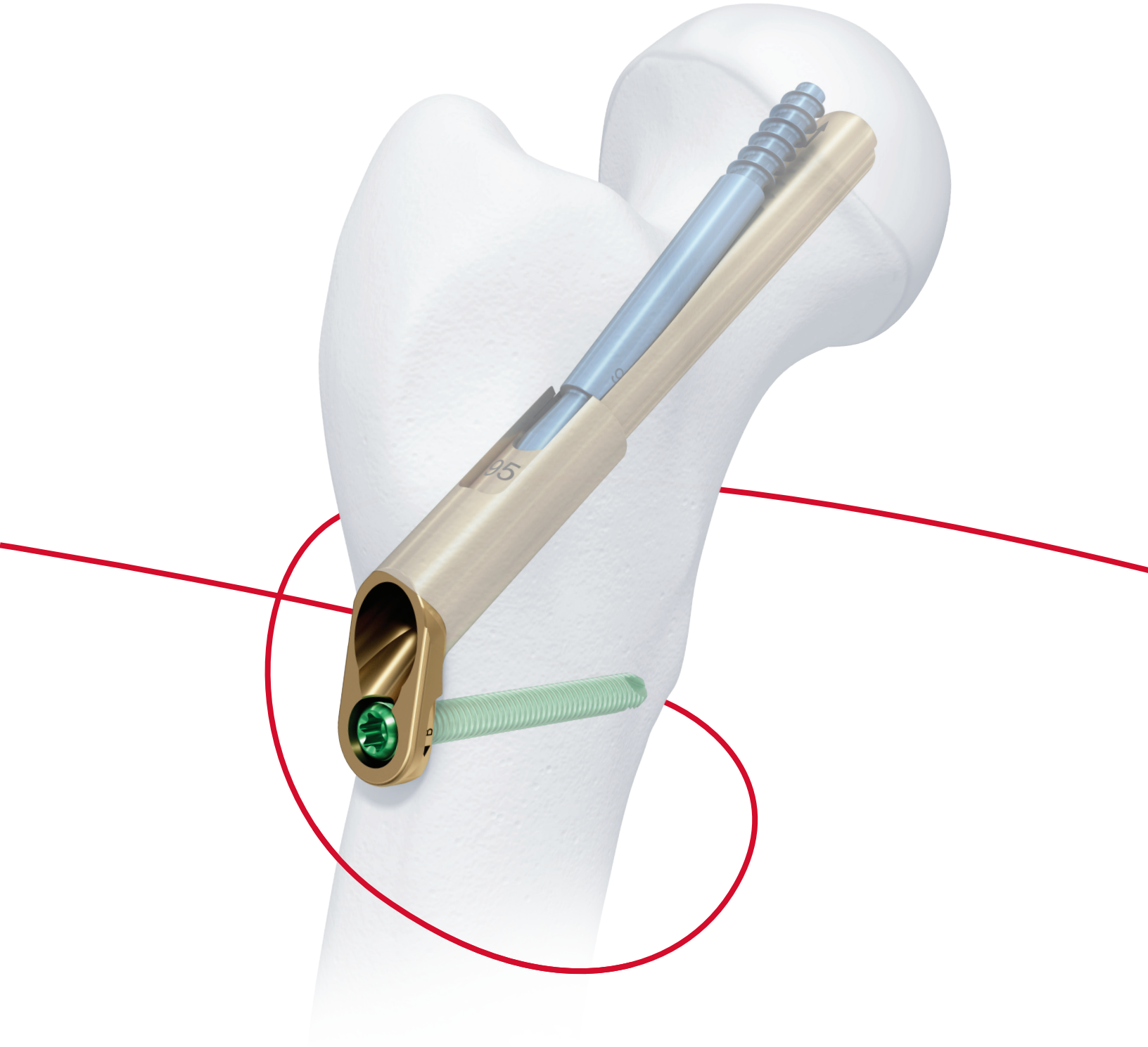
FEMORAL NECK SYSTEM (FNS)

