

June 19, 2008

1 Introduction

Biomechanical and mechanical tests were performed to compare the Bioretec ActivaScrews™ with a competing bioabsorbable pin implants from INION. Testing was conducted by Bioretec Ltd¹, Tampere Finland, using Bioretec's test facilities. Testing was performed with 2.0mm and 4.5mm (outer diameter) screw implants.

Product Descriptions

Product Description	Product Reference Code	Diameter	Length
Bioretec ActivaScrew™ 2.0 x 20 mm	B-AS-2020	2.0 mm	20 mm
Bioretec ActivaScrew™ 4.5 mm x 45 mm	B-AS-4545	4.5 mm	45 mm
Inion 2.0 x 20 mm OTPS™ Screw	FRF-1289	2.0 mm	20 mm
Inion 4.5 x 45 mm OTPS™ Screw	FRF-1245	4.5 mm	45 mm

Bioretec ActivaScrew™ is constructed of the bioabsorbable PLGA copolymer (L-lactide-co-glycolide). The PLGA polymers have a long history of safe medical use², and degrade *in-vivo* by hydrolysis into alpha-hydroxy acids that are metabolized by the body.

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

¹ Tornier has exclusive rights to distribute Bioretec products in the United States under the NexFix™ RFS brand. Test data on file at Bioretec Ltd.

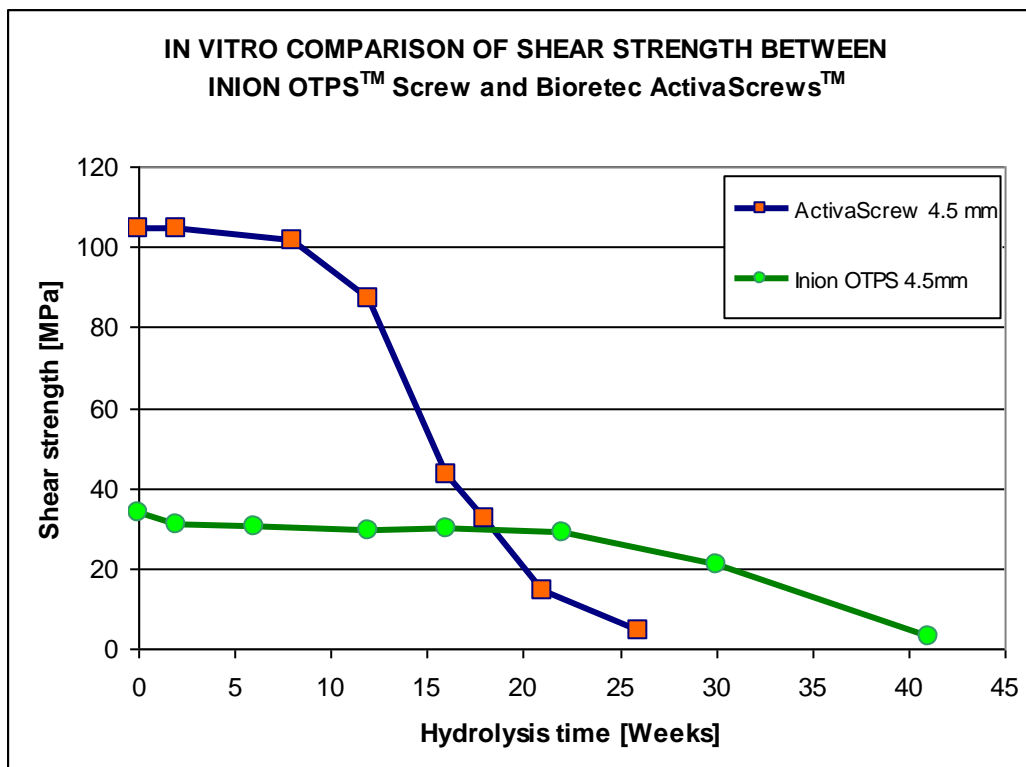
² Data on file at Tornier.

2 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 strength value was used to compare load carrying capacities of the devices with several different diameters.

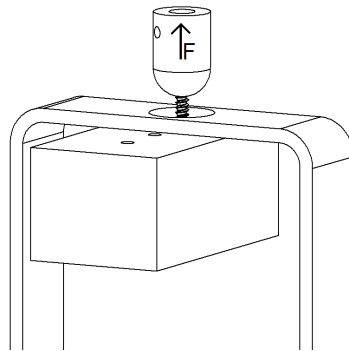
In this comparison, the Bioretec ActivaScrew™ demonstrated a higher initial Shear Strength than the Inion OTPS™ Screw. The results are represented graphically in the figure below.



