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A Hydrogel Meniscal Replacement: Knee Joint Pressure and Distribution in an Ovine Model Compared to Native Tissue

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Abstract

Pressure distribution of the native ovine knee meniscus was compared to a medial meniscectomy and three treatment conditions including a suture reattachment of the native tissue, an allograft, and a novel thermoplastic elastomer hydrogel (TPE) construct. The objective of this study was to assess the efficacy of a novel TPE hydrogel construct at restoring joint pressure and distribution. Limbs were loaded in uniaxial compression at 45°, 60°, and 75° flexion and from 0–181kg. The medial meniscectomy decreased contact area by approximately 50% and doubled the mean and maximum pressure reading for the medial hemijoint. No treatment condition tested within this study was able to fully restore medial joint contact area and pressures to the native condition. A decrease in lateral contact area and increase in pressures with the meniscectomy was also seen; and to some degree, all reattachment and replacement conditions including the novel TPE hydrogel replacement helped to restore lateral pressures. Although the TPE construct did not perform as well as hoped in the medial compartment, it performed as well as, if not better, than the other reattachment and replacement options in the lateral. Further work is necessary to determine the best anchoring and attachment methods.

Keywords

osteoarthritis; meniscectomy; allograft; reattachment; Tekscan; pressure mapping; thermoplastic elastomer polymer

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1. Introduction

The menisci play a vital role in knee biomechanics and distribution of pressure during both stance and locomotion. Removal of meniscal tissue has consistently been shown to increase peak and mean contact pressures and decrease contact area²³. These pressure distribution changes can, in turn, lead to osteoarthritis, a degenerative disease of the underlying articular cartilage, which is why total meniscectomies are no longer common clinical practice¹³. Rather than simply removing the entire meniscus, efforts have been made to repair or replace the damaged tissue^{25,29}.

One of the more common replacement approaches includes tissue engineering and the use of scaffold material as a base for new tissue deposition^{7,21,31}. Menaflex CMI (Collagen Meniscus Implant, ReGen Biologics Inc., Cary, NC, USA) and Actifit® (Orteq Bioengineering, London, UK) are two clinically available scaffolds. The Menaflex CMI is a collagen matrix scaffold and the Actifit® is a polyurethane scaffold, but both are porous crescent-shaped wedges allowing for ingrowth of fibrovascular tissue before ultimately degrading themselves. However due to the limited blood supply, researchers have found it challenging to achieve a tissue-engineered replacement which maintains its mechanical integrity within the joint over time and scaffold collapse, lack of tissue ingrowth, and scaffold tearing have all been reported^{3,10,37}. Thus, others have investigated inert replacements for the meniscus.

The only clinically available inert replacement is the NuSurface® (Active Implants, LLC., Memphis, TN, USA). Short-term clinical results are promising, however, this polycarbonate-urethane implant has material properties that are very different from the native tissue and it is a free-floating replacement thus requiring a healthy meniscal rim for implantation¹². For this reason, it could be advantageous to develop an inert meniscal replacement material which is mimetic of the native meniscus, and upon implantation results in a similar pressure distribution to the underlying articular cartilage as the native meniscus delivers.

Contact mechanics and pressure distribution have been widely studied in the human cadaveric knee^{1,8,27,36}. However, when developing replacement technologies, an *in vivo* large animal model is necessary for evaluation prior to clinical trials. Ovine models have been found to have a similar anatomy^{2,9,26,32} and similar meniscal material properties to those of humans^{14,19}. For this reason, the ovine model has been used frequently when studying meniscal replacements and scaffolds^{10,20,23,24,40}. Two technologies commonly used to measure tibiofemoral pressure distribution include prescale pressure sensitive films and electronic sensors. Pressure sensitive films such as Fuji® film is advantageous from a shape perspective since the film can be cut to fit the unique shape of the knee joint but only provides singular static readings so the film must be replaced between load and angle changes. Electronic sensors such as Tekscan® have the ability to take dynamic measurements and do not need to be replaced during knee motion and loading. Tekscan® has also been reported to be more reproducible and reliable and is now commonly used in the biomechanics community¹⁶.

One material of interest as a meniscal replacement is a thermoplastic elastomer (TPE) hydrogel composed of polystyrene – poly(ethylene oxide) (SO) diblock and polystyrene – poly(ethylene oxide) – polystyrene (SOS) triblock copolymer blend. This blend allows for the formation of nanostructured spherical micelles which become physically tethered to each other via the triblock. Increasing the triblock or SOS concentration causes the TPE hydrogel to become stiffer. SOS72, or a blend that is 72 mol% triblock has been mechanically characterized in prior studies and has some similar material properties to the native meniscus as well as the ovine meniscus^{14,15}. Some of these properties include an elastic compressive modulus of 0.52MPa and an equilibrium compressive modulus of 0.5MPa. The shear and dynamic complex modulus at 1 Hz have been reported to be 0.18MPa and 0.58MPa respectively. This TPE material is 80% water by weight with a density of approximately 1g/cm³ and a swelling ratio of approximately 100%. Due to its thermoplastic nature not only can this material be molded into a meniscus-like shape during the melt phase and retain that shape after swelling. Although the bulk compressive and shear properties are comparable, ultimately any meniscal replacement needs to be able to successfully transfer load and distribute pressure to the underlying articular cartilage when implanted into the knee joint.

