Value Analysis Brief

# TFN-ADVANCED®

## PROXIMAL FEMORAL NAILING SYSTEM

## Featuring TRAUMACEM™ V+ Augmentation System

DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

# Executive Summary

## CLINICAL VALUE

### Unmet Need

Cut-out is a major post-operative complication of intramedullary hip nailing.[1] It may also cause severe injuries to both the hard and soft tissues surrounding the hip joint.[2]

Cut-out rates for cephalomedullary nails have been reported as high as 8%[3] and frequently require reoperation.[5]

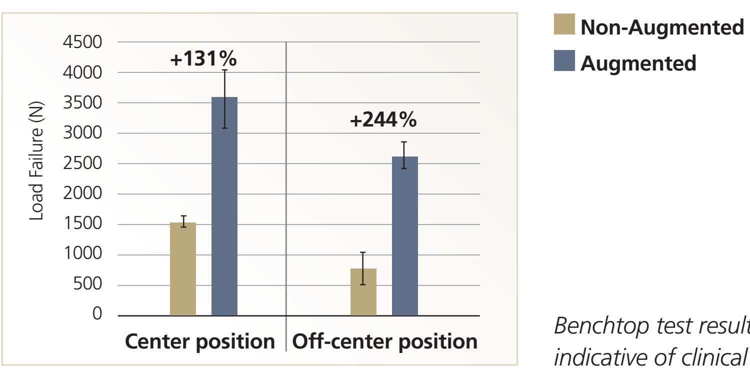
### The Solution: TFNA System featuring TRAUMACEM V+ Augmentation System

The TFN-ADVANCED® Proximal Femoral Nail System (TFNA) offers augmentation through the head element with the TRAUMACEM V+ Augmentation System. Augmentation has been shown to enhance fixation stability and resistance to cut-out, cut through, and unexpected blade migration, especially in osteoporotic bone.[5] The use of augmentation is optional, and the decision to augment may be made during surgery, providing surgeons with flexible intra-operative solutions for their patients.

- Early results from clinical studies have reported 0% cut-out in patients treated with PFNA (a predicate of the TFNA System) using cement augmentation.

| Clinical Outcome | Kammerlander et al., 2011 (N = 59)[5] | Kammerlander et al., 2014 (N = 62)[6] |
|---|---|---|
| Mean follow-up | 4 months | 15.3 months |
| Mean volume of cement injected | 4.2 mL | 3.8 mL |
| Percentage of patients reaching their pre-fracture mobility level | 55.3% | 59.6% |
| Overall surgical complication rate | 3.4% | 3.2% |
| Complications related to cement augmentation | None | None |
| Cut-out rate | 0% | 0% |

- Biomechanical tests designed to evaluate cut-out resistance show whether the head element is in the center or off-center position, augmented head elements withstood significantly higher loads prior to failure (p= 0.000).[7] Additionally, augmented constructs resisted varus collapse for significantly more cycles than non-augmented constructs (p= 0.000).[7]




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

# ECONOMIC VALUE

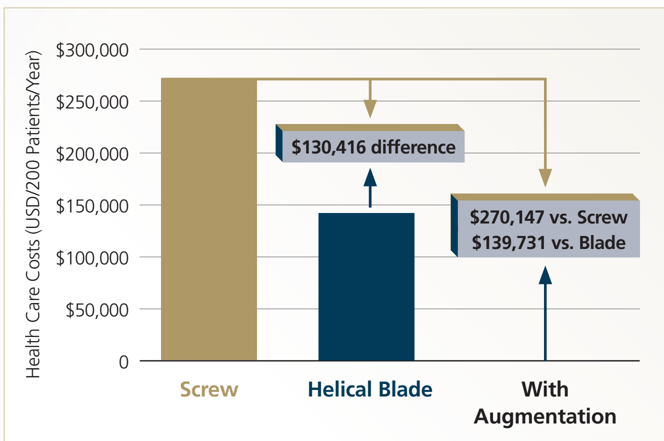
## Economic Challenge

High cost of reoperation places economic burden on hospitals and healthcare systems.

## The Solution: TFNA System featuring the TRAUMACEM V+ Augmentation System

Reduction in reoperations due to cut-out may reduce costs to the hospital and the healthcare system. A sample hospital budget impact analysis was developed to evaluate the potential economic impact of using the TFNA System. 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.[13,16,17] The model 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-augmentated constructs through the potential reduction in reoperations due to cut-out.

