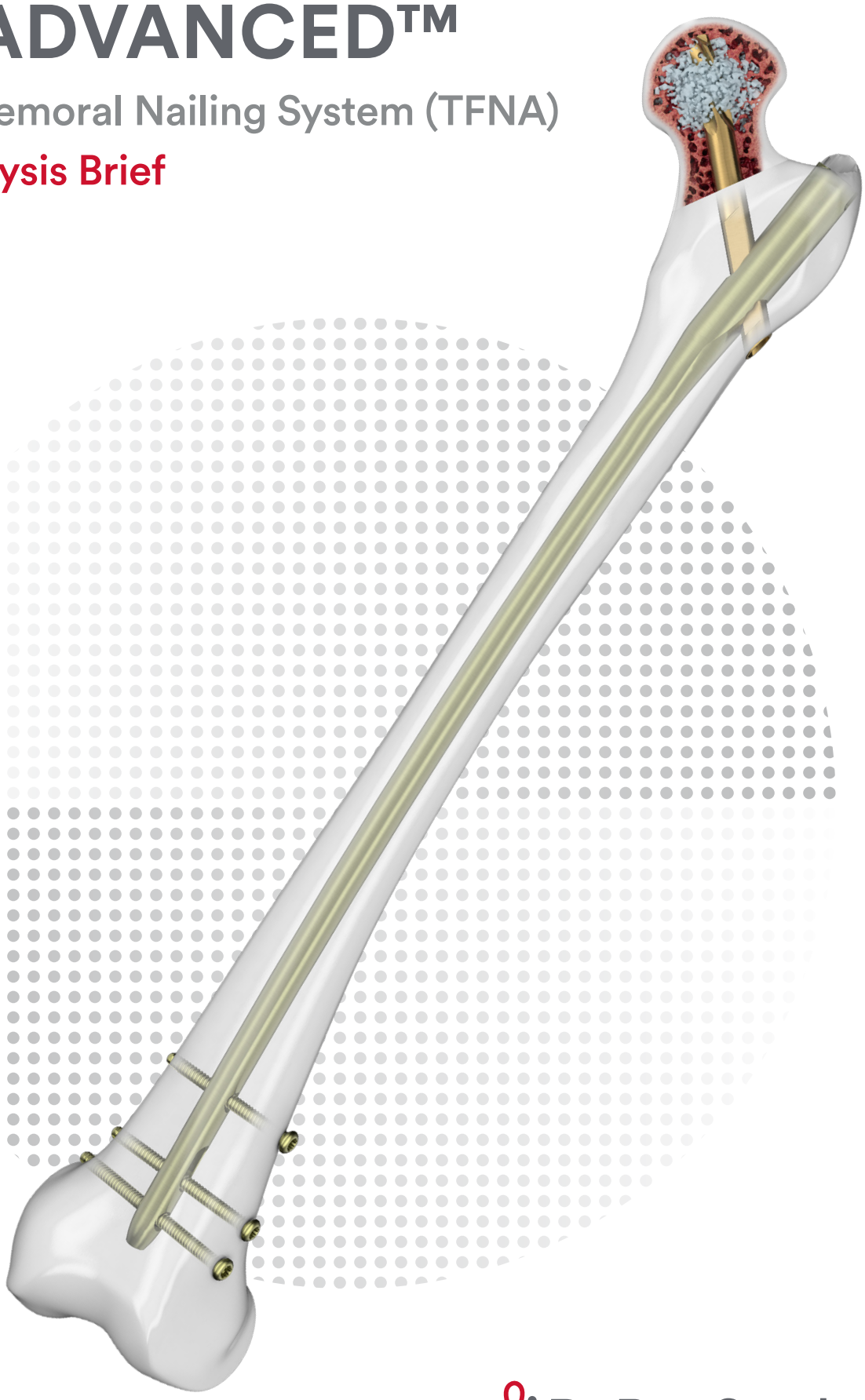
TFN-ADVANCED™

Proximal Femoral Nailing System (TFNA)