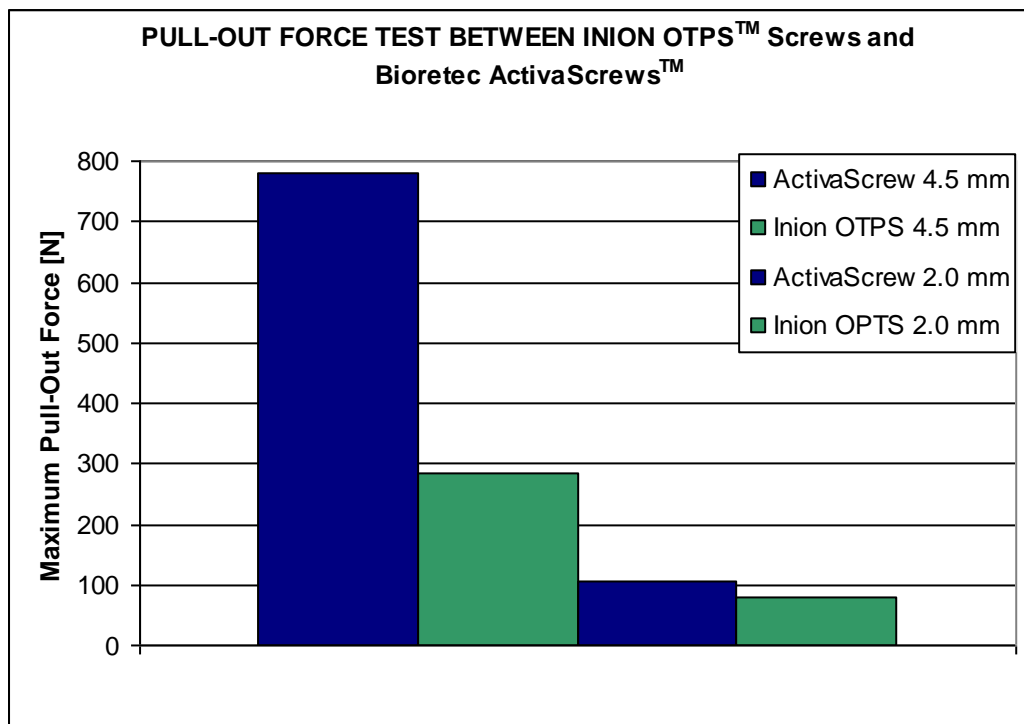
3 Pull-Out Force

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

To better compare the results, artificial bone (Sawbones Europe AB, Grade 20pcf) was used as a test substance. All the tested screws were inserted with 5 threads outside the test substance.



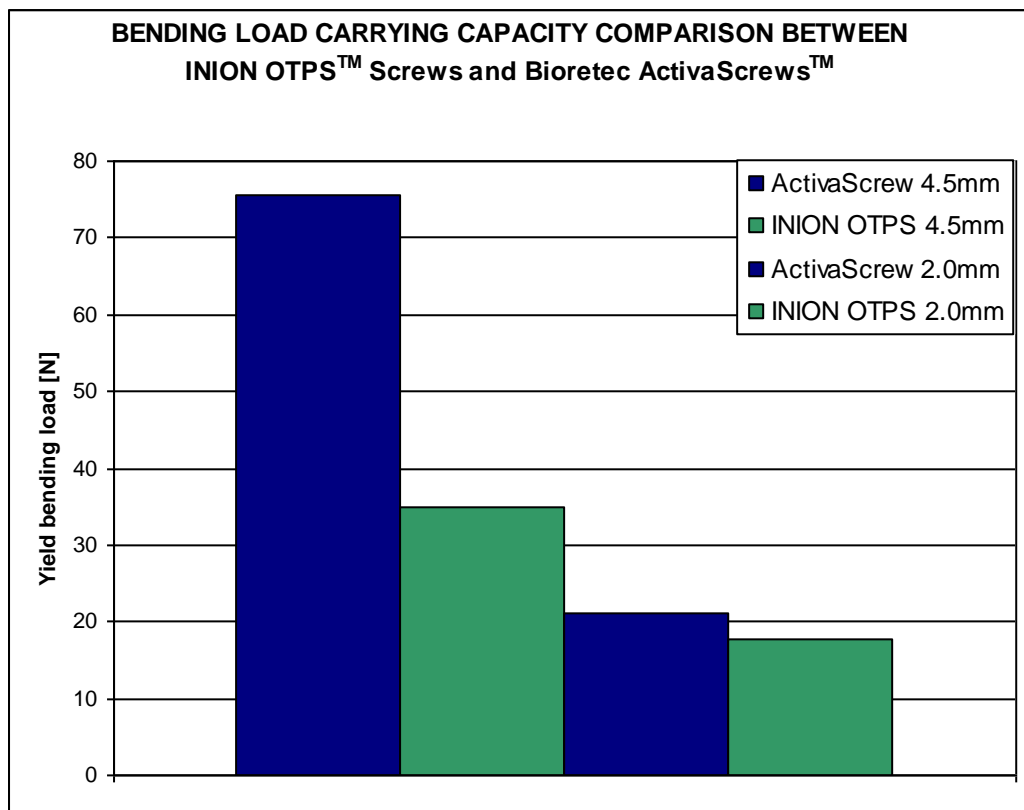
In this comparison, the Bioretec ActivaScrew™ demonstrated a clearly higher Pull-Out force requirement than the Inion OTPS™ Screw.



