CYCLIC LOADING

Will the pins deform or deflect, causing graft laxity?

A cadaver test was conducted to evaluate the effects of cyclic loading. The test compared RIGIDfix™ 3.3-mm-diameter ACL Cross Pins to the EndoButton® for ACL reconstruction using hamstring tendons. No statistical difference emerged between the RIGIDfix 3.3-mm ACL Cross Pins and the EndoButton.[4]

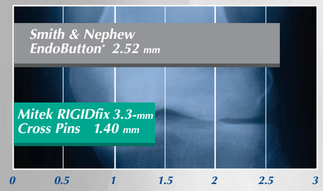


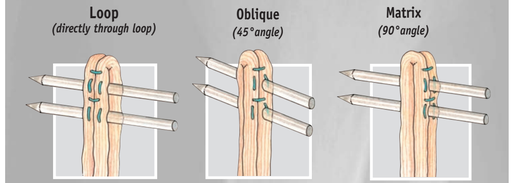
Figure 3.—Average Migration—RIGIDfix Cross Pins versus EndoButton*

*EndoButton with 25-mm length of Dacron tape.

ORIENTATION

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 semi-t 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.[5]

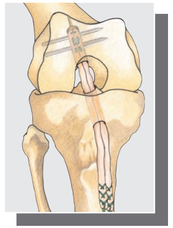


Average Migration—RIGIDfix Cross Pins versus EndoButton

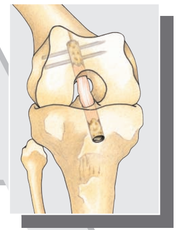
[4] *From a cadaver study conducted by Benjamin J. Ellis and Jeffrey A. Weiss: Cyclic stability of Mitek cross pins when used for hamstring and bone-tendon-bone grafted ACL reconstruction. Orthopedic Biomechanics Institute, Salt Lake City, May 1998. Study on file at Mitek Products, Westwood, Mass.*

[5] *From a study by John R. West and Richard Greenwald: In vitro evaluation of the effect of cross-pin orientation on the ultimate strength of hamstring grafts in anterior cruciate reconstruction. Orthopedic Biomechanics Institute, Salt Lake City, October 1997. Study on file at Mitek Products, Westwood, Mass.*

Soft-Tissue (ST)



Bone-Tendon-Bone (BTB)



Mitek® PRODUCTS
ETHICON
a Johnson & Johnson company

RIGIDfix™
ACL CROSS PIN SYSTEM

INDICATIONS

Femoral fixation of autograft or allograft ACL graft material, either soft-tissue (semitendinosus and gracilis) or bone-tendon-bone (patellar tendon, etc.).

CONTRAINDICATIONS

1. Pathologic conditions of bone, such as cystic changes or severe osteopenia, that would compromise secure cross-pin fixation.
2. Pathologic conditions in the graft to be attached which would impair secure fixation with the cross pins.
3. Physical conditions that would eliminate or tend to eliminate adequate implant support or that would retard healing, such as blood supply limitations, infection, etc.
4. Conditions that would tend to preempt the patient's ability to recover during the healing period, such as senility, mental illness, or alcoholism.

PRECAUTIONS

1. Surgeons should not attempt clinical use of the Mitek RIGIDfix ACL Cross Pin System before reviewing the instructions for its use and mastering the installation procedure in a skills laboratory.
2. Discard used stepped trocar in a sharps container.
3. Use Mitek RIGIDfix ACL Cross Pin instruments only with the Mitek RIGIDfix 2.7-mm (BTB) Cross Pin kit and the Mitek RIGIDfix 3.3-mm (ST) Cross Pin kit.
4. Discard used sleeve assemblies and interlocking trocars in a sharps container.

WARNINGS

Inspect all instruments for damage before use.

Do not attempt to repair a damaged instrument.

Polylactic (PLA) implants have been shown to cause some tissue reaction in a small percentage of patients.

Never re-use a Mitek RIGIDfix Cross Pin kit.

Do not re-sterilize.

Discard opened and unused RIGIDfix Cross Pins, sleeve assemblies, and interlocking trocar.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

For more information, call your Mitek representative at 1–800–382–4682 or visit www.mitek.com.
Mitek Products, Division of ETHICON, Inc., 60 Glacier Drive, Westwood, Massachusetts 02090

RIGIDfix™
ACL CROSS PIN SYSTEM

Bioabsorbable ACL Reconstruction

[1] *A study of bone-to-bone grafts showed 100% circumferential ingrowth at 12 weeks. Study conducted by Steven Arnoczky et al.: The healing of corticocancellous bone plugs fixed with Mitek BTB cross pins or an absorbable interference-fit screw (Linvatec BioScrew™) — an experimental study in dogs. Laboratory for Comparative Orthopaedics, College of Veterinary Medicine, Michigan State University. Study on file at Mitek Products, Westwood, Mass.*

TECHNICAL SUPPORT DATA

The Mitek RIGIDfix Cross Pin System offers an absorbable means of fixing grafts during anterior cruciate ligament (ACL) reconstruction, providing 360° of bone-to-graft contact.[1] 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-tendon-bone (BTB) grafts. The following studies prove that the RIGIDfix System meets or exceeds all industry criteria for reliable performance.

Q&A

Mitek® PRODUCTS

PULLOUT STRENGTH

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

Soft Tissue (ST)

An in vitro comparison of Mitek® RIGIDfix 3.3-mm absorbable cross pins to the Smith & Nephew ACUFEX® EndoButton® was conducted in cadavers, using hamstring (semi-t and gracilis) to reconstruct the ACL. The comparison demonstrated no significant difference in the initial fixation strength and stiffness of the two fixation methods.

