DePuy Synthes

VALUE ANALYSIS BRIEF

TFNAdvanced™
PROXIMAL FEMORAL NAILING SYSTEM
Executive Summary

Unmet clinical need:

Distal cortical impingement may occur in up to 25% of cases and is often the result of the curve of the natural femoral anatomy being greater than the curve of the hip nail causing a “mismatch”.1-3 This complication may lead to a fracture at the distal nail tip, called anterior perforation, which requires revision surgery.1,4,5

Cut-out is the major cause of implant failure in the fixation of proximal hip fractures, and may cause severe injuries in hard and soft tissues surrounding the hip joint.7,8 Cut-out rates for cephalomedullary nails have been reported as high as 8%, and frequently require reoperation.7

Nail breakage may occur in as many as 5% of hip fracture patients treated with cephalomedullary nails and requires revision surgery.11,13 Nail breakage is often a result of fractures that take longer to heal or fail to heal (delayed union or nonunion, respectively).14
The TFNA System was designed to address clinical challenges:

The TFNA System was designed with a 1.0 m radius of curvature (ROC) to reduce the risk of distal cortical impingement and anterior perforation compared to competitive nail systems with larger ROCs.

A multi-ethnic, 3-D computational study showed the TFNA nail (1.0 m ROC) resulted in a better fit than Gamma3 (1.5 m ROC).6

- Nail protrusion measurements are significantly smaller for the TFNA Nail compared to Gamma36

<table>
<thead>
<tr>
<th>Mean total surface area</th>
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<tbody>
<tr>
<td>TFNA Nail</td>
<td>915.8 mm²</td>
<td>1.9 mm²</td>
</tr>
<tr>
<td>Gamma3 Nail</td>
<td>1181.6 mm²</td>
<td>2.1 mm²</td>
</tr>
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</table>

- Distal Nail Tip Position:
  - TFNA Nail had a higher number of center positions than Gamma3 (13 vs. 7, respectively).6
  - The far anterior position for the nail tip was observed markedly less often with the TFNA nail compared with the Gamma3 nail (16 vs. 30, respectively).6

TFNA Helical Blade technology was designed to compress bone during insertion, which enhances implant anchorage and may reduce the risk of cut-out. Resistance to cut-out in osteoporotic bone is further improved by cement augmentation of the TFNA Helical Blade or screw.9,10

- A prospective, randomized clinical trial showed lower cut-out rates in the cohort treated with a helical blade (1.5%) compared to the screw (2.9%).11
- Biomechanical testing of off-center placement showed significant improvement in cut-out resistance for the TFNA Helical Blade compared to both the TFNA Screw and Gamma3 Screw.12 These results show the TFNA Helical Blade is more forgiving in regards to head element positioning.
- A clinical study with 15.3 months of follow-up showed no cut-out events for patients treated with Helical Blade Technology and augmentation (n=62 patients).9

TiMo titanium alloy and BUMP CUT™ Design provides the TFNA System with improved fatigue strength when compared with existing nails of similar size.15

Results of biomechanical testing showed greater fatigue strength for the TFNA System compared to Gamma3 and InterTAN nails (p<0.05).15

*Differences are statistically significant (p<0.05)*
ECONOMIC VALUE

Economic Challenge: High Cost of Reoperation

TFNA Solution:
Reduction in revision surgeries due to cut-out or other complications may result in cost reductions for the hospital.

- A budget impact analysis was developed to show the potential economic impact to a hospital using the TFNA System with a helical blade compared with a proximal nail system with a screw. Results showed a hospital performing 200 proximal hip nailing cases per year may save £23,923 annually due to the difference in cut-out rates for helical blades versus screws.

**Annual Cost of Inpatient Hospital Care**

<table>
<thead>
<tr>
<th></th>
<th>Screw</th>
<th>Helical Blade</th>
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<tbody>
<tr>
<td>Annual Cost of Inpatient Hospital Care (GBP)</td>
<td>£40,555</td>
<td>£25,632</td>
</tr>
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</table>

- In patients with severely osteoporotic bone, the use of augmentation with the helical blade enhances implant anchorage and further reduces the risk of cut-out. The use of augmentation provides additional value to the hospital when enhanced implant anchorage is needed in patients with severe osteoporotic bone.

Hospital Standardization

Aligning surgeons with hospital cost reduction initiatives, such as standardization of physician preference items, is an important step in reducing clinical supply spending and creating opportunities for hospital savings.

- 86% of surgeons using the TFNA System "Strongly Agreed/Agreed" that they would "Recommend this new proximal femoral nailing system".
- The flexibility of the TFNA System allows the surgeon to optimize the procedure based on patient need and surgeon preference.

For the hospital, the TFNA System offers a single hip nail system providing surgeons with the choices they need to treat a wide variety of fracture types while promoting hospital standardization strategies.

Procedural Efficiency in OR

The instruments used with the TFNA System introduce design features, such as QUICK CLICK™ Self-Retaining Technology and radiolucent insertion handles with radiographic indicators designed to streamline the procedure in the OR, potentially reducing OR time and minimizing pain points within the surgical procedure for OR staff and surgeons.