Value Analysis Brief



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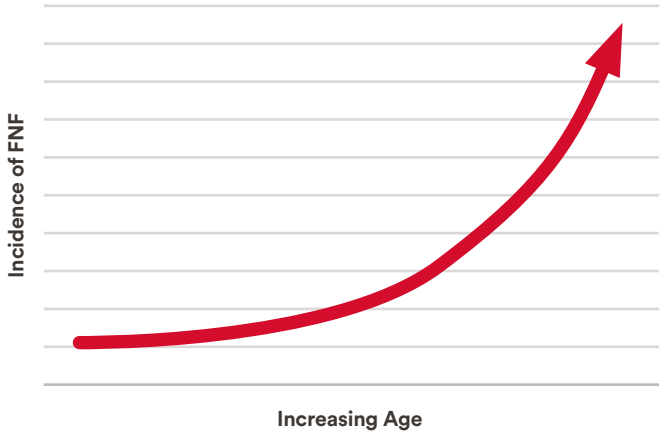
FEMORAL NECK SYSTEM (FNS)

Clinical & Economic Burden

Epidemiology of Femoral Neck Fractures

A majority of hip fractures occur in the femoral neck.[1] In older people, femoral neck fractures (FNF) are the most common traumatic injuries which can lead to severe disability.[2] Patients with FNF have been on the rise in the last three decades, and the incidence rate of FNF will be continuously increasing in the coming 30 years.[3] North America has the highest incidence of FNF in the world at 201 (per 100,000) per year in men and 511 (per 100,000) in women.[4]



Economic Burden

An estimated 1.66 million FNFs have been reported worldwide, and this figure is expected to approach 6.26 million by 2050.[5]

In the United States, the economic burden of hip fractures is amongst the top 20 most expensive diagnoses, with approximately $5.96 billion spent annually.[6]

The increasingly aging population of the world will face the challenge of coping with the growing number of FNFs and associated economic burden to the healthcare system.[4]

Unmet Need

High Rate of Reoperation

Reoperation rate up to **34%**[8]

Significant Loss of Function

Decreased mobility & independence in function, health, quality of life and higher rates of institutionalization.[7]

20-60%

required assistance for various self-care tasks 1 and 2 years after fracture.[7]

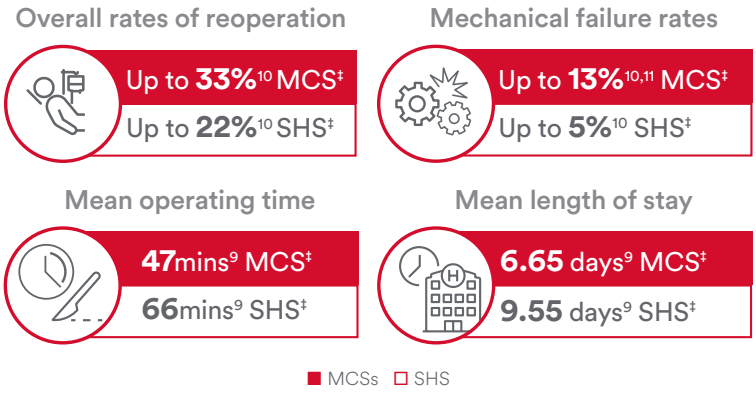
Increased Cost of Treatment

High risk of **reoperation & mortality**[8] in the elderly which may lead to overall higher treatment cost.[8]

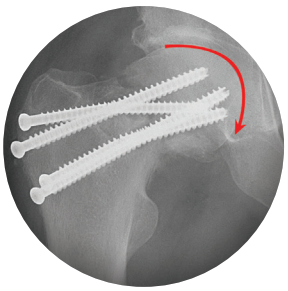
Need For an Improved Solution

Surgical treatment options for FNFs consist of internal fixation, hemiarthroplasty (HA) and total hip arthroplasty (THA).

Internal fixation, including multiple cannulated screws (MCS) or sliding hip screws (SHS), is often a method chosen for patients with non-displaced fractures.[9] Unfortunately, each of these options have their drawbacks.



