Executive Summary

Unmet need:

**Distal cortical impingement** may occur in up to 25% of hip fracture repair 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 a major cause of implant failure in the fixation of proximal femur fracture, and may cause severe injuries in hard and soft tissues surrounding the hip joint. 6,7
Cut-out rates for cephalomedullary nails have been reported as high as 8%, and frequently require reoperation. 6

**Nail breakage** may occur in as many as 5% of hip fracture patients treated with cephalomedullary nails and requires revision surgery. 6,10
Nail breakage is often a result of fractures that take longer to heal or fail to heal (delayed union or nonunion, respectively). 11
The TFN-ADVANCED® Proximal Femoral Nailing System (TFNA) solution:

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, 3D computational study showed the TFNA Nail (1.0 m ROC) resulted in a better fit than Gamma3 (1.5 m ROC).\(^{12}\)

- The mean total surface area of the nail protrusion was 29% less for TFNA Nail than Gamma3 (915.8 vs. 118.6mm, \(^2\) p< 0.05).\(^{12}\)
- The distal nail tip was positioned close to the anterior cortex for 30 Gamma3 samples compared to 16 TFNA Nail samples (difference of 53%).\(^{12}\)

**TFNA Helical Blade technology** was designed to compress bone during insertion, which enhances implant anchorage and may reduce the risk of cut-out.\(^{19}\) Resistance to cut-out in osteoporotic bone is further improved by **augmentation** of the Head Element.\(^{16,17}\) The decision to use augmentation to increase the stability in unstable fractures and osteoporotic bone\(^{58}\) is made intra-operatively; thereby giving surgeons multiple options for treating their patients.\(^{58}\)

- 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 showed the TFNA Helical Blade was more forgiving compared to screws in regards to head element positioning.\(^{15}\)
- Biomechanical tests designed to evaluate cut-out resistance showed, whether the head element is in the center or off-center position, augmented head elements withstood high loads prior to failure.\(^{14}\) Additionally, augmented constructs resisted varus collapse for more cycles than non-augmented constructs.\(^{14}\)
- A clinical study showed lower cut-out rates in the cohort treated with a helical blade (1.5%) compared to a screw (2.9%).\(^{13}\) Early results from clinical studies of PFNA (a predicate of the TFNA System) with augmentation showed cut-out rates of 0%.\(^{16,17}\)

Cut-out rates in the chart below were reported in three published clinical studies: Stern et al. 2011 (n=335 patients), Kammerlander et al. 2011 (n=59 patients), and Kammerlander et al. 2014 (n=62 patients).\(^{13,16,17}\)

<table>
<thead>
<tr>
<th>Implant</th>
<th>Screw</th>
<th>Helical Blade</th>
<th>PFNA Head Element with augmentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut-out rate</td>
<td>2.9%</td>
<td>1.5%</td>
<td>0%</td>
</tr>
</tbody>
</table>

The TFNA System was shown to be **47% stronger** than InterTAN\(^{18}\)

The TFNA System was made out of a **unique titanium alloy** (TiMo alloy) that allows the proximal diameter of the nail to be reduced, while maintaining a high level of fatigue strength. This material, combined with the BUMP CUT\(\text{TM}\) Design of the proximal hole, provides improved fatigue strength compared with existing nails of similar size.\(^{18}\) Results of biomechanical testing showed greater fatigue strength for the TFNA System compared to Gamma3 and InterTAN nails (difference of 24% and 47%, respectively; p< 0.05).\(^{18}\)

*Benchtop test results may not be indicative of clinical performance.*
ECONOMIC VALUE

Economic Challenge: High Cost of Reoperation

Reduction in reoperations due to cut-out may reduce costs to the hospital and the healthcare system. A sample budget impact analysis was developed to show the potential economic impact to a hospital. The analysis evaluated the use of a proximal nail system with a screw compared to a blade, and both head elements compared to augmentation using data points from published studies. Results demonstrated that a hospital with an annual procedural volume of 200 cases per year may recognize savings of up to $270,147 when comparing augmented to non-augmented constructs through the reduction in reoperations due to cut-out.

