X-Bolt Pro-X1™ Trochanteric Nail

X-Bolt Trauma Orthopedics

VALUE+ ANALYSIS BRIEF

VALUE+
ANALYSIS BRIEF

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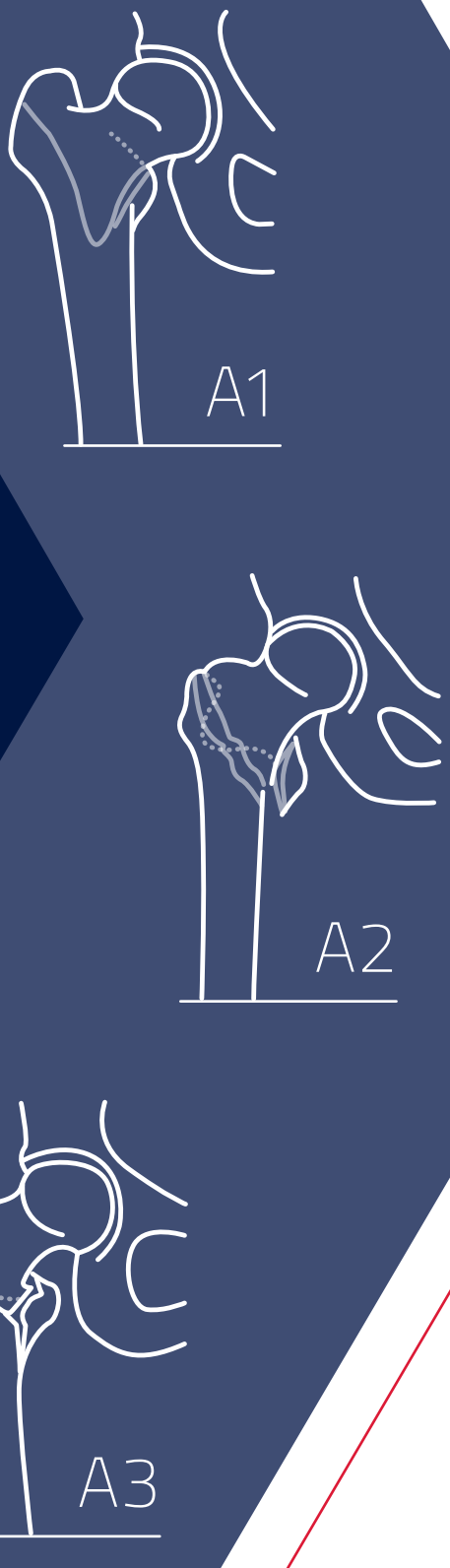
BACKGROUND:
HIP FRACTURES

Hip fractures present a significant global challenge. As the population ages, osteoporotic fractures become increasingly common, and are escalating costs to health care services worldwide.

1-in-6 white women will suffer a hip fracture in their lifetime. The 1-year mortality rate after a hip fracture is as high as 30%. A large proportion of patients who survive beyond this often require prolonged supportive care.[1,2]

In the UK, nearly 2% of all acute hospital beds are occupied by hip fracture patients and this one injury carries a total cost equivalent of approximately 1% of the whole NHS budget.[3]

Proximal Femoral (Hip) Fractures
(AO/OTA classifications)



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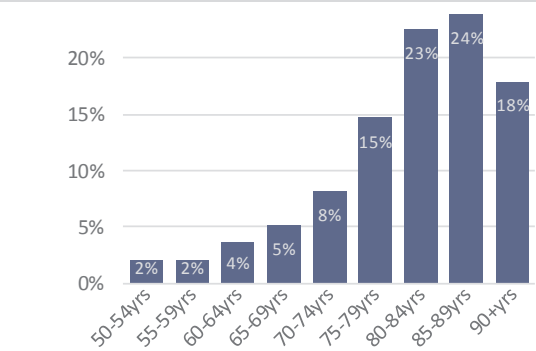
EPIDEMIOLOGY

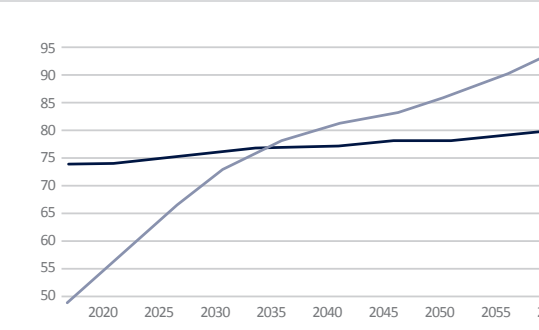
80% of hip fractures occur in those over the age of 75 years (median age 84 years).[3-5]
Approximately 300,000 hip fractures occur each year in the United States.[6]
Over 1 million hip fractures occur between the EU27 and North America each year.[6,7]
Extracapsular fractures account for approximately 50% of all hip fractures recorded and are generally 'fixed' with a nail or plate. Intracapsular fractures are generally 'replaced' with a hemiarthroplasty or total hip replacement.[1-5]



