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1 Introduction

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

Product Descriptions

Product Description	Product Reference Code	Diameter	Length
ActivaScrew™ Cannulated 4.5 mm x 45 mm	B-ASC-4545	4.5 mm	45 mm
Inion 4.5 x 90 mm OTPS™ Cannulated Screw	FRF-1275	4.5 mm	90 mm

Bioretec ActivaScrews™ Cannulated are 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™ Cannulated 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.

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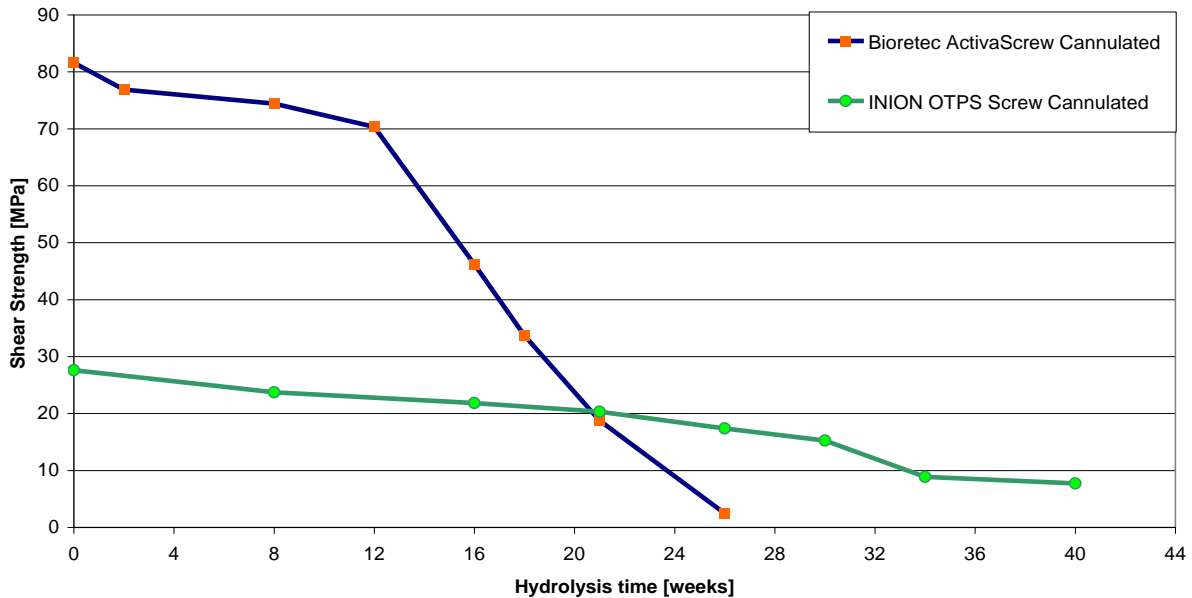
2 Shear Strength

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™ Cannulated demonstrated a higher initial Shear Strength than the Inion OTPS™ Cannulated Screw. The results are represented graphically in the figure below.

Shear Strength of 4.5 mm Cannulated Screws

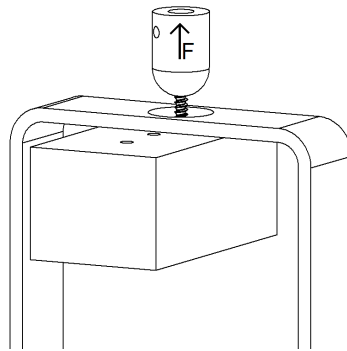


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3 Pull-Out Force

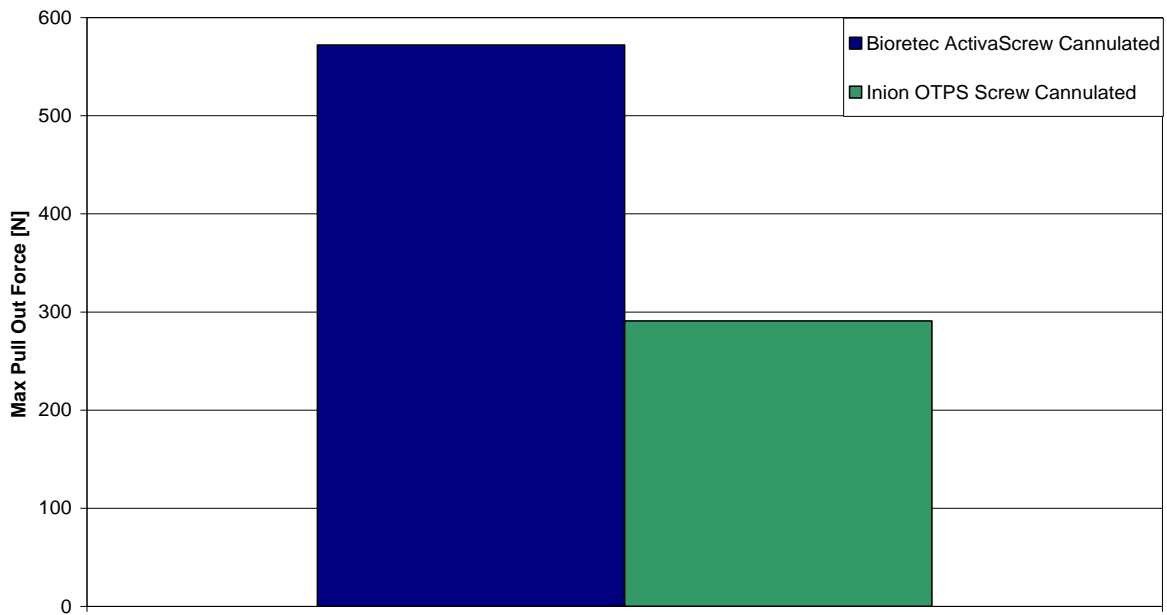
Pull-Out Force measures the force required to dislodge a seated implant.