Procedural Efficiency in the Operating Room

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 (n=57 out of 77) "Strongly Agreed" or "Agreed" that "I felt the new system improved the overall procedural efficiency compared to previously used nailing systems".
- 77% of surgeons (n=59 out of 77) "Strongly Agreed" or "Agreed" that "The new instrument is easier than what I used previously".

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 cost savings.

- 86% of early surgeon users (n=77) of the TFNA System stated they "Strongly Agreed" or "Agreed" that they would "Recommend this new proximal femoral nailing system".
- The flexibility of the TFNA System allows the surgeon to customize 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.

Budget Impact Analysis – Annual Costs of Reoperation May Be Less for Augmented Constructs Compared to Non-Augmented Based on Differences in Cut-Out

Budget impact analysis assumptions: Cost of reoperation was $46,577; Reoperation rates due to cut-out were 2.9% for the screw, 1.5% for the blade, and 0% with augmentation; Procedure volume of 200 hip fracture cases per year.

<table>
<thead>
<tr>
<th>Healthcare Costs (USD/200 Patients/Year)</th>
<th>Screw</th>
<th>Helical Blade</th>
<th>With Augmentation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$130,416 difference</td>
<td>$139,731 vs. Blade</td>
<td>$270,147 vs. Screw</td>
</tr>
</tbody>
</table>

Budget Impact Analysis – Annual Costs of Reoperation May Be Less for Augmented Constructs Compared to Non-Augmented Based on Differences in Cut-Out

$300,000 | $250,000 | $200,000 | $150,000 | $100,000 | $50,000 | 0
Hip fractures are common in the elderly, and the incidence is expected to rise as the population ages. Costs of managing hip fractures in the elderly were nearly $20 billion in 2010. Reducing the reoperation rate, estimated at 6.3%, provides an opportunity for hospitals to reduce costs.

**HIP FRACTURES**

A hip fracture is a femoral fracture that occurs in the proximal end of the femur (thigh bone), near the hip. The term “hip fracture” is commonly used to refer to the fracture patterns 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 risk to these patients.
Epidemiology

Each year, approximately 300,000 hip fractures occur in the United States (U.S.). Hip fracture rates increase exponentially with age, with almost 90% of hip fractures occurring in people aged 65 years and older. As the U.S. population ages, the incidence of hip fracture is expected to increase substantially. It is estimated that by 2040, the annual incidence of hip fractures will exceed 500,000 in the U.S. These continuing trends will place a financial burden on patients, families, insurers, and governments.

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

• 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%.

• In young patients, intertrochanteric fractures are typically associated with high-energy trauma events, such as motor vehicle, bicycle, and skiing accidents.

Economic Burden

The economic burden of managing hip fractures in elderly individuals in the U.S. was estimated at $17-20 billion in 2010. A typical U.S. 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. In the U.S., hip fractures are responsible for approximately 3.5 million hospital days per year, which is more than tibial, vertebral, and pelvic fractures combined.

Clinical Burden

Hip fractures result in pain, loss of mobility, and high rates of mortality. Nearly all patients are hospitalized and most undergo surgical repair of the fracture 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 hip fracture. 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.

The reoperation rate of cephalomedullary hip nailing has been estimated at approximately 6.3%. The most common complications resulting in revision include distal cortex penetration (≤ 3% revision rate), proximal cut-out or lateral extrusion (≤ 8% revision rate), implant breakage (≤ 5% revision rate) or severe thigh pain. Reoperations increase the risk to the patient and are costly to the healthcare system. Revision surgery is associated with a 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.
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 literature review of Ovid Medline, Ovid Embase, and PubMed for clinical and economic studies published from 2003-2017.

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 are referenced as “Data on File”.

