ORTHOPEDIC DESIGNS
NORTH AMERICA, INC.

Talon™ DistalFix™ Proximal Femoral Nail

Biomechanics

The studies presented in the subsequent pages were performed at the following labs:

Knight Mechanical Testing
6016B Highview Drive
Fort Wayne, IN 46818

Phillip Spiegel Orthopaedic Research Laboratory
Foundation for Orthopaedic Research and Education
13020 N. Telecom Parkway
Tampa, FL 33637

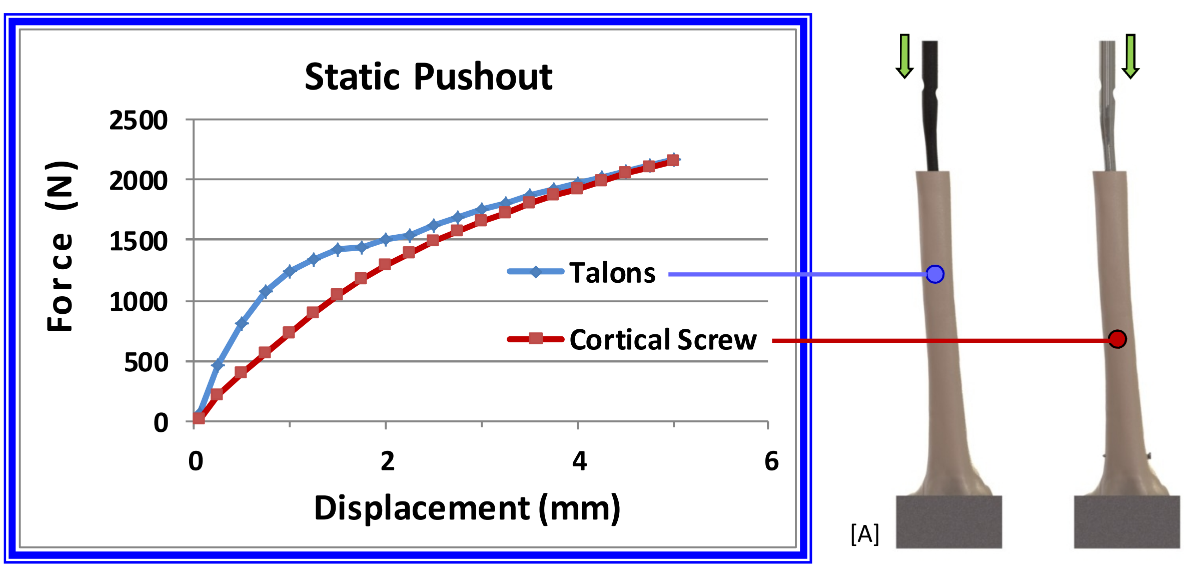
Their cooperation is much appreciated.

Overview

The Talon™ DistalFix™ Proximal Femoral Nail was evaluated using a series of biomechanical tests to establish the following: (1) Talon™ superiority over our existing stainless steel cortical screw; (2) axial fatigue strength of the distal Talons™; (3) rotational stability of the distal Talons™; (4) overall performance as the total construct. The first three tests were conducted using Fourth-Generation Composite Femurs (Sawbones, Vashon, WA). The fourth test was conducted using the bilateral femora from an 82-year old female donor with a T-score indicative of osteopenia/osteoporosis. The following pages summarize the parameters of each test as well as the results.

