

April 8, 2008

## Introduction

Biomechanical and mechanical tests were performed to compare the Bioretec ActivaPin™ with a competing bioabsorbable pin implants from INION. Testing was conducted by Bioretec Ltd<sup>1</sup>, Tampere Finland, using Bioretec's test facilities. Testing was performed with 1.5mm and 2.0mm (diameter) pin implants.

## Product Descriptions

Product Description	Product Reference Code	Diameter	Length
ActivaPin™ 1.5 mm	B-AP-1540	2.0mm	40mm
ActivaPin™ 2.0 mm	B-AP-2040	2.0mm	40mm
ActivaPin™ 3.2 mm	B-AP-3240	3.2mm	40mm
Inion 1.5 OTPS™ Pin	REF PIN-1540	1.5 mm	40 mm
Inion 2.0 OTPS™ Pin	REF PIN-2040	2.0 mm	40 mm

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

Inion OTPS™ Pins are made of degradable co-polymers composed of L-lactic, D-lactic and trimethylene carbonate.

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<sup>1</sup> Test data on file at Bioretec Ltd.

<sup>2</sup> Data on file at Bioretec Ltd.

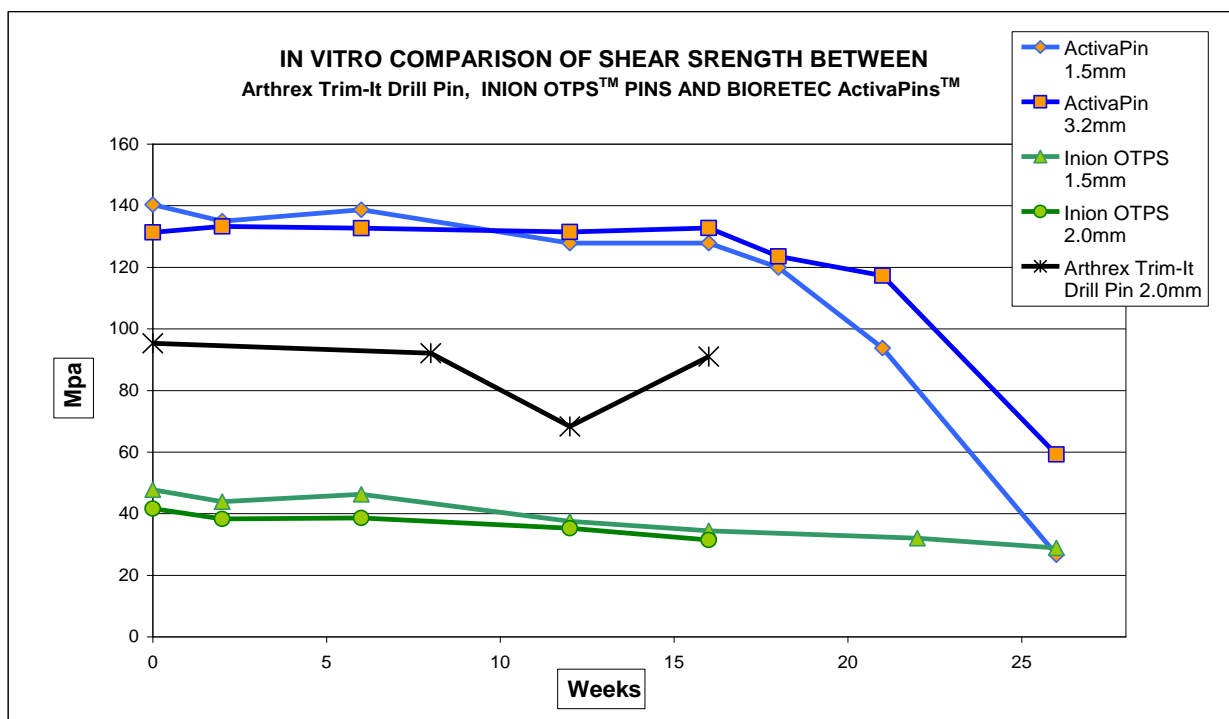
April 8, 2008

## Shear Strength

The objective of this test was to measure and compare the maximum shear load carrying capacity of the test specimen. Shear Load Carrying Capacity measures the maximum force that a material can withstand before rupturing. *In Vitro* testing was carried out to compare the shear strength retention behavior of the test specimen.

The Shear Strength (MPa) was calculated by dividing the load (N) by the area of the sheared cross section. Shear load value was used, to compare load carrying capacities of the devices with several different diameters.

In this comparison, the ActivaPin™ demonstrated a higher initial Shear Strength than the Inion OTPS™ Pin. The results are represented graphically in the figure below.