Published results included studies reporting outcomes for proximal hip nails 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 Antitrotation (PFNA) Systems.*

• The LATERAL RELIEF CUT™ is comparable to the lateral relief cut of the Proximal Femoral Nail Antitrotation-II (PFNA-II) System.*

• The augmentation option available with the TFNA System is analogous to the cement augmentation option available with the PFNA System.

* PFNA and PFNA II do not have 510(k) clearance and are not available for sale in the US.
Penetration of the anterior cortex of the distal femur is a complication associated with treating proximal femoral fractures with intramedullary devices. 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." 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). Published clinical studies have reported rates of distal cortical impingement of up to 49.6%, and this complication may lead to a fracture at the distal nail tip in the early post-operative period. This fracture event, called anterior cortex perforation, occurs in up to 3% of cases and requires revision surgery.

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). 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.

Prior to the launch of the TFNA System, the ROCs for commercially available cephalomedullary nails ranged from 1.3 m to 3.0 m, and clinical experiences from recent studies have shown that these ROCs may lead to complications resulting from nail-canal mismatch. 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. This study reported rates of distal cortical impingement of 12% with a 2.0 m ROC nail (InterTAN Nail System with 2.0m AP bow, Smith and Nephew) but only 3% with a 1.5 m ROC nail (InterTAN Nail System with 1.5m AP bow, Smith and Nephew). A nail resting against the anterior femur also may be associated with thigh or knee pain. Therefore, continuing to decrease the nail ROC to more closely match anatomical measurements may further improve treatment outcomes.

**FIGURE 2:** Curvature of the TFNA Hip Nail System (1.0 m ROC) and nail with 1.5 m ROC

**ROC = Radius Of Curvature**

Note: The gold nail represents the TFNA Nail with 1.0 m ROC. The blue nail represents a nail with 1.5 m ROC.
The TFNA Nail was designed with a ROC of 1.0 m to more closely match the femoral anatomy compared to hip nails with larger ROCs (i.e., straighter nails). The TFNA Nail was evaluated in a 3D computer modeling study that quantified whether the 1.0 m ROC provides a better anatomical fit compared with existing nail with a bow design (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 3D computer modeling showed:

- TFNA Nail had a significantly smaller mean total surface area of nail protrusion than the Gamma3 nail (915.8 vs. 1181.6 mm²; p < 0.05).
- Mean maximum distance of nail protrusion in the axial plane was significantly less for the TFNA Nail than the Gamma3 nail (1.9 vs. 2.1 mm; p = 0.007).
- 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).

The distal nail tip position was also evaluated. The distal nail tip was positioned close to the anterior cortex for 30 Gamma3 samples compared to 16 TFNA Nail samples, a difference of 53% (Figure 3). Additionally, the TFNA Nail had a considerably higher number of center positions than the Gamma3 nail (n=13 vs. 7).

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

![Figure 3: Distal Nail Tip Position for TFNA System Compared to Gamma3](image)
The study also showed that an average Caucasian sample with a ROC of 1.015 m resulted in a slightly smaller mismatch in the sub-trochanteric region for the TFNA Nail compared with the Gamma3 Nail (Figure 4). Distally, the TFNA Nail achieved a center position while the Gamma3 nail showed an anterior position. The results 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.

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 nail fit. The small proximal diameter and the LATERAL RELIEF CUT Design of the TFNA Nail (Figure 5) were designed to 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 Helical Blade and Screw was designed to reduce lateral protrusion on the soft tissues when compared with that of a standard cut head element.

