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Shear Force at Failure and Stiffness of All-Inside Meniscal Repair Devices

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Abstract The purpose of this study was to determine the failure load and stiffness of various meniscal repair devices. Sixty-one fresh-frozen porcine menisci (medial and lateral) were used for the study. A 30 mm vertical full thickness tear was created and repaired using one of three all-inside fixation devices and one inside-out repair in the vertical mattress pattern. We used the Maxbraid inside-out suture as a control. The other devices tested were the Meniscal Cinch™, Ultra FasT-fix™, and the MarXmen MaxFire™. In addition, two devices, MaxFire™ MarXmen™ and Ultra FasT-fix™, were tested using a horizontal mattress configuration. Using the vertical mattress pattern, the Meniscal Cinch™ had the highest average load to failure. The Meniscal Cinch™ was significantly less stiff than the other three devices ($p<0.04$). For the MarXmen™ and Ultra FasT-fix™, no differences were noted for load to failure between horizontal and vertical mattress patterns. The mode of failure was significantly different when comparing the two different surgical techniques for the MaxFire™ MarXmen™ ($p=0.005$). The MaxFire™ MarXmen™ device produced a significantly stiffer ($p<0.001$) construct when following the manufacturer's instructions (5.8 N/mm) as compared to the technique used for the other all-inside devices (2.5 N/mm) The Meniscal Cinch™ had the highest load to failure value but the lowest stiffness of the group in the vertical mattress configuration. There was little difference in biomechanical properties between vertical and horizontal repair. Importantly, there was a significant difference in stiffness and failure mode for the MaxFire™ MarXmen™ when the manufacturer guidelines were not specifically followed.

Keywords meniscal repair, meniscus biomechanics, all-inside fixation devices, knee

BACKGROUND

Knee arthroscopy, including partial excision of the medial or lateral meniscus, is the most commonly performed orthopaedic procedure according to the American Board of Orthopaedic Surgery. [1] Menisci are the most commonly injured structure in the knee, either acutely in younger patients or as chronic degeneration in older patients. Meniscal tears were historically treated by open complete meniscectomy but, this procedure was found to lead to the advancement of osteoarthritis. [2] Over time, the treatment goal for meniscal tear became partial resection and more recently, a more aggressive approach to perform meniscal repair over meniscectomy.

Many techniques were developed to improve the outcome of meniscal repair including open, outside-inside, inside-outside, or all-inside techniques. There are certain advantages and disadvantages of each type of repair. In general, the all-inside repairs are preferred for simpler meniscal tears that are easily reducible using arthroscopy. There are several different types of all-inside repair devices. The repair technique selected and the device used can depend on ease of use, surgical time, surgeon experience, and initial fixation strength.

The initial strength of the repair at time zero is a factor to be considered when determining which repair device is preferred. Several studies have examined the biomechanical strength of repair techniques for meniscal lesions focusing on the strength, stiffness and displacement of the repair in tension. [3-8] However, meniscal injuries often occur secondary to a rotational force while under axial loading. The resultant oblique vector is defined as a shear force. Few biomechanical studies have addressed shear forces relative to meniscal repairs despite the fact that these may more closely mimic knee kinematics in the postoperative rehabilitation or athletic setting. [8-10] It is possible that weight bearing in conjunction with tibiofemoral rotation during knee flexion could produce shear forces capable of disrupting healing meniscal tissue, particularly if the fixation strength was inadequate. Traditional teaching supports weight-bearing limitations during the initial 4 to 8 weeks after meniscal repair. In theory, weight bearing alone should not disrupt healing meniscal tissue because the hoop stresses are primarily absorbed at the periphery of the meniscus. Reports have recommended earlier weight bearing to promote the restoration of a functional meniscus. [11,12] The purpose of the current study was to evaluate and compare the load to failure and stiffness of three new all inside meniscal repair devices with the standard inside out repair in shear.

