Tensile and Shear Loading Stability of All-Inside Meniscal Repairs

An In Vitro Biomechanical Evaluation
Abstract:

Background:
Most biomechanical studies for evaluation of the structural properties of meniscus repairs have been performed in tensile loading scenarios perpendicular to the circumferential meniscal fibers. However, meniscal repair constructs are also exposed to shear forces parallel to the circumferential meniscal fibers during healing particularly in the mid-portion of the meniscus.

Hypothesis:
Material properties of meniscus repair devices cannot be extrapolated from tensile load to shear force scenarios.

Study Design:
Controlled laboratory study.

Methods:
In 84 harvested and isolated bovine lateral menisci following removal of adjacent soft tissue, a standardized vertical lesion was set followed by repair using all-inside flexible (FasT-Fix, FasT-Fix AB, RapidLoc) and rigid meniscal repair devices (Meniscus Screw, Meniscus Arrow). 2.0-Ethibond vertical and horizontal sutures were used as controls. The repaired meniscal construct was tested in a tensile (parallel to the axis of the tested repair device) and
shear force scenario (perpendicular to the axis of the tested repair device) at 5mm/min and 37°C environmental temperature. Maximum load-to-failure, stiffness, and failure mode were recorded.

Results:
The absolute load-to-failure values of each repair device in the shear scenario were only marginally different to the tensile load scenario. However, the stiffness of the most tested devices were markably reduced in the shear scenario. In both scenarios, large differences of the load-to-failure and the stiffness between the implant types up to 5-fold were found (P < .05). The failure mode of several all-inside flexible repair devices was different in the shear force vs. tensile load scenario, while the failure mode of the rigid systems was similar in both scenarios.

Conclusions:
All-inside meniscal repair devices exposed to shear force scenarios have comparable maximum load-to-failures to tensile load scenarios. However, the stiffness of the majority of the flexible meniscal repair implants in a shear force scenario is markably reduced. The applied scenario also affects the failure mode in several flexible meniscal repair devices.

Clinical Relevance:
Meniscal repair devices with sufficient stiffness and stability against shear loading may be favored for meniscal repair especially within the mid-portion of the meniscus where shear forces are occurring during healing.

**Keywords:**

meniscus; meniscus repair; all-inside meniscal repair device; tensile load; shear load; biomechanics
Introduction

Meniscal repair represents the gold standard for treatment of vertical meniscus tears within the vascularized zone, if healing can be biologically expected. However, surgical repair may be technically demanding and time-consuming. Various rigid or flexible meniscal repair systems have therefore been developed for the purpose. Of particular interest are all-inside repair systems which have been primarily designed to facilitate the otherwise technically difficult repair of the posterior horn.

Overall, the mechanical stability of surgical soft tissue repair procedures should ideally restore the mechanical properties of the native tissue. With respect to the biomechanical loading patterns of the native menisci, which include not only compression and distraction forces, but also shear forces within the collagen fiber system of the meniscus as well as the adjacent meniscocapsular area, the meniscal repair device must withstand these various load impacts until healing has occurred. Distraction forces are not the primary factor for the mechanical stability of meniscal repair within the healing period. Other risk factors such as shear forces may be of greater significance for failure of meniscal repairs.

In most biomechanical studies, however, the repaired meniscal constructs were mostly exposed and tested to distraction loading scenarios with tensile load perpendicular to the circumferential fibers of the meniscus, while shear force scenarios are rarely performed. Fisher and coworkers
first studied ultimate shear tests of meniscal repair devices in vitro, and Zantop and collaborators\textsuperscript{20} performed cyclic loading of meniscal repairs in an axial distraction and shear force scenario using horizontal and vertical outside-in suture techniques. But to our knowledge, no data are available for currently and commonly used all-inside meniscal repair devices in a shear loading “worst-case” scenario.

In addition, environmental test temperature may have a considerable impact on the material properties of bioabsorbable or partially bioabsorbable meniscal repair implants, such as the FasT-Fix AB (absorbable), RapidLoc, Meniscus Screw, and Meniscus Arrow. Biomechanical studies of bioabsorbable suture anchors have demonstrated inferior biomechanical strength at 37°C (body temperature) compared to 20°C (room temperature).\textsuperscript{12}

The objective of the study was therefore to evaluate the biomechanical properties of bioabsorbable, partially bioabsorbable, and non-bioabsorbable all-inside meniscus repair systems in vitro using a standardized “worst-case” tensile load vs. shear force scenario in a body temperature environment. We hypothesized that (1) the mechanical performance of the meniscal repair systems within tensile load scenarios cannot be extrapolated to shear force scenarios and that (2) the failure mode is dependent on the applied test scenario.