**FIGURE 4:** Distal Nail Tip Position of the TFNA Nail is Positioned Less Anteriorly than the Gamma3 Nail in a Caucasian Model with ROC 1.015 mm

**FIGURE 5:** TFNA System: Designed with a Small Proximal Diameter, Oblique cut, and LATERAL RELIEF CUT Design
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. The use of augmentation is an option for providing additional cut-out resistance, when needed, in patients with poor bone quality. Cut-out is a major cause of implant failure in dynamic hip screws, accounting for more than 80% of failures.50,78

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 extrusion, or cutting-out, of the screw or blade element from the femoral head (Figure 6). Revision surgery is frequently necessary when cut-out occurs.16

Cut-out is the major cause of implant failure in the fixation of proximal femur fractures, accounting for more than 80% of failures in cases using dynamic hip screws.60,78 Cut-out rates for cephalomedullary nail devices were reported at 3.2% in a Cochrane review of the literature,39 and have also been reported as high as 8%.6 Cut-out continues to be a major complication for intramedullary hip nailing devices13 and may cause severe injuries in hard tissues as well as in soft tissues surrounding the hip joint.7 The TFNA System has incorporated two features that were designed to reduce the risk of cut-out: the helical blade and augmentation.

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 the bone loss that occurs with the drilling and insertion of the standard hip screw. Figure 7 shows the TFNA Helical Blade and Screw. The helical blade is designed to be implanted without pre-drilling, which displaces the bone in the voids of the surrounding cancellous bone material (Figure 8). The bone compression that results from inserting a helical blade50 increases trabecular bone density in the surrounding area.60 This enhances implant anchorage and provides additional purchase (i.e., a firm grip) in osteoporotic bones, which may result in a decreased risk of cut-out.50 Additionally, this increase in bone compaction may minimize the potential for rotation of the blade.

Helical blades have shown a higher potential for rotational stability compared with screw-based nails.7 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.7 Anti-rotation wires are often required with screws to counterbalance these forces.51 Use of the blade lessens the need for anti-rotation wires, which may add to the procedural efficiency of the surgical technique.
The resistance to cut-out of the TFNA Helical Blade was compared to the TFNA Screw and the Gamma3 Screw in a biomechanical study using a foam model with properties that mimic osteoporotic bone. Head elements were tested for fatigue strength in the foam model based on the position of the head element (either center or anterior off-center). These measurements showed the range of placement options that may occur during a hip nailing procedure. Center position is the optimal placement of the head element, however, actual 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 included in the analysis for the center position (range of 1489N to 1613N). For the off-center study group, the TFNA Helical Blade is more forgiving than the TFNA Screw and Gamma3 Screw in terms of positioning and also shows greater resistance to cut-out.

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

- 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%). All cases of cut-out resulted in reoperation.
- A multicenter, case-series of 315 fractures concluded that nails with a helical blade limit the effects of early rotation of the head/neck fragment in unstable trochanteric fractures; likely preventing rotation-induced cut-out.
- In a single-center, case-series study of 322 patients with proximal femur fractures, cut-out rates were lower with third-generation nails with helical blades (cut-out rate 2.5%-7.0%) than with second-generation nails with lag screws (14% cut-out rate).

Mingo-Robinet and colleagues (2015) evaluated the relationship between the type of intramedullary device and the presence of cut-out complications. The Trochanteric Gamma Nail (Stryker) and Gamma3 Nail (Stryker), both using lag screws, were included in the analysis of 218 fractures. Results show cut-out rates of up to 3.9% in patients with undisplaced fractures treated with Gamma Nail and up to 33.3% in patients treated with Gamma3. The authors noted that unstable fracture was one of the most important risk factors for fixation failure.

The TFNA Helical Blade Technology provides the enhanced stability that is critical for reducing the risk of cut-out compared to a lag screw.

**FIGURE 8:** TFNA Helical Blade technology: Designed to Compress Bone During Insertion

**FIGURE 9:** Cut-Out Resistance in vitro Modeling

Note: Cross-sections of bone illustrating TFNA Helical Blade (left) and TFNA Screw (right)
Advantages of Augmentation

Failure of fixation and cut-out are common problems in the treatment of osteoporotic hip fractures.\textsuperscript{57,58} 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.\textsuperscript{57} Achieving stable fixation contributes to early patient mobilization and good fracture healing.\textsuperscript{58}

Augmentation of poor quality bone with polymethylmethacrylate (PMMA) or calcium phosphate bone cement may increase the stability of nail osteosynthesis, especially in osteoporotic bone.\textsuperscript{17} Augmentation involves injecting the cement into the femoral head; the process takes approximately 10 to 15 minutes.\textsuperscript{16} The decision to augment may be made during surgery, allowing for full intra-operative flexibility for the surgeon.