For the current study, three specific questions were considered: First, was there a difference in strength and stiffness between three new all-inside devices and the standard inside-out vertical mattress suture pattern. Second, for two of the devices, we examined the biomechanical properties when repairs were performed using horizontal sutures. Third, would there be a difference in load to failure or stiffness of two different insertional techniques using a single all-inside device.

Our hypothesis was that the standard inside-out repair would be stiffer and have a higher load to failure than the all-inside devices. We also hypothesized that the vertical mattress pattern would be stiffer and have a higher load to failure than a horizontal mattress repair pattern using the same all-inside device. Lastly, we hypothesized that failure to strictly follow technical guidelines of insertional technique could lead to decreased biomechanical performance for one of the devices.

METHODS

Sixty-one fresh-frozen porcine menisci (medial and lateral) from thirty-two knees were obtained from skeletally mature, healthy animals from a local abattoir. Only normal-appearing knees without visible signs of cartilage degeneration were used. Menisci with any visual evidence of previous damage were excluded. A power analysis revealed that a minimum seven samples in each group was required to detect a difference of 25 N with 0.80 power.

The menisci were dissected free, leaving the adhering capsule intact, double wrapped in saline soaked gauze, sealed in plastic bags and stored at -20°C. The specimens were thawed overnight at 4ºC prior to the day of testing. Using a scalpel (#11 blade) a 30 mm vertical longitudinal full thickness lesion was created 3 mm from the peripheral rim in the middle third of the meniscus. We used a digital caliper and marker to uniformly create the site of the incision where we wanted to simulate a meniscal tear. The isolated tear was then repaired using one of four fixation techniques (listed below).

For each device we contacted the manufacturer to confirm the proper insertion technique for their specific device or followed the guidelines provided. A fellowship trained sports medicine orthopaedic surgeon who was familiar with the particular device was present during fixation of the devices. All devices were implanted by a single senior resident orthopaedic surgeon who had been instructed by the attending surgeon and engineers from the representative devices.

Meniscal Repair – Vertical Mattress

As a control, MaxBraid™ (Biomet, Warsaw IN) suture was placed in the vertical mattress pattern in the standard inside-out technique and hand tied on the outside of the peripheral rim of the meniscus using alternating half-hitches. For the fixation devices, a single vertical mattress repair was also applied for each device using the protocol recommended by the respective manufacturer. The first arm of the device was placed in the central portion of the meniscus and the second arm was placed in the peripheral portion. The limbs of the mattress sutures were placed 5 mm apart. After repair, the tears were completed across the entire circumference of the meniscus. The meniscus effectively became two separate segments held only by the repair. This was used to ensure that the fixation and not the meniscal tissue provided the fixation's stability. [8,13]

Group 1 Control (n=9)
2-0 MaxBraid ™ meniscus needles (made of Ultra High Molecular Weight Polyethylene) (Biomet, Warsaw, IN)
Group 2 (n=9)
Ultra Fast-Fix (Smith and Nephew, Andover, MA)
Group 3 (n=10)
Meniscal Cinch ™ (Arthrex, Naples, FL)
Group 4 (n=9)
MaxFire™ MarXmen™ (Biomet, Warsaw, IN)

Meniscal Repair – Horizontal Mattress

For the horizontal repair group, the menisci were prepared as above. The horizontal mattress repair was performed with each suture limb 5 mm apart. The tears were again completed across the entire circumference of the meniscus, thus separating the meniscus into two segments held only by the repair. The horizontal repair groups included the following.