April 8, 2008

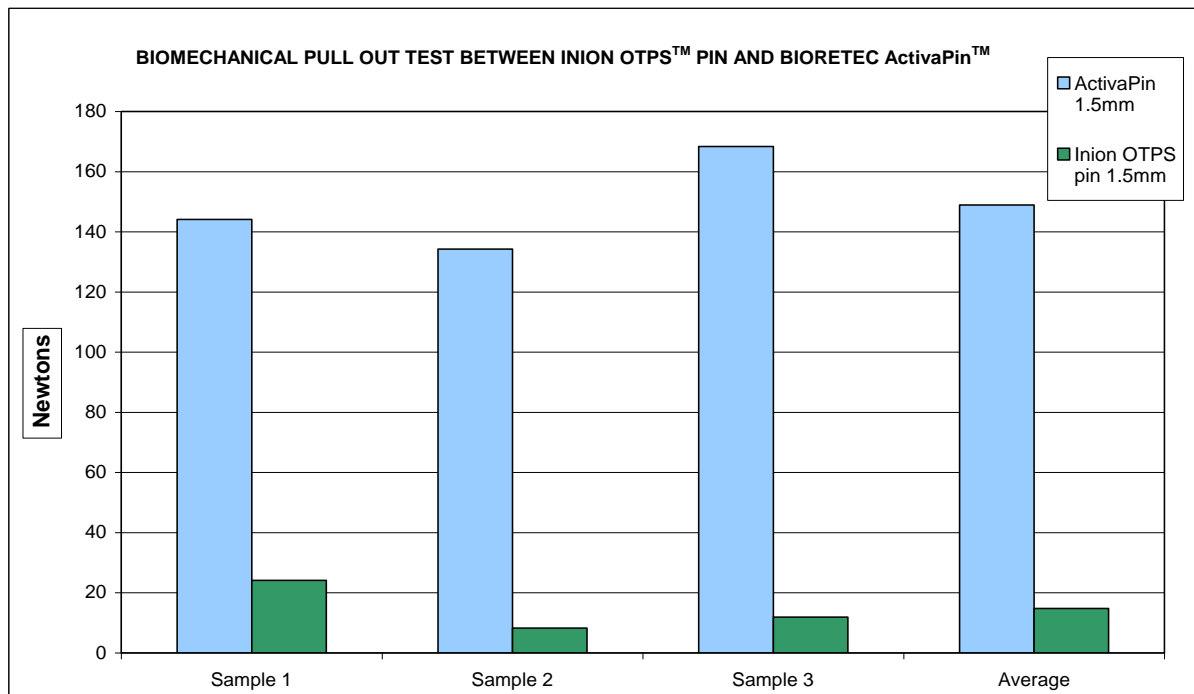
## Biomechanical Pull-Out

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

All the tested pins were inserted into the same porcine cancellous bone to minimize the effect of different bone qualities. Insertion depth into the bone was same (20mm) for all test specimens.



In this comparison, the ActivaPin™ demonstrated a clearly higher Pull-Out force requirement than the Inion OTPS™ Pin.



