April 8, 2008

Introduction

Biomechanical and mechanical tests were performed to compare the Bioretec ActivaPin™ with a competing bioabsorbable pin implant. Testing was conducted by Bioretec Ltd[1]., Tampere Finland, using Bioretec's test facilities. Testing was performed with 2.0mm (diameter) pin implants.

Product Descriptions

Product Description	Product Reference Code	Diameter	Length
ActivaPin™ 2.0mm	B-AP-2040	2.0mm	40mm
Arthrex Trim-It Drill Pin™ 2.0mm	AR-4152DS	2.0mm	100mm

Bioretec ActivaPin™ implants are constructed of the bioabsorbable PLGA copolymer (L-lactide-co-glycolide). The PLGA polymers have a long history of safe medical use[2], and degrade *in-vivo* by hydrolysis into alpha-hydroxy acids that are metabolized by the body.

Arthrex Trim-It™ Drill Pins are manufactured from bioabsorbable partially crystalline PLLA polymer (poly-L-lactide).

Arthrex packaging includes the Trim-It™ Drill Pin with metallic trocar head, scored guidewire and scored piston. ActivaPin™ packaging includes the ActivaPin™ (delivered inside blue plastic holder) and Disposable Pin Applicator kit including scored guidewire with stepped shaft, piston and sleeve.

Arthrex Trim-It Drill Pin (left) and ActivaPin™ (right).

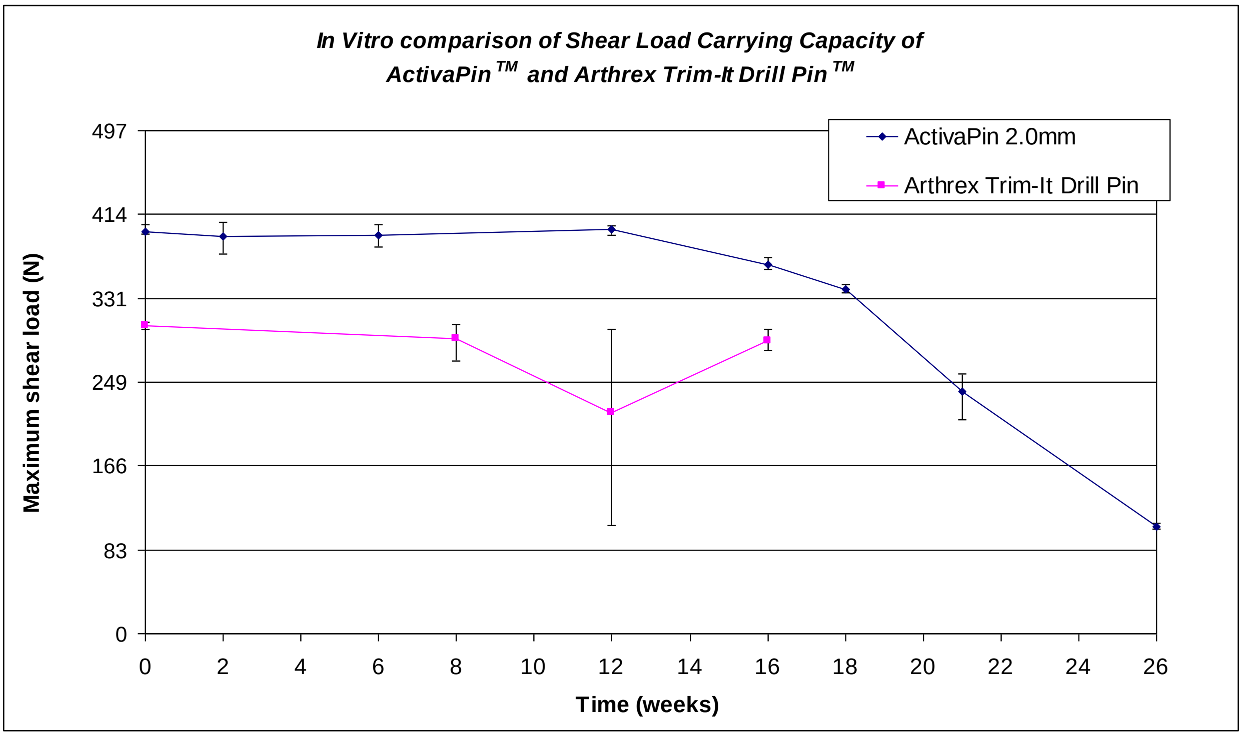
[1] Test data on file at Bioretec Ltd.
[2] Data on file at Bioretec Ltd.

Shear Load Carrying Capacity

The objective of this test was to measure and compare the maximum shear load carrying capacity of the test. *In Vitro* testing was carried out to compare the shear strength retention behavior of the test specimen.