Materials and Methods:
Specimen Preparation

The intact lateral menisci of 84 freshly slaughtered bovine (age 5-10 months) knee joints were harvested. The adjacent tissue except the adhering capsule was removed. The anterior-posterior-diameter of the lateral menisci averaged 6 cm. Only intact and complete lateral menisci without any macroscopic degenerative changes were selected for biomechanical testing. The specimen were stored at -21°C prior final preparation, meniscal repair, and biomechanical evaluation. One hour before testing, a standardized artificial vertical lesion was created 4 mm apart from the peripheral meniscal rim within the mid-portion of the meniscus (Figure 1A) representing a bucket-handle tear within the red-red zone of the meniscus. Due to the unequal loading directions in the tensile loading and the shear force scenario, the meniscal part adjacent to the repair zone was prepared differently: In the tensile loading scenario, the vertical lesion was completed over the entire meniscal mid-portion (Figure 1B), while in the shear force scenario, the vertical lesion was completed in a Z-shaped mode (Figure 1C). The artificial tear was repaired using different all-inside meniscal repair devices according to the instructions of the manufacturers. In detail, 3 flexible implant systems (FasT-Fix [horizontal suture technique], FasT-Fix AB [absorbable] [horizontal suture technique], RapidLoc) and 2 rigid implant systems (Meniscus Screw, Meniscus Arrow) were tested. The main difference between the tested flexible and the rigid implant devices is that the flexible devices include suture
material in addition to their backstop system, while the rigid devices are absent of suture material. As two control groups representing an inside-out technique, either a vertical or a horizontal 2.0 Ethibond (Ethicon, Norderstedt, Germany) suture loop technique was performed. Each meniscus tear was repaired utilizing one implant and each meniscus-implant-construct was tested only once. Each implant type encompassed six single tests in each test scenario representing overall 84 experiments. Thirty minutes prior and during biomechanical testing, the repaired menisci were stored in a physiological fluid solution (Ringer, B. Braun Medical Inc., Bethlehem, PA, USA) at 37°C according to a physiological body temperature. Automatic stirring and continuous measurement of the temperature was performed for maintaining the equilibration of the fluid temperature.

Biomechanical Tensile Testing

Tensile Testing was accomplished using a uniaxial material testing machine (universal testing instrument model 4204, Instron Corporation, Canton, MA, USA) equipped with a 5000 N load cell (Instron Corporation). In both tensile load and shear force scenarios, the mid-portion of the meniscus was mounted to a custom-made metallic tissue clamp (Figure 2A) and the peripheral part of the meniscus was fixed with a specifically designed mechanical interlocking system. In detail, two stiff metallic batons were interposed within the artificial meniscal tear adjacent to the repair area parallel to the circumferential meniscal collagen fibers in the tensile load scenario (Figure 2A). In contrast,
one stiff metallic baton was interposed within the Z-shaped lesion perpendicular to the circumferential meniscal collagen fibers in the shear force scenario (Figure 2B). These fixation devices enabled a rigid interface between the meniscal tissue and the clamp as well as the mounting system. The custom-made tissue clamp was attached via a universal joint to the crosshead of the material testing machine, and the mechanical interlocking system was fixed to a stationary post within the physiological water bath (Figure 2C).

In the tensile load and in the shear force scenario, the force of the tensile testing was applied parallel and perpendicular to the meniscal repair construct, respectively (Figure 1B and 1C). Both test setups ensured an isolated testing for evaluation of the material properties of the meniscus-implant-construct in tensile and shear loadings. Prior to testing, the repair device-meniscus-construct was mechanically preconditioned with 5 N for equilibration of the strain. The test speed of the mechanical loading was 5 mm/min according to Albrecht-Olsen et al.\textsuperscript{1} and Borden et al.\textsuperscript{9} until structural failure occurred. Structural failure was defined as the point beyond the maximum load-to-failure represented by negative slope of the load/elongation curve. Maximum load-to-failure and stiffness were determined as the maximal load of the load/elongation curve and the slope of the linear portion of the curve, respectively. In addition, the failure modes of the meniscus-implant-construct were analyzed.
Statistics

For achievement of a Gaussian normal distribution, a square root transformation of the parameter “stiffness” was necessary. SPSS 11.0 (SPSS, Chicago, Illinois, USA) was used for analysis of variance (ANOVA). Post-hoc Bonferroni correction was applied based on multiple comparisons. The level of significance was set at P < .05.