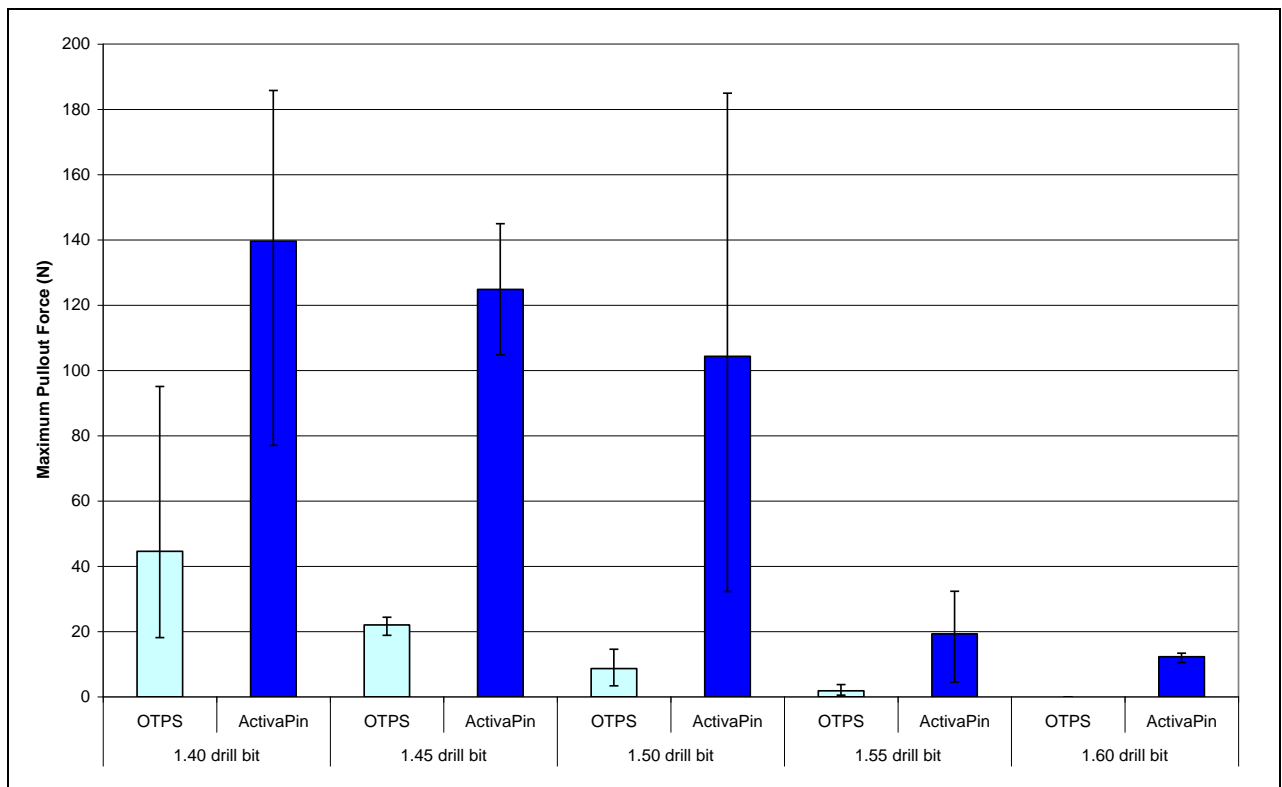
April 8, 2008

## Biomechanical Pull-Out Test with Variable Drill Holes

The objective for the test was to compare influence of the different drill bit diameters into the biomechanical pull-out forces. This test was executed to evaluate and certify the adaptability of the pins into inaccurate drill holes caused by inaccurate drill bit diameter or multiple reaming.

Pins were inserted into the distal end of a porcine cadaver femur. Three parallel samples of both pins were inserted 20 mm deep into drill holes made with 1.40, 1.45, 1.50, 1.55 and 1.6 mm drill bit.

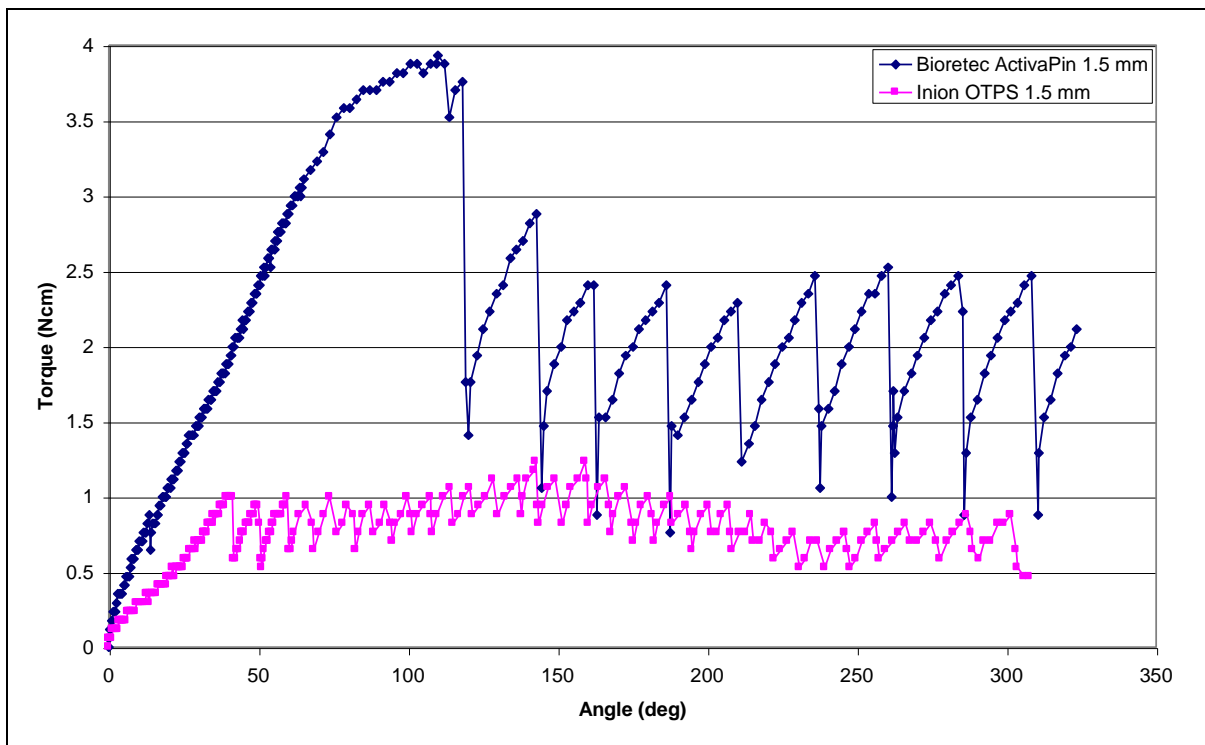
The biomechanical average maximum pull-out force of Bioretec ActivaPin™ 1.5 mm was at least three times higher than that of Inion OTPS™ 1.5 mm Pin. Test results demonstrate that the surface design of ActivaPin™ reduces the risk of unstable fixation and gives more tolerance for instrumentation, bone quality and surgical procedure.



April 8, 2008

## Biomechanical Torsional Stability

Biomechanical Torque test measures the force required to rotate an object about its longitudinal axis. In this comparison, the ActivaPin™ with grooved surface design demonstrated improved rotation stability and a clearly higher Torque resistance than the Inion OTPS™ Pin.



## Conclusion

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