TFNA Helical Blades and Screws may be augmented with TRAUMACEM\textsuperscript{TM} V+ Injectable Bone Cement. This cement is inserted through the head element with a syringe and a specific needle kit compatible with the TFNA Helical Blades and Screws (Figure 10).\textsuperscript{61} The cannulation of the implant, and additional fenestrations in the TFNA Helical Blades and Screws, enable the controlled injection of cement into the surrounding bone tissue after implant insertion.

FIGURE 10: TFNA Helical Blade with Augmentation

Source: DePuy Synthes Trauma.
Biomechanical Studies

Biomechanical studies have been conducted to evaluate the performance of the TFNA System with augmentation. The failure load (which is the maximum amount of force that can be applied to the nail construct in a biomechanical simulation, after which the cut-out event occurs) of the TFNA Head Element was evaluated for constructs with and without augmentation. The study included samples with the head elements in the center position as well as the off-center position. While center position is the optimal placement of the head element, placement may vary from surgeon to surgeon resulting in off-center positioning. This study used an artificial bone material that mimics human osteoporotic bone in the femoral head. Results demonstrated a significant (p= 0.000) increase in failure load (simulated decrease in cut-out) when the TFNA Head Element is augmented. The increased failure load exceeded 131% compared with non-augmented constructs in the center position. The greatest improvement in failure load (simulated cut-out event) was observed for the TFNA Construct in the off-center position, which improved by 244%. Furthermore, augmented constructs resisted varus collapse for more cycles than non-augmented constructs both in the center (+271%) and off-center (+346%) positions. This study demonstrated that augmentation of the TFNA Helical Blade and Screw allowed the constructs to withstand higher loads for more cycles, which may correlate with increased cut-out resistance in osteoporotic bone.

FIGURE 11A: Augmented Head Elements Withstood Higher Loads Prior to Failure

FIGURE 11B: Augmented Constructs Resisted Varus Collapse for More Cycles Than Non-Augmented Constructs

*Benchtot test results may not be indicative of clinical performance.*
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. These early clinical results show augmentation of the PFNA blade resulted in no cut-out, cut through, unexpected blade migration, implant loosening or implant breakage, and led to good functional results within the study period.

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 unexpected blade migration was observed. Augmentation with the PFNA blade led to good functional results and was 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 1: Side-by-Side Comparison of Short-Term and Long-Term Results of Cement Augmentation of the PFNA

<table>
<thead>
<tr>
<th>Clinical Outcome</th>
<th>Kammerlander et al., 2011 (N = 59)</th>
<th>Kammerlander et al., 2014 (N = 62)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean follow-up</td>
<td>4 months</td>
<td>15.3 months</td>
</tr>
<tr>
<td>Mean volume of cement injected</td>
<td>4.2 mL</td>
<td>3.8 mL</td>
</tr>
<tr>
<td>Percentage of patients reaching their pre-fracture mobility level</td>
<td>55.3%</td>
<td>59.6%</td>
</tr>
<tr>
<td>Overall surgical complication rate</td>
<td>3.4%</td>
<td>3.2%</td>
</tr>
<tr>
<td>Complications related to cement augmentation</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Cut-out rate</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>
IMPLANT STRENGTH

Delayed unions or nonunions are defined as broken bones that take longer than usual to heal or fail to heal, respectively.\(^1\) Instances of delayed unions or nonunions create excess stress on the nail.\(^2\) Excess stress can 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.\(^3\) Nail breakage requires revision surgery to replace the broken nail with a total hip arthroplasty, a hemiarthroplasty, or another hip nail.\(^4\)

