TFN-ADVANCED™ Proximal Femoral Nailing System (TFNA)

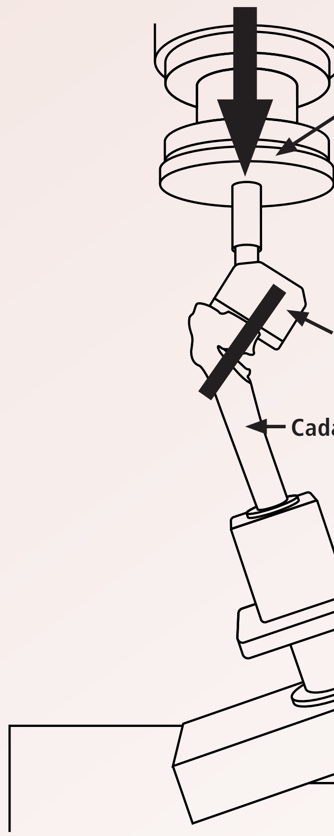
Comparative Evaluation of Head Element Fixation

ABSTRACT

Cephalomedullary (CM) nailing of unstable trochanteric femur fractures can be challenging due to loss of fixation in the femoral head, especially in patients with osteoporotic bone. Implant improvements have been made to address this, however, mechanical complications associated with unstable trochanteric fractures remain.

The TFN-ADVANCED™ Proximal Femoral Nailing System (TFNA) provides surgical options to address a wide range of patient and surgeon needs, with fixation options including the lag screw, helical blade, and bone cement augmentation (TRAUMACEM™ V+ Injectable Bone Cement).

Biomechanical testing in foam models evaluated the stability of a lag screw, helical blade, and bone cement augmentation in the center-center and off-center positions within the femoral head. The helical blade with-stood higher loads prior to varus collapse and was more rotationally stable compared to a lag screw (off-center position).[1] With augmentation added, the lag screw and helical blade performed similarly, withstood higher loads prior to varus collapse, and provided more rotational stability compared to without augmentation.[1,2]



Biomechanical testing in cadaveric specimen, performed by the AO Research Institute, evaluated the stability of a helical blade, bone cement augmentation, and an integrated interlocking screw (TRIGEN INTERTAN Nail, Smith & Nephew) in the center-center position within the femoral head. The helical blade demonstrated comparable stability to an integrated interlocking screw.[3] The augmented helical blade demonstrated superior stability to an integrated interlocking screw.[3]

For unstable trochanteric femur fractures, the helical blade provides comparable stability to an integrated interlocking screw, and both designs provide increased stability compared to a lag screw.[1,2,3] Augmentation, used with either the lag screw or helical blade, provides increased stability compared to non-augmented head elements and the integrated interlocking screw.[1,2,3]

Head Element Options to Increase Fixation and Stability

Cephalomedullary (CM) nails have traditionally offered single lag screw head elements based on the design of sliding hip screws. In unstable trochanteric femur fractures, a lag screw may not provide adequate stability for the fracture as the cylindrical shape of the lag screw may allow the femoral head to rotate about its axis. This could be further complicated by the patient's bone quality, as patients treated with CM nails typically have osteoporotic bone and subsequently have poor implant fixation in the femoral head. These situations may lead to clinical complications for the patient, specifically cut-out and cut-through which are a result of loss of stability of the implant-bone interface.

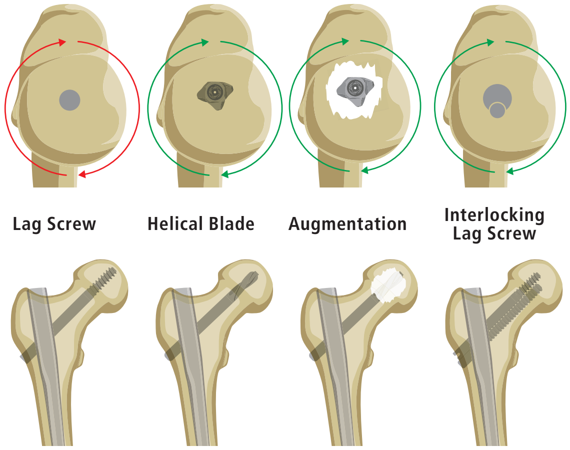


Fig. 1: Head element options for cephalomedullary nails.

Implant improvements have been made to address this, with companies developing unique solutions aimed at improving stability compared to a single lag screw device. The DePuy Synthes TFN-ADVANCED Proximal Femoral Nailing System (TFNA) offers the helical blade and bone cement augmentation while the Smith & Nephew TRIGEN INTERTAN Nail offers an integrated interlocking screw [Figure 1].

Helical Blade and Augmentation Provide Increased Fixation

The TFNA System set out to address complications associated with hip fracture fixation. Two options are provided including the helical blade and a polymethylmethacrylate (PMMA) bone cement augmentation (TRAUMACEM V+ Injectable Bone Cement).