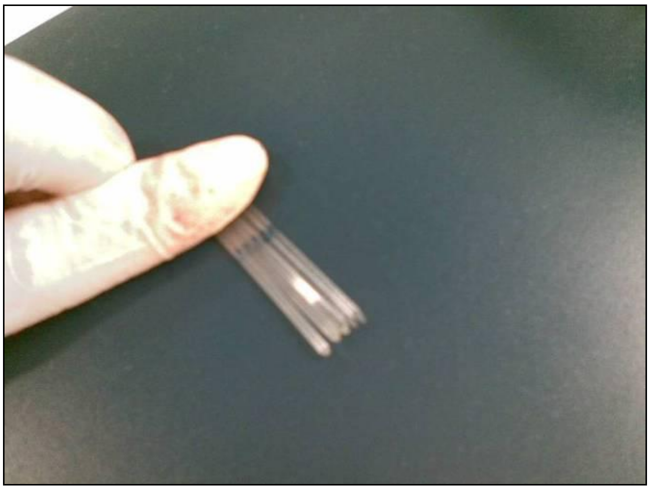
Shear Load Carrying Capacity measures the maximum force that a material can withstand before rupturing. In this comparison, the ActivaPin™ demonstrated a higher initial shear load carrying capacity than the Arthrex Trim-It™ Drill Pin, and demonstrated a more consistent declination curve.

The results are represented graphically in the figure below. The error bars represent the measured minimum and maximum values at a specific time point.

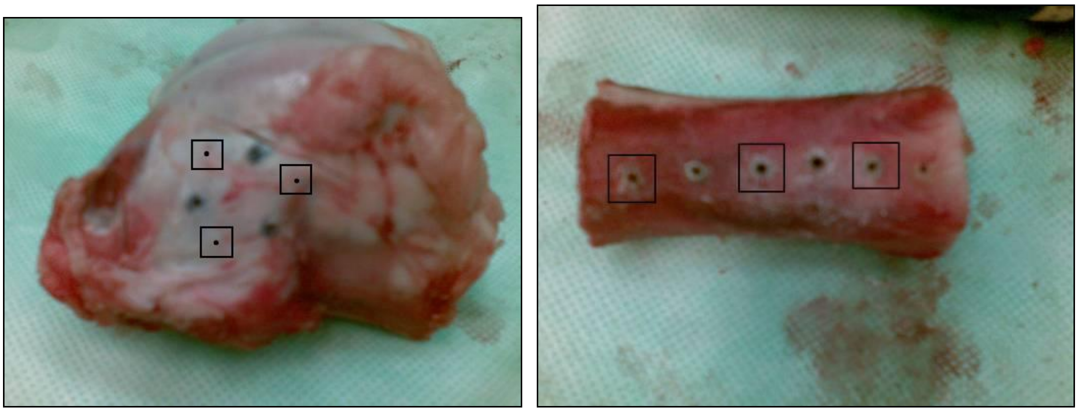


Biomechanical Pull-Out

Biomechanical Pull-Out measures the force required to dislodge a seated implant.



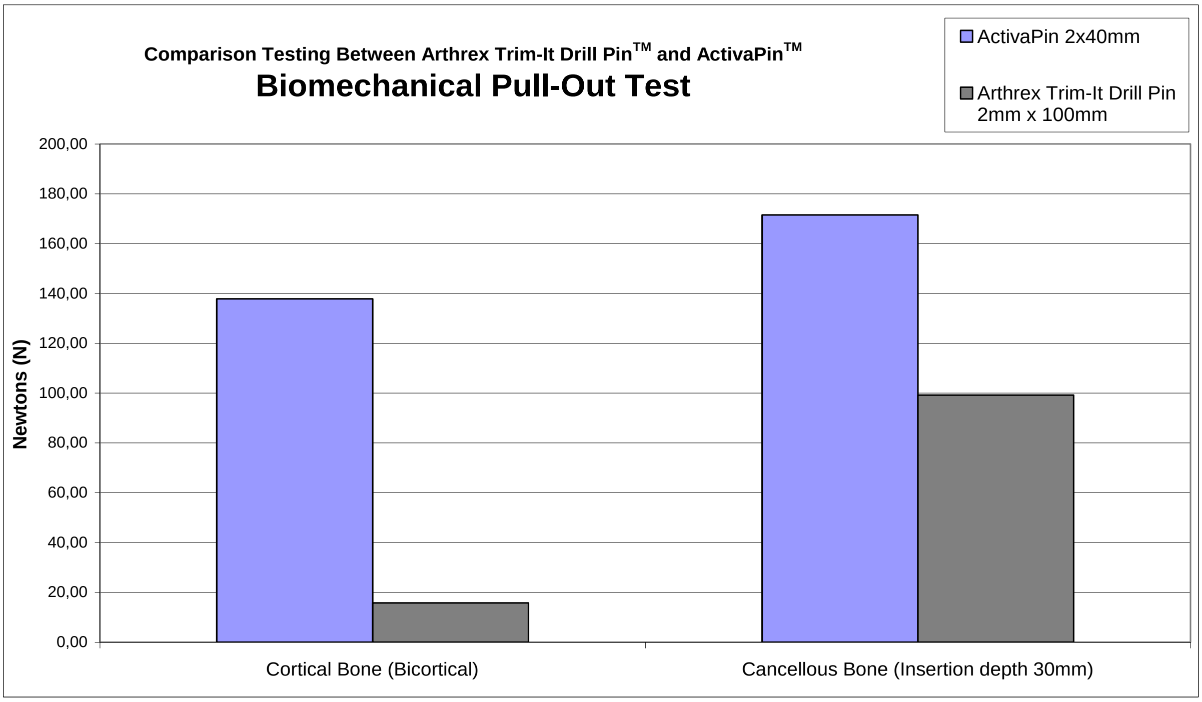
Because the nominal length of the ActivaPin™ implants were 40mm and the Arthrex implants were 100mm, all samples were marked with a 30mm insertion depth line, and the same insertion depth was used for all samples during testing.