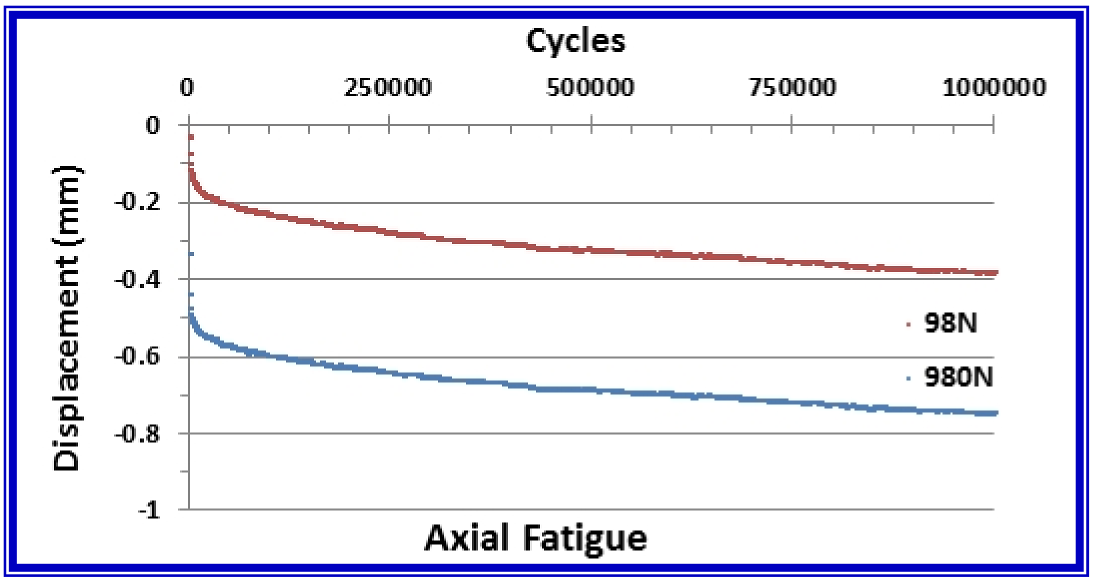
Distal Talon™ Superiority

Establishing distal Talon™ superiority over our existing stainless steel cortical screw was vital for proof of concept. To do this, the proximal ends of two composite femora were removed and the stainless and DistalFix™ nails were implanted such that the distal tips of the nails were approximately 48mm superior of the distal femur [A]. A static load was applied to the tops of the nails under displacement control at a rate of 25 mm/min and the force recorded at regular intervals until the maximum displacement of 5mm was reached. The results below show the **Talon™ DistalFix™ nail requires more force for a given displacement**. Distal Talons™ were successfully retracted upon completion of the test.



Axial Fatigue Strength

The durability of the distal Talons™ was determined by applying a cyclic load to the proximal nail in a manner similar to the static pushout test shown previously [A]. The cyclic load was established at 98N to 980N (approximately 220lbs) based on a past study of a similar construct (Steinberg et al., *Journal of Biomechanics*, 2005). The test was run at 5Hz for 1 million cycles under load control and displacement of the nail was recorded. The results of two tests were averaged and appear below. **The average displacement observed at 1 million cycles was 0.74mm**.

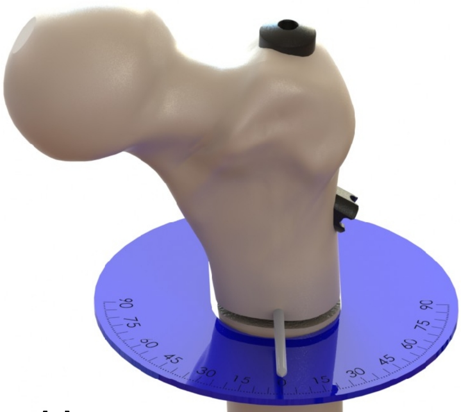


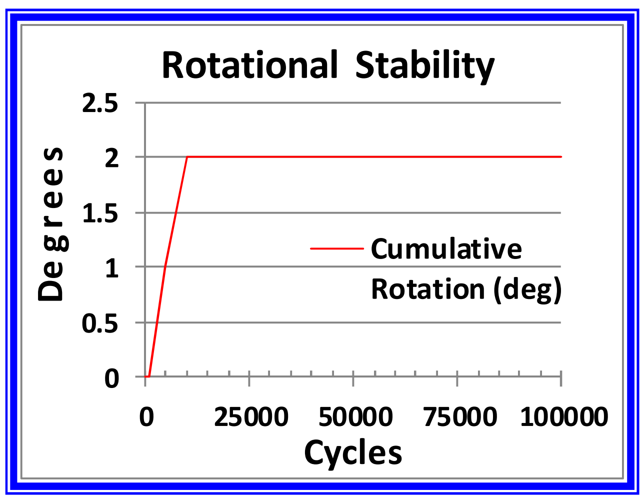
[A]

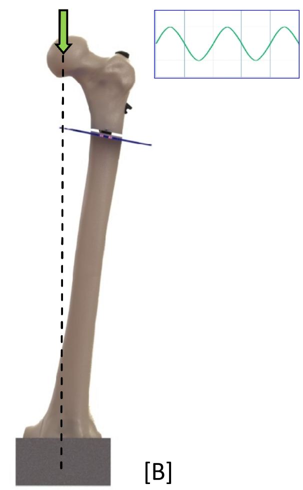
Beyond 1 million cycles (not depicted above) the load was increased 100N every 100,000 cycles for a total of 1.5 million cycles. The final 100,000 cycles was run with a maximum load of 1480N (approximately 332lbs). **The average displacement at 1480N was 3.32mm**. Distal Talons™ were successfully retracted upon completion of the test.