### Budget Impact Analysis of Annual Hospital Costs of Reoperation May Be Less for Augmented Constructs Compared to Non-Augmented Based on Differences in Cut-Out[1,5,6,25]




*Budget impact analysis assumptions: Cost of reoperation was $46,577;[25] Reoperation rates due to cut out were 2.9% for the screw,[1] 1.5% for the blade,[1] and 0% with augmentation;[5,6] Procedure volume of 200 hip fracture cases per year.*

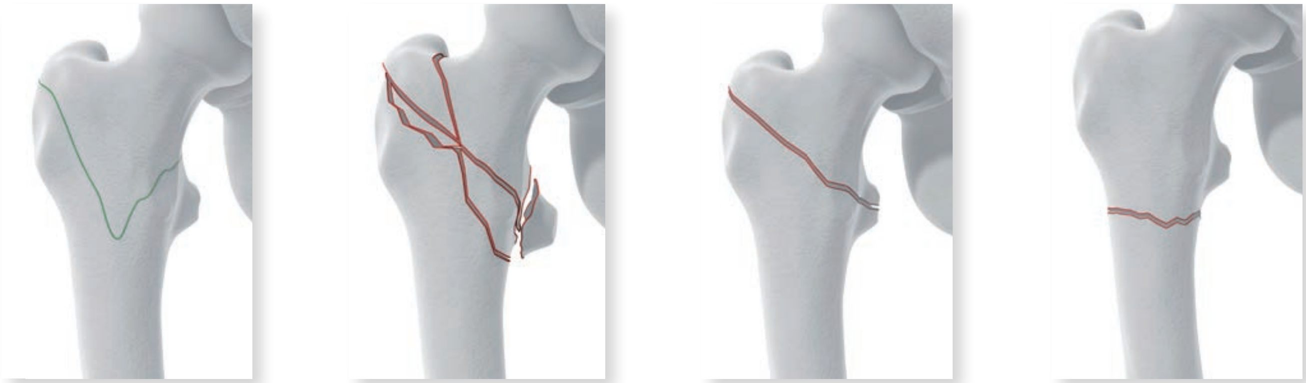
# BACKGROUND

Hip fractures are common in the elderly, and the incidence is expected to rise as the population ages.[16] Costs of managing hip fractures in the elderly were nearly $20 billion in 2010.[11] Reducing the reoperation rate, estimated at 6.3%, provides an opportunity for hospitals to reduce costs.[23]

## 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.[14] Hip fractures in people with normal bone are often the result of high-energy trauma such as car accidents, falling from heights (> 10ft), or sports injuries.[14]

FIGURE 1: **Types of hip fracture patterns[9]**



**Pertrochanteric, simple** | **Pertrochanteric, multifragmentary** | **Intertrochanteric** | **Subtrochanteric**

Most hip fractures are treated with orthopedic surgery which involves implanting an orthopedic device. The fracture takes approximately 4-6 months to heal.[18] The surgery is a major stress on the patient, particularly in the elderly. Revision procedures should be avoided given the increased surgical risks in these patients.

## Epidemiology

Each year, approximately 300,000 hip fractures occur in the United States (U.S.).[15] Hip fracture rates increase exponentially with age, with almost 90% of hip fractures occurring in people aged 65 years and older.[17,28] 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.[30] These continuing trends will place a financial burden on patients, families, insurers, and governments.[16]

- Intertrochanteric fractures constitute up to 55% of proximal femoral fractures and occur predominantly in elderly patients.[10] Most commonly, intertrochanteric fractures are caused by low-energy trauma events, such as falls from a standing position, usually in combination with osteoporosis.[11]
- 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%.[13]
- In young patients, intertrochanteric fractures are typically associated with high-energy trauma events, such as motor vehicle, bicycle, and skiing accidents.[10]

## Economic Burden

The economic burden of managing hip fractures in elderly individuals in the U.S. was estimated at $17-20 billion in 2010.[11] A typical U.S. patient with a hip fracture spends $40,000 in the first year following the fracture on direct medical costs and almost $5,000 in subsequent years.[11] 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.[22]

## Clinical Burden

Hip fractures result in pain, loss of mobility, and high rates of mortality.[12] 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.[24] Many patients lose their independence and need long-term care.[20] Comorbidity is an important contributory factor to hip fractures and is often a determinant of outcome.[12,19]

The reoperation rate of cephallomedullary hip nailing has been estimated at approximately 6.3%.[23] The most common complications resulting in revision surgery is proximal cut out proximal cut-out (≤ 8% revision rate).[3] Reoperations increase the risk to the patient and are costly to the health care 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.[21]

# TFNA SYSTEM CLINICAL VALUE

The TFNA System offers technologies designed to reduce the risk of cut-out, a serious post-operative complication often resulting in reoperation. Helical Blade technology compresses bone during insertion, which enhances implant anchorage and may reduce the risk of cut-out. The TFNA System also offers augmentation of the head element. Augmentation has been shown to enhance fixation stability, enhance cut-out resistance, and reduce cut-through and medial migration, especially in osteoporotic bone.[5] The decision to augment may be made during surgery, providing surgeons with flexible, intra-operative solutions for their patients.

