TFN-ADVANCED™ Proximal Femoral Nailing System (TFNA)

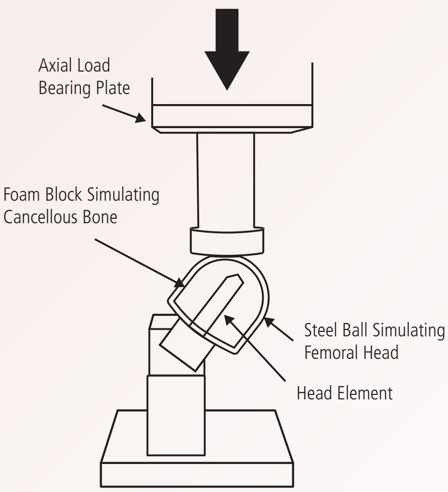
Augmentation Provides Enhanced Implant Anchorage

ABSTRACT

The TFN-ADVANCED™ Proximal Femoral Nailing System (TFNA) provides surgical options to address a wide range of patient needs. While the helical blade technology has demonstrated rotational stability improvements over a lag screw, loss of fixation in the femoral head, especially in osteoporotic bone, remains a challenge.

The TFNA System was designed to accommodate the injection of a proprietary polymethylmethacrylate (PMMA) bone cement (TRAUMACEM™ V+ Injectable Bone Cement) through the cannulated instruments and helical blade/lag screw. The fenestrations in the helical blade and lag screw allow for the intra-operative choice to inject the cement into the femoral head, augmenting the head element, for at-risk patients.

Biomechanical testing was completed to evaluate the stability of non-augmented and augmented TFNA Head Elements. Test setups included center-center and off-center (both anterior and posterior) head element placement to demonstrate resistance to varus collapse. Augmented TFNA Head Elements withstood higher loads prior to varus collapse and were more rotationally stable compared to non-augmented TFNA Head Elements.[1,2]



Additionally, biomechanical testing was completed to evaluate the peak load to failure comparing non-augmented and augmented TFNA Head Elements in a cut-through test. Similarly, augmented TFNA Head Elements were able to withstand higher loads compared to non-augmented TFNA Head Elements.[1]

These biomechanical tests are supported with a series of clinical publications demonstrating zero reported cases of head element migration in augmented TFNA Head Elements, along with no reported cases of complications as a result of injecting cement into the femoral head.[3,4,5,6]

Loss of Fixation in the Femoral Head Leads to Clinical Complications

Cephalomedullary (CM) nails have traditionally offered lag screw head elements based on the design of sliding hip screws, however, lag screws are rotationally unstable. To improve upon this, DePuy Synthes developed the helical blade technology, intended to compress bone around the implant improving anchorage and thus becoming more rotationally stable. Nevertheless, patients treated with CM nails typically have poor bone quality and subsequently have poor implant fixation in the femoral head leading to clinical complications.

Cut-out is a loss of head element anchorage in the bone that causes the femoral neck-shaft angle to collapse, leading to the extrusion, or "cutting out," of the head element in the femoral head. Cut-out continues to be a major complication for CM nails with a Cochrane review reporting a 3.2% rate, and other literature reporting rates as high as 8%.[7,8]

Cut-out is thought to be the result of rotational and axial forces distributed on the implant from loading or weight bearing. While the helical blade technology has shown lower reported rates compared to a lag screw, cut-out remains a clinical complication.

Cut-through is another clinical complication where the femoral head collapses along the axis of the head element leading to the protrusion of the head element. While the head element may be positioned properly in the femoral head, this complication persists and may be a result of slight fracture gaps between the femoral neck and shaft or poor bone quality.

TFNA System Designed with Surgical Options for Enhanced Implant Stability

The TFNA System set out to address complications associated with hip fracture fixation, specifically cut-out and cut-through, which are a result of loss of stability of the implant-bone interface. Using polymethylmethacrylate (PMMA) bone cement, contact between the implant and bone can be enhanced (or augmented) compared to constructs without bone cement, leading to improved fixation.[1,2]

The TFNA System offers fenestrated lag screws and helical blades, allowing for the intra-operative choice to inject cement into the femoral head, augmenting the head element. The TRAUMACEM™ V+ Augmentation System was designed specifically to deliver a targeted amount of cement (3-6 mL) into the femoral head through cannulated TFNA System instruments. The TRAUMACEM V+ Injectable Bone Cement is a proprietary PMMA cement developed to have the flow characteristics required to travel through the TFNA Instruments yet have the mechanical properties to provide resistance to compressive loads.

