

# Load to Failure Testing of New Meniscal Repair Devices

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**Purpose:** New all-inside meniscal repair devices include those combining sutures with anchors and that allow for an “adjustable” repair. This study’s purpose was to compare the failure strength of new meniscal repair devices with suture repairs. **Type of Study:** Experimental laboratory biomechanical study. **Methods:** A single repair was placed in a vertical longitudinal peripheral tear made in fresh adult porcine menisci. Group 1 had a vertically oriented suture using the FasT-Fix (Smith & Nephew Endoscopy, Andover, MA) device. Group 2 had a horizontally oriented mattress suture using the FasT-Fix device. Group 3 had a repair using 2 Arthrex (Naples, FL) meniscal darts. The Group 4 repair used a RapidLoc (Mitek Surgical Products, Westwood, MA) device. The Group 5 repair used the Arthrotek meniscal screw (Biomet, Warsaw, IN). Group 6 had a single vertical suture, and group 7 a single horizontal suture, both of 2-0 Mersilene (Ethicon, Somerville, NJ). Load to failure testing was performed. **Results:** The vertical FasT-Fix suture had a mean load to failure of 70.9 N (1 SD  $\pm$  33). The horizontal FasT-Fix suture had a mean load to failure of 72.1 N ( $\pm$  23.5). The double Dart repair had a mean load to failure of 61.7 N ( $\pm$  19). The RapidLoc repair had a mean load to failure of 43.28 N ( $\pm$  3.98). The Arthrotek meniscal screw repair had a mean load to failure of 28.09 N ( $\pm$  7.93). Failure occurred with device pullout of the inner rim (9 of 10) for the Darts, device pullout of the inner rim (6 of 10) and pullout of the outer rim (4 of 10) for the Arthrotek screw, and suture breakage for the FasT-Fix and the RapidLoc devices. The vertical sutures’ mean load to failure was 80.43 N ( $\pm$  8.5), and all 13 failed by suture breaking. The horizontal sutures’ mean failure load was 55.9 N ( $\pm$  18.8), and failure was by both suture breaking (6 of 10) and pulling through the meniscal tissue (4 of 10). **Conclusions:** Some of the newer meniscal repair devices show improved loads to failure over earlier generations. **Key Words:** Meniscus repair—Dart—RapidLoc—FasT-Fix—Screw—All inside repair.

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Several all-inside techniques are available,<sup>1,2</sup> which avoid the passage of sutures through the skin and the potential for damage to the posterior lateral or posterior medial knee structures. Devices allowing an all-inside meniscal repair are gaining increasing acceptance,<sup>3-6</sup> and biomechanical testing has provided some basic data.<sup>4-8</sup> The purpose of this study is to compare the load to failure strength of several new meniscal repair techniques in a way that allows a comparison with previous reports.<sup>9,10</sup>

## METHODS

A vertical longitudinal tear 3 mm from the periphery of the meniscus was created with a knife in freshly harvested, never-frozen adult porcine menisci. To facilitate the repair placement, the length of the tear was not extended into the anterior and posterior meniscal horns at first to allow better control of the meniscus. A single technique was used for each meniscus to accomplish the meniscal repair. All meniscal repairs were performed centrally (at the midpoint) in the test meniscus. After the repair was complete, the two remaining tissue bridges at the meniscal horns were divided, completely separating the meniscus into two free segments, connected only by the repair. The repaired meniscus was then kept refrigerated until the completion of biomechanical testing the next day.

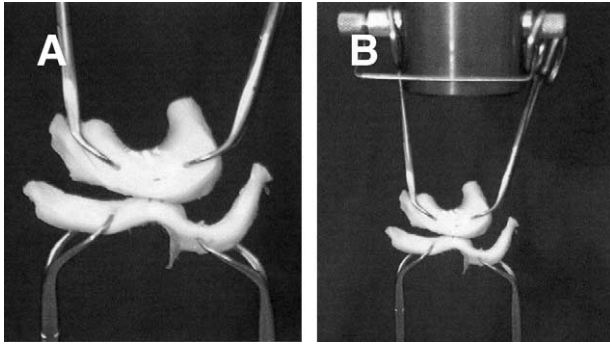
Testing was conducted on a servohydraulic materials testing machine (model 1321; Instron, Canton,

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**FIGURE 1.** Loads were parallel to the axis of the repair technique tested with both portions of the repaired meniscus (A) held with metal clamps (B) attached to the Instron machine.