Rotational Stability

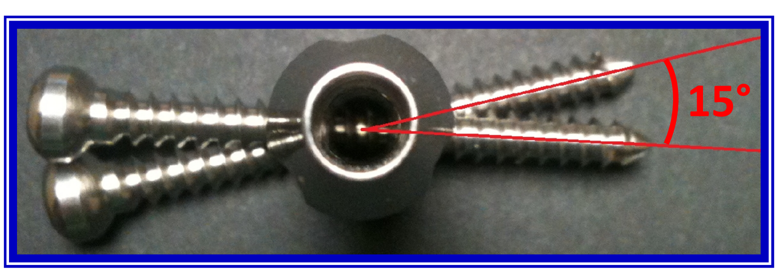
Distal locking does more than simply provide axial strength for weight bearing. In unstable fractures, distal locking provides rotational stability as well. To determine the rotational stability afforded by the distal Talons™, a complete Talon™ DistalFix™ Proximal Femoral Nail was implanted in a composite femur and a rotationally unstable subtrochanteric fracture was created. A dial was fixed to the distal fragment (just below the fracture) and a pin was placed in the proximal fragment (just above the fracture) as seen in the model below [A]. The specimen was tested with a cyclic load (98N to 980N) applied to the femoral head, as depicted below [B], at 2Hz for 100,000 cycles. The pin position with respect to the dial was recorded at regular intervals and the results are reported in the graph. **The cumulative rotation through the fracture site was 2°**. This rotation occurred within the first 10,000 cycles, suggesting that early on the nail settled in and then remained fixed henceforth. Distal Talons™ were successfully retracted upon completion of the test.


[A]




[B]

As a point of comparison, the cortical screw employed in our previous stainless steel nail had a 15° "range of motion" through the distal interlocking hole [C]. What this means is that while the screw is fixed by the cortices of the bone, the nail would likely rotate to some extent and settle in the orientation of lowest energy. This would be similar to, and perhaps more so, than what was seen in the above test.



[C]

Cadaver Study

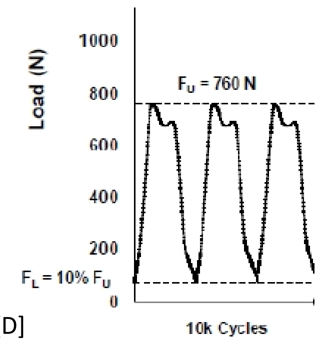

[A]


[B]

The left femur of an 82-year old female donor with a T-score indicative of osteopenia/osteoporosis was implanted with a 360mm Talon™ DistalFix™ Proximal Femoral Nail and a rotationally unstable subtrochanteric fracture was created ([A] and [B]). The specimen was oriented such that the line of applied force passed through the center of the femoral head and the center of the epicondyles. Cyclic loading at 1Hz consisted of the characteristic double-peak loading curve reported by Bergmann et al. (Bergmann et al., *J Biomechanics*, 2001) that represents the average hip joint contact force experienced during the flexion-extension gait cycle ([C] and [D]).

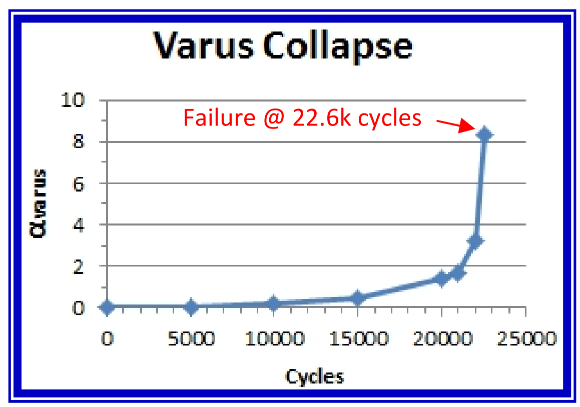
F_U	Cycles	% BW	F_L (10% F_U)
760N (170lbs)	0-10k	100	76N (17lbs)
1140N (255lbs)	10-15k	150	114N (25.5lbs)
1520N (340lbs)	15-20k	200	152N (34lbs)
1710N (383lbs)	20-21k	225	171N (38.3lbs)
1900N (425lbs)	21-22k	250	190N (42.5lbs)
2090N (468lbs)	22-23k	275	209N (46.8lbs)
2280N (510lbs)	23-24k	300	228N (51lbs)
2470N (553lbs)	24-25k	325	247N (55.3lbs)

[C] Note: Beyond 20,000 cycles the intent was to induce failure--bone or implant



[D]

Measured variables included the relative rotation between the femoral head with respect to the shaft (α_{varus}) and neck (α_{neck}) and axial displacement of the nail with respect to the shaft. All fluoroscopic images were taken at 100% body weight. α_{varus} is plotted to the right and illustrated in various x-rays below [E-G]. **The lag screw position does not change relative to the femoral head throughout the test**. **α_{neck} was <0.1° throughout the test**. **Nail subsidence was not detected after completion of the test**. All Talons™ were successfully retracted after completion of the test.