Group 5 (n=8)
Ultra Fast-Fix (Smith and Nephew, Andover, MA)
Group 6 (n=7)
MaxFire™ MarXmen™ (Biomet, Warsaw, IN)

Meniscal Repair – Variable Repair Technique

We performed a second vertical mattress test with the MaxFire™ MarXmen™ using a repair technique that differed slightly from that described by the manufacturer. In the manufacturer's recommended technique, a vertical mattress repair is performed by placing the first suture pass peripheral to the tear and the second pass central to the tear. Alternately, technique 2 was a vertical mattress repair where the first pass was inserted central to the tear and the second pass was inserted peripheral to the tear. The goal was to determine whether varying the technique would alter the biomechanical properties of the device since the other device guidelines recommend the opposite insertional order. We compared these two groups because repairs are generally made using technique 2. (Fig. 1)

Group 4, technique 1 (n=9)
MaxFire™ MarXmen™ (Biomet, Warsaw, IN)
Group 7, technique 2 (n=9)
MaxFire™ MarXmen™ (Biomet, Warsaw, IN)

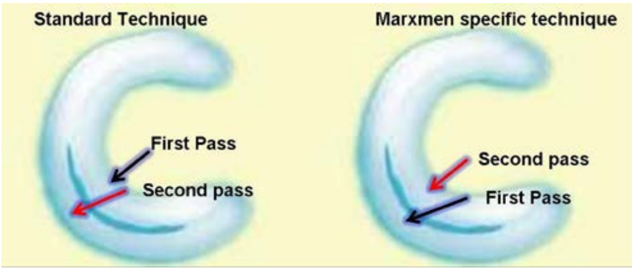

Figure 1.

Biomechanical Testing

The meniscal specimens were secured to a custom-made fixation device that interfaced with a uniaxial servo-hydraulic materials testing machine (Instron Model 8500, Canton, MA, USA). The repaired meniscal specimens were nailed to a wooden board at their periphery using two nails. The central portion was allowed to lay flat against the board which was attached to the Instron. The tests were performed at room temperature and the menisci were kept moist with saline solution during mounting and testing. The shear force was then applied by pulling on a stay suture limb tied to the central meniscal portion in parallel to the length of the meniscus. This testing setup was modified from that previously described. [10] A pre-load of 2 N was applied and load-to-failure testing was performed at a constant displacement rate of 12.5 mm/sec. This displacement rate was consistent with previous studies that evaluated the ultimate pullout strength of sutures and suture anchors and is reflective of a rapid loading force. [7,8,14] The mode and location of failure were recorded for each specimen. The mode of failure was described as: 1) suture breakage, 2) intact suture pulled through meniscus, or 3) knot loosening.

Statistical Analysis

The load and displacement of the Instron were recorded. The stiffness of the repair was calculated using the linear portion of the load displacement curve. The single peak load to failure, displacement at failure and stiffness were compared by ANOVA to determine significance; $p<0.05$ was considered statistically significant. The mode of failure was recorded and compared using the two-tailed Fisher exact probability test ($p<0.05$). As stated previously, a power analysis revealed that a minimum seven samples in each group was required to detect a difference of 25 N with 0.80 power.

RESULTS

Vertical Mattress

When testing shear forces and the vertical mattress repair techniques, 28/37 repairs failed via suture pulling through the tissue implying that the fixation was stronger than the meniscal tissue itself. There were no significant differences between the failure modes for any of the groups ($p>0.05$). (Table 1)

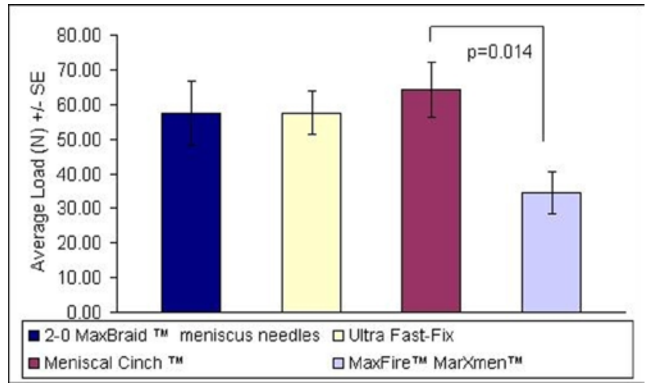

Figure 2. Mean Load Failure – Vertical Mattress (N +/- SE)