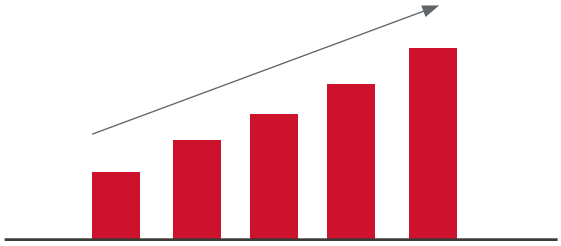
Value Analysis Brief



DePuy Synthes

THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Clinical and Economic Burden



Annually, it is estimated that there are between 260,000 and 300,000 admissions for hip fractures in the US, with projections of more than 500,000 per year by 2040.[1]

<50% | **Of patients have the same walking ability as they did prior to hip fracture[5]**

30% | **Mortality rate in first year post-op[5,7]**

5.0 % | **Reoperation rates for short CM nails[8]**

3.8 % | **Reoperation rates for long CM nails[8]**

2.5x | **Increased cost of treatment compared with an uncomplicated case[9]**

$40,000

Typical patient cost in 1st year[10]

Epidemiology of Hip Fractures

Hip fractures are expected to rise from 4 million today to up to 6.3 million in 2050.[1]

Hip fracture rates increase exponentially with age, with almost 90% of hip fractures occurring in people aged 65 years and older.[2,3]

As the population ages, the incidence of hip fracture is expected to increase substantially.[4]

Unmet Need

Hip fractures result in significant loss of function. 1 year after the fracture, fewer than 50% of patients have the same walking ability they had prior to the hip fracture.[5] Many patients lose their independence and need long-term care.[6]

Due to the patients' advanced age and multiple comorbidities, fractures of the proximal femur are often life threatening: in the first postoperative year, **mortality rates may be as high as 30%.[5,7]**

In 2016 a study published the data for reoperation rates for short and long cephalomedullary (CM) nails. The rate of re-operation was 5.0 % and 3.8 % for short and long CMN, respectively.[8]

Revision surgery is associated with poor prognosis, an increase in mortality, a decrease in the number of patients able to return to their original residence, and a **2.5-times increase in the cost of treatment** compared with an uncomplicated case. (Uncomplicated cases - patients who did not have revision surgery within one year of injury)[9]

A typical US patient with a **hip fracture spends $40,000** in the first year following hip fracture on direct medical costs and almost $5,000 in subsequent years.[10]

In the US, hip fractures are responsible for approximately **3.5 million hospital days per year,** which is more than tibial, vertebral, and pelvic fractures combined.[11]

Need for an Improved Solution

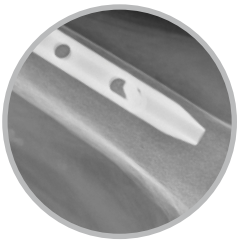
The treatment of proximal femoral fractures continues to be less than optimal due to a moderate complication rate. Since its introduction, cephallomedullary nailing is a widely accepted treatment option for this type of fracture.[12]

Despite numerous advancements in implant design, complications exist, and mortality rates remain high. Complications may result from a variety of issues which in turn may require revision surgery. In 2016 a study published the data for reoperation rates for short and long CM nails. The rate of re-operation was 5.0 % and 3.8 % for short and long CMN, respectively.[8]

Common Complications

Proximal cut-out

A major complication associated with surgery to repair proximal femoral fractures is the cut-out of the head element, defined as "the collapse of the neck-shaft angle into varus, leading to extrusion of the screw or blade head element from the femoral head."[13] Cut-out rates for cephallomedullary nails have been reported as high as 8%, and frequently require reoperation.[14]



Non-anatomical fit

Although the radius of curvature of nails has decreased over time and has generally yielded good results, recent studies have shown that there can still be a misfit between a patient's anatomy and nail design during anterograde nailing. This can result in complications such as distal anterior cortical encroachment.[15]

Implant breakage

In some complex, unstable fractures which may take more time to heal and/or have challenges in achieving anatomic reduction, healing may be compromised. In cases of delayed union or nonunion of the fracture, excessive loads may be placed on the implant which may lead to nail breakage.[10] Nail breakage may occur in as many as 5% of hip fracture patients treated with cephallomedullary nails and requires revision surgery.[16,17]

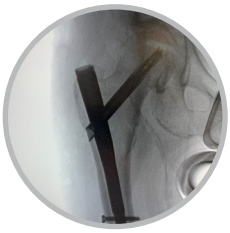
Current evidence suggests that a solution is required that improves fixation stability especially in poor bone quality and improves the anatomic fit of the implant to the native femoral anatomy.