The objective of this study was to assess the native pressure distribution of the ovine knee meniscus and compare mean and max pressures as well as contact area from the native condition to a medial meniscectomy and three treatment conditions including a novel TPE hydrogel construct. Specifically, the three treatment conditions will include a suture reattachment of the native meniscus, an allograft from a donor limb, and the TPE hydrogel construct. It is hypothesized that a medial meniscectomy will result in increased contact pressures and decreased contact areas primarily in the medial hemijoint and that all three treatment conditions will improve upon the meniscectomy condition and restore contact area and pressures to that of the native intact condition.

2. Methods

2.1. Dissection

Eight female ovine (*Ovis aris* Rambouillet X Columbia breed) limbs, four left and four right, were harvested from animals euthanized as part of unrelated studies which were approved by the local animal use ethics committee. Animals were between 3–4 years old and weighed between 63–90 kg. Limbs were immediately removed of skin, excess musculature, and amputated 135mm from the knee joint line on the tibia and 145mm from the joint line on the femur. Once dissected, with the knee joint synovial sac intact, limbs were frozen for later testing.

Prior to testing, joints were allowed to thaw overnight under refrigeration. The quadriceps complex and patella were peeled back exposing the stifle joint. The femoral attachment of the lateral collateral ligament was located and a pilot hole drilled 6mm above the attachment. Subsequent enlargements were made until the through hole was 10.5mm in diameter. The tibial plateau and posterior aspect of the femoral condyles were used as guides with the direction of the tunnel running parallel to both. A second hole parallel to the first with an end diameter of 10.5mm was created in a similar fashion 80mm from the condyle hole centered in the femoral shaft. The second hole was created using a custom upper flexion

fixture to ensure alignment. The limb was set to a flexion angle of 60 degrees and potted using Smooth Cast 321 (Smooth-On, Easton, PN). Polyethylene thread was tied around the dissected quadriceps complex providing an anchoring point for a 10lb weight to be used for patella tensioning. This weight was selected to provide enough force to maintain the patella position during testing.

2.2. Tekscan Calibration

Contact pressure and area were measured with thin film piezoelectric pressure sensors (K-scan model 4041, Tekscan, South Boston, MA, USA) selected based on overall specifications including size and sensitivity. These sensors are created by overlaying a series of rows and columns creating a matrix of intersecting points, or sensels. For the sensors, each of the two prongs has a total of ninety 1mm^2 sensels from which temporal changes in electrical charge due to loading can be gathered and based on calibration back calculated for pressure readings. The choice of a calibration method for Tekscan sensors has been reported to affect the accuracy of readings^{4,18}, so a custom 12 point calibration curve was utilized along with sensitivity adjustments within the Tekscan software for each sensor independently. This calibration approach was found to result in the least amount of error. Sensors were placed stacked between two leather covered metal plates and loaded using a servohydraulic test system (Bionic Model 370.02 MTS Corp., Eden Prairie, MN) to their max pressure of 13.79MPa. At this maximum pressure, using the built-in Tekscan software, the sensitivity of the sensor was adjusted such that it would be its most sensitive to load changes. All loads were then removed from the sensor and slowly reapplied until all sensels were reading load, recording the minimum load the sensor could register. In addition to this minimum pressure reading, readings were taken at 0.54MPa, and from there in increments of 1.08MPa up to 13.46MPa. Custom written Matlab (Mathworks, Natick, MA) code was then used to average all raw value sensel readings and create a calibration curve from a linear interpolation of the applied pressure vs average raw values. Raw values from subsequent *in-situ* testing were applied to this curve to ascertain the apparent pressure at each individual sensel.

2.3. Testing Fixture

Limbs were tested in a custom fixture designed to fix flexion angle of the femur but allow for natural orientation of tibia with respect to the femur using a universal joint and platform with medial-lateral and anterior-posterior translations (Figure 1). Limbs were tested at 45°, 60°, and 75° which cover the active range of motion of a sheep during gait^{33,34}. At each angle loads ranging from 0–181 kg were applied in increments of 22.7 kg effectively testing the unloaded condition through at least 2x bodyweight encompassing previously reported *in vivo* peak loading conditions^{33–35}. To ensure positioning was consistent across testing conditions, location markers were used to maintain medial-lateral translation, varus-valgus rotation, and internal and external abduction compared to the native intact condition.

2.4. Tekscan Implantation

Sensors were covered with polypropylene film to prevent delamination due to moisture exposure. The lateral long digital extensor tendon was excised to allow sensor insertion. Likewise, the synovial capsule attachment to