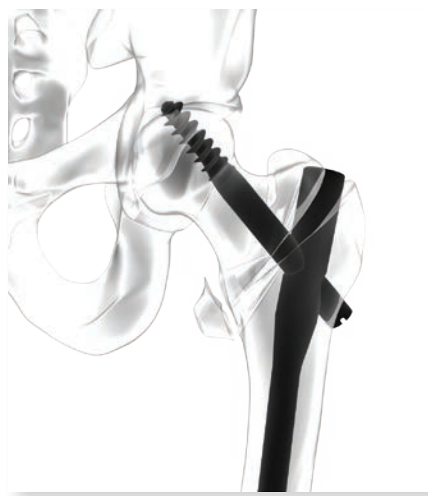
## PROXIMAL CUT-OUT

### 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 2). Revision surgery is frequently necessary when cut-out occurs.[5]

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.[8,31] Cut-out rates for cephalomedullary nail devices were reported at 3.2% in a Cochrane review of the literature,[23] and have subsequently been reported as high as 8%.[3] Cut-out continues to be a major complication for intramedullary hip nailing devices[1] and may cause severe injuries in hard tissues as well as in soft tissues surrounding the hip joint.[2] The TFNA System has incorporated two functions that are designed to reduce the risk of cut-out: the helical blade and augmentation.

FIGURE 2: **Example of Cut-Out**



*Source:* DePuy Synthes Trauma.

### Advantages of Augmentation

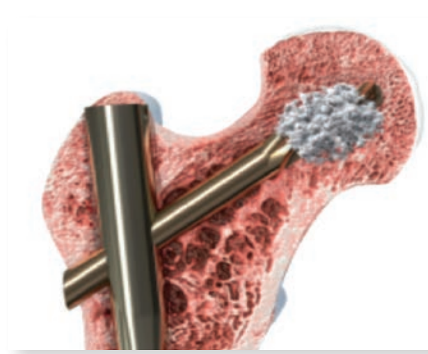
Low bone mineral density and thin cortices not only are major risk factors for hip fractures but also contribute to the failure of fixation postfracture.[26] Achieving stable fixation contributes to early patient mobilization and good fracture healing.[27]

Augmentation of the weak bone with polymethylmethacrylate (PMMA) may stabilize nail osteosynthesis, especially in unstable fractures and osteoporotic bone.[6]

Augmentation involves injecting the cement into the femoral head, the process takes approximately 10 to 15 minutes.[5] The decision to augment may be made during surgery, allowing for full intra-operative flexibility for the surgeon.

TFNA Helical Blades and TFNA Screws may be augmented with TRAUMACEM™ 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 Blade and Screw (Figure 3).[4] The cannulation of the implant, and additional fenestrations in the TFNA Head Elements and TFNA Screws, enable the controlled injection of cement into the surrounding bone tissue after implant insertion.

FIGURE 3: **TFNA Helical Blade with Augmentation**



*Source:* DePuy Synthes Trauma.

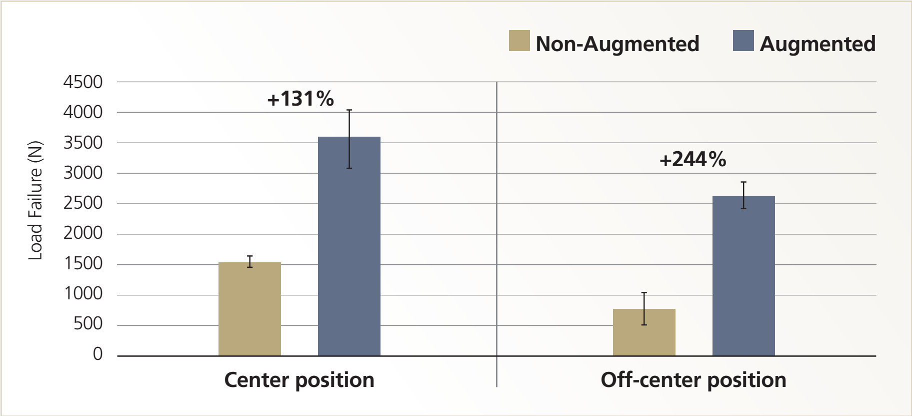
## Biomechanical Studies

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 Helical Blades and TFNA Screws was evaluated for constructs with and without augmentation.