The TFNA System Solution

The TFN-ADVANCED™ Proximal Femoral Nailing System is for intramedullary fixation of proximal femoral fractures.

The TFNA System was designed to reduce the risk of post-operative complications associated with hip fractures by providing surgical options to enhance stability in poor bone and improving the anatomic fit of the nail to the native femur. The implant anchorage assists in preventing implant cut-out or cut-through, caused by several factors including poor bone quality, which is a top complication in treating osteoporotic hip fractures.

Enhanced Stability in Poor Bone Quality



Helical Blade

Helical Blade technology is designed to compress bone during insertion, which enhances implant anchorage and is intended to reduce the risk of cut-out.[18] Clinical results have shown a lower cut-out rate compared to a lag screw (1.5% vs 2.9%)[19]

Augmentation

Augmentation is an optional enhancement to the TFNA System lag screw or helical blade. Intra-operative injection of a polymethylmethacrylate (PMMA) cement increases bone-implant surface contact area which significantly increases fixation strength compared to no augmetation.[20]

Improved Fit & Strength

Anatomical Fit

Improved nail shape (1.0m anatomic bow) based on multi-ethnic 3-D computational study designed to better fit patient anatomy[15,21] and to help avoid impinging the anterior cortex compared to nails with larger radius of curvature.

Implant Strength

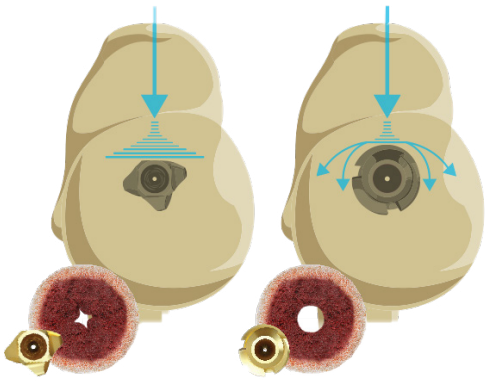
Small proximal diameter (15.66mm) and LATERAL RELIEF CUT™ Design help to preserve bone in insertion area due to reduced critical width. High strength titanium alloy (Ti-Mo) and the BUMP CUT™ Design of proximal hole provides improved fatigue strength compared to existing nails of similar size.*[22]

* Pre-Clinical test data is not necessarily indicative of clinical performance

Proximal Cut-Out

A major complication in proximal femoral fractures is the cut-out of the head element.[13] Cut-out rates for cephallomedullary nails have been reported as high as 8%, and frequently require reoperation.[14]

Solution

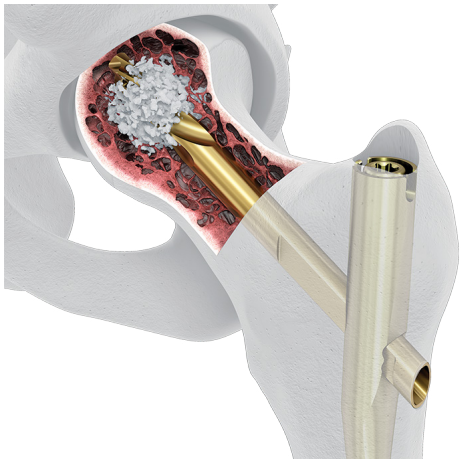


Resistance to Varus Collapse | **Rotation of femoral head**

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.

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.[20]



Augmentation

Bone cement interdigitating with cancellous bone in femoral head, used with the lag screw or helical blade.