Augmentation Provides Improved Resistance to Rotational Loads and Varus Collapse

Biomechanical testing was conducted to evaluate and compare the load at failure of the TFNA Head Elements without and with augmentation. The testing was intended to simulate conditions leading to varus collapse or rotation of the femoral head-neck fragment.

Constructs were mechanically tested in a setup simulating an unstable pertrochanteric fracture with lack of posteromedial support and load sharing at the fracture gap. Varus–valgus and head rotation angles were monitored by an inclinometer mounted on the femoral head.

For the non-augmented constructs, a starting load of 400 N was used with an increase of 0.1 N per cycle until failure was reached. For augmented constructs, a starting load of 1,000 N was used with the same increase of 0.1 N per cycle. Implants were assembled and loaded into a test fixture where the head element was loaded as shown in Figure 1.

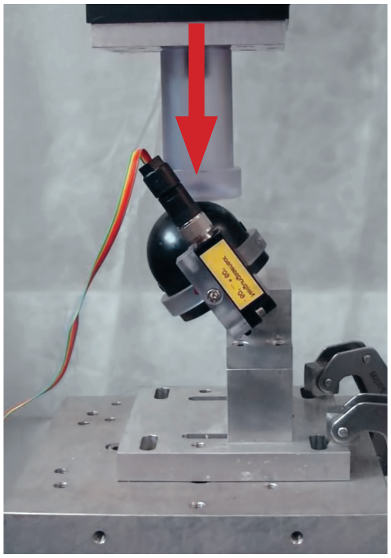


Fig. 1: Test setup with nail construct sample mounted for mechanical testing. Arrow denotes loading direction.

Surrogate specimens simulating femoral cancellous bone with defined geometry and material properties (0.16 g/cc and 23 MPa compressive modulus) were manufactured of cellular polyurethane foam (10 pcf, # 1522-10, Pacific Research Inc., Malmö, Sweden). This selected foam material has been shown to be a reasonable replacement of human osteoporotic bone at the femoral head.[9]

All testing was performed using nails with a 130° caput-collum-diaphyseal (CCD) angle and run in ambient laboratory conditions. Four groups of twelve (12) TFNA Nails with lag screws and four groups of twelve (12) TFNA Nails with helical blades were tested. Within each group, the respective head elements were tested in three scenarios: center-center, 7 mm anterior off-center, or 7 mm posterior off-center (Figure 2).

BEFORE

AFTER

Fig. 2: Sample of head element positions in the before and after positions (ex. Center-center)

RESULTS:

Clinical failure was defined as either a varus collapse of 5° or a rotation of the head of 10°, indicative of loosening of the implant. The point of failure was defined for whichever of the two events occurred first. The number of load cycles to failure and the corresponding failure load were calculated for all specimens and analyzed using an ANOVA analysis with a significance level of $\alpha = 0.05$.

Results of the testing are summarized below, and comparison of the non-augmented and augmented TFNA Head Elements are displayed in Figure 3.

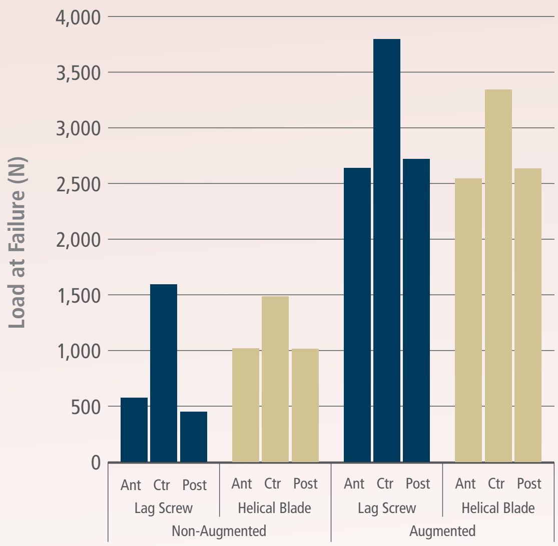


Fig. 3: Results comparison of non-augmented and augmented head elements in rotation and varus collapse [1,2]

