A study of bone-to-bone grafts showed 100% circumferential ingrowth at 12 weeks for ACL reconstruction using hamstring tendons. No statistical difference emerged between the RIGIDfix 3.3-mm ACL Cross Pins and the EndoButton.

In a soft-tissue procedure, how do I get the tendons to loop over the pins?

It is not necessary to loop the graft over the pins. The semitendinosus and gracilis tendons are whipstitched at the looped end, forming a tight bundle that is placed into the femoral tunnel. This allows RIGIDfix absorbable pins to cross the graft in any plane and still provide rigid fixation.

**Figure 3.** Average Migration—RIGIDfix Cross Pins versus EndoButton

<table>
<thead>
<tr>
<th>Orientation</th>
<th>Average Migration (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long (parallel to axis)</td>
<td>1.40</td>
</tr>
<tr>
<td>Oblique</td>
<td>1.60</td>
</tr>
<tr>
<td>Matrix</td>
<td>1.40</td>
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</tbody>
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The Mitek RIGIDfix Cross Fix System offers an absorbable means of fixing grafts during anterior cruciate ligament (ACL) reconstruction, providing 360° of bone-to-graft contact. The pins are available in two sizes: the 3.3-mm diameter, used for soft-tissue (ST) grafts, and the 2.7-mm diameter, used for bone-to-tendon-bone (BTB) grafts. The following studies prove that the RIGIDfix System meets or exceeds all industry criteria for reliable performance.
PULLOUT STRENGTH

How does the pullout strength of RIGIDfix™ ACL Cross Pins compare to market standards for soft-tissue and bone-tendon-bone procedures?

Biological Ingrowth

What advantages do Mitek RIGIDfix Cross Pins provide in a bone-tendon-bone procedure, compared to a bioabsorbable interference screw?

Related Issues

What happens to pin strength during the first 8 weeks of healing?

Soft Tissue (ST)

As in vitro comparison of Mitek® RIGIDfix™ 2.7-mm absorbable cross pins in the literature, 2-mm BioScrew™ was conducted in cadavers using bone-patellar tendon-bone grafts to reconstitute the ACL. The comparison demonstrated no significant difference in the initial fixation strength and stiffness of the two fixation methods.

Bone-Tendon-Bone (BTB)

As in vitro comparison of Mitek® RIGIDfix™ 2.7-mm absorbable cross pins in the literature, 2-mm BioScrew™ was conducted in cadavers using bone-patellar tendon-bone grafts to reconstitute the ACL. The comparison demonstrated no significant difference in the initial fixation strength and stiffness of the two fixation methods.

Figure 1.—Initial Strength and Stiffness in Soft-Tissue ACL

Reconstruction Procedure: RIGIDfix Cross Pins versus Smith & Nephew EndoButton

Figure 2.—Initial Strength and Stiffness in BTB

Reconstruction Procedure: RIGIDfix Cross Pins versus Smith & Nephew EndoButton

Figure 3.—Percentage of Cross Pins Failure in Short-Term Studies

Figure 4.—Percentage of Cross Pins Failure in Long-Term Studies

3-Week Results: Both the Mitek cross-pin and the BioScrew groups demonstrated a close apposition between the bone plug and the drill hole. Both groups showed early signs of healing, and there was no apparent adverse local reaction in the Mitek BTB cross-pin and the BioScrew. In both groups, alignment (wedge) between the endo Button and the bone plug appeared to be “stabilized” around the screw. This suggests that the plug may have split at the interface and that the screw may settle deeper in the plug.

6-Week Results: The bone plugs showed good integration into the surrounding bone in both groups. Evidence of undehumified bone repair was apparent throughout the interface of the bone plug and the surrounding bone. There was no evidence of implant migration, bone loss, or reaction in any of the specimens examined. There was no evidence of tissue reaction to either implant. Two of the 6-week BioScrew specimens wrapped the screw to “settle” deeper into the plug.

12-Week Results: Mature bone was seen bridging the interface between the bone plug and the surrounding bone tissue in all specimens. Evidence of endochondral ossification during the first 8 weeks of healing? This study demonstrates that Mitek BTB cross pins do not affect the normal incorporation of a cortical/ cancellous bone plug in comparison to an absorbable interference screw (Linvatec BioScrew). The study also shows that Mitek BTB cross pins permit a significantly (p<0.001) larger healing surface area for the bone plug compared to an absorbable interference screw (Linvatec BioScrew).

Studies conducted by Mitek Products staff engineer. On file at Mitek Products, Westwood, Mass.

Studies conducted by Steven Arnoczky et al.: The healing of corticocancellous bone plugs fixed with Mitek BTB cross pins and with an absorbable interference screw (Linvatec BioScrew). Results were statistically significant at all time periods.

Bone Healing: All bone plugs demonstrated a progressive incorporation into the host bed and there were no indications of implant migration, failure, or reaction in any of the specimens examined.

Bone-Tendon-Bone (BTB) Repair

The bone plugs showed good integration into the surrounding bone in both groups. Evidence of undehumified bone repair was apparent throughout the interface of the bone plug and the surrounding bone. There was no evidence of implant migration, bone loss, or reaction in any of the specimens examined. There was no evidence of tissue reaction to either implant. Two of the 6-week BioScrew specimens wrapped the screw to “settle” deeper into the plug.

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