Table 1
Modes of Failure

Device	Suture Pulled Through Tissue	Device Failure	Other*
2-0 MaxBraid ™ (n=9)	6	2	1
Ultra Fast-Fix (n=9)	7	2	0
Meniscal Cinch ™ (n=10)	8	2	0
MaxFire™ MarXmen™ (n=9)	7	2	0

* stay structure breaking

The Meniscal Cinch™ had the highest average load to failure (64.1 N). This value was significantly higher than the MaxFire™ MarXmen™ (34.4 N; $p=0.014$). There was a trend indicating that the MaxFire™ MarXmen™ failed at a lower load than the Ultra Fast-Fix (57.5 N; $p=0.06$) (Fig. 2). The Meniscal Cinch™ (3.4 N/mm) was significantly less stiff than the other three devices ($p<0.04$; Fig. 3). No significant difference in stiffness was found between MaxBraid™ suture (4.7 N/mm), Ultra Fast-Fix (5.2 N/mm) and MaxFire™ MarXmen™ (5.8 N/mm) (Fig. 3). There was significantly less displacement ($p<0.01$) at failure load for the MaxFire™ MarXmen™ (7.7 mm) when compared to the MaxBraid™ sutures (17.1 mm) and the Meniscal Cinch ™ (18.5 mm).

The MaxFire™ MarXmen™ device produced a significantly stiffer ($p<0.001$) construct when following the manufacturer's instructions (5.8 N/mm) as compared to the technique used for the other all-inside devices (2.5 N/mm) (Fig. 4). There was no significant difference in peak loads.

Horizontal Mattress

There was no significant difference in mode of failure for the MaxFire™ MarXmen™ when comparing vertical to horizontal repairs ($p=0.30$). For the horizontal mattress suture pattern, the MaxFire™ MarXmen™ failed by pulling through the tissue (3/7) and failed with the knot loosen-

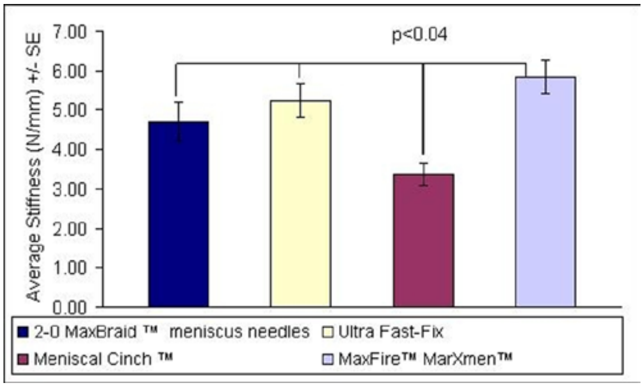

Figure 3. Mean Stiffness – Vertical Mattress (N/mm +/- SE)

ing (4/7). The Ultra Fast-Fix also failed by pulling through the tissue (6/7) and suture breaking (1/7).

There was no significant difference in peak load to failure between horizontal and vertical mattress patterns using the MaxFire™ MarXmen™ (p=0.072) or Ultra Fast-Fix (p=0.37) devices. The MaxFire™ MarXmen™ device was significantly stiffer (p=0.008; Fig. 5) when using a vertical mattress pattern (5.8 N/mm) compared the horizontal mattress pattern (3.9 N/mm). There was no significant difference in stiffness for the Ultra Fast-Fix device when comparing horizontal and vertical suture patterns (p=0.359). There was no significant difference in displacement between the groups.

Variable Repair Technique

The mode of failure was significantly different when comparing the two different surgical techniques for the MaxFire™ MarXmen™ (p=0.005). When specifically following the manufacturer's instructions for the MaxFire™ MarXmen™, 7/9 failed by pulling through the tissue and 2/9 failed by breaking or loosening. When, instead, the first pass was inserted inferior and medial to the tear and second pass inserted superior and lateral to the tear, 9/10 failed with the suture coming undone and sliding through the tissue and only 1 failed by pulling through the tissue.