- In non-augmented constructs, the helical blade is superior in rotational stability and resisting varus collapse (off-center head element position) compared to the lag screw. There is no difference between the lag screw or helical blade in a center-center head element position.[1,2]
- Augmentation increases resistance to varus collapse in both the lag screw (+138%) and helical blade (+124%), as demonstrated through the center-center position. [1,2]
- Augmentation increases the resistance to rotational forces in both the lag screw and helical blade, as demonstrated through anterior and posterior off-center positions.[1,2]
- A lag screw with augmentation performs superior to a non-augmented helical blade in both rotational stability and resisting varus collapse.[1,2]

Augmentation Enhances Fixation and Resistance to Cut-through

Biomechanical testing was conducted to evaluate and compare the peak load to failure for TFNA Head Elements without and with augmentation. The testing was intended to simulate conditions leading to cut-through of the head element through the femoral head.

Constructs were mechanically tested such that a load was applied axially on the lateral end of the head element. Implants were assembled and loaded into a test fixture where the head element was loaded as shown in Figure 4.

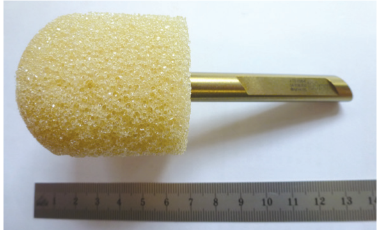
For both the non-augmented and augmented constructs, a starting load of 5 N was used with a test speed of 5mm/min until failure was reached.

Surrogate specimens simulating femoral cancellous bone with defined geometry and material properties (0.16 g/cc and 23 MPa compressive modulus) were manufactured of cellular polyurethane foam (10pcf, # 1522-10, Pacific Research Inc., Malmö, Sweden).

Testing was completed in ambient laboratory conditions. Two groups (non-augmented and augmented) of eight (8) lag screws and two groups (non-augmented and augmented) of eight (8) helical blades were tested. All head elements were positioned in center-center position (Figure 5).

Fig. 4: Test setup with nail construct sample mounted for mechanical testing. Arrow denotes loading direction.

BEFORE



AFTER

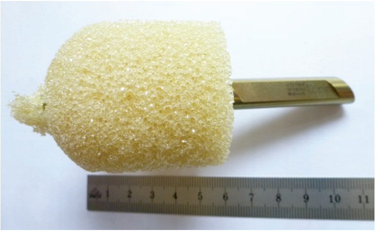


Fig. 5: Sample of head element position in the before and after positions.

RESULTS:

Clinically relevant failure was considered as either a 15mm dislocation from initiation or when the force needed to push the head element reached less than 10% of the peak load applied. The point of failure was defined for which-ever of the two events occurred first. The number of load cycles to failure and the corresponding failure load were calculated for all specimens and analyzed using a one-sided T-test with a 95% confidence level.

Results of the testing are summarized below, and comparison of the non-augmented and augmented TFNA Head Elements are displayed in Figure 6.

- Augmentation increases resistance to cut-through in both the lag screw (+111%) and helical blade (+208%).[1]

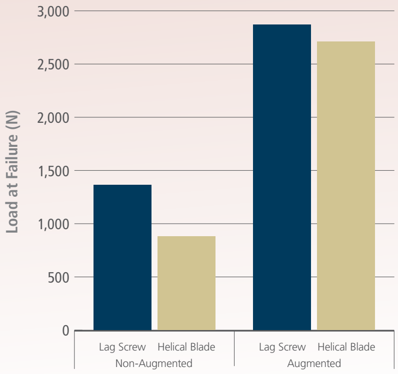


Fig. 6: Results comparison of non-augmented and augmented head elements in cut-through.

Discussion and Clinical Experience

With varying patient needs, the TFNA System offers the lag screw, helical blade, and augmentation, each providing additional degrees of stability.

Since first launching in EMEA in 2008, TRAUMACEM V+ Injectable Bone Cement has been used in over 10,000 cases.[10] Clinical literature to date has cited no cases of cut-out or head element migration when using augmentation, and no complications related to cement have been reported.[3,4,5,6] The use of augmentation for improved anchorage in the clinical setting supports the biomechanical testing.

In conclusion, this data and clinical literature suggests that augmentation of the TFNA Head Elements may decrease risk of fixation failure.

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10. DePuy Synthes Worldwide Sales Data. 2019. Data on file.

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