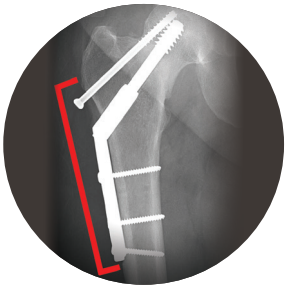
Common Clinical Complications‡



① Varus Collapse with MCS

MCS have been shown to lack the mechanical stability of sliding hip screws, as they do not provide a fixed angle with additional fixation into the femoral shaft.[10,11]

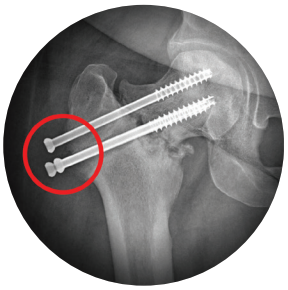
This lack of stability is often associated with higher rates of reoperation, which can be as high as 13% due to mechanical failure.[10,11]



② High Infection Rate with SHS

While SHS offer greater stability when compared to MCS, they require a more invasive approach for implant insertion due to the size of the implant and surgical technique.

This may ultimately result in a larger drop in hemoglobin levels and longer hospital stays.[9,12,13]



③ Pain Due to Lateral Implant

Lateral protrusion can either occur when the implant moves laterally while the femoral neck is shortening during fracture healing, or when the side plate protrudes from the side of the hip.

In either case, it often results in lateral thigh pain.

Rates of lateral protrusion have been shown to be as high as 5.3% and 3.6% for MCSs and SHSs respectively.[12,14]

Current evidence suggests[2-7] there is a **need for a solution** that combines the **angular stability of SHSs** with the **minimal invasiveness of MCSs** while **reducing lateral thigh pain and procedural complexity**.

‡ Percentages are taken from the results of the cited literature. Other publications may report different results.

Femoral Neck System Solution

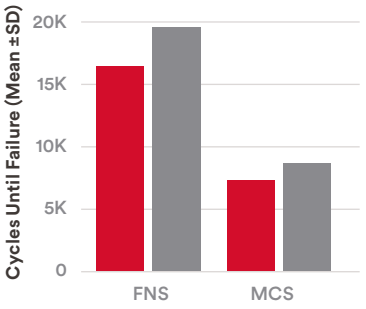
① Stability[15,16]

The FNS was designed to provide higher mechanical stability than MCS.

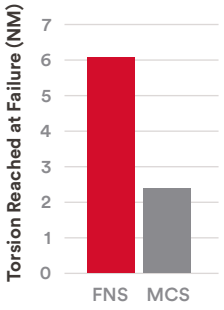
These FNS design features are intended to reduce varus collapse and rotational failures, potentially reducing reoperations due to mechanical instability to a similar level as SHSs.

BENEFITS:

These FNS design features are intended to reduce varus collapse and rotational failures, potentially reducing reoperations due to mechanical instability to a similar level as sliding hip screws.



FNS is **at least 100% more resistant to varus collapse** due to leg and neck shortening when compared to MCS[15*]



Use of FNS is associated with **at least 150% more rotational stability**, when compared to MCS[16]

② Minimally Invasive[17]

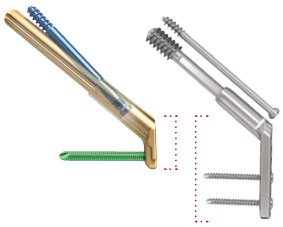
With its compact design, the FNS was created to minimize implant footprint on the bone. Furthermore, the FNS was designed to reduce the length of incision necessary for implant insertion when compared to a SHS system.

FNS may help reduce blood loss and length of stay, potentially reducing reoperations due to invasiveness to a similar level as MCS.

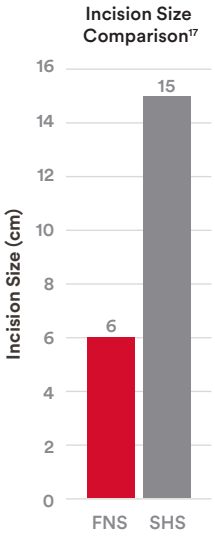
BENEFITS:

FNS may help reduce blood loss and length of stay, potentially reducing reoperations due to invasiveness to a similar level as MCSs.

71% **reduction** in footprint compared to SHS[17]



60% **reduction** in incision size compared to SHS[17]

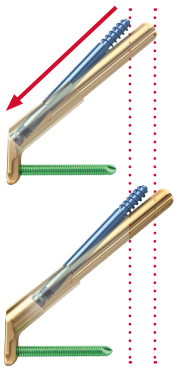


③ Reduced Protrusion[17]

The bolt design allows the FNS to freely glide within the barrel of the base plate. This allows for 20 mm of controlled collapse of the head fragment, with no lateral protrusion for the first 15 mm.