Resistance to Nail Breakage: Nail Strength

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

The TFNA System is constructed of T-15Mo (TiMo) titanium alloy. Gamma3 (Stryker) and InterTAN (Smith and Nephew) are both made of Ti-6Al-4v (TAV) ELI alloy while other commercially available hip nails are made of 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 Ti15Mo is 33% higher than TAV and 28% higher than TAN (see Figure 12).\(^5\) Additional testing showed that Ti-15Mo is not only stronger, but it is also as flexible as TAV and TAN.\(^6\)

The increased strength in combination with the BUMP CUT™ Design of the proximal hole (Figure 13), and other design improvements in the TFNA System provides improved fatigue strength in benchtop testing when compared with existing nails of similar size.\(^7\)

**FIGURE 12: TFNA System Material Strength**

**FIGURE 13: TFNA System BUMP CUT Design**

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*Benchtop test results may not be indicative of clinical performance.*
Physical fatigue load testing was conducted to compare the strength of the TFNA System to Gamma3 (Stryker) and InterTAN (Smith and Nephew). 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) (Figure 14), differences that were statistically significant. These results showed the increased strength of the TFNA Nail compared to other nail systems with similar proximal diameters (Figure 14).

An 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 Was Greater for TFNA Nails than Gamma3 and InterTAN Nails

FIGURE 15: TFNA Nail Showed Greater Fatigue Strength than the Gamma3 Nail

* Differences compared to the TFNA System were statistically significant (p< 0.05)

Benchtop test results may not be indicative of clinical performance.
Static Locking

Most cephalomedullary nail systems provide surgeons the ability to rotationally lock the head element in position allowing for translation of the head element but not rotation, which 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 head element is prevented by friction. Post-operative complications, such as excessive fracture collapse from head element sliding and prominent hardware pain, may be prevented with static locking.

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

**FIGURE 16: Static Locking: Mean Slippage Load of the TFNA System Was Greater than Gamma3 and InterTAN**

* Differences compared to the TFNA System were statistically significant (p< 0.001)

* Benchtop test results may not be indicative of clinical performance.
The TFNA System includes Helical Blade Technology and the option for cement augmentation; and both features may reduce the risk of cut-out. Reduction in cut-out and subsequent reduction in reoperations may result in substantial economic savings to the hospital system.

HIP FRACTURES: HOSPITAL INPATIENT STATISTICS

Table 2 shows 2014 Centers for Medicare and Medicaid Services national statistics for Medicare Severity Diagnosis-Related Groups (MS-DRGs) related to treating hip fractures with cephalomedullary nails. Both primary hip nailing procedures and revisions fall under MS-DRGs 480, 481, or 482, depending on severity of complications and comorbidities.

TABLE 2: National Statistics from the Centers for Medicare and Medicaid Services (CMS)

<table>
<thead>
<tr>
<th>MS-DRG</th>
<th>Total Number of Discharges per DRG</th>
<th>% of Patients on Medicare</th>
<th>Length of Stay (Mean)</th>
<th>Hospital Charges (Mean)</th>
<th>Hospital Costs (Mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>480 Hip &amp; femur procedures except major joint w/ mcc</td>
<td>44,805</td>
<td>78.4%</td>
<td>8.1</td>
<td>$88,715</td>
<td>$23,324</td>
</tr>
<tr>
<td>481 Hip &amp; femur procedures except major joint w/ cc</td>
<td>139,140</td>
<td>77.8%</td>
<td>5.1</td>
<td>$59,481</td>
<td>$15,877</td>
</tr>
<tr>
<td>482 Hip &amp; femur procedures except major joint w/o cc/mcc</td>
<td>66,785</td>
<td>52.5%</td>
<td>3.7</td>
<td>$48,924</td>
<td>$13,191</td>
</tr>
<tr>
<td><strong>Weighted Average</strong></td>
<td></td>
<td></td>
<td>5.3</td>
<td><strong>$61,893</strong></td>
<td><strong>$16,492</strong></td>
</tr>
</tbody>
</table>

cc = complications and comorbidities; mcc = major complications and comorbidities; w/ = with; w/o = without