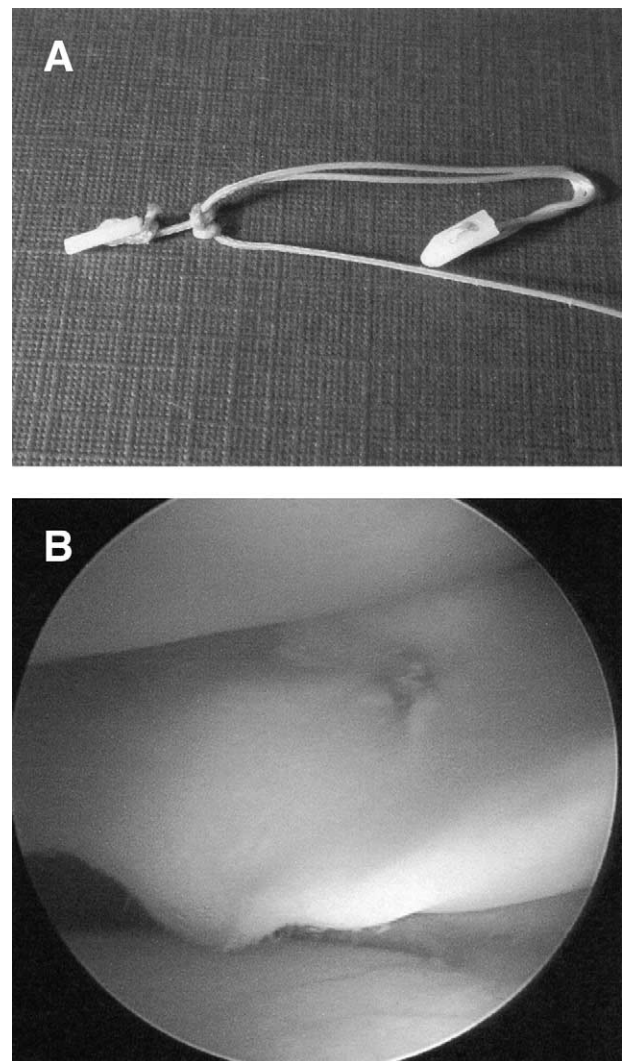
MA) to determine load to failure strength. The pullout stress was always parallel to the axis of the repair technique tested. A displacement rate of 5 mm/min was selected to be consistent with previous studies<sup>9,10</sup> and a previous part of this study.<sup>9</sup> Both portions of the repaired meniscus were held with metal clamps that were attached to the Instron machine (Fig 1). This allowed the consistent application of force to the repair system and eliminated the plastic deformation associated with suture materials. The sampling rate for force and position data was 50/s. This was downloaded into a spreadsheet, processed using a visual basic for applications encoded Excel (Microsoft, Redmond, WA) spreadsheet program, and analyzed using SAS (SAS Institute, Cary, NC). Data were subjected to descriptive statistical analysis, analysis of variance (ANOVA), Duncan's multiple range tests, correlation analysis, and linear modeling as appropriate.

Group 1 had a vertically oriented suture using the FasT-Fix device (Smith & Nephew Endoscopy, Andover, MA) (Fig 2A) placed on the superior surface of the meniscus, 3 mm inside the tear and angled to orient one arm toward the superior peripheral capsule and the second toward the inferior meniscal capsule (n = 14). The FasT-Fix device consists of two 5-mm polyacetyl bars connected by a double No. 0 braided polyester suture that has a pretied slip knot for easy deployment (Fig 2B). Group 2 had a horizontally oriented mattress suture using the FasT-Fix device placed on the superior surface of the meniscus 3 mm inside the tear with arms 3 mm apart (n = 16).