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™ Cannulated demonstrated a clearly higher Pull-Out force requirement than the Inion OTPS™ Cannulated Screw.

Pull-Out Force of 4.5mm Cannulated Screws



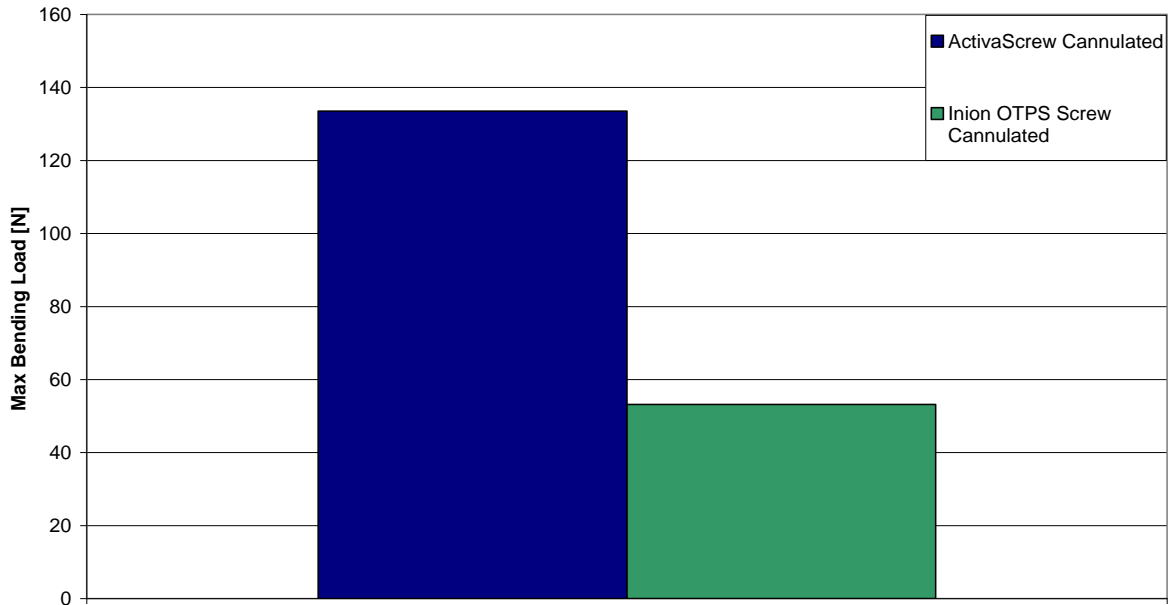
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4 Bending Test

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 Bioretec ActivaScrews™ Cannulated was higher than that of Inion OTPS™ Cannulated Screws.

4.5 mm Cannulated Screw Bending Load Carrying Capacity

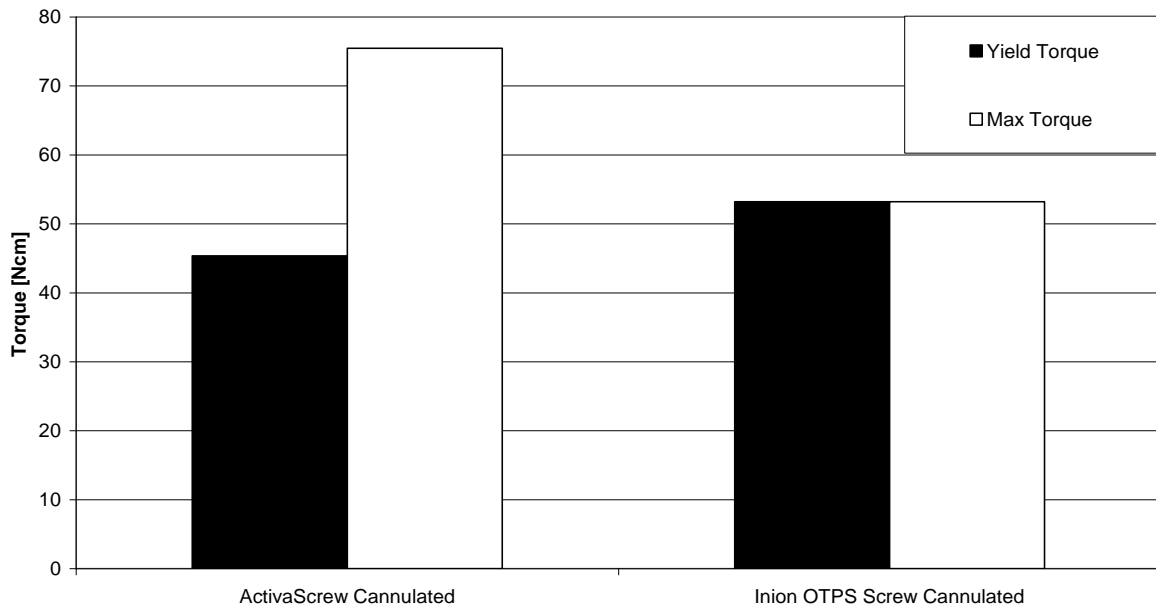


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5 Torsional Stability

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

4.5mm Cannulated Screw Torque Test



6 Conclusion

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