- 74% of surgeons "Strongly Agreed/Agreed" that "I felt the new system improved the overall procedural efficiency compared to previously used nailing systems."
- 77% of surgeons "Strongly Agreed/Agreed" that "The new instrument is easier than what I used previously."
Hip fractures are common in the elderly; The number and costs of hip fractures are expected to rise as the population ages. Reducing the reoperation rate, which has been estimated at 6.3%, provides an opportunity for hospitals and health care systems to save costs.

**HIP FRACTURES**

A hip fracture is a femoral fracture that occurs in the proximal end of the femur (the long bone running through the thigh), near the hip. The term "hip fracture" is commonly used to refer to the fracture patterns as shown in Figure 1. In the vast majority of cases, a hip fracture is a fragility fracture due to a fall or minor trauma in someone with weakened osteoporotic bone. Hip fractures in people with normal bone are often the result of high-energy trauma such as car accidents, falling from heights (>10 ft.), or sports injuries.

**FIGURE 1: Types of Hip Fracture Patterns:**

Most hip fractures are treated by orthopedic surgery, which involves implanting an orthopedic device. The fracture takes approximately 4-6 months to heal. The surgery is a major stress on the patient, particularly in the elderly. Revision procedures should be avoided given the increased surgical risk in these patients.
Epidemiology

Hip fractures are a major public health problem in terms of patient morbidity, mortality, and costs to health and social care. The incidence of hip fracture increases steeply with age due to higher rates of osteoporosis and falls in the elderly population. Hip fractures account for the majority of osteoporotic fragility fractures and for over 40% of the estimated burden of osteoporosis worldwide. In 2010, there were an estimated 600,000 incident hip fractures in the European Union, and this number is expected to rise to 972,000 by 2050.

Trochanteric fractures constitute up to 55% of proximal femoral fractures and occur predominantly in elderly patients. Most commonly, trochanteric fractures are caused by low-energy trauma events, such as falls from a standing position, usually in combination with osteoporosis.

Due to the patients’ high age and comorbidities, fractures of the proximal femur are often life threatening: in the first postoperative year, mortality rates may be as high as 30%. In young patients, trochanteric fractures are typically associated with high-energy trauma events, such as motor vehicle, bicycle, and skiing accidents.

Economic Burden

In 2010, there were an estimated 600,000 incident hip fractures in the European Union, costing €20 billion and accounting for 54% of the total costs of osteoporosis. These costs are expected to increase exponentially following the growing incidence rate.

The economic burden of treating hip fractures is substantial:

- UK – Total annual hospital costs associated with incident hip fractures were estimated at £1.1 billion in 2013.
- Germany – 109,341 patients experienced a hip fracture in 2002, and the annual cost of care was €2,998,000,000.
- Portugal – Mean individual fracture-related costs were estimated at €13,434 for the first year and €5985 for the second year following the fracture. In 2011 the economic burden attributable to osteoporotic hip fractures in Portugal could be estimated at €216 million.
- Netherlands – The healthcare costs due to osteoporosis-related hip fractures (approximately €11,000–€13,000 per person) substantially exceeded those of other osteoporosis related fractures, such as spine, upper extremity, lower extremity, and wrist/distal forearm.
- Italy – A total of 85,762 hospitalizations due to hip fractures (17,597 men and 66,674 women) were recorded in 2005 for people >65 years old. Hospital costs were €467 million in 2005, with rehabilitation costs reaching €532 million in the same year.
Clinical Burden

Hip fractures result in pain, loss of mobility, and high rates of mortality.\textsuperscript{33} Nearly all patients are hospitalized, and most undergo surgical repair of unstable fractures using cephalomedullary nails. Fractures of the hip are associated with significant loss of function; one year after the fracture, fewer than 50% of patients have the same walking ability they had prior to the fracture.\textsuperscript{34} Many patients lose their independence and need long-term care. Comorbidity is an important contributory factor to hip fractures and is often a determinant of outcome.\textsuperscript{33}

The reoperation rate of cephalomedullary hip nailing has been estimated at approximately 6.3%.\textsuperscript{19} The most common types of complications resulting in revision include distal cortex penetration (≤3% revision rate\textsuperscript{4,5}), proximal cut-out (≤8% revision rate\textsuperscript{7,19}), and implant breakage (≤5% revision rate\textsuperscript{13}). Revision surgeries are associated with a poor prognosis, an increase in mortality, and a decrease in the number of patients able to return to their original residence.\textsuperscript{35}
METHODS

This value analysis brief presents information on the potential clinical, and economic benefits of using the TFNA System. The referenced data were obtained through a systematic literature review of Ovid Medline, Ovid Embase, and PubMed for clinical and economic studies published from 2003-2016. This literature search resulted in a total of 97 publications that met the inclusion and exclusion criteria. Papers were selected for use in this value analysis brief based on the highest level of clinical, biomechanical, and economic evidence. Recently completed biomechanical studies were also included to support the value propositions for the TFNA System and referenced as “Data on File”.