Age distribution of Hip Fractures
(Norwegian Hip Fracture Registry)

THE RATIONALE FOR OPERATIVE HIP FRACTURE CARE

The key driver for operative management is the prevention of pre-terminal decline. Failure to recover some form of mobility renders these already highly vulnerable patients, more liable to develop venous thromboembolism, chest infections and pressure sores. Problems with personal hygiene, independence and activities of daily living rise exponentially with an unfixed fracture. Pain is also a key indication for surgery; from a humanitarian perspective, operative fixation is akin to a palliative procedure to allow comfort for patients in their last days. Hip surgery should be performed urgently, noting that pain and immobility are key indications for surgery. The goal of surgery is to restore mobility and to ameliorate any decline in the patient's independence and ability to function.



Population Predictions for Seniors & Children
(US Bureau of Census)

ECONOMIC BURDEN

An analysis of the 2014 Medicare database[8] showed the estimated cost per patient within acute care intertrochanteric hip fractures is **$52,512** in the first 365 days ($44,135 in first 90 days). Another paper with data from Medicare 2013-2015 shows one year costs for an intertrochanteric fracture without a reoperation was **$55,701**.

In Europe[7], the one-year costs for hip fractures are also substantial, averaging **$41,832** per patient episode.

EUROPE	Hip Fracture numbers	Annual cost per episode
France	73,630	$39,717
Germany	129,849	$36,995
Italy	90,539	$49,642
Netherlands	13,395	$47,119
Spain	40,473	$44,409
Sweden	20,280	$45,870
UK	79,243	$29,072
AVERAGE		$41,832

ECONOMIC IMPACT OF REOPERATION

Data from Medicare between 2013 and 2015 shows that the additional one year cost for those needing a reoperation following intertrochanteric fracture fixation was **$38,029** versus those patients who did not have a reoperation ($93,730 vs $55,701).[9]

Episode cost without reoperation (US)	Episode cost with reoperation (US)
$55,701	$93,730

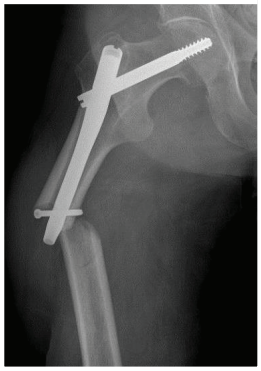
MAJOR CAUSES OF REOPERATION

A metanalysis of randomized evidence[10] published in 2015 analysing intertrochanteric fracture showed:

5.5% (248/4506) **All-Cause Reoperation %**

3.5% **Cut-Out %**

1.2% **Distal Femur Fracture %**

Cut-Out	Fracture at distal nail tip
	

UNMET NEED

SOLUTION

Cut-Out is the leading cause of failure of fixation in proximal femoral fractures accounting for half of all reoperations.

Cut-out rates for trochanteric hip nails with screw or helical blade femoral head fixation on average 3.5%.[10,11]

The X-Bolt is 25% stronger to push-out and 380% stronger in rotational stability vs hip screws or helical blades.[12,13]

The expanding wings give haptic feedback to the surgeon on the bone quality.

Large multi-center clinical trials with the X-Bolt have cut-out rates consistently <1%, before the recent design improvements giving better ergonomics and better tip-apex distance.[14,15]

Distal Fracture at the tip of either a short or long nail is the second leading cause of fixation failure at 1.2%.[10,11]

High stress concentration at the tip of a short or long nail, as well as mismatch of femoral curvature, lead to increased risk of fracture at distal nail tip.

The Pro-X1™ Nail has a distal taper and prongs to alleviate stress concentration at the tip of the nail. Biomechanical studies have shown this to significantly reduce strains in the femur at the nail tip.[16]

The Pro-X1™ long nails have been designed with a radius of curvature of 1.25m for nails 300mm to 375mm and 1.50m.

Over-engineered solutions contribute to excess operative time and deflect from the important clinical steps, such as fracture reduction, implant placement and tip-apex distance.[11]

The Metro Jig™ is a curved jig with flexi-drive that allows surgeons to 'operate around a corner' and facilitates faster surgery. It is especially useful in overweight and obese patients.

The simple surgical technique allows surgeons to concentrate on the important aspects such as fracture reduction, implant placement and tip-apex distance.