Results:

Load-to-Failure

Maximum load-to-failures of the tested all-inside meniscal repair devices and the control groups are shown in Figure 3. Overall, the maximum load-to-failures of each implant type did not differ significantly in the shear force compared to the tensile load scenario. However, the RapidLoc, the Meniscus Screw, and the Meniscus Arrow demonstrated significantly (P < .05) lower maximum load-to-failures in both scenarios compared to Ethibond 2.0 vertical or horizontal loops as well as to the FasT-Fix and FasT-Fix AB. In detail, the Meniscus Screw and the Meniscus Arrow had up to 5 times lower maximum load-to-failure values compared to the other tested all-inside meniscal repair devices.

Stiffness
The stiffness of the tested all-inside meniscal repair devices are illustrated in Figure 4. In all cases except in the RapidLoc and the Meniscus Screw, the stiffness was lower in the shear force vs. the tensile load scenario. In the Ethibond 2.0 vertical and the horizontal loop as well as in the FasT-Fix, the lower stiffness in the shear force scenario reached the significance level (P < .05).

**Failure Mode**

In all experiments, a slippage of the meniscal tissue within the interlocking system was observed neither on the mounting nor on the clamping system site. In 100% of the cases, the weakest link was the meniscal repair device or the interface between the meniscal repair device and the meniscal tissue. The failure modes of the tested all-inside meniscal repair devices are listed in Table 1. Overall, the applied force scenario had a considerable influence on the failure mode of the meniscus-implant-construct. In most of the flexible meniscal repair devices (FasT-Fix and FasT-Fix AB), the typical failure mode in the shear force scenario was breakage of the suture at the knot, while in the axial force scenario the breakage of the suture occurred at the eyelet (Figure 5). In the RapidLoc device, however, in more than 40% not the suture itself, but the bioabsorbable backstop system was the weakest link of the meniscus-implant-construct. In none of the cases of flexible meniscal repair devices, a cutting of the suture through the meniscal tissue was observed. In contrast, the failure mode of the rigid implants was predominantly located at
the interface between the implant and the meniscus tissue due to slippage of
the implant. This failure mode was independent of the applied force scenario.

**Discussion:**

Little information exists on the mechanical performance of meniscal repair
devices under shear load.\(^{10, 20}\) Shear load, however, is one of the
predominant forces acting on the meniscus with flexion and extension
movements of the knee.\(^{6, 10}\) Therefore, the objective of this study was to
evaluate the biomechanical properties of all-inside meniscal repair devices in
a “worst-case” tensile load vs. shear force scenario in a controlled laboratory
setup at a body temperature environment and under physiological fluid
conditions.

The most unexpected result was, that under shear load the stiffness of the
repair construct with either the suture or the FasT-Fix system was significantly
decreased, while in the repair with the RapidLoc, the Meniscus Screw and
Meniscus Arrow this significant effect was not seen. However, the decreased
stiffness of the aforementioned devices did not negatively affect the ultimate
strength of these meniscal repair constructs under shear load. Indeed, the
maximum load-to-failures of the tested meniscal repair devices was not
significantly altered between shear compared to the tensile load scenario.

Another interesting finding was, that the failure mode of the flexible, but not of
the rigid implants, did considerably differ between the shear force and the
tensile load scenario. It seems that the weakest link of the flexible all-inside
repair devices, especially in the FasT-Fix and the FasT-Fix AB device, does change its location depending on the applied force scenario. In contrast, slippage of the rigid implants was observed in all but one case independently of the applied force. Overall, the first hypothesis that the mechanical performance of the meniscal repair systems within tensile load scenarios cannot be extrapolated to shear force scenarios was only confirmed for the stiffness, but not for the maximum load-to-failure of some flexible all-inside meniscal repair devices. In other words, most of the meniscal repair devices demonstrate similar biomechanical properties in tensile load compared to shear force scenarios, however, significant differences of the maximum load-to failure and the stiffness can be found between the tested implant types. The second hypothesis was confirmed for the flexible, but not for the rigid all-inside meniscus repair devices that the failure mode is dependent on the applied test scenario.