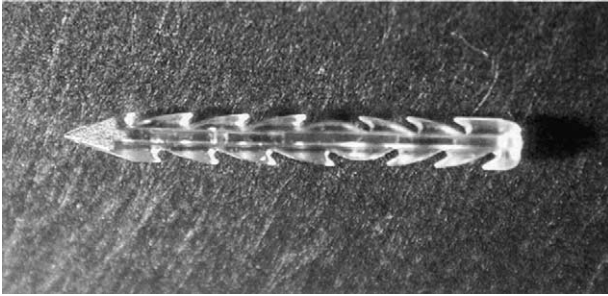
Group 3 had a repair using two 12-mm Arthrex meniscal Darts (Arthrex, Naples, FL) inserted by a gun 3 mm in from the tear, and impacted to place the device below the meniscal surface (n = 10). The Dart

is a poly-D (30%) L (70%) lactic acid copolymer that is gamma irradiated. It possesses a double reverse bard design without a head and must be used as a pair. The Dart has a diameter of 1.3 mm and is available in 10-, 12-, and 14-mm lengths (Fig 3). Two Darts were used for this repair because Arthrex recommends that 2 devices (not one) be used for a repair, and this stipulation is also in the Food and Drug Administration (FDA)-approved product guide.

Group 4 had a repair using a RapidLoc device (Mitek Products, Westwood, MA) inserted using the associated insertion gun 3 mm inside the tear (n = 14). It consists of a poly-L-lactic acid (PLLA) "top



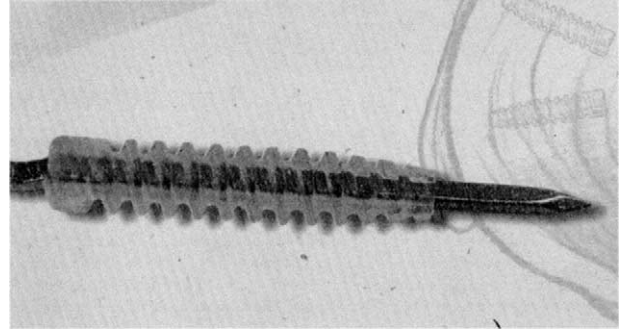
**FIGURE 2.** (A) Meniscal repair devices tested include the FasT-Fix, which has 2 polyacetyl bars connected by a double No. 0 braided polyester suture. (B) When implanted, only the suture is visible.



**FIGURE 3.** The Dart is a headless PDLLA device with reversed barbs. The Dart has a diameter of 1.3 mm and is available in 10-, 12-, and 14-mm lengths.

hat” and bar that are connected by either 2-0 Ethibond or Panacryl (Ethicon, Somerville, NJ) sutures. The bar serves as an anchor that is passed through the meniscus into the capsule. Clinically, the insertion of this device requires use of a guide to avoid the soft tissue (Fig 4A). The “top hat” is backed up by a sliding knot, which when advanced by pulling the suture and pushing the top hat using a single lumen knot pusher, should dimple the meniscal surface (Fig 4B).

Group 5 had a repair using the Arthrotek meniscal screw (Biomet, Warsaw, IN) placed 3 mm inside the tear (while firmly approximating the 2 meniscal segments) by pressure from the hand drill during insertion ( $n = 10$ ). The cannulated screw has a constant pitch and is made of 82% PLLA and 18% poly glycolide