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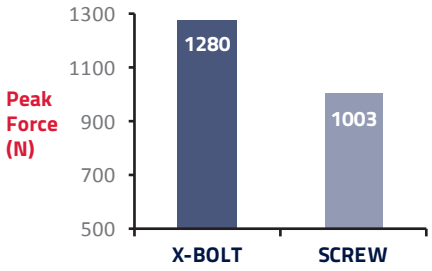
FEMORAL HEAD CUT-OUT

X-Bolt Design

> Four orthogonal wings expand radially
> Compacts surrounding cancellous bone
> Tip-apex distance kept constant
> No spinning of femoral head
> Easily reversible



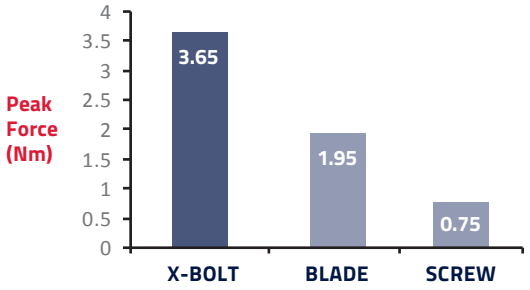
Push-out test, cyclic loading

Biomechanical Studies

Cyclic loading push-out testing showed the X-Bolt having a **28% greater peak force at cut-out**[12] versus a SHS screw, which has a thread outer diameter of 12.7mm. (Note: The thread outer diameters for Gamma3 and TFNA lag screws are smaller at 10.5mm and 10.35mm, respectively).

The femoral head rotates throughout a walking cycle or when standing from a seated position. Torque testing showed a **380% greater resistance to peak torque**[13] versus SHS screw and 87% greater than a helical blade.

X-Bolt placement is more forgiving than a screw. A study published in 2019 shows that push-out strength is superior for X-Bolt throughout a variety of tip-apex distances.[17]

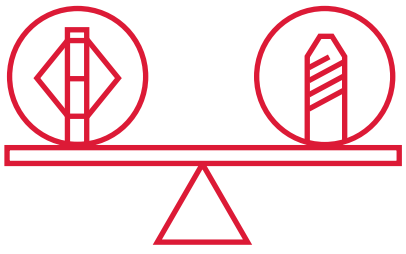


Torque resistance test

Clinical Studies

The X-Bolt has been the subject of two large randomised clicnal trials in the UK, WHITE1[14] (n=100) and WHITE4[15] (n=1,128), where the X-Bolt XHS was compared to a generic SHS screw. Both constructs used a side plate and all other parameters were similar for both groups.

The overall **cut-out rate for the X-Bolt was 0.8%** (4/526). To date, there has not been a femoral head fixation device that has recorded a lower cut-out rate than the X-Bolt, and the clinical studies validate the superior biomechanical performance against cut-out.