Published results included studies reporting outcomes for proximal hip nails currently on the market with similar features as the TFNA System. The TFNA System builds upon the clinical heritage of existing DePuy Synthes Trauma technology:

- The TFNA Helical Blade technology is similar to the existing Helical Blade technology used in the Trochanteric Fixation Nail (TFN) and Proximal Femoral Nail Antirotation (PFNA) Systems.
- The TFNA LATERAL RELIEF CUT™ is comparable to the lateral relief cut of the Proximal Femoral Nail Antirotation-II (PFNA-II) System.
- The augmentation option available with the TFNA System is analogous to the cement augmentation option available with the PFNA System.
Penetration of the anterior cortex of the distal femur is a complication associated with treating proximal femoral fractures with intramedullary devices.¹ Use of long cephalomedullary nails may result in the distal tip of the nail abutting the anterior cortex of the femur, which is called “nail impingement”.¹ Distal cortical impingement is often the result of the curve of the femoral anatomy being greater than the curve of the hip nail (nail-canal mismatch, see Figure 2).¹ ³ Published clinical studies have reported rates of distal cortical impingement of up to 25%,¹ and this complication may lead to fracture at the distal nail tip in the early post-operative period.¹ This fracture event, called anterior cortex perforation, occurs in up to 3% of cases and requires revision surgery.⁴ ⁵

Cephalomedullary nail designs include both short and long nails. The long nails extend to the end of the distal femoral metaphysis (i.e. wide portion of the bone above the femoral condyles).³ ³⁶ The distal nail design, specifically the radius of curvature (ROC) of a long nail, as well as the nail entry point, and proximal nail geometry are important factors for clinical success.³

Prior to the launch of the TFNA System, the ROCs for commercially available cephalomedullary nails ranged from 1.3 m to 3.0 m,³⁷ ³⁹ and clinical experiences from recent studies have shown that these ROCs may lead to complications resulting from nail-canal mismatch.³ ³⁹ ⁴⁰ Collinge and Beltran (2013) reported that femoral nails with a ROC of 1.5 m more closely approximate the femoral bow of geriatric patients with hip fracture than nails with a ROC of 2.0 m, and may be less likely to cause complications, such as anterior cortical abutment, perforation, or fracture.³ This study reported rates of distal cortical impingement of 12% with a 2.0 m ROC nail (InterTAN Nail System with 2.0 m AP bow, Smith and Nephew) but only 3% with a 1.5 m ROC nail (InterTAN Nail System with 1.5 m AP bow, Smith and Nephew).³ A nail resting against the anterior femur also may be associated with thigh or knee pain.³ Therefore, continuing to decrease the nail ROC to more closely match anatomical measurements may further improve treatment outcomes.
The TFNA Nail was designed with a ROC of 1.0 m to more closely match the femoral anatomy than hip nails with larger ROCs (i.e. straighter nails). A 3D computational study showed the 1.0m ROC of TFNA resulted in a better fit than the 1.5 m ROC nail (Gamma3 Long Nail R1.5, Stryker Trauma). This study included samples derived from Caucasian (n=31), Japanese (n=28), and Thai (n=4) subjects with a mean age of 77 years (range 65 to 103 years). The results showed:

**Nail Protrusion**

- Nail protrusion measurements are significantly smaller for the TFNA Nail compared to Gamma3:

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<thead>
<tr>
<th></th>
<th>ROC</th>
<th>Mean total surface area</th>
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<th>p</th>
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<td>&lt;0.05</td>
</tr>
</tbody>
</table>

- Subgroup analyses showed mean total surface area of nail protrusion was significantly smaller with the TFNA nail compared to Gamma3 in Caucasian (p=0.0009) and Asian samples (p=0.000002).

**Distal Nail Tip Position**

- TFNA Nail had a higher number of center positions than Gamma3 (13 vs. 7, respectively).
- The far anterior position for the nail tip was observed markedly less often with the TFNA nail compared with the Gamma3 nail (16 vs. 30, respectively).

These biomechanical results showing the improved fit of the TFNA Nail of this study showed the TFNA Nail, with a 1.0 ROC design, resulted in a better fit compared with the Gamma3 nail with a 1.5m ROC design. This could result in clinical improvements in implant fit and potentially fewer post-operative complications.

**FIGURE 3: Distal Nail Tip Position for TFNA Compared to Gamma3**

![Distal Nail Tip Position](image-url)
Case Study

Applying 3D computer modelling to an average Caucasian sample with an ROC of 1.015m resulted in a slightly smaller misfit in the subtrochanteric region for the TFNA Nail compared with the Gamma3 nail (Figure 4). Distally, the TFNA achieved a center position whereas the Gamma3 nail showed an anterior position (Figure 4).

**FIGURE 4:** Case Study of Caucasian Model with an ROC of 1.015m Shows Better Fit with TFNA Nail (1.0m ROC) vs. Gamma3 (1.5m ROC)

This 3D computational study showed the TFNA Nail with a 1.0m ROC design resulted in a better fit compared with the Gamma3 nail with a 1.5m ROC design as evaluated by protrusion area, protrusion distance, and far anterior nail tip positions.

In addition to nail-canal mismatch and anterior perforation of the cortex, lateral extrusion of the nail and impingement are also potential complications associated with the fit of the nail. The small proximal diameter and the LATERAL RELIEF CUT™ Design (Figure 5) of the TFNA Nail avoid impingement on the lateral cortex while preserving bone in the insertion area, potentially reducing the risk of fracture displacement. Additionally, the oblique cut on the lateral end of the TFNA Blade and Screw reduces lateral protrusion on the soft tissues when compared with that of a standard cut head element.