DISCUSSION

The purpose of this study was to examine the biomechanical properties of several meniscal repair devices. We found that the MaxFire™ MarXmen™ failed at a significantly lower load in shear than Meniscal Cinch™ but was not as stiff as the other constructs in a vertical mattress suture pattern. The MaxFire™ MarXmen™ was significantly less stiff when the first pass was inserted central to the tear and the second pass was inserted peripheral to the tear. This technique also caused the device to fail at the knot of the repair.

Fisher et al. examined the strength and stiffness of the T-fix, meniscal staple, arrow, and horizontal #1 PDS in shear and found that the ultimate strength of the T-fix was similar to the horizontal suture and both were superior to

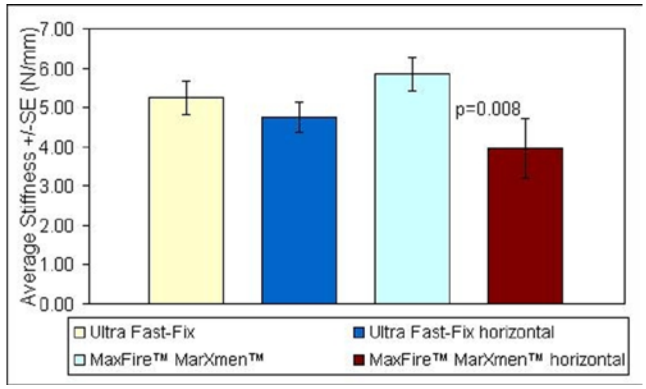

Figure 4. Mean Stiffness – Vertical vs. Horizontal Mattress (N/mm +/- SE)

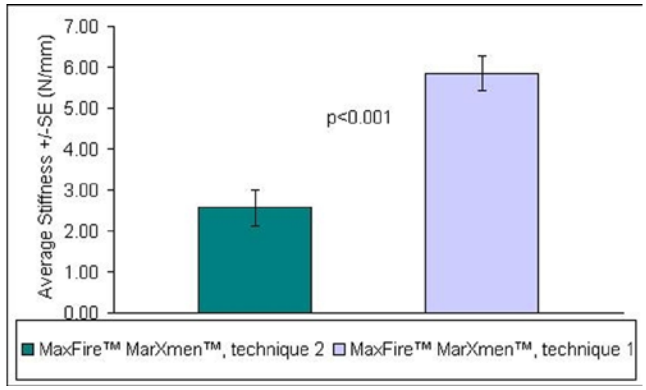

Figure 5. Mean Stiffness – Technique 1 vs. Technique 2 for the MaxFire™ MarXmen™ (N/mm +/- SE)

the staple and arrow. [10] Zantop et al. examined the difference between horizontal and vertical suture patterns by applying a cyclic load in shear. They found that horizontal suture had less elongation between cycles and higher load to failure than vertical sutures, but did not examine any of the all-inside devices. [8] Recently, several second and third generation devices have been developed and tested biomechanically. [3-7,15-18] Farng et al. performed a clinical and biomechanical review of several all-inside device studies. They found a large variation in study methodology especially in loading rate. [17] This made direct comparisons difficult in part due to the viscoelastic properties of the meniscus. [17] Generally, prior studies showed that vertical suture repair had superior strength when compared with horizontal and all-inside repair. [3,7,8,13] In our study, we found that there was no significant difference in peak load when comparing vertical and horizontal repairs. We did find that the MaxFire™ MarXmen™ device was significantly stiffer when using a vertical mattress pattern compared to the horizontal mattress pattern.