Many biomechanical studies have evaluated the meniscal repair devices in vitro using a uniaxial axial distraction setup, while meniscus tears may occur most commonly secondary to a twisting force in combination with an axial load, subjecting the meniscus to shear forces under simultaneous compressive loading. However, biomechanical testing of meniscal repair techniques in an in vitro shear force scenario was only rarely performed. Fisher and coworkers were the first who evaluated meniscal repair devices using a shear loading scenario. They found significant differences in peak
loads of the meniscus repair in an axial vs. shear force setup. While the Meniscus Arrow performed better under axial load, the T-Fix Anchor (precursor model of the FasT-Fix) demonstrated superior results in load-to-failure under shear loading. In contrast, our results do not indicate any significant differences of the ultimate load-to-fails in the shear load scenario compared to the axial load scenario; however, considerable differences up to 5-fold can be found between flexible and rigid meniscal repair devices in both setups. The different results of our study compared to Fisher et al. may be due to a different fixation technique of the meniscus, variable material testing machine, test speed, and test temperature. Zantop and coworkers have investigated the structural properties of a horizontal and vertical meniscal suture repair technique in an axial distraction and shear force scenario under cyclic loading. Interestingly, they have found that meniscal repair with a horizontal suture technique can withstand elongation due to shear forces more effectively than a vertical suture technique which may be important for limitation of meniscal tissue displacement at the meniscal repair site during the healing process. However, this significant difference of elongation at the repair site between horizontal and vertical inside-out suture techniques did not influence the stiffness and the maximum load of the corresponding repaired meniscus construct in the shear compared to the axial distraction force scenario, which is consistent with our results. The unequal peak levels of the load-to-failure and stiffness in
both studies may be explained by the variable test protocol (cyclic vs. non-cyclic), test speed, test temperature, and animal model.

It is yet unclear which quantity and quality of distraction, compression, and shear forces are needed for structural damaging of the meniscus. In addition, only limited data are available for the biomechanical prerequisites of sufficient stabilization of the meniscal repair site during healing. In a controlled laboratory study, Becker et al.\textsuperscript{6} demonstrated that distraction forces are not the primary factor compromising the mechanical stability of meniscus repair construct. They concluded that other forces, e.g. shear forces, may be considered as a greater risk factor for jeopardizing the meniscal repair integrity until healing has occurred.\textsuperscript{6}

Limitations of our study are the isolated testing configuration using a uniaxial and continuously acting tensile load or shear force setup, which represents the loading conditions of the repaired meniscus \textit{in vivo} only in parts, since the meniscal repairs are also exposed to compression forces and cyclic loading.\textsuperscript{6, 15, 18, 20} Usually, critical axial distraction forces do not occur at the meniscal repair site since compression forces counteract the distraction forces within the healing period if correct rehabilitation is performed. However, unpredictable loading of the knee within the rehabilitation period by undesired squatting, pivoting, or twisting motions may cause deleterious distraction at the repair site. Another limitation might be the utilization of bovine instead of human menisci. However, structural, morphometrical, and biomechanical properties of the bovine meniscus approximately resemble the properties of
the human meniscus.\textsuperscript{13} Therefore, we believe this limitation seems advantageous compared to the alternative of cadaveric human menisci obtained from elderly donors, which usually show random degenerative alterations. In addition, several biomechanical studies of meniscal repair have been performed on bovine meniscus.\textsuperscript{1, 2, 8, 11, 14}

The impact of the test temperature on the mechanical properties of bioabsorbable or partially bioabsorbable all-inside meniscal repair devices has yet to be determined. Certainly, body temperature and physiological fluid environment represents the \textit{in vivo} conditions more closely than room temperature and ambient air, respectively. Arnoczky and Lavagnino\textsuperscript{2} demonstrated a significant impact of environmental fluid temperature on the hydrolysis time of several bioabsorbable meniscal repair devices over a 24-week period. In our study, however, relevant hydrolysis of the bioabsorbable materials within the physiologic water bath at body temperature will not occur within our short-term test period. Since Meyer et al.\textsuperscript{12} observed inferior biomechanical properties of bioabsorbable suture anchors at body compared to room temperature, bioabsorbable meniscal repair devices may be also susceptible to higher test temperature which may mislead to a systematic overestimation of their mechanical properties at room temperature. However, body temperature and fluid environment are so far neglected test parameters in most biomechanical meniscus repair studies.\textsuperscript{1, 5, 6, 8-11, 14, 16, 17, 19, 20}

Therefore, we have privileged the higher test temperature (body temperature)
in a physiological fluid environment even accepting limited comparability to other biomechanical studies performed at room temperature.

In conclusion, the present study showed that all-inside meniscal repair devices exposed to shear force scenarios have comparable maximum load-to-failures to tensile load scenarios. However, the stiffness of the majority of the flexible implants in a shear force scenario is markedly reduced. Especially repair of the central portion of the meniscus where shear forces are occurring while passive and active knee motions, meniscal repair devices with sufficient stiffness and stability against shear loading may be favored in this area. To our knowledge, this is the first study analyzing commonly used all-inside meniscal repair devices in a shear force vs. tensile load scenario at a physiological fluid environment and body temperature. Further studies may focus on combined tensile, shear, and compression loads which simulate the in vivo conditions more closely.
References:


### Tables:

#### Table 1  Failure Modes of All-Inside Meniscal Repair Devices in Tensile Load vs. Shear Force Scenario Compared to Vertical and Horizontal Ethibond 2.0 Suture Loops.