**FIGURE 5:** TFNA System: Designed with a Small Proximal Diameter, Oblique Cut, and LATERAL RELIEF CUT™
TFNA Helical Blade technology is designed to compress bone during insertion, which enhances implant anchorage and may reduce the risk of cut-out, a serious post-operative complication often resulting in reoperation. Cut-out is the major cause of implant failure in dynamic hip screws, accounting for more than 80% of failures.\textsuperscript{7}

**PROXIMAL CUT-OUT**

**Definition of Cut-Out**

Implant cut-out is a loss of implant anchorage in the bone that causes the femoral neck-shaft angle to collapse, leading to the extrusion, or cutting-out, of the screw or blade element from the femoral head (Figure 6). Revision surgery is often necessary when cut-out occurs.\textsuperscript{42}

Cut-out is the most common\textsuperscript{43} cause of implant failure in the fixation of trochanteric fractures, accounting for more than 80% of failures in cases using dynamic hip screws.\textsuperscript{7} Cut-out rates for cephalomedullary nail devices were reported as 3.2\% in a Cochrane review of the literature,\textsuperscript{19} are often reported as high as 8\%,\textsuperscript{7,43} and have also been reported as high as 33.3\%.\textsuperscript{43}

A recent study published by Mingo-Robinet and colleagues (2015) evaluated the cut-out rates of 218 fractures treated with either the Gamma Nail (Stryker) or Gamma3 Nail (Stryker) System with lag screws.\textsuperscript{43} Cut-out rates in patients treated with Gamma3 were 4.87\% for stable fractures and 33.3\% for unstable fractures.\textsuperscript{43} These values for Gamma3, a second-generation nail system, were greater than cut-out rates reported for Gamma, a first-generation nail system (p<0.05).\textsuperscript{43} The authors concluded the Gamma3 lag screw design may be the cause of the worse clinical results compared with the Gamma Nail in unstable fractures.\textsuperscript{43}

Cut-out continues to be a major complication for intramedullary hip nailing devices\textsuperscript{11} and may cause severe injuries in hard tissues as well as in soft tissues surrounding the hip joint.\textsuperscript{8}

**Advantages of Helical Blades**

Helical blade devices offer an advantage in fracture repair because they allow for bone compaction around the head element and avoid bone loss that occurs with the drilling and insertion of the standard hip screw. Figure 7 shows an image of the helical blade and screw from the TFNA System. The helical blade is designed to be implanted without pre-drilling, which compresses the surrounding bone\textsuperscript{7,44} resulting in an increase in trabecular bone density in the surrounding area (Figure 8).\textsuperscript{7} This enhances implant anchorage\textsuperscript{45} and provides additional purchase (i.e. grip) in osteoporotic bones,\textsuperscript{7} which may result in a decrease in the risk of cut-out. Additionally, this increase in bone compaction minimizes the potential for rotation of the blade.\textsuperscript{7}

Helical blades have shown a higher potential of rotational stability compared with the screw-based nails.\textsuperscript{8} Furthermore, the helical blade is associated with a statistically significant 2- to 4-fold higher torque resistance reducing rotational forces during insertion compared with a screw system.\textsuperscript{8} Anti-rotation wires are often required with screws to counterbalance these rotational forces.\textsuperscript{44} Use of the blade lessens the need for the anti-rotation wires, which may add to the procedural efficiency of the surgical technique.
The cut-out resistance of the TFNA Helical Blade was compared to the TFNA Screw and the Gamma3 Screw in a biomechanical study conducted by the AO Foundation using a foam model with properties that mimic osteoporotic bone. Head elements were tested for fatigue strength in the foam model based on position of the head element as either center or off-center. These measurements show a range of placement options that may occur during a hip nailing procedure. Center position is the optimal placement of the head element; however, placement may vary from surgeon to surgeon resulting in off-center positioning of the head element.

The mean failure load was calculated for each study group (TFNA Helical Blade, TFNA Screw, and Gamma3) to determine the resistance to cut-out. Results showed failure loads in a similar range for all head elements tested in the center position (range of 1489N to 1613N). For the off-center study group, the TFNA Helical Blade showed statistically significant higher resistance to cut-out compared to the TFNA Screw and Gamma3 Screw (Figure 9). These results show that the TFNA Helical Blade is more forgiving than a screw in terms of positioning and also shows greater resistance to cut-out.

In addition to the AO study evaluating the TFNA System, several biomechanical studies have been published showing the improved cut-out resistance of helical blades compared to lag screws.

- A computational study was published by Goffin and colleagues (2013) evaluating the role of bone compaction with respect to implant cut-out using a CT scan-based finite element model of trochanteric fractures. The effect of bone compaction resulting from the insertion of a proximal femoral nail anti-rotation (PFNA) with a helical blade provided additional bone purchase in an osteoporotic femoral head bone model characterized as 75% of the initial bone density. The authors concluded that the helical blade has the potential to decrease the number of cut-out cases in severely osteoporotic patients.