Augmentation (TRAUMACEM™ V+ Augmentation System) provides additional fixation, in osteoporotic bone and unstable fractures, by "augmenting" the head element and increasing the bone to implant surface contact area.[23, 24]

The decision to perform augmentation can be made during surgery, and the cost will only be incurred if augmentation is chosen.

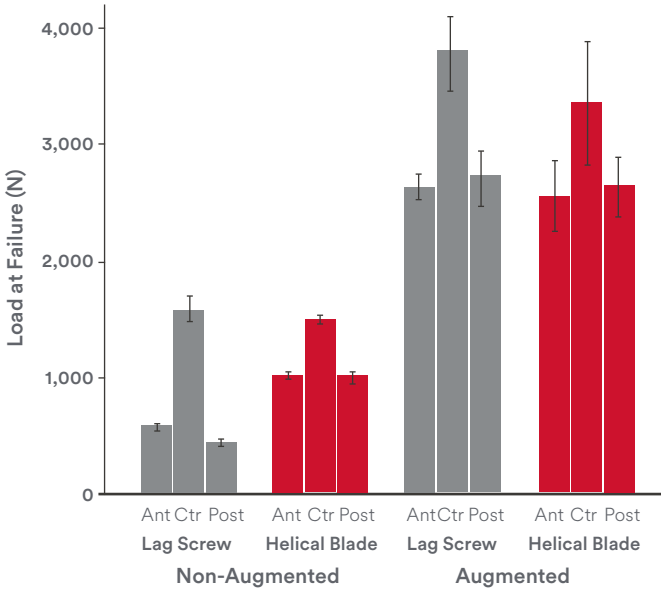
Biomechanical testing was performed to evaluate head-to-head performance of the lag screw, helical blade, and augmentation to evaluate fixation. Testing was also completed to evaluate these devices compared to an integrated interlocking screw.

Helical Blade provides greater rotational stability compared to a lag screw

The lag screw and the helical blade are both equally stable when placed in the center of the femoral head. However, the helical blade has increased rotational stability when placed off-center, meaning that it can withstand more rotational force before it fails.[20,25]

Implant augmentation significantly increases stability compared to a non-augmented lag screw or helical blade. Implant augmentation increases implant anchorage only and has no influence on the position/relationship of fracture fragments.[20,25,26]

Results comparison of head elements in rotation and varus collapse

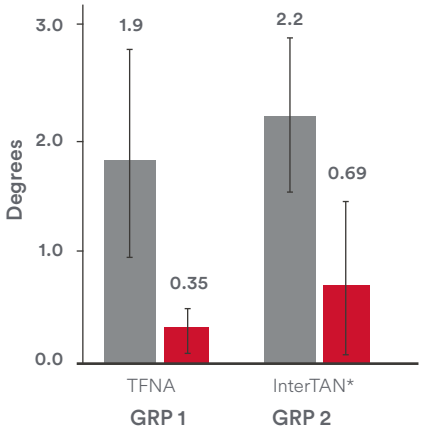


Helical blade provides comparable rotational stability to an integrated locking screw.

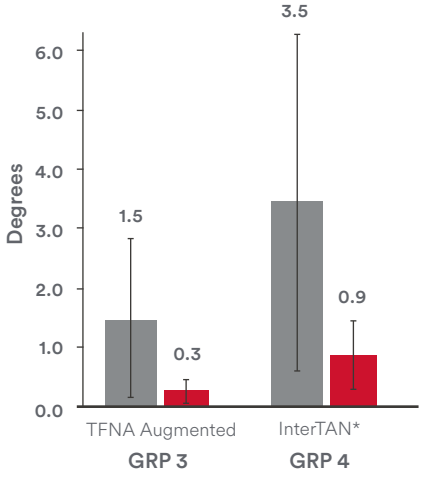
The **helical blade demonstrated comparable stability** to the integrated interlocking screw.[25,27] This is achieved by a single implant compared to the integrated interlocking screw requiring two individual components.

