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Biomechanical Comparison of 8 Soft Tissue Devices for Tibial Fixation of Anterior Cruciate Ligament Reconstruction Grafts

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Summary:
The purpose of this study was to biomechanically evaluate eight different intratunnel tibial soft tissue fixation devices in response to cyclic and pull-to-failure loading.

Abstract:
Background:
The tibial fixation site has been reported to be the weakest point in anterior cruciate ligament (ACL) reconstructions. Numerous interference screws and combination sheath and screw devices are available for soft tissue fixation. The purpose of this study was to biomechanically evaluate eight different intratunnel tibial soft tissue fixation devices in response to cyclic and pull-to-failure loading. We hypothesized that all tested devices would provide sufficient fixation properties to allow for secure primary fixation of the graft.

Materials and Methods:
Eight different intratunnel tibial soft tissue fixation devices were biomechanically tested in a porcine model with bovine tendons, with 10 specimens per group. The soft tissue fixation devices included three interference screws – the Biointerference screw, BIOSURE PK, and RCI Screw – and five combined sheath and screw devices (combination devices) – the AperFix II, BIOSURE SYNC, ExoShape, GraftBolt, and INTRAFIX. The specimens were subjected to cyclic and pull-to-failure loading with a dynamic tensile testing machine. Ultimate failure load (N), cyclic displacement (mm), pull-out stiffness (N/mm), displacement at failure (mm), load at 3 mm displacement (N), mechanism of failure, and device removal time (sec) were recorded.

Results:
The ultimate failure loads (N) were highest for the GraftBolt (1136 ± 115.6), followed by the INTRAFIX (1127 ± 155.0), AperFix II (1122 ± 182.9), BIOSURE PK (990.8± 182.1), Bio-Interference Screw (973.3 ± 95.82), BIOSURE SYNC (829.5 ± 172.4), the RCI Screw (817.7 ± 113.9) and ExoShape (814.7 ± 178.8). The AperFix II, GraftBolt, and INTRAFIX devices were significantly stronger than the BIOSURE SYNC, RCI Screw, and ExoShape. The least amount of cyclic displacement (mm) after 1000 cycles was observed for the GraftBolt (0.65 ± 0.09), followed by the INTRAFIX (0.76 ± 0.07), RCI Screw (0.97 ± 0.22), AperFix II (1.58 ± 0.21), Bio-Interference Screw (1.61 ± 0.22), ExoShape (1.68 ± 0.30), BIOSURE PK (1.72 ± 0.29), and BIOSURE SYNC (1.92 ± 0.59). The GraftBolt and INTRAFIX devices and the RCI Screw allowed significantly less displacement than all other groups ($P<0.05$).

Conclusion:
We confirmed our hypothesis that all tested devices would provide sufficient fixation characteristics to allow for secure primary tibial fixation of a soft tissue graft.