- A biomechanical study by Sommers and colleagues (2004) simulated implant cut-out in an unstable pertrochanteric fracture model. This model accounted for dynamic loading, osteoporotic bone, and a defined implant offset. Foam models were used to determine differences in cut-out resistance between two lag screws (dynamic hip screw, Gamma3) and two blade-type implant designs (dynamic helical hip system, trochanteric fixation nail). Results showed trochanteric fixation nail implants with a helical blade demonstrated the highest cutout resistance of all implants included in the analysis.

- A biomechanical study published by Lenich and colleagues (2011) compared previously published experimental data of two fixation screws (DHS/Synthes®, Gamma3 nail/Stryker®) and helical blades (TFN/Synthes®, PFNA/Synthes®) and compared them to a theoretical model using loads acting in the hip during daily activities. The helical blades showed greater stability compared to the screws with regards to implant rotation in the de-central position. This study concluded that center positioning of the head element is the optimal position for both helical blades and screws; however, the helical blade provides greater stability in a de-central position compared to screws.
The improved cut-out resistance of helical blades compared to lag screws has also been studied clinically. The following clinical studies report the cut-out rates of helical blades compared to screws:

- Stern and colleagues (2011) published a prospective, randomized clinical trial of 335 pertrochanteric and intertrochanteric fractures and compared cut-out rates of screw vs. helical blade constructs. Results showed cut-out rates were lower in the blade group (1.5%) compared with the screw group (2.9%). All cases of cut-out resulted in reoperation.11

- Lenich and colleagues (2010) published a single-center, case-series examining 322 patients with trochanteric fractures treated with either third generation nails with helical blades or second generation nails with lag screws. Results showed cut-out rates were lower in the cohort treated with helical blades (cut-out rate range of 2.5%-7%) compared with lag screws (14% cut-out rate).48

- A multicenter case-series of 315 fractures published by Simmermacher and colleagues (2008) concluded that nails with a helical blade limit the effects of early rotation of the head/neck-fragment in unstable trochanteric fractures, likely preventing or at least delaying rotation-induced cut-out.49

The TFNA Helical Blade Technology provides the enhanced stability that is critical for reducing the risk of cut-out compared to a lag screw.
The TFNA System offers cement augmentation of the head element. Augmentation provides fixation stability, enhanced cut-out resistance, and reduced cut-through and medial migration, especially in osteoporotic bone.50

Failure of fixation and cut-out are common problems in the treatment of osteoporotic hip fractures.51,52 Low bone mineral density and thin cortices not only are major risk factors for hip fractures but also contribute to the failure of fixation postfracture.51 Achieving stable fixation contributes to early patient mobilization and good fracture healing.52

Augmentation of the weak bone with polymethylmethacrylate (PMMA) or calcium phosphate bone cement may increase the stability of nail osteosynthesis, especially in unstable fractures and osteoporotic bone.9

Augmentation involved injecting the cement at the level of the neck of the femur;53 the process takes approximately 10 to 15 minutes.50 The decision to augment may be made during surgery, allowing for full intra-operative flexibility for the surgeon.

Biomechanical Studies

Several biomechanical studies have been conducted to evaluate the performance of cement augmentation. Sermon and colleagues (2012) conducted a study comparing PFNA blades implanted in paired femurs either with or without cement augmentation.54 Cut-out resistance and rotational stability under cyclic loading were evaluated. Results indicated that:

• Bone mineral density was significantly related to the number of cycles to failure in non-augmented group (P < 0.001), but not in the augmented group (P = 0.91).54

• Augmented samples showed a significantly greater number of cycles to failure (P = 0.012) than non-augmented.54

• In the groups with center position of the PFNA blade, cement augmentation led to an increase in loading cycles of 225%. In the groups with off-center positioning of the blade, this difference was even more substantial (933%) (see Figure 10).54

The authors concluded that augmentation with small amounts of PMMA significantly enhances cut-out resistance in proximal femoral fractures. The procedure may improve patient care, especially in osteoporotic bone.54

FIGURE 10: Cement Augmentation Increases Cut-Out Resistance54

<table>
<thead>
<tr>
<th>Augmented center</th>
<th>Augmented off-center</th>
<th>Non-Augmented center</th>
<th>Non-Augmented off-center</th>
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PFNA = proximal femoral nail antirotation.
In a cadaveric-bone study, Fensky and colleagues (2013) compared augmented with non-augmented PFNA fixation. Cyclic testing was performed with axial loads up to 1,400 N at 10,000 cycles to simulate full postoperative weight bearing. Results showed that stiffness after instrumentation was significantly greater for the cement-augmented group than for the non-augmented group (300.6 ± 46.7 N/mm vs. 250.3 ± 51.6 N/mm; P = 0.001). Results indicated that the cement augmentation of PFNA may increase implant stability, especially in osteoporotic pertrochanteric fractures.

Clinical Studies

Kammerlander and colleagues (2011) reported the results of a prospective, multi-center study to evaluate the technical performance and early clinical results of augmentation of the PFNA blade with PMMA bone cement (mean volume=4.2 mL). A total of 59 patients with osteoporosis were included in the study (mean age=84.5 years); mean follow-up was 4 months. Results showed 55.3% of the patients reached the same or better mobility than before the fracture. No events of cut-out, cut-through, unexpected blade migration, implant loosening, or implant breakage were observed. The overall surgical complication rate was 3.4%; however, no complications were related to the cement augmentation. Results indicated that augmentation of the PFNA blade prevents blade migration within the head-neck fragment, enhances implant anchorage, and leads to good functional outcomes.