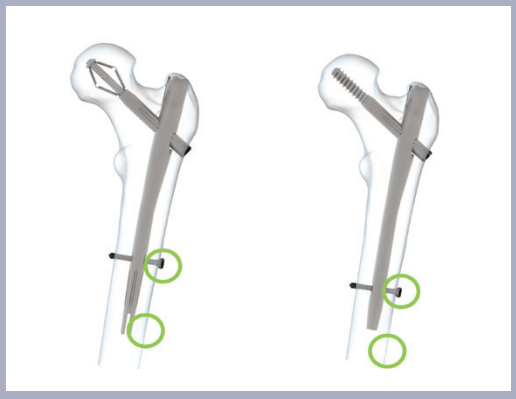


X-Bolt Cut-Out Rate [14,15]	Traditional Screw Cut-Out Rate [10]
0.8%	3.5%

DISTAL STRESS MODULATION

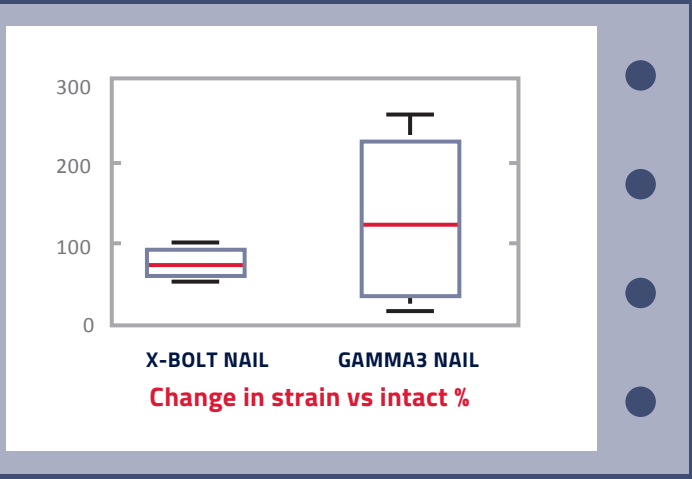
Nail Design

> Distal taper and prongs
> Alleviates stress concentration at tip of nail



Biomechanical Studies

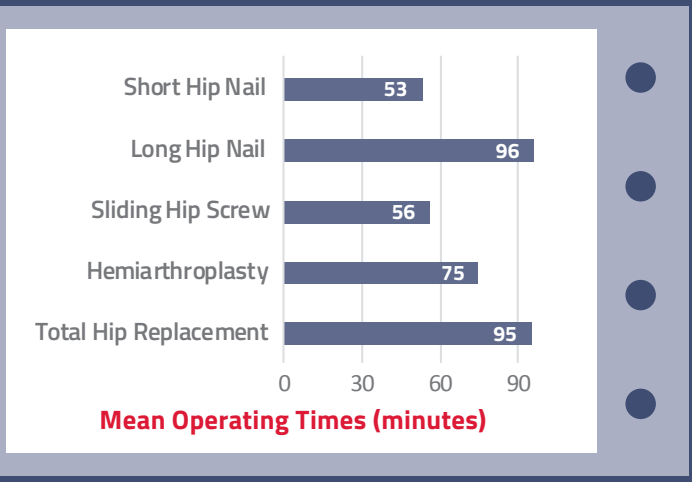
Biomechanical studies have shown the design to consistently reduce strains in the femur at the nail tip, which thus will lessen the risk of a distal femoral fracture.[16]



FASTER OPERATIVE TIME

Average operating times from the Norwegian Hip Fracture database[5] for each type of hip fracture operation are shown opposite. The mean operating time for a traditional short hip nail is 53 minutes. The average cost per minute for operating room use is estimated at $36/minute.[18]

Just a 5-minute saving from use of the curved Metro Jig™ and the easy-to-use Pro-X1™ surgical technique will save a hospital $180 per case and **$36,000 annually** for a procedural volume of 200 cases per annum.



ECONOMIC VALUE:
THE X-BOLT® PRO-X1™ SOLUTION

Reducing The High Cost of Reoperation

Reduction in reoperation from cut-out and distal femoral fracture will substantially reduce costs to the hospital and healthcare system. A sample budget impact analysis was developed to show the potential impact to a typical hospital that manages 200 hip fracture fixation per annum. The analysis evaluated the use of the X-Bolt Pro-X1™ nailing system and compared to a traditional screw-based hip nailing system, using data from published studies.[10,14,15] Results demonstrated that a typical hospital may recognize savings of up to **$240,000** from the reduction in reoperations for fixation failure, mostly though a virtual elimination of distal femoral fracture and of 'cut-out'.

Faster Hospital Discharge

Published clinical studies[14,15] have also shown better patient outcome scores for hip fracture patients treated with an X-Bolt device versus a screw-based device. Average difference in EQ-5D outcome score was +0.04 in favour of the X-Bolt at four months post-operatively. The difference seen was even greater at the 4-week mark at +0.09. Benchmarking against a similar hip fracture hemiarthroplasty trial[19] where a modern hemiarthroplasty achieved similar EQ-5D outcome score of +0.04, and a reduction a mean length of hospital stay of 0.67days (9.67days vs 9.00 days, $p<0.05$).

An estimated faster average hospital discharge of just 0.5 days translates into savings of $1,186 per patient episode[20] in the US and **$237,000** for a typical hospital with an annual procedural volume of 200 cases per year.

Faster Surgical Time

The simplicity of the Pro-X1™ implant's design and use of the novel Metro Jig™ can save valuable minutes of the standard operating time. In particular the Metro Jig™ allows all-outside operation of the set screw deployment step and the jig decoupling step. The Metro Jig™ in effect allows the surgeon to 'operate around a corner' and is particularly useful in overweight or obese patients.

A 5-minute saving in average operating time results in savings of $180 per case and **$36,000** for a typical hospital[18] with an annual procedural volume of 200 cases per year.

Total Hospital Savings

up to $513,000 per annum

Total Savings

Combining the above, a typical hospital with an annual procedural volume of 200 cases per year could expect savings of up to **$513,000** per annual using the X-Bolt® Pro-X1™.

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For further information, or to order, please contact:

X-Bolt Orthopaedics
Unit 5, Northwood Court
Santry, Dublin D09AX54
Ireland
IE: **+353 1 443 3880**
US: **+1 813 358 3980**
W: **www.x-bolt.com**

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