

**LABORATORY DATA:
INITIAL FIXATION STRENGTH OF THE
RIGIDfix™ TIBIAL 3.3 MM ST CROSS PIN SYSTEM
WHEN USED FOR HAMSTRING GRAFTED
ACL RECONSTRUCTIONS**

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METHOD:

Eight matched pairs of human cadaver tibias were used to compare the initial tibial fixation strength of knees reconstructed using RIGIDfix Tibial 3.3 mm ST Cross Pins to Linvatec BioScrews. Each specimen was reconstructed using the appropriate device and tensile tested until failure occurred. The results were as follows:

<u>RESULTS:</u>	Ultimate Strength (N)	Stiffness (N/mm)
RIGIDfix	641 ± 196	52.3 ± 15.7
BioScrew	422 ± 208	47.2 ± 17.5

MODES OF FAILURE:

All of the RIGIDfix reconstructions failed by both pins failing. All of the BioScrew samples failed by the graft slipping past the screw.

CONCLUSION:

The Mitek RIGIDfix Tibial 3.3 mm Cross pins provided significantly stronger fixation than the Linvatec BioScrew ($p = 0.008$). There was no significant difference in the stiffness.

Indications:

The Mitek RIGIDFIX Tibial 3.3mm ST Cross Pin Kit is intended for tibial fixation of autograft or allograft ACL soft tissue grafts (semitendinosus and gracilis).

Contraindications:

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

Warnings:

1. Polylactic acid (PLA) implants have shown to cause some tissue reaction in a small percentage of patients.
2. The Mitek RIGIDFIX Tibial 3.3mm ST Cross Pin Kit must never be reused. Do not re-sterilize.
3. Discard opened and unused RIGIDFIX Cross Pins, Sleeve Assemblies and Interlocking Trocar.

Precautions:

1. Harvest the soft tissue (semitendinosus and gracilis) graft.
2. Discard used sleeve assemblies and interlocking trocars in a sharps container.



For more information, call your DePuy Mitek representative at 1-800-382-4682 or visit us at www.mitek.com. DePuy Mitek Inc., 325 Paramount Drive, Raynham, Massachusetts 02767

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