Augmentation provides superior fixation compared to integrated locking screw. Augmentation significantly increases stability compared to the integrated interlocking screw.[27]

Helical blade compared to integrated locking screw[27]



Augmented helical blade compared to integrated locking screw[27]



Varus deformation Femoral head rotation

*Intertrochanteric Antegrade Nail (InterTAN)

Clinical Results

The TFNA Helical Blade and Augmentation have been shown to improve patient outcomes in a clinical setting.

Helical Blade

The helical blade helps reduce failure rates by compacting the surrounding bone during insertion and therefore leads to higher stability compared to lag screws.

1.5% vs 2.9%

Lower cut out rates

A prospective, randomized clinical trial of 335 pertrochanteric and intertrochanteric fractures reported lower cut-out rates in the blade group (1.5%) compared with the screw group (2.9%).[19]

Augmentation

Multiple studies demonstrate that augmentation improves anchorage of the head element in the femoral head and by generating greater cut-out resistance compared to non-augmented constructs.[23,24,28,29]

0%

Implant cut-out or cut through with augmentation

A study looking at **early clinical results** of augmentation, found no complications related to the use of PMMA cement. While reported implant cut-out rates would be between 2-3.6%, there were no complications of cut-out or cut-through in the augmentation group.[23]

Several studies demonstrate similar experience with augmentation – in 5 case studies with over 70 patients, there were zero reported events of implant loosening, cut-out, or cut-through.[30-34]

0% vs 4.4%

Reoperation rate in randomized controlled trial

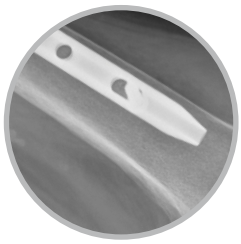
A large multicenter **randomized controlled trial (RCT)** compared clinical and patient outcomes with and without augmentation in patients with unstable proximal femur fractures.

The results showed that although both treatments led to comparable outcomes of improving patients' mobility, augmentation might have the potential to prevent reoperations by strengthening the osteosynthesis construct.[35]

Non-Anatomical Fit

Non-anatomical fit such as distal cortical impingement may occur in up to 25% of hip fracture repair cases and is often the result of cut out/perforation of the nail tip or the curve of the natural femoral anatomy being greater than the curve of the cephallomedullary nail causing a "mismatch". This applies mostly to pronounced antecurvation of the femur which is typical for osteoporotic bones. This complication may also lead to a secondary fracture around the nail which requires revision surgery in up to 3% of cases.[8,36-38]

Solution



Distal "Anterior" cortical impingement

ROC = Radius of Curvature
Gold nail represents the TFNA Nail with 1.0m ROC, blue nail represents a nail with 1.5m ROC

Proximal geometry of the TFNA nail including the lateral relief cut design

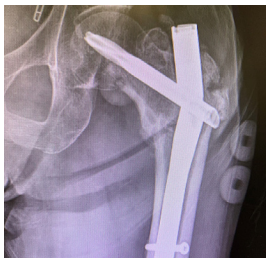
The TFNA Nail is designed to fit patient anatomy and be a better fitting implant such that the fit to the anatomic bow of the femur and the proximal body of the nail is superior to previous cephallomedullary nails especially in osteoporotic conditions.[15]

The radius of curvature (ROC) of a long nail is an important factor for clinical success to match the native anatomy. By using a 1.0m ROC, the TFNA Nail has a significantly smaller mean total surface area (Stryker Gamma3, e.g.) of nail protrusion compared with a nail of 1.5m ROC (915.8 vs. 1181.6 mm^2; $P < 0.05$) in human femora of different ethnicites. The TFNA Nail also had a significantly smaller mean maximum distance of nail protrusion in the axial plane compared with a nail of 1.5m ROC (i.e., Stryker Gamma3) (1.9 vs. 2.1 mm; $P = 0.007$). **The study concluded that the 1.0m ROC TFNA Nail resulted in better fit than 1.5m ROC nails.**[15] Also, nail insertions requires less force with the 1 m bow.[21]

The proximal diameter of the TFNA Nail was reduced from its prior generation nails to 15.66 mm to **preserve bone in the insertion area of the proximal femur while also catering to small stature patients.** The smaller diameter of the proximal nail may help in minimizing disruption to the patient anatomy by requiring less bone removal during drilling/reaming and reducing the insertion wedging effect.