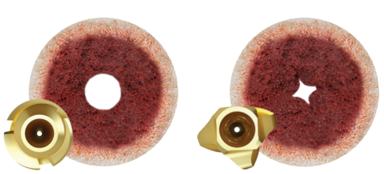


Fig. 2: Illustration of bone removal for a lag screw and helical blade.

The TFNA helical blade is designed to provide better resistance to varus collapse and increased rotational stability compared to a lag screw. The helical blade is designed to compact bone during insertion which enhances implant anchorage [Figure 2]. The design of the helical blade utilizes a flat superior aspect, intended to prevent the femoral head from collapsing into varus, and acts as a larger fin to stabilize the femoral head from rotating.

Augmentation is an optional enhancement to the lag screw or helical blade. Augmentation is designed to interdigitate with the bone following injection of a controlled amount of cement into the femoral head, resulting in increased contact between the implant and bone [Figure 3].

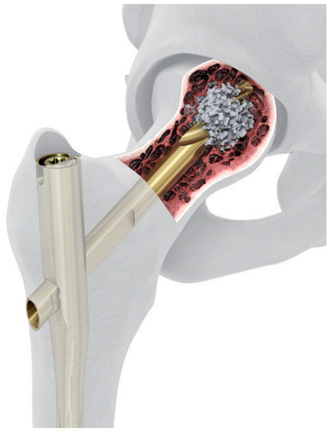


Fig. 3: Bone cement interdigitating with cancellous bone in femoral head.

Biomechanical testing was conducted to evaluate and compare the load at failure of these options versus a lag screw – in the center-center and off-center positions within the femoral head – in foam selected to simulate femoral cancellous bone. The foam selected for this study has been shown to be a reasonable replacement of human osteoporotic bone at the femoral head.[4]

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.

RESULTS:

Results of the testing are summarized below, and comparison of the TFNA System head element options are displayed in Figure 4.

- While the lag screw and helical blade are comparable in a center-center placement, the helical blade provides increased rotational stability as demonstrated in the increase in load prior to failure in off-center placement.[1,2]
- Augmentation provides a significant increase in stability when added to the lag screw or helical blade compared to without augmentation. When augmented, the lag screw and helical blade perform similarly.[1,2,5]

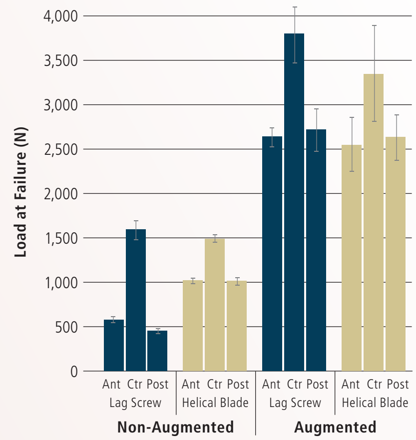


Fig. 4 Results comparison of head elements in rotation and varus collapse.

Head-to-Head Testing Comparing Helical Blade, Augmentation, and Integrated Interlocking Screw

The TRIGEN INTERTAN Nail provides an integrated interlocking screw intended to provide increased stability compared to a single lag screw device.[6] This head element design is non-circular, intended to provide an increase in rotational stability in the femoral head compared to a cylindrical lag screw [Figure 5].

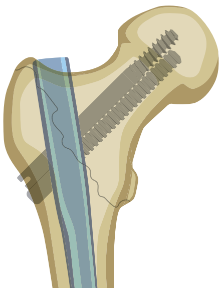


Fig. 5 Integrated interlocking screw.

The AO Research Institute conducted a biomechanical analysis to subject these head element designs to comparative testing. The testing was intended to simulate conditions leading to varus collapse or rotation of the femoral head-neck fragment.

Constructs were biomechanically tested in a setup simulating an unstable pertrochanteric fracture (AO/OTA 31-A2.2) with lack of posteromedial support and load sharing at the fracture gap [Figure 6]. Head elements were placed in the center-center position. Twelve osteoporotic and osteopenic human cadaveric femoral pairs were assigned for pairwise implantation. Testing was performed in ambient laboratory conditions. Four implant groups were created for comparison, and all specimens were biomechanically tested until failure.

- Group 1 (TFNA Nail with helical blade) compared to Group 2 (INTERTAN Nail with integrated interlocking screw)
- Group 3 (TFNA Nail with helical blade, with augmentation) compared to Group 4 (INTERTAN Nail with integrated interlocking screw)

Clinical failure was defined as 5° varus of the femoral head fragment with respect to the femoral shaft, indicative of loosening of the implant in the femoral head. The corresponding number of load cycles to failure and failure load were calculated for all specimens.