Drill Hole Matrix for cancellous (left) and cortical bone (right)

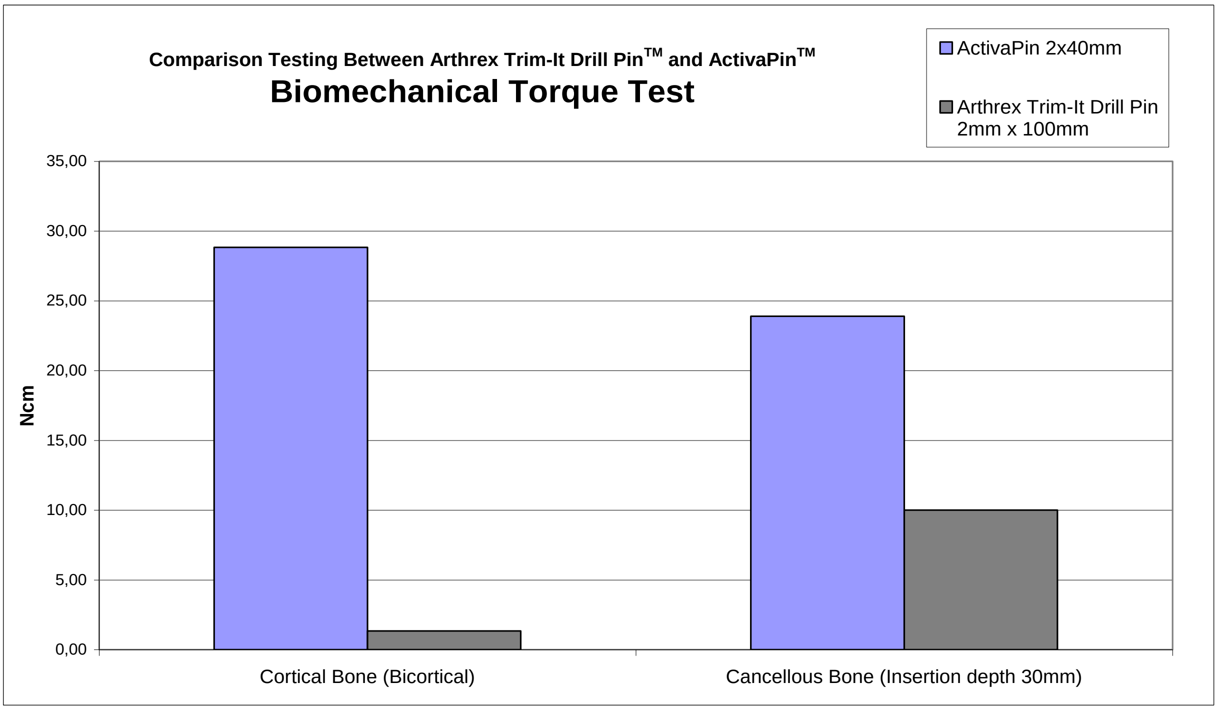
All pins were inserted into the same porcine cadaver bone (distal head of femur) with decentralization matrix to minimize effects of the bone quality. All tests were made using three parallel test specimens from both companies inserted into the same piece of bone.

In this comparison, the ActivaPin™ demonstrated a clearly higher Pull-Out force requirement than the Arthrex Trim-It™ Drill Pin.



Biomechanical Torsional Stability

Biomechanical Torque test measures the force required to rotate an object about its longitudinal axis. In this comparison, the ActivaPin™ demonstrated a clearly higher Torque resistance than the Arthrex Trim-It™ Drill Pin.



Conclusion

Biomechanical and mechanical properties of the Bioretec ActivaPin™ and a competitive device, the Arthrex Trim-It Drill Pin™, were tested with comparison bench tests. These tests demonstrated that the manufacturing method and material composition of the Bioretec ActivaPin™ creates higher mechanical strength and better biomechanical performance when compared with the competitive device regardless of the tested bone type or quality.