

Biomechanical Testing of the Arcuro Medical SuperBall™ and the Smith & Nephew FAST-FIX™ 360 Implants

Objective

The objective of this test procedure as designed was to evaluate the displacement throughout the application of repeatable tension (cyclic loading) and the force required for the retraction, i.e., the pullout force of the implant after its deployment. This test has been designed as a comparison study evaluating the displacement through cyclic loading and the force required for said pullout force for both the Arcuro Medical SuperBall™ and the Smith & Nephew FAST-FIX™ 360 implants utilizing an identical test method and test media.

Methods and Materials

The test articles were deployed upon the meniscus simulating material, both according to manufacture specifications. After deployment, the test articles were mounted upon a designated universal testometric tensile testing machine fixture and direct cyclic loading was applied to a predetermined rate for a total of 1000 cycles. The maximal displacement was measured.

Following the applied 1000 cycles, a tensile force was applied until a failure occurred. A failure was characterized as either a suture failure or an implant detachment (pullout) from the simulating material.

Results and Conclusions

Not only were the displacement ranges for the Arcuro Medical SuperBall™ implants better than the Smith & Nephew FAST-FIX™ 360 implants but the noted variations were also smaller (Table 1). The force [N] required for the pulling of the SuperBall™ implants from the simulating material, yielded higher results (on average) when compared to the FAST-FIX™ 360 device implants. The average force [N] required for the ultimate pullout of the SuperBall™ implants was documented at 107.8N while the average force for the FAST-FIX™ 360 implants was documented at 76.9N (Table 2).

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Table 1: Mean - Displacement [mm] after 1000 Cycles

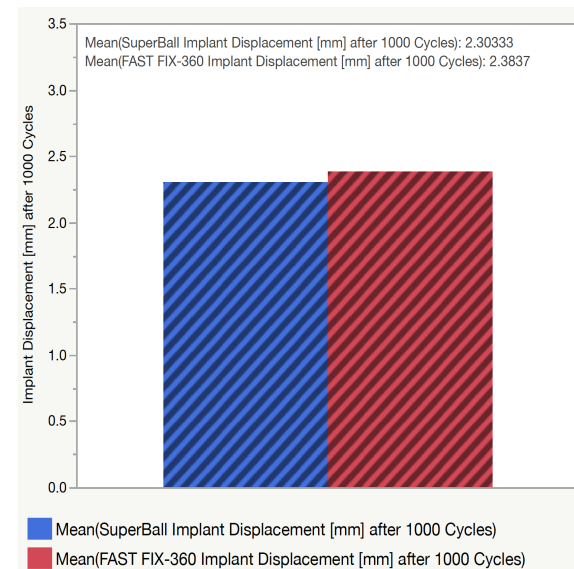


Table 2: Mean – Peak Load [N] after 1000 Cycles