Kammerlander and colleagues (2014) reported long-term results (mean follow-up=15.3 months) from an enlarged population of the same patient group from the study published in 2011. In the 62 patients included in the analysis, 59.6% of patients reached their pre-fracture mobility level within the follow-up time frame. The overall surgical complication rate was 3.2%, with no complications related to the cement augmentation. The mean hip joint space did not change significantly at follow-up, and there were no signs of osteonecrosis in the follow-up x-rays. In addition, no blade migration was observed. Augmentation with the PFNA blade leads to good functional results and is not associated with cartilage or bone necrosis. Table 1 presents a side by side comparison of the results from the two analyses of this patient group.

<table>
<thead>
<tr>
<th>TABLE 1: Side-by-Side Comparison of Short-term and Long-term Results of Cement Augmentation of the PFNA</th>
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<tbody>
<tr>
<td><strong>Clinical Outcome</strong></td>
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<tr>
<td>Mean follow-up</td>
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<tr>
<td>Mean volume of cement injected</td>
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<tr>
<td>Percentage of patients reaching their pre-fracture mobility level</td>
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<tr>
<td>Overall surgical complication rate</td>
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<td>Complications related to cement augmentation</td>
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PFNA = proximal femoral nail antirotation.
As with PFNA, the TFNA head elements can be augmented with TRAUMACEM™ V+ bone cement. This cement is applied through the head element around the tip of the implant with syringes and a specific needle kit compatible with the TFNA HELICAL BLADE™ Technology and the TFNA Screw.41,56

The failure load of the TFNA Helical Blade and the screw were evaluated with and without augmentation in a foam bone model that mimics human osteoporotic bone in a study conducted by the AO.10 The analysis included samples with the head elements in the center position as well as the off-center position.10 Figure 11 shows the use of cement augmentation with the helical blade significantly improves the resistance to cut-out in both the center and off-center positions (p<0.001).10

**FIGURE 11: TFNA Helical Blade with Augmentation Shows Greater Resistance to Cut-Out in the Center and Off-Center Position in Osteoporotic Bone**

![Graph showing the comparison between non-augmented and augmented TFNA Helical Blade and Screw in terms of load at failure in N at the center and off-center positions.](image)

Similar findings were observed for the TFNA Screw. The use of augmentation with the screw significantly improves the resistance to cut-out in both the center and off-center positions (p<0.001).10 This study shows augmentation of the TFNA Helical Blade and Screw provides increased cut-out resistance in an osteoporotic bone model.10
IMPLANT STRENGTH

Delayed unions or nonunions are defined as broken bones that take longer than usual to heal or fail to heal, respectively.\textsuperscript{14} Instances of delayed unions or nonunions create excess stress on the nail\textsuperscript{57} and may cause nail failure, which frequently occurs at the proximal hole of the nail. Nail breakage may occur in as many as 5\% of hip fracture patients treated with cephalomedullary nails.\textsuperscript{13} Nail breakage requires revision surgery to replace the broken nail with a total hip arthroplasty, a hemiarthroplasty, or another hip nail.\textsuperscript{58}

Resistance to Nail Breakage: Nail Strength

The TFNA Nail was designed with specific features and materials to increase its fatigue strength while allowing it to have a reduced proximal diameter without compromising strength.

The TFNA System is constructed of T-15Mo (TiMo) titanium alloy. Other commercially available hip nails are made of either Ti-6Al-4v (TAV) ELI alloy [Gamma3 (Stryker) and InterTAN (Smith and Nephew)] or Ti-6Al-7Nb (TAN). TiMo was chosen as the alloy for the TFNA System because of its combination of high strength and fatigue resistance. TiMo is a biocompatible titanium alloy that meets the requirements of ASTM F 2066 testing protocol. When heat treated, the minimum mechanical strength of TiMo is 33\% higher than TAV and 28\% higher than TAN (see Figure 12).\textsuperscript{59,60} Additional testing showed TiMo is not only stronger than TAV and TAN, but also maintains a similar level of flexibility.\textsuperscript{61,62}

The increased strength in combination with the BUMP CUT\textsuperscript{TM} Design of the proximal hole (Figure 13), and other design improvements in the TFNA System, provides improved fatigue strength when compared with existing nails of similar size.\textsuperscript{15}

\textbf{FIGURE 12: TFNA Material Strength\textsuperscript{1}}

\textbf{FIGURE 13: TFNA System BUMP CUT Design}

\begin{figure}[h]
\centering
\includegraphics[width=0.4\textwidth]{figure12.png}
\caption{TFNA Material Strength\textsuperscript{1}}
\end{figure}
The strength of the TFNA System was compared to Gamma3 and InterTAN nails in a biomechanical study. The median fatigue limit for the TFNA Nails was 24% greater than the Gamma3 nail (p<0.05) and 47% greater than the InterTAN nail (p<0.05). These results show the TFNA Nail is stronger than other nail systems with similar proximal diameters (Figure 14).

The increase in fatigue strength of the TFNA system compared to Gamma3 was also observed using finite element analysis (FEA). These results are shown in Figure 15.