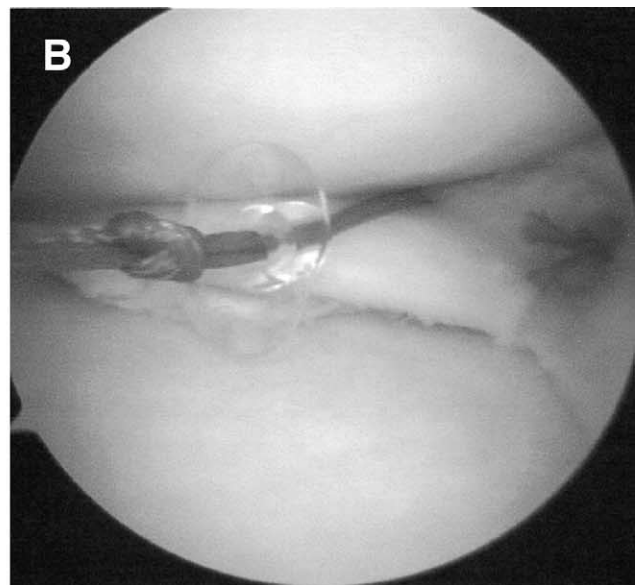
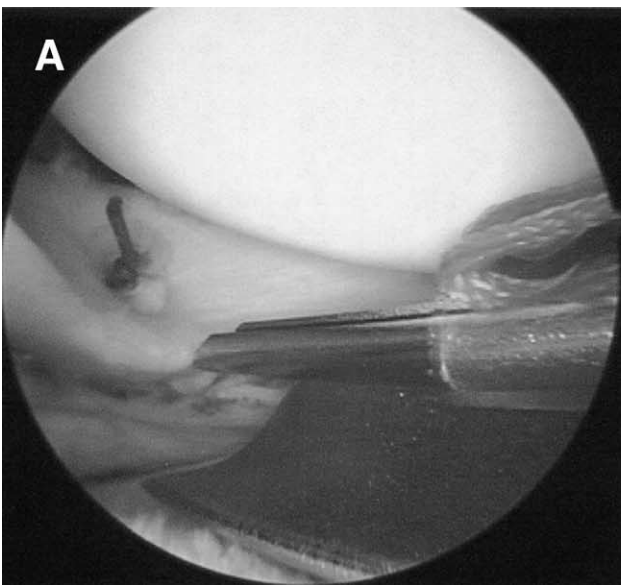


**FIGURE 5.** Arthrotek meniscal screw is 11 mm long with a constant pitch and is made of 82% poly L-lactide (PLLA) and 18% poly glycolide (PGA).

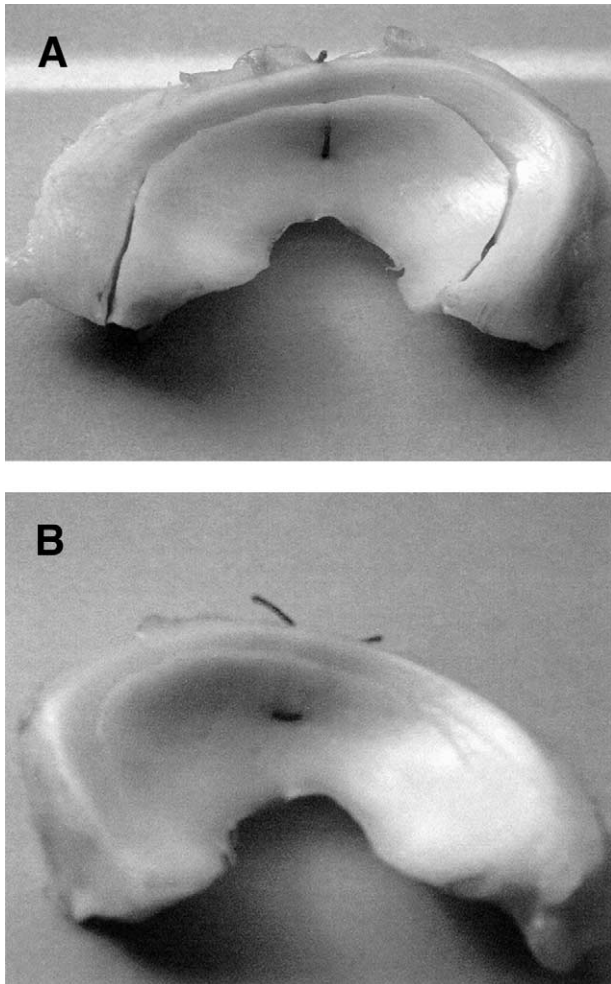
(PGA). It is 11 mm long with a diameter of 2.25 mm and inserted over a square needle (Fig 5).