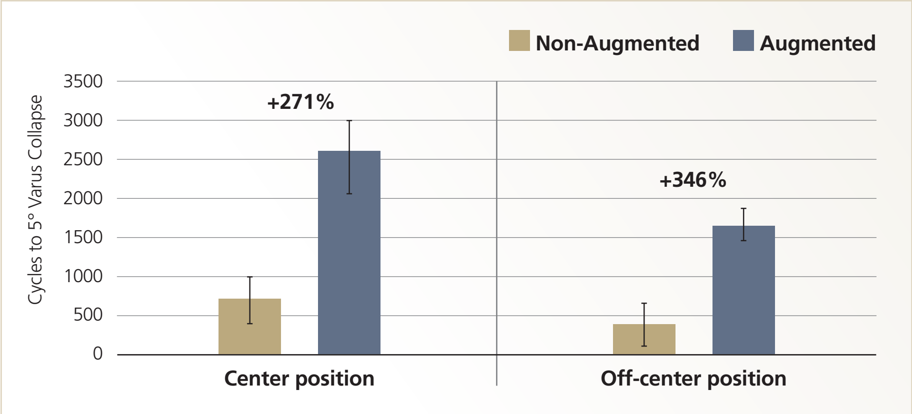
One biomechanical study included samples with the head elements in the center position as well as the off-center position.[7] While center position is the optimal placement of the head element,[7] placement may vary from surgeon to surgeon resulting in off-center positioning.[29] This study used an artificial bone material that mimics human osteoporotic bone in the femoral head.[7] Results demonstrate a significant ($p< 0.001$) increase in failure load (simulated decrease in cut-out) when the TFNA Helical Blades and TFNA Screws 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 Nail in the off-center position, which improved by 244%.[7] Furthermore, augmented constructs resisted varus collapse for more cycles than non-augmented constructs both in the center (+271%) and off-center (+346%) positions.[7] 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. These results are shown in Figures 4A and 4B.

### FIGURE 4A: **Augmented Head Elements Withstood Higher Loads Prior to Failure[7]**




### FIGURE 4B: **Augmented Constructs Resisted Varus Collapse for More Cycles Than Non-Augmented Constructs[7]**




*Benchtop 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).[5] 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.[5]

Furthermore, 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.[5,6] 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.[6] 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**[5,6]

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

* PFNA and PFNA II do not have 510(k) clearance and are not available for sale in the US.

# TFNA SYSTEM ECONOMIC VALUE

The TFNA System includes Helical Blade Technology and the option for cement augmentation; and both features may reduce the risk of cut-out.[5,6] Reduction in cut-out and subsequent reduction in reoperations may result in substantial economic savings to the hospital system.

Reduction in reoperations due to cut-out may reduce the overall economic burden of treating hip fractures. Reducing reoperations may be a direct way to reduce costs to the hospital as well as to the health care system.[21]

Quantification of the economic impact of treating complications and revisions may be assessed using a sample budget impact analysis. The sample analysis below shows the potential economic impact to a hospital. 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):

| | Lag Screw | Helical Blade | Augmented Construct |
|---|---|---|---|
| **Reoperation Rates Due to Cut-Out** | 2.9%[1] | 1.5%[1] | 0%[5,6] |
| **Mean 90-Day Direct Costs of Reoperation[25]** | $46,577 | $46,577 | $46,577 |
| **Annual Hospital Volume*** | 200 | 200 | 200 |

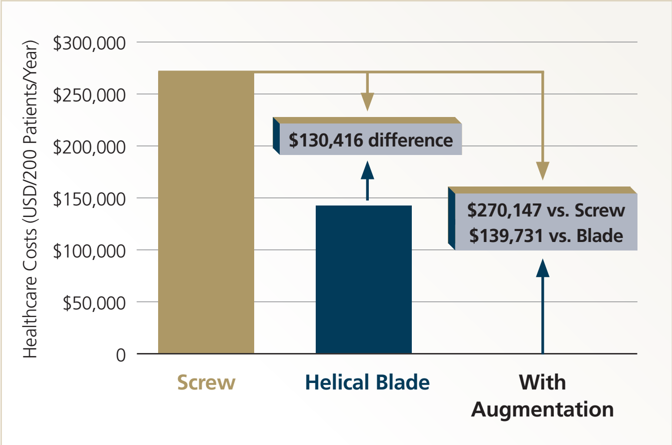
**Hospital volume assumption is representative of a mid-volume hospital.*

Under these assumptions, the potential annual hospital cost savings due to the reduction in reoperation rates due to cut-out are reported below and shown in Figure 5:

- $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 greater when the reductions in other postoperative complication rates are factored into the analysis. Technologies designed to reduce costly reoperations, such as the TFNA System, should be considered in support of IHI triple aim strategies and may result in opportunities for reductions in the overall economic burden on the healthcare system.

FIGURE 5: **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[25] x 2.9%[13] = $270,146.60*

*TFNA Helical Blade: 200 x $46,577[25] x 1.5%[13] = $139,731*

# SUMMARY

The TFNA System is 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, including the option for augmentation, was developed to deliver clinical and economic value to patients, surgeons, and hospitals through improved outcomes and cost savings opportunities.

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