**Figure 14: Fatigue Limit is Greater for TFNA Nails than Gamma3 and InterTAN Nails**

**Figure 15: FEA Results: TFNA Nail Shows Greater Fatigue Strength than the Gamma3 Nail**

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**Static Locking**

Most cephalomedullary nails systems provide surgeons the ability to rotationally lock the head element in position allowing for translation of the head element but not rotation; this is commonly referred to as guided collapse. The TFNA System provides surgeons with the option to statically lock the head element thus preventing both rotation and translation. Static locking involves fully tightening the set screw onto the head element so that linear movement of the lag screw is prevented by friction. Post-operative complications, such as excessive fracture collapse from lag screw sliding, and prominent hardware pain, may be prevented with static locking.

Mean slippage load of the statically locked TFNA System was compared to statically locked Gamma3 and InterTAN constructs. The TFNA System showed a 47% improvement in slipp load compared to InterTAN (p<0.001) and 48% improvement compared to Gamma3 (p<0.001). These results are shown in Figure 16. The TFNA System was the only implant system able to complete the dynamic portion of the testing without slippage of the head element.

**Figure 16: Static Locking: Mean Slippage Load of TFNA is Greater than Gamma3 and InterTAN**

*Note: *differences compared to TFNA are statistically significant (p < 0.001)
ECONOMIC VALUE OF THE HELICAL BLADE TECHNOLOGY

Although the overall revision rate for hip fractures is low (6.3%19), revision procedures increase the risk of postoperative complications. The costs of hospitalization for patients who experience a complication after hip fracture surgery are substantially higher than those for patients without complications.35 Reduction in complications and reoperations are direct ways to reduce healthcare costs.

The TFNA System offers Helical Blade Technology to enhance stability and reduce the risk of cut-out. Complications, such as cut-out, cut-through, and medial migration are expensive to treat and frequently require a reoperation.36 Costs of complications and revision surgeries place a substantial economic burden on the hospital and healthcare system.

Quantification of the economic impact of complications and revisions may be assessed using a budget impact analysis. The analysis in Figure 17 shows the potential cost savings for a hospital that switches from using a proximal hip nailing system with a screw to a system with a helical blade. The following input parameters were used:

- Stern and colleagues (2011) reported cut-out rates of 2.9% with a screw and 1.5% with the helical blade.11
- Mean hospital costs of revision were £8,544 (converted to €10,944) as published by Leal and colleagues (2016)23
- Annual volume was estimated at 200 cases per year.

Under these assumptions, the annual economic impact to the hospital of revision surgeries is estimated to be of £49,555 for cephalomedullary nail systems using a screw and £25,632 for systems using a helical blade. Based on this model, a hospital performing 200 hip fracture cases per year may save £23,923 annually by using a helical blade hip nailing system compared to a hip nailing system with a screw. This potential cost reduction is due to the difference in revision rates for helical blades versus screws. These data show how small differences in revision rates have the potential to make a large economic impact to the healthcare system.

ECONOMIC VALUE OF THE TFNA SYSTEM

The TFNA System includes Helical Blade Technology and the option for cement augmentation, both features reduce the risk of costly reoperations due to cut-out.11,50 Reduction in reoperations may result in substantial economic savings to the hospital system.
AUGMENTATION OPTION PROVIDES ADDITIONAL VALUE IN PATIENTS WITH SEVERE OSTEOPOROTIC BONE

Failures due to cut-out mainly occur in patients with severe osteoporotic bone; therefore, the cut-out rates may be even higher than the 2.9% published by Stern et al.\textsuperscript{11} Using cement augmentation with Helical Blade Technology has been shown to enhance implant anchorage and reduce the rate of cut-out in severely osteoporotic patients.\textsuperscript{9,50} Cement augmentation of the blade gives the fixation construct much more stability due to a larger bone-implant interface.\textsuperscript{9} In a clinical study published by Kammerlander and colleagues (2014), no complications or revisions due to cut-out were reported for patients treated with augmentation and Helical Blade Technology (n=62 patients, average follow-up of 15.3 months).\textsuperscript{9} The use of augmentation provides additional value to the hospital when enhanced implant anchorage is needed in patients with severe osteoporotic bone (Figure 18).

FIGURE 18: Potential for Additional Value to the Hospital by Reducing Costs of Reoperation Due to Reduced Rates of Cut-Out with Augmentation

This economic value analysis only focused on one post-operative complication, cut-out. The economic impact to the hospital may be even greater when the reductions in other post-operative complications are factored into the analysis. Reducing the risk of complications and revisions may result in opportunities for additional cost savings and reductions in the overall economic burden to the healthcare system.

Budget Impact Calculations: hospital cost = annual volume x hospital cost of reoperation x reoperation rate

\[ \text{hospital cost} = \text{annual volume} \times \text{hospital cost of reoperation} \times \text{reoperation rate} \]
The TFNA System is optimized for hospital standardization, designed for procedural efficiency, and offers a wide array of options to address surgeon preference when treating a full range of fracture types.

FACILITATING STANDARDIZATION AND OPERATING ROOM EFFICIENCY

Hospitals that choose to use the TFNA System may realize indirect cost-savings opportunities from the standardization of surgeon preference items and improving operating room efficiency. These indirect cost savings combined with direct cost savings from potential reduction in complications and revisions contribute to the overall value of the TFNA System to the hospital.