Group 6 had a vertical simple suture of 2-0 Mersilene (Ethicon, Somerville, NJ) placed 3 mm inside the tear extending from the superior surface to the inferior surface of the meniscus and tied by hand on the capsular side of the meniscus approximating the two fragments of meniscus (inside-out vertical stitch) (Fig 6A).

Group 7 had a horizontal mattress suture of 2-0 Mersilene placed on the superior surface of the meniscus 3 mm inside the tear with arms 3 mm apart, exiting through the peripheral capsule and tied by



**FIGURE 4.** (A) The RapidLoc device consists of a PLLA top hat and a bar that are connected by either 2-0 Ethibond (as shown here) or Panacryl sutures. (B) After the bar is placed through the meniscus, the top hat is advanced to complete the repair.



**FIGURE 6.** A vertical simple suture of 2-0 Mersilene was placed (A) 3 mm inside the tear for testing, (B) and a horizontal mattress suture also of 2-0 Mersilene was placed on the superior surface of the meniscus 3 mm inside the tear with arms approximately 3 mm apart.

hand on the capsular side of the meniscus tear (inside-out horizontal stitch) (Fig 6B).

Each group was evaluated for failure mode (such as suture breakage, device breakage, or tissue failure), and force elongation curves were recorded. A different investigator than the one responsible for device insertion performed load to failure testing.

## RESULTS

The mean loads to failure with the standard deviations and number of tests performed to achieve these results are listed in Table 1. The mechanism of failure varied somewhat for the different devices. Failure

**TABLE 1.** Loads to Failure of Repair Devices Tested

Device	Mean	Standard Deviation	No.	Range
FasT-Fix vertical	70.9 N	± 33	14	36.5-136.9 N
FasT-Fix horizontal	72.1 N	± 23.5	16	37.3-106.7 N
Dart (2)	61.7 N	± 19	10	34.0-98 N
RapidLoc	43.3 N	± 3.98	14	36.5-52.5 N
Arthrotek screw	28.1 N	± 7.9	10	16.0-38.2 N
Vertical 2-0 suture	80.4 N	± 8.5	13	63-93 N
Horizontal 2-0 suture	55.9 N	± 18.8	10	21-79 N

occurred in one of 3 ways: by device pullout of the inner rim, device pullout of the outer rim, or device (suture) breakage. The modes of failure are listed in Table 2.

## DISCUSSION

All-inside techniques using devices that avoid posterolateral or posteromedial incisions offer surgeons attractive alternatives to inside-out or outside-in suturing techniques for appropriately selected meniscal tear patterns if those devices can reliably result in clinical healing without complications. This study compared the load to failure strength of new meniscal repair techniques using an established protocol that allows comparison of the new data with previously published reports.<sup>9,10</sup> The pig meniscus was selected because of published observations that the porcine model provides more consistent mechanical properties than elderly human cadavers and is comparable to young adult human menisci.<sup>8</sup> However, the values generated in this study may not necessarily have a direct comparison with the human model.

No matter how well the meniscus tear is approximated, effective healing requires establishing an effective blood supply to the tear. Additionally, the repair must be strong enough to protect the healing

**TABLE 2.** Modes of Failure

Device	Pullout From Inner Section	Pullout From Outer Section	Device Break
FasT-Fix vertical	—	—	14
FasT-Fix horizontal	—	—	16
Dart (2)	9	1	—
RapidLoc	—	—	14
Arthrotek screw	6	4	—
Vertical 2-0 suture	—	—	13
Horizontal 2-0 suture	4	—	6

tear from the forces placed on the repair site by daily activities until healing is complete. With this in mind, the best rehabilitation program may not be the same for suture repairs as for repairs using new meniscal repair devices. As yet no studies comparing different rehabilitation programs using these devices have been published. The theoretical ideal is a repair that allows for an immediate return to full activity and at the same time minimizes the potential for complications and delayed healing. Biomechanical testing helps to provide a basic understanding of how these devices function and how they compare with other techniques.