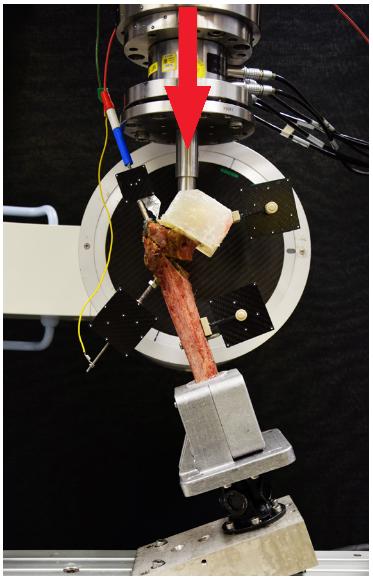


Fig. 6 Test setup with nail construct sample mounted for biomechanical cadaveric testing. Arrow denotes loading direction.

RESULTS:

Varus deformation and femoral head rotation around the neck axis were measured. Results of the testing are summarized below, and comparison of the groups are displayed in Figure 7.

- The helical blade is comparable to the integrated interlocking screw, as demonstrated by the findings in Group 1 and Group 2.[3]
- Augmentation increases resistance to varus collapse and femoral head rotation compared to the integrated interlocking screw, as demonstrated by a statistically significant difference between Group 3 and Group 4 ($p \leq 0.04$).[3]

Cycles to failure and load at failure (N) after 5° varus collapse were also measured. Results of the testing are summarized below, and comparison of the groups are displayed in Figure 8.

- The helical blade is comparable to the integrated interlocking screw, as demonstrated by the findings in Group 1 and Group 2.[3]
- Augmentation provides greater resistance to varus collapse compared to the integrated interlocking screw, as demonstrated by a statistically significant difference between Group 3 and Group 4 ($p = 0.04$).[3]

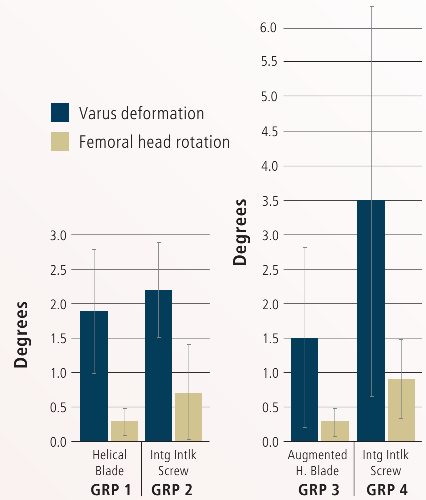


Fig. 7 Results comparison of head elements in rotation and varus collapse at 10,000 cycles.

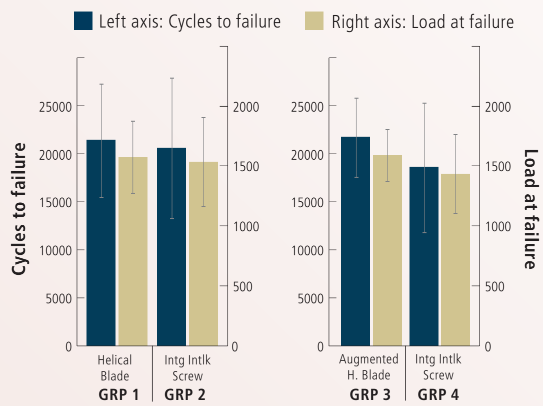


Fig. 8 Results comparison of head elements in rotation and varus collapse at 10,000 cycles.

Discussion & Clinical Experience

Through this testing, it was demonstrated that for unstable trochanteric femur fractures, the helical blade provides comparable stability to an integrated interlocking screw, and both designs provide increased stability over a lag screw.[1,2,3] Augmentation may be used with either the lag screw or helical blade; when augmentation is added, the lag screw and helical blade perform similarly, and provide increased stability compared to non-augmented head elements and the integrated interlocking screw.[1,2,3]

With varying patient needs and surgeon preferences, the TFNA System offers a comprehensive set of options including the lag screw, helical blade, and augmentation, each providing additional fixation and stability.[1,2,3,5] Factors to consider the additional stability provided by the helical blade or augmentation include patients with unstable fractures (i.e., lack of posteromedial support) and/or osteoporosis. These patients make fracture reduction and implant placement more challenging and are at risk of failure.

Discussion & Clinical Experience (continued)

Both foam model and cadaveric testing reduce the number of variables (i.e., fracture type, reduction, surgical technique) compared to clinical studies and are beneficial ways of evaluating implants. Furthermore, using a standardized test method across all devices helps to compare head-to-head performance.

Since first launching in Europe in 2008, augmentation (TRAUMACEM V+ Injectable Bone Cement) has been used in over 30,000 cases globally.[7] Augmentation was subsequently launched in the US in 2017 and has been used in over 6,500 cases.[11] Clinical literature to date has cited no cases of cut-out or head element migration when using augmentation, and no complications related to cement application have been reported (i.e., avascular necrosis or challenges with implant removal). [8,9,10,11] The use of augmentation for improved anchorage in the clinical setting is in agreement with the biomechanical testing.

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† Benchtop testing may not be indicative of clinical performance

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