Facilitating Standardization

Standardization of physician preference items is one method for enhancing a hospital’s supply chain and driving profitability. In addition to cost reduction, standardizing implants can improve efficiency and quality of care.

Aligning surgeons with hospital cost-reduction initiatives, such as standardization of physician preference items, is an important step in reducing clinical supply spending and creating opportunities for cost savings. However, surgeons often develop a strong preference for a specific device or manufacturer creating a challenge for the hospital to incentivize alignment with standardization strategies that require surgeons to change devices.

A survey of 77 surgeons included three questions related to their clinical experience with the TFNA System:

- 86% of surgeons stated they “Strongly Agreed/Agreed” they “would recommend this new proximal femoral nailing system”.
- 74% of surgeons “Strongly Agreed/Agreed” they “felt the new system improved the overall procedural efficiency compared to previously used Nailing systems”.
- 77% of surgeons “Strongly Agreed/Agreed” that “the new instrumentation is easier than what I used previously”.

These survey results indicate a high level of surgeon satisfaction with the TFNA System. The strong willingness to recommend the TFNA System is a good indicator of potential surgeon alignment in support of hospital standardization strategies.

Procedural Efficiency in the Operating Room

Orthopedic instruments should be intuitive to use allowing the surgeon and operating room (OR) team to focus completely on the patient and the procedure. The instruments used with the TFNA System introduce features, such as QUICK CLICK™ Self-Retaining Technology and radiolucent insertion handles with radiographic indicators. These instruments were designed to streamline the procedure in the OR, potentially reduce OR time, and minimize pain points within the surgical procedure for surgeons and OR staff.
QUICK CLICK Self-Retaining Technology (Figure 19) was designed to ensure a fast and effective link between the insertion handle and intramedullary nail, potentially improving surgical efficiency and reducing OR time. A mishandled instrument or implant may result in the need for immediate-use steam sterilization or traditional steam sterilization, respectively. Unexpected sterilization may delay the surgical procedure as much as 30 min.70 Re-sterilizations and longer surgical times lead to a greater risk of infection and blood loss for the patient.70,71 For hospitals, longer procedure times and re-sterilizations result in increased costs in addition to the risk of infection and readmissions.

Radiolucent insertion handles with radiographic indicators allow x-ray visualization and assist with guide wire placement (Figure 20). Placement of the guide wire in the femoral head is a critical step in a hip-nailing procedure. Guide wire position dictates final placement of the femoral head element. Studies have shown that proper positioning is correlated with clinical success of the implant.11

**Flexibility of the TFNA System**

The TFNA System offers the surgeon a wide portfolio of intramedullary nailing options for the proximal femur. The flexibility of the TFNA System allows the surgeon to optimize the procedure based on patient need and surgeon preference. For the hospital, the TFNA System offers a single hip nail system providing surgeons with the choices they need to treat a wide variety of fracture types while promoting hospital standardization strategies.

**SUMMARY**

The TFNA System was designed to solve a wide range of unmet needs for surgeons, OR staff, and hospital administrators. This system offers advancement in hip fracture treatment, including outcome-based design, reduced procedural complexity, and comprehensive surgical options. The TFNA System was developed to deliver clinical and economic value to patients, surgeons, and hospitals through improved outcomes and cost savings opportunities.
PRODUCT DESCRIPTION

The DePuy Synthes Trauma TFN-ADVANCED Proximal Femoral Nailing System is a cephalomedullary proximal femoral nailing system (Figure 21) designed to match patient femoral anatomy, to help improve patient outcomes, and address a wide variety of patient needs. Specifically, the TFNA Nail includes:

- A radius of curvature of 1.0 m
- LATERAL RELIEF CUT Design
- BUMP CUT Design
- Helical Blade Technology
- Cannulated head elements to allow for augmentation with PMMA bone cement

To suit a wide variety of clinical needs and surgeon preferences, the system includes an array of options, including both short and long nails and the option for augmentation. Further, it is the only system to offer both helical blade and screw options using one nail. In addition, the long nail provides three distal locking options, including a unique oblique distal hole offset 10°, designed to better target bone in condyles.

The TFNA System also offers a preassembled locking mechanism in the nail with the ability to both rotationally and statically lock the helical blade or screw. All nails in The TFNA System are made from a high-strength titanium alloy (TiMo alloy), and the instrumentation is designed for procedural efficiency and improved x-ray visualization.

FIGURE 21: TFN-ADVANCED Proximal Femoral Nailing System, Showing Both Blade and Screw Options

1Based on biomechanical bench testing. May not be indicative of clinical performance.

For a complete list of indications for use, warnings, and precautions, please see the package insert or surgical technique.
DEPUY SYNTHES TRAUMA: FOCUSED ON PATIENTS AND HOSPITALS

Trusted Quality and Innovation

• A century of breakthroughs that create value

Delivering Solutions That Help Improve Clinical Outcomes

• Industry leader in trauma
• Provide a broad, high-quality product portfolio that addresses all your trauma needs

Advanced Technical Support and Training

• Highly-trained, trauma-focused team
• Commitment to education and training
• Industry-leading, customisable education and training programs for entire OR staff
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