The data from this study show some variation in the single pull load-to-failure strength. The single pull load-to-failure force recorded for the Arthrotek meniscal screw is in the range previously reported for the Mitek meniscal repair system, SDsorb staple (Surgical Dynamics, Norwalk, CT), Clearfix screw (Mitek, Westwood, MA), Arthrotek staple, and the Arrow (Linvatec, Largo, FL) at about 30 N. A higher mean load to failure was shown with repairs using the RapidLoc device, the Dart, and the FasT-Fix. These devices were comparable to previous tests performed using the horizontal mattress stitch, the BioStinger (Linvatec), and the original T-Fix device (Smith & Nephew Endoscopy). Interestingly, no strength difference was found between repairs created by inserting the FasT-Fix in a horizontal or vertical suture configuration. Clinicians should note that the Dart technique used two devices to be consistent with the manufacturer's submittal of the product for FDA approval. This double technique is certainly consistent with any staple product that has two "prongs." The Dart technique might be viewed as a staple device without a connecting link. However, this "double technique" requires two separate passes to place the two Darts, which will increase both time and expense.

The mechanisms of failure were also evaluated. All of the "self-adjusting suture" techniques (FasT-Fix inserted in either a horizontal or vertical arrangement and the RapidLoc repair) failed by the suture breaking. The pretied slip knot was not the weakest point for any of these. This is consistent with previous studies that showed that repair failure did not occur at the knots. The Dart failed by pullout from the inner rim (or bucket handle piece) in a fashion similar to previous tack-like devices (Arrow or BioStinger). This was anticipated because of the absence of any crosspiece or head on the device. The Arthrotek screw failed by two mechanisms, similar to the Clearfix screw: device pullout of the inner rim (6 of 10) and device pullout of the outer rim (4 of 10). The only

mechanism of failure that the Arthrotek screw did not show that was reported with the Clearfix screw was device breakage.

Mode of failure has a clinical impact, especially when the device material is considered. The FasT-Fix is completely nonabsorbable, containing two 5-mm polyacetyl (nonabsorbing plastic) bars connected by a strand of No. 0 braided polyester suture. Although these are nonabsorbable, the fact that they are embedded into the peripheral capsule makes it unlikely that they will become loose bodies or cause articular cartilage damage. The RapidLoc device has a top hat and a bar, both of absorbable PLLA. The device comes with either a nonabsorbable braided polyester suture or an absorbable Panacryl suture. Although the RapidLoc's bar (like the FasT-Fix bars) is also embedded in the peripheral capsule and unlikely to be a concern, the top hat portion is clearly in the joint. It is uncertain whether this will present a problem. The PLLA material takes years to degrade, and during that period has the potential to cause articular cartilage scuffing.

The Arthrex Dart is composed of poly dextro (30%) levo (70%) lactic acid (PDLLA), which is gamma irradiated. This irradiation speeds the device degradation, as does the amorphous nature of the polymer. Because the demonstrated method of Dart failure was pullout of the inner rim, the Dart will probably migrate peripherally and lodge in the joint capsule.

The Arthrotek meniscal screw is composed of Lactosorb (Biomet) material, which is a copolymer of PLLA (82%) and PGA (18%). The degradation of this material is faster than pure PLLA, and the predominant mode of failure for the Arthrotek screw (pullout of the inner rim) makes it more likely for this device to migrate into the peripheral capsule, where it will degrade more rapidly than the devices made from PLLA.

This test protocol may not accurately recreate the mechanism by which a meniscal repair fails. In fact, at this point exactly how much force is required to hold the repaired meniscal edges together during loaded flexion and extension is unclear. Rather, the purpose of this study was to evaluate a single parameter for different meniscal repair configurations that would allow a comparison with other existing devices.

This information is only one indication of device performance and may not correlate with clinical healing results. We have yet to determine how much repair strength is enough and the long-term effects of the materials used in these devices. Any of these repair devices may be clinically appropriate, and the sur-

geon's choice should ultimately be based on clinical results.

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