Biomechanical Testing of the Arcuro Medical SuperBallTM and the Smith & Nephew FAST-FIXTM 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 SuperBallTM and the Smith & Nephew FAST-FIXTM360 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.

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

3.5

Mean(SuperBall Implant Displacement [mm] after 1000 Cycles): 2.30333
Mean(FAST FIX-360 Implant Displacement [mm] after 1000 Cycles): 2.3837
3.0

2.0

1.5

0.5

Mean(SuperBall Implant Displacement [mm] after 1000 Cycles): 2.3837

Mean(SuperBall Implant Displacement [mm] after 1000 Cycles)

Mean(FAST FIX-360 Implant Displacement [mm] after 1000 Cycles)

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 SuperBallTM implants better than the Smith & Nephew FAST-FIXTM360 implants but the noted variations were also smaller (Table 1). The force [N] required for the pulling of the SuperBallTM implants from the simulating material, yielded higher results (on average) when compared to the FAST-FIXTM 360 device implants. The average force [N] required for the ultimate pullout of the SuperBallTM implants was documented at 107.8N while the average force for the FAST-FIXTM360 implants was documented at 76.9N (Table 2).

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