The suture materials also played a role in the strength of repair. Barber et al. showed that use of ultra high molecular weight polyethylene (UHMWPE) suture was significantly stronger than traditional braided polyester suture. [4] Similarly, the meniscal repair devices that used the newer suture (Ultra-FasT Fix and MaxFire™ MarXmen™) were comparable to the isolated UHMWPE vertical suture repair in load to failure testing. Richards concluded that the forces across the meniscus are less than the actual breaking strength of the recently investigated techniques. [19,20] We also demonstrated that, in general, most repairs failed when the suture tore through the meniscus as opposed to suture breakage.

Flanigan tested bovine menisci using the MaxFire™ MarXmen™ and Smith and Nephew Fast-fix using both vertical and horizontal mattresses in a technique similar to that described here. [21] He found that the load to failure for MaxFire™ MarXmen™ vertical mattress and horizontal mattress repairs was similar to the FasT-Fix horizontal and vertical repairs. [21] They also showed that the mattress orientation, vertical or horizontal, was equivalent when testing load to failure. We showed a trend toward lower load to failure for the MaxFire™ MarXmen™ device compared to the Ultra Fast-fix (p=0.06). Our study did show a significant difference in stiffness for the MaxFire™ MarXmen™ device only - it was stiffer using the vertical mattress pattern compared to the horizontal mattress pattern.

Due to increased material strength, the use of new high molecular weight polyethylene suture in implants may eliminate the historic differences seen in implant orientation for vertical or horizontal mattress. In addition, the all-inside devices incorporate design technology that allows the surgeon to self-adjust and self-tension the repair. The Meniscal Cinch™ allows surgeons the option of horizontal or vertical mattress repair with 2-0 FiberWire suture. The preset sliding knot and the FiberWire properties create a low profile knot that can be countersunk into the meniscus. The external depth-stop is designed to protect structures external to the capsule. The MaxFire™ MarXmen™ incorporates a one-handed trigger delivery system. The cannula houses the needle sled, which guides deployment of the device and is available in curved and straight geometries. The MaxFire™ MarXmen™ "ziploop technology" uses a pattern where one strand is woven through itself two times in opposing directions. Theoretically, this technology allows a surgeon to tailor the implant's length and tension to fit the meniscal tissue without the use of knots. As a result, a specific surgical technique is required where the suture is passed peripheral to the tear first and then medial to the tear. This emphasizes the importance of surgeon education and availability of technical guides. In our study, when these specific instructions were not followed, the repair was less stiff and the suture came undone and slid through the meniscus.

Maintaining anatomic reduction of the meniscal tissue is important. Poor healing has been reported to be strongly associated with lack of contact between a polymer implant and meniscal tear. [22] Pujol noted a significant correlation between the rate of meniscal narrowing after repair and the healing rate. The best clinical outcomes were in narrowed and healed menisci. [23] Clearly, when surgically repairing meniscal tears, a sufficiently stiff, strong repair to prevent gap formation is favored to encourage healing.

This was an in-vitro biomechanical study, conducted immediately after repair and represents time zero of a repair. A limitation was that it does not examine the effects of healing in-vivo. However, our study reports on the initial time point where maximum repair strength is required since no healing is as yet present.

CONCLUSION

We examined the biomechanical properties of four different meniscal fixation groups: 1) Three meniscal repair devices and meniscal suture needles using the vertical mattress pattern 2) Horizontal versus vertical mattress pattern of two all-inside repair devices; and 3) Two different surgical insertional techniques using a single device. The MaxFire™ MarXmen™ failed at a significantly lower load in shear than Meniscal Cinch™ and was not as stiff as the other constructs in a vertical mattress suture pattern. However, no significant difference in load to failure exists when comparing vertical to horizontal suture patterns. For the MaxFire™ MarXmen™, the horizontal pattern was significantly less stiff than the vertical pattern. Following the manufacturer guidelines proved to be the key to fixation stiffness for the MaxFire™ MarXmen™. There was a significant difference in stiffness and failure mode for this device when the manufacturer guidelines were specifically followed. It was not made clear in manufacturer's literature that a change in technique would result in inferior results.

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