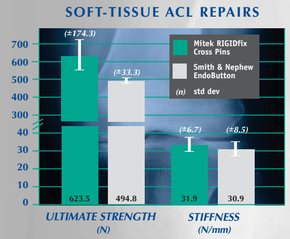


Figure 1.—Initial Strength and Stiffness in Soft-Tissue ACL Repairs: RIGIDfix Cross Pins versus Smith & Nephew EndoButton[2]

Bone-Tendon-Bone (BTB)

An in vitro comparison of Mitek RIGIDfix 2.7-mm absorbable cross pins to the Linvatec 9-mm BioScrew™ was conducted in cadavers using bone-patellar tendon-bone grafts to reconstruct the ACL. The comparison demonstrated no significant difference in the initial fixation strength and stiffness of the two fixation methods.[3]

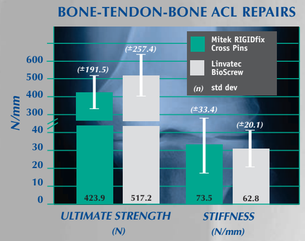


Figure 2.—Initial Strength and Stiffness in BTB ACL Reconstruction Procedures: RIGIDfix Cross Pins versus Smith & Nephew EndoButton[3]

[2]*From a cadaver study by John R. West and Richard Greenwald: In vitro comparison of Mitek 3.3-mm absorbable cross pins to ACUFEX EndoButton in hamstring-grafted anterior cruciate ligament reconstruction. Orthopedic Biomechanics Institute, Salt Lake City, October 1997. Study on file at Mitek Products, Westwood, Mass.*

[3]*Cadaver study conducted by John R. West and Richard Greenwald of Orthopedic Biomechanics Institute: In vitro investigation of Mitek 2.7-mm absorbable cross pins in patellar tendon-grafted anterior cruciate ligament surgery versus BioScrew absorbable interference screw. Study on file at Mitek Products, Westwood, Mass.*

BIOLOGICAL INGROWTH

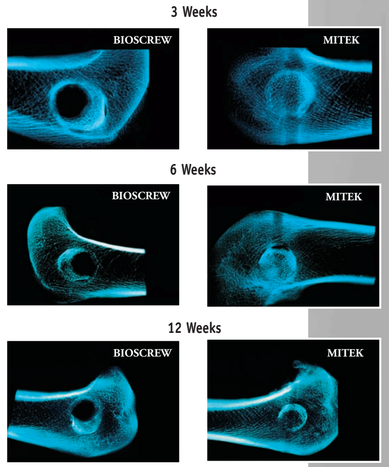
What advantages do Mitek RIGIDfix Cross Pins provide in a bone-tendon-bone procedure, compared to a bioabsorbable interference screw?

An animal study examined the osseous incorporation of a corticocancellous bone plug fixed with Mitek BTB cross pins and with an absorbable interference-fit screw (Linvatec BioScrew™).[6] Results were assessed at 3, 6, and 12 weeks' time.

The study shows that the Mitek BTB cross pin permitted 360° of bone contact between the bone plug and the walls of the drill hole. In addition, placement of the 2.7-mm pin with the guide frame allowed central positioning of the pins.

Bone Contact: The bone-to-bone contact between the bone plug and the walls of the bone tunnel was 100% in the Mitek BTB cross-pinned group and an average of 74.7% of the bone plug surface in the Linvatec BioScrew interference-fit group. 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.



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 to the Mitek BTB cross pins or the BioScrew. In three of the 3-week Linvatec BioScrew specimens, the bone plug appeared to be "wrapped around" the screw. This suggests that the plug may have split or fragmented, allowing the screw to "settle" deeper into the plug.

6-Week Results: The bone plugs showed good integration into the surrounding bone in both groups. Evidence of endochondral bone repair was apparent throughout the interface of the bone plug and surrounding host bone in all specimens. Clinical union (mineralized callus spanning the plug and the host bone) was observed in all specimens. Two of the 6-week BioScrew specimens wrapped around the screw. This suggests that the plug may have split or fragmented, allowing the screw to settle deeper in the plug. There was no evidence of tissue reaction to either implant.

12-Week Results: Mature bone was seen bridging the interface between the bone plug and the surrounding host bone in all specimens. There was no evidence of tissue reaction to either implant.

This study demonstrates that Mitek BTB cross pins do not affect the normal incorporation of a corticocancellous bone plug in comparison to an absorbable interference-fit 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-fit screw (Linvatec BioScrew).

RELATED ISSUES

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

In vitro mechanical studies conducted to assess the strength of Mitek RIGIDfix ACL Cross Pins over time showed virtually no strength reduction through 8 weeks.[7]

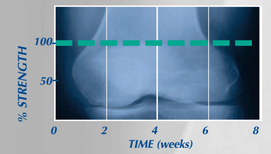


Figure 4.—Percentage of RIGIDfix ACL Cross Pin Strength Retained over Time

Is it necessary to make a lateral incision to insert the sleeves or pins?

No. Unlike other cross-pinning systems, Mitek trocar and sleeve assemblies pass percutaneously through the skin into the bone.

[6]*Study conducted by Steven Arnoczky et al.: The healing of corticocancellous bone plugs fixed with Mitek BTB cross pins or an absorbable interference-fit screw (Linvatec BioScrew)—an experimental study in dogs. Laboratory for Comparative Orthopaedics, College of Veterinary Medicine, Michigan State University. Study on file at Mitek Products, Westwood, Mass.*

[7]*Studies conducted by Mitek Products staff engineer. On file at Mitek Products, Westwood, Mass.*

RIGIDfix™ ACL Cross Pin System