<table>
<thead>
<tr>
<th>Implant System</th>
<th>Brand Name</th>
<th>Company</th>
<th>Tensile Load Scenario</th>
<th>Shear Force Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethibond 2.0</td>
<td>Ethicon</td>
<td></td>
<td>6x knot breakage</td>
<td>6x knot breakage</td>
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<tr>
<td>(vertical)</td>
<td></td>
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<tr>
<td>Ethibond 2.0</td>
<td>Ethicon</td>
<td></td>
<td>6x knot breakage</td>
<td>6x knot breakage</td>
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<tr>
<td>(horizontal)</td>
<td></td>
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<tr>
<td>FasT-Fix</td>
<td>Smith &amp; Nephew</td>
<td></td>
<td>2x knot breakage</td>
<td>5x knot breakage</td>
</tr>
<tr>
<td>(horizontal)</td>
<td></td>
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<td></td>
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<tr>
<td>FasT-Fix AB</td>
<td>Smith &amp; Nephew</td>
<td></td>
<td>1x knot breakage</td>
<td>4x knot breakage</td>
</tr>
<tr>
<td>(horizontal)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RapidLoc</td>
<td>DePuy Mitek</td>
<td></td>
<td>3x suture breakage</td>
<td>4x suture breakage</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3x eyelet breakage</td>
<td>2x eyelet breakage</td>
</tr>
<tr>
<td>Meniscus Arrow</td>
<td>Linvatec</td>
<td></td>
<td>5x migration of Arrow</td>
<td>6x migration of Arrow</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>1x Arrow head breakage</td>
<td></td>
</tr>
<tr>
<td>Meniscus Screw</td>
<td>Arthrotek</td>
<td></td>
<td>6x migration of Screw</td>
<td>6x migration of Screw</td>
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</table>
Figure Legends:

Figure 1  Preparation of the bovine lateral meniscus. A, The anterior and the posterior horn of the lateral meniscus was removed for testing the mid-portion of the meniscus. Subsequently, a standardized vertical lesion within the mid-portion of the meniscus 4 mm apart from the peripheral rim was set. B, Adjacent to the meniscal repair zone, the lesion was completed in the tensile load scenario; C, a modification of the cutting technique of the adjacent meniscal tissue was necessary for sufficient fixation in the shear force scenario. Fixation points and direction of loading (arrow) are illustrated; red rectangle represents meniscal repair area (figure without meniscal repair device).

Figure 2  Biomechanical setup for isolated testing of tensile and shear loading on the meniscus-repair device-construct. A, Setup of the interlocking system setup for tensile load testing (anterior metallic baton partially retrieved for visualization of the peripheral meniscal rim) including the metallic clamp; B, setup of the interlocking system for shear force loading (direction of loading is illustrated by arrows; red rectangle represents meniscal repair area); C, material testing machine including physiologic water bath and temperature control unit.
Figure 3  Average load-to-failure (±SD) of the tested meniscal repair systems in tensile vs. shear force scenario.

* P < .05 compared to Ethibond 2.0 vertical, Ethibond 2.0 horizontal, FasT-Fix (horizontal), and FasT-Fix AB (horizontal).

Figure 4  Average stiffness (±SD) of the tested meniscal repair systems in tensile vs. shear force scenario.

* P < .05 tensile vs. shear force stiffness in Ethibond 2.0 vertical, Ethibond 2.0 horizontal, and FasT-Fix (horizontal).

Figure 5  A, knot breakage of the FasT-fix predominantly observed in the shear force scenario; B, suture breakage at the eyelet of the FasT-Fix predominantly found in the tensile load scenario.
Figure 3

![Bar graph showing Load-to-Failure in N for various fixation methods. The x-axis represents different fixation methods: Ethibond 2.0 (vertical), Ethibond 2.0 (horizontal), Fast-Fix (horizontal), Fast-Fix AB (horizontal), RapidLoc, Meniscus Screw, and Meniscus Arrow. The y-axis represents Load-to-Failure in N, ranging from 0 to 120 N. The graph compares Shear Load (black bars) and Axial Load (gray bars) for each fixation method. Significant differences are indicated by asterisks (*).]