BENEFITS:

This FNS design feature is intended to reduce incidences of lateral thigh pain.



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

Clinical Value

Lower Complications & Improved Efficacy

He et al.[18] compared the clinical efficacy of the FNS and cannulated screws (CS) in the treatment of FNF in young adults. The FNS had lower rates of overall complications compared to CS (25.0% [9/36] vs. 6.1% [2/33], p=0.032).

Moreover, compared with CS, the FNS reduced the number of intraoperative fluoroscopies (10.58 ± 1.89 vs 18.33 ± 3.82, p<0.000), radiation exposure to medical staff and patients, and short-term complications including femoral neck shortening (3% vs 8.3%) and bone nonunion (0% vs 5.6%).[18]

FNS Compared to MCS[18,20,21]

- Lower rates of overall complications
- Lower rates of non-union
- Lower rates of femoral neck shortening
- Fewer intraoperative fluoroscopies
- Lower rates short-term complications

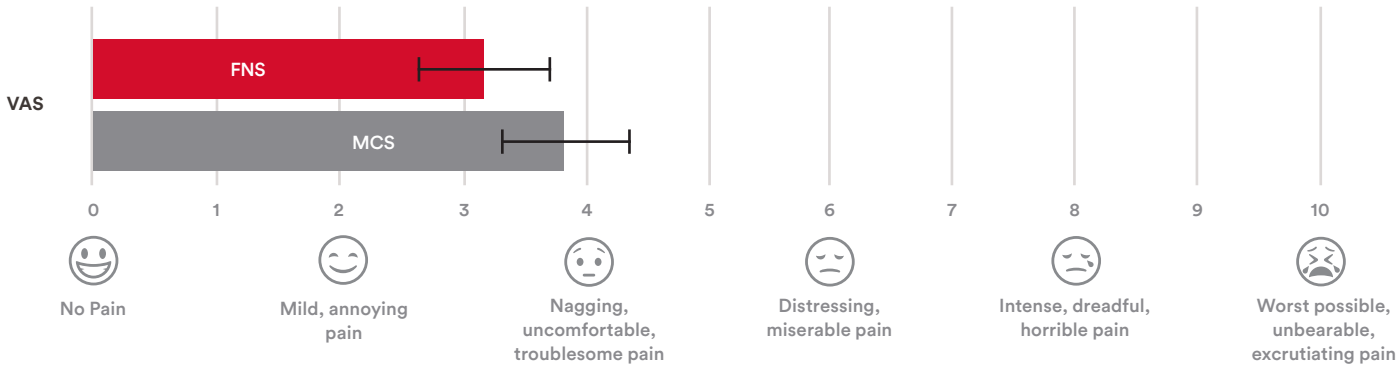
Clinical Efficacy

Cintean et al. compared the outcome of elderly patients with multiple comorbidities with non-displaced FNFs treated with a hemiarthroplasty or the FNS. For the treatment of non-displaced# FNFs, FNS use was associated with faster recovery with shorter hospitalization time (9.8 ± 3.8 vs 15.1 ± 5.1 days, P < 0.001) compared to patients treated with hemiarthroplasty.[19]

In addition, the study by Zhou et al. compared the early clinical effects of the FNS and three cannulated screws for the treatment of patients with unstable FNFs. Results of the study showed that compared to cannulated screws, FNS demonstrated lower postoperative Visual Analog Scale (VAS) scores (3.13 ± 1.07 vs 3.77 ± 1.04, P = 0.018), and earlier time to walking without crutches (5.23 ± 1.33 vs 6.03 ± 1.45, P < 0.001).[20$]

Further, Stoffel et al. prospectively assessed the rate of early implant-related complications in FNF osteosynthesis using the FNS. Patients treated with FNS regained their preinjury function and quality of life within one year.[21*]

FNS demonstrated better clinical efficacy such as lower postoperative Visual Analog Scale (VAS) scores[20$]



* Harris hip score (HHS), Pre-injury =100 (90.2–100.0), 12 months= 94.4 (70.9–97.0); EQ-5D-5L index score, Pre-injury = 1.0 (0.83–1.00), 12 months= 0.9 (0.79–1.00)
# nondisplaced (Garden Type 1 and Type 2) versus displaced (Garden Type 3 and Type 4).[22]
$ The Visual Analog Scale (VAS) is a validated, subjective measure of acute and chronic pain related to surgical intervention. A higher score indicates greater pain intensity.