The LATERAL RELIEF CUT™ Design further minimizes the proximal geometry. 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 however the diameter could be reduced to aid insertion and **minimize lateral impingement.**

Implant Breakage



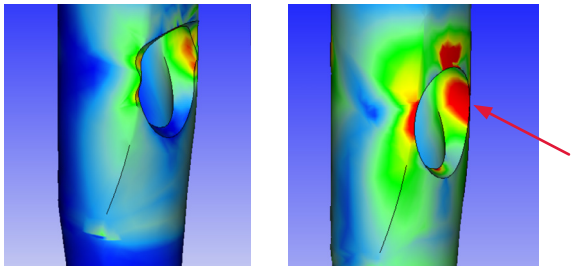
Nail Breakage

In unstable pertrochanteric fractures, reverse obliquity fractures and subtrochanteric proximal femoral shaft fractures, reduction and fixation can be difficult and healing may be compromised and/or delayed. Fatigue nail breakage may result under these conditions as a consequence.[10] Nail breakage may occur in as many as 5% of hip fracture patients treated with cephallomedullary nails and requires revision surgery.[16,17]

Solution

The TFNA Nail is designed to minimize breakages and reoperations through unique geometry and material selections. Cephallomedullary 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. The TFNA Nail is made from a unique high strength titanium alloy (Ti-Mo) that is stronger than alternative materials typically used in these devices.

A Finite Element Analysis (FEA) analysis comparing TFNA Nail without and with BUMP CUT™ Design

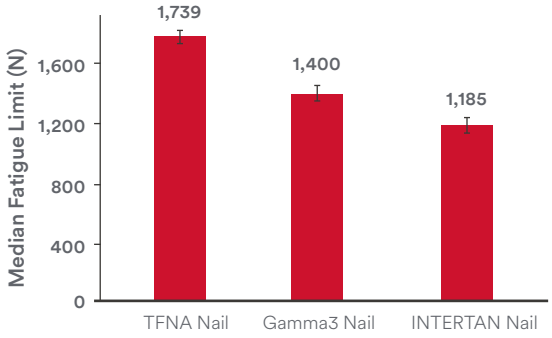


With BUMP CUT™ Design | **Without BUMP CUT™ Design**

High strength titanium alloy (Ti-Mo) is used to increase nail strength. By reducing the proximal diameter, the nail strength is impacted. Therefore alternative materials were considered to compensate for this.

To further impact the strength of the nail, **the BUMP CUT™ Design was developed to reduce implant stress at the proximal hole.** The BUMP CUT™ Design feature improves the distribution of stress at the proximal nail hole, combined with the use of a Titanium Alloy, contribute to improved implant fatigue strength when compared with existing nails of similar size.*[22,39-42]

Biomechanical testing was performed to evaluate head-to-head fatigue strength of the TFNA Nail compared to the Stryker Gamma3 Nail and Smith & Nephew INTERTAN Construct Nail.



TFNA Nail median fatigue limit greater than Gamma3

TFNA Nail has greater strength compared to other cephallomedullary nails

Biomechanical fatigue testing was completed and found: The TFNA Nail is **24% stronger** than the Gamma3 Nail[43]

The TFNA Nail is **47% stronger** than the INTERTAN Nail[44]

*Pre-Clinical test data is not necessarily indicative of clinical performance

Clinical Results

The TFNA Nail has been shown to have low, and comparable, breakage rate to other cephallomedullary nails.