Note: DRGs 480/481/482 include treatment of hip fractures with intramedullary devices and plates. Total hip arthroplasty and hemi-arthroplasty procedures are covered under separate DRG categories. Hospital costs and charges for inpatient procedures are publicly available from CMS as reported in the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS).
The TFNA System was designed to reduce costly reoperations resulting from cut-out. To understand the full economic impact of a reoperation, the healthcare costs of hip fracture reoperations were evaluated for both the acute-care setting as well as during the 90-day post-operative period, as many post-operative services are part of the hospital network. A retrospective claims database analysis was published by Lerner and colleagues (2016) to determine the cost of reoperation associated with cephalomedullary fixation in patients aged 65+. Direct medical resource utilization (claims payments) across multiple settings of care were explored for the 90-day period after index hospitalization. Costs of hospitalization as a result of reoperation were reported as being $14,785 (referred to as “Index Hospitalization” in Table 3) and total cost of reoperation, inclusive of the 90-day post-operative period, were demonstrated to be $46,577 (Table 3). Table 3 also reports days of service for each post-acute care setting. The average hospital length of stay for these patients was 5.3 days. The highest cost for post-acute care service was time spent in a skilled nursing facility. Patients stayed in this setting of care for an average of 37 days for a cost of $12,002. Costs associated with the physician, inpatient rehabilitation, home health care, and additional inpatient readmissions were also substantial.

### TABLE 3: Total 90-Day Costs of Reoperation Associated with Cephalomedullary Fixation in Patients Aged 65+

<table>
<thead>
<tr>
<th>Setting of Care</th>
<th>Days of Service</th>
<th>Payment Amounts (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Index hospitalization</td>
<td>5.3</td>
<td>2.8</td>
</tr>
<tr>
<td>Physician</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Durable Medical Equipment</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Home Health Agency</td>
<td>15.6</td>
<td>25.0</td>
</tr>
<tr>
<td>Skilled Nursing Facility</td>
<td>37.0</td>
<td>28.7</td>
</tr>
<tr>
<td>Inpatient Rehab Facility</td>
<td>2.2</td>
<td>7.2</td>
</tr>
<tr>
<td>Other inpatient admissions</td>
<td>3.1</td>
<td>5.8</td>
</tr>
<tr>
<td>Hospice</td>
<td>3.5</td>
<td>15.6</td>
</tr>
<tr>
<td>Total</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

USD = US Dollars; SD = Standard Deviation

The cost of reoperation shown in Table 3 is the average cost per episode. For a hospital treating multiple hip fracture patients per year, the economic impact of treating reoperations may become quite significant. Technologies designed to reduce costly reoperations, such as the TFNA System, should be considered in support of Institute for Healthcare Improvement (IHI) Triple Aim strategies.
ECONOMIC VALUE OF THE TFNA SYSTEM

Reduction in reoperations due to cut-out or other complications may reduce the overall economic burden of treating hip fractures and are direct ways to reduce costs to the hospital as well as to the health care system. Complications following hip fracture, such as infection, implant removal, fracture, and fixation failure are costly.37

Quantification of the economic impact of complications and revisions may be assessed using a sample budget impact analysis with input parameters based on published data sources and annual volume assumptions. The sample analysis below shows the potential economic impact to a hospital using a proximal hip nailing system with a helical blade compared to a screw. The following input parameters were used and included cut-out rates reported in three published clinical studies: Stern et al. 2011 (evaluating screw vs. blade; 335 patients), Kammerlander et al. 2011 (evaluating PFNA with augmentation; 59 patients), and Kammerlander et al. 2014 (evaluating PFNA with augmentation; 62 patients):