4 Bending Test

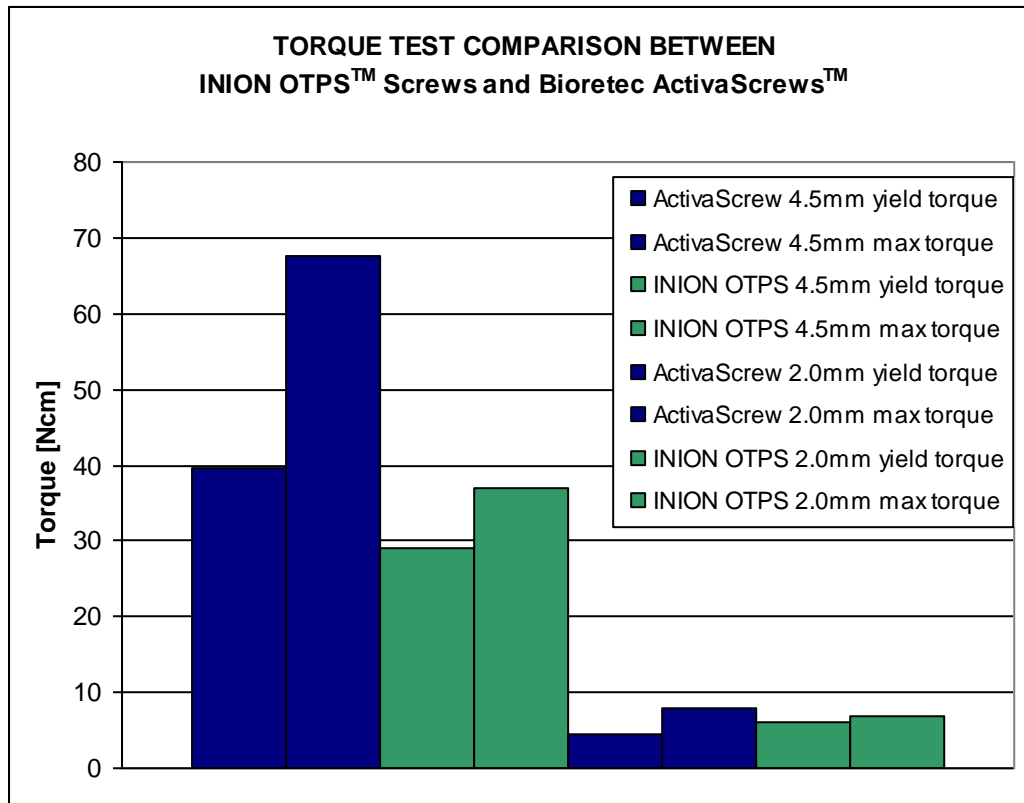
The objective for the bending test was to compare the bending load carrying capacity of the sample screws. The identical test setup was used for screws of similar size to better compare the results.

In this comparison, the yield bending load carrying capacity Bioretect ActivaScrew™ was higher than that of Inion OTPS™ Screws.



5 Torsional Stability

Torsional Stability test measures the torque required to break an object by twisting. In this comparison, the Bioretec ActivaScrew™ demonstrated improved Torsional Stability and a clearly higher Torque resistance than the Inion OTPS™ Screw.



6 Conclusion

Mechanical properties of the Bioretec ActivaScrew™ and a competitive device, the Inion OTPS™ Screw, were tested with comparison bench tests. These tests demonstrated that the manufacturing method and material composition of the Bioretec ActivaScrew™ creates higher mechanical strength and better mechanical performance when compared with the competitive device.