Economic Value

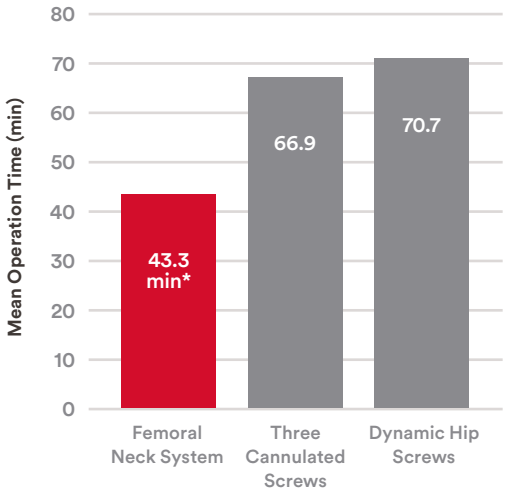
Reduced Operative Time

FNS is indicated for patients with FNF. It provides angular and rotational stability.[15,17,23] Due to the minimized size of the implant, FNS facilitates insertion through reduced incision.[17]

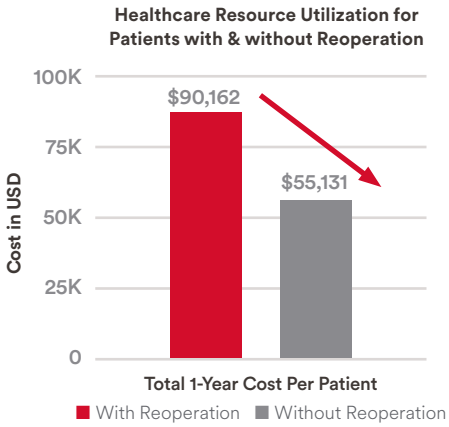
Vazquez et al. compared the operation time for three cannulated screws, dynamic hip screws (DHS), and FNS for non-displaced (Garden I and II) FNF osteosynthesis. Mean operation time was significantly shorter with FNS (43.3 ± 10.1 minutes) compared to three cannulated screws (66.9 ± 25.4 minutes) or DHS system (70.7 ± 20.0 minutes, P < 0.001).[24]

In a study comparing the FNS to a group of other implants which included a compression hip screw (CHS), Hansson Twin Hook (HTH), three 6.5 mm cannulated compression screws (CCS), & Hansson Pins (HP), the average surgical time was significantly shorter for FNS. (42 ± 13 min vs 53 ± 21 min; P = 0.032).[25]

Significantly Reduced Operative Time With FNS[24]



*p<0.001



SAVINGS OF

$35K

PER PATIENT FOR EACH

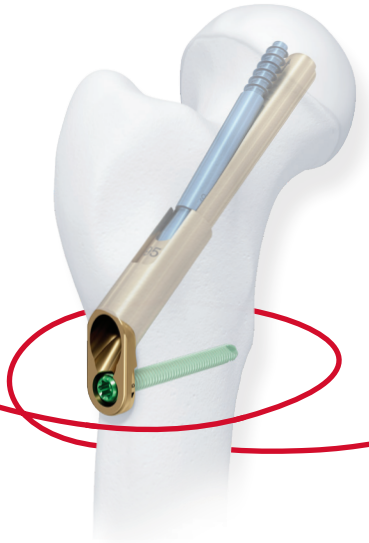
REVISION SURGERY

AVOIDED[28]

Rate of Reoperation Reduced

Compared to other implants*, patients treated with FNS have a significantly lower incidence of reoperation (0% vs 22%, P = 0.023).[25]

Revision procedures resulting from the failed fixation of the hip can be detrimental to the patient, increasing the risk of mortality, decreasing the ability for patients to return to their original state, and resulting in a two to threefold rise in average cost of treatment.[26,27]



The **Femoral Neck System** was designed with the aim of **reducing the incidence of costly reoperations and complications**.[29] This may provide the opportunity for **cost savings** for the health care system.

*Other implants (compression hip screw: CHS, Hansson Twin Hook: HTH, three 6.5mm cannulated compression screw: CCS, and Hansson pins: HP)

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