[E] [F] [G]

[E] 0 cycles @ 100% BW

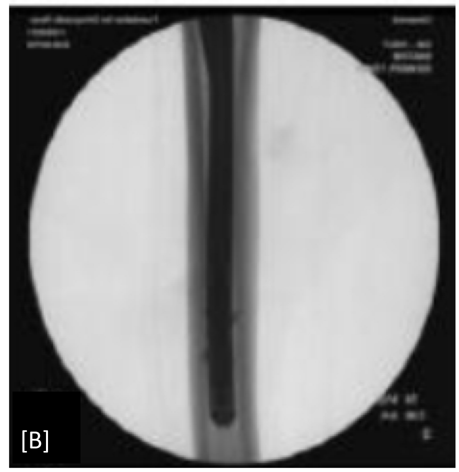
[F] 20k cycles @ 200% BW

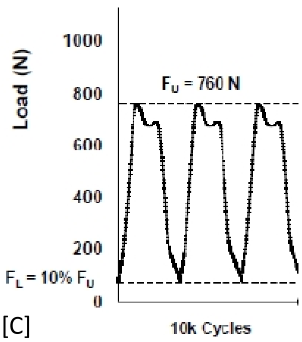
[G] 22k cycles @ 250% BW

VIRTUALLY NO CUT-OUT

Cadaver Study (cont.)

The right femur of the same 82-year old female donor was implanted with a 220mm Talon™ DistalFix™ Proximal Femoral Nail and an intertrochanteric fracture lacking infero-medial support was created ([A] and [B]). The specimen was oriented such that the line of applied force passed through the center of the femoral head and the center of the epicondyles. Cyclic loading at 1Hz consisted of the characteristic double-peak loading curve reported by Bergmann et al. (Bergmann et al., *J Biomechanics*, 2001) that represents the average hip joint contact force experienced during the flexion-extension gait cycle ([C] and [D]).





[C]

[D]

FU	Cycles	% BW	FL (10% FU)
760N (170lbs)	0-10k	100	76N (17lbs)
1140N (255lbs)	10-15k	150	114N (25.5lbs)
1520N (340lbs)	15-20k	200	152N (34lbs)
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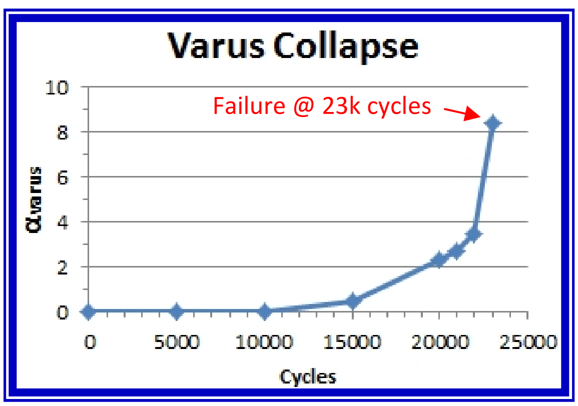
Note: Beyond 20,000 cycles the intent was to induce failure--bone or implant

Measured variables included the relative rotation between the femoral head with respect to the shaft (α_{varus}) and neck (α_{neck}) and axial displacement of the nail with respect to the shaft.



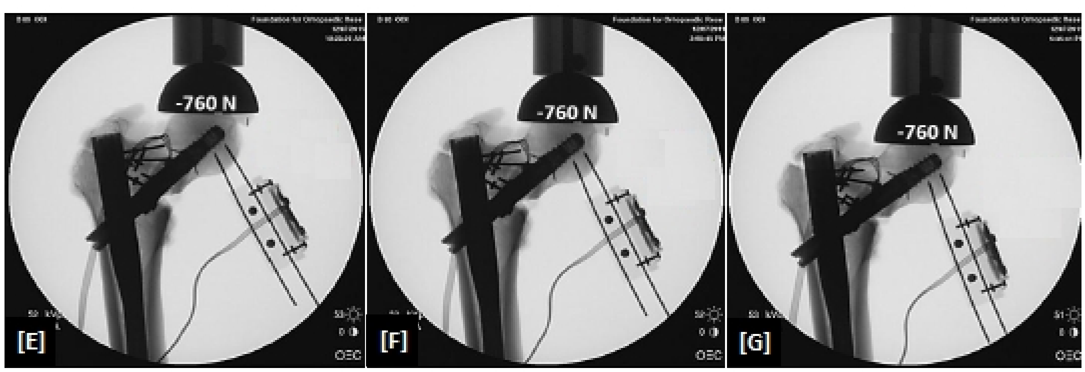
All fluoroscopic images were taken at 100% body weight. α_{varus} is plotted to the left and illustrated in various x-rays below [E-G]. **The lag screw position does not change relative to the femoral head throughout the test. α_{neck} was <0.1° throughout the test. Nail subsidence was not detected after completion of the test.** All Talons™ were successfully retracted after completion of the test.

[E] 0 cycles @ 100% BW

[F] 20k cycles @ 200% BW

[G] 22k cycles @ 250% BW

VIRTUALLY NO CUT-OUT



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Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.