Real-world clinical evidence shows low rates of TFNA Nail breakages from health system database.[12]

0/733

Nail breakages

A retrospective database study of Mercy health system's orthopedics database evaluated the risk of TFNA Nail breakage during a 2-year follow-up period and included 733 patients treated with TFNA Nails between 2016 to 2020. Results found there were no cases of nail breakage identified.[12]

Real-world clinical evidence compared breakage rates of the TFNA Nail to other similar cephallomedullary nailing systems and found rates to be comparable while time to failure was longer with the TFNA Nail. [45]

0.25%

Risk of nail breakages

4.72 **vs**
4.05 **months**

TFNA time to breakage greater than competitors

A study was conducted using data from Premier, a large US healthcare database, to evaluate and compare risk of breakage between TFNA Nails and comparable cephallomedullary nails including Stryker Gamma3 and Zimmer® Natural Nail® (identified as "non-TFNA") at 18 months post procedure.

Data from 14,370 patients implanted with TFNA Nails and 8,260 non-TFNA Nails from 365 hospitals found:[45]

TFNA Nails and non-TFNA Nails have **similar breakage rates** (0.25%).

Time to failure for TFNA Nails is longer vs non-TFNA Nails (4.72 months versus 4.05 months).

The use of cement augmentation for fixation of trochanteric fractures is associated with fewer complications, re-operations, and shorter hospital stays and it is cost-effective compared to no cement augmentation.[46,47]

1.9 days

Shorter hospital stay

Potential cost savings

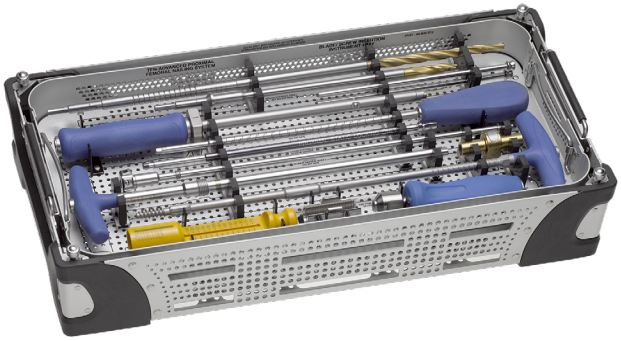
The meta-analysis by Rompen[46] et al concluded that:

- Cement augmentation in fixation of trochanteric femoral fractures leads to fewer overall complications (28.3% versus 47.2%), re-operations (1.6% versus 7.4%), and shorter hospital stay (1.9 days shorter in the augmented group) compared to no augmentation.[46]
- Cement-augmented patients can regain pre-operative mobility faster and suffer from significantly less pain post-operatively compared to no augmentation.[46]

The study by Joeris et al.[47] assessed the cost-effectiveness of cement augmentation from the German payer's perspective.

- Fixation with cement augmentation leads to a potential cost savings compared to fixation without augmentation demonstrating the extra cost of cement augmentation is a good value for the healthcare system.[47]

Advanced Nailing System



The DePuy Synthes Advanced Nailing System provides stability solutions to empower you and your patients to do more.

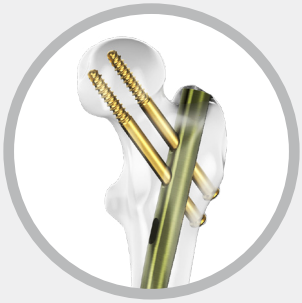
With a growing fragility fracture population, the Advanced implants are specifically designed to address the challenges of reduction and fixation as well as the importance of early mobilization in compromised bone.

Designed for simple to complex cases, we provide efficiency and performance by uniting intuitive, connected instrumentation with the Advanced implant family.

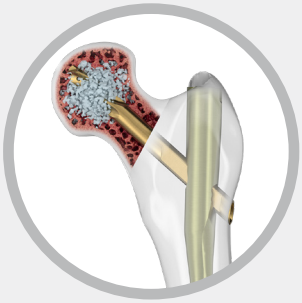
Stability to do more™

TN-ADVANCED™
Tibial Nailing System

RFN-ADVANCED™
Retrograde Femoral Nailing System



FRN-ADVANCED™
Femoral Recon Nailing System



TFN-ADVANCED™
Proximal Femoral Nailing System (TFNA)

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