<table>
<thead>
<tr>
<th></th>
<th>Lag Screw</th>
<th>Helical Blade</th>
<th>Augmented Construct</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reoperation Rates Due to Cut-Out</td>
<td>2.9%13</td>
<td>1.5%13</td>
<td>0%16,17</td>
</tr>
<tr>
<td>Mean 90-Day Direct Costs of Reoperation</td>
<td>$46,577</td>
<td>$46,577</td>
<td>$46,577</td>
</tr>
<tr>
<td>Annual Hospital Volume*</td>
<td>200</td>
<td>200</td>
<td>200</td>
</tr>
</tbody>
</table>

*Hospital volume assumption is representative of a mid-volume hospital.

Under these assumptions, the potential annual economic impact of reoperations due to cut-out is shown in Figure 17:

- $270,147 for a hospital using the TFNA System with augmentation compared to using the TFNA Screw without augmentation.
- $139,731 for a hospital using the TFNA System with augmentation compared to using the TFNA Helical Blade without augmentation.
- $130,416 for a hospital using the TFNA Helical Blade compared to the TFNA Screw, both without augmentation.

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

FIGURE 17: Annual Hospital Costs of Reoperation May Be Less for Augmented Constructs Compared to Non-Augmented Based on Differences in Cut-Out Rate

Note: Sample Calculation = volume x cost of reoperation x reoperation rate due to cut-out:
TFNA Screw: 200 cases x $46,577 x 2.9% = $270,146.60
TFNA Helical Blade: 200 x $46,577 x 1.5% = $139,731
FACILITATING OPERATING ROOM EFFICIENCY AND HOSPITAL STANDARDIZATION

In addition to reduction in reoperation, further opportunities for cost offsets with the TFNA System include the standardization of surgeon preference items and improved operating room efficiency.

Procedural Efficiency in the Operating Room

Orthopedic instruments should be intuitive to use to allow the surgeon and operating room (OR) team to focus completely on the patient and the procedure. The instruments used with the TFNA System introduce design features, such as QUICK CLICK Self-Retaining Technology and radiolucent insertion handles with radiographic indicators that were 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.

QUICK CLICK Self-Retaining Technology (Figure 18) is 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 minutes. Re-sterilizations and longer surgical times lead to a greater risk of infection and blood loss for the patient. 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 19). 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.

FIGURE 18: TFNA System QUICK CLICK Technology Instrumentation

FIGURE 19: TFNA System Radiolucent Insertion Handle
Facilitating Standardization

The standardization of physician preference items is one way to enhance a hospital’s supply chain and drive profitability. Two recent case studies examining the standardization of orthopedic physician preference items show an 8% savings in a single Florida hospital ($400,000) and 32% savings in a Midwest 3-hospital system ($1.9M). In addition to cost reduction, standardizing implants may 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 substantial 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.

In a survey of 77 early users of the TFNA System, the surgeons were asked three questions related to their clinical experience with the product:

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

These 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.

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 customize 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, hospital administrators, and patients. 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.
The DePuy Synthes Trauma TFNA System is a cephalomedullary proximal femoral nailing system (Figure 20) designed to match patient femoral anatomy, help improve patient outcomes, and address a wide variety of patient needs. Specifically, the TFNA System includes:

- A radius of curvature of 1.0 m
- LATERAL RELIEF CUT Design
- BUMP CUT Design
- Helical Blade Technology
- Fenestrated head elements to allow for use with TRAUMACEM V+ Augmentation System

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 and the intra-operative option of augmentation. In addition, the long nail provides three distal locking options, including a unique oblique distal hole offset 10°, designed to better target bone 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 (Ti-Mo Alloy), and the instrumentation is designed for procedural efficiency and improved x-ray visualization.

For a complete list of indications for use, warnings, and precautions, please see the package insert or surgical technique.
REFERENCES


REFERENCES


Please refer to the package insert for a complete list of indications, contraindications, precautions and warnings.

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