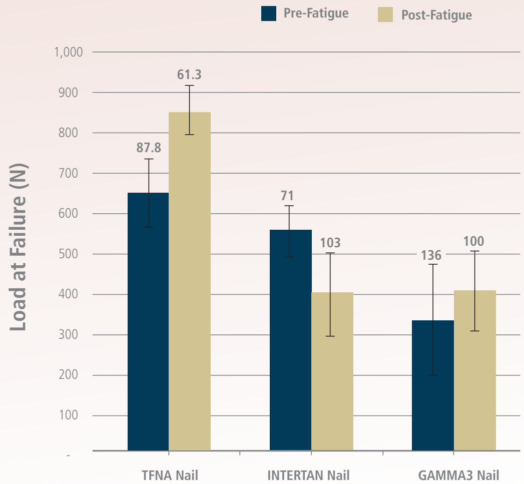


Fig. 6: Results comparison of pre-conditioning and post-conditioning static slippage loads for each nailing system.[1]

DISCUSSION

Static locking designs of the TFNA Nail and INTERTAN Nail, and the overtightening of the set screw in the Gamma3 Nail, are all based on interference fits intended to restrict sliding of the head element. Unique designs of each locking mechanism result in different performance levels as demonstrated in mechanical testing.

While none of these static locking designs prevent sliding in extreme loading conditions, the TFNA Nail has been designed to restrict sliding more than the INTERTAN Nail and the Gamma3 Nail.[1]

Worth noting, the TFNA Nail and the Gamma3 Nail post-conditioning slippage loads were greater than pre-conditioning slippage loads. The conditioning was intended to evaluate any impact dynamic loading had on the nail constructs. Given the increased mean slippage load in post-conditioning, this could be due to settling of the locking mechanism against the head element during the conditioning phase.

References:

1. DePuy Synthes Trauma, TFNA Pre/Post Fatigue Sliding Data Analysis. July 14, 2015. MT15-273.
2. Galal S, Nagy M. Non-parallel screw fixation for femoral neck fractures in young adults. Journal of Clinical Orthopaedics and Trauma. 8 (2017) 220-224.

DePuy Synthes *People inspired*™
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Manufactured or distributed by:

Synthes USA, LLC
1101 Synthes Avenue
Monument, CO 80132

To order (USA): 800-523-0322
To order (CANADA): 855-946-8999

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46582
Tel: +1 (800) 366-8143
Fax: +1 (800) 669-2530

DePuy (Ireland)
Loughbeg, Ringaskiddy
Co. Cork, Ireland
Tel: +353 (21) 491-4000
Fax: +353 (21) 491-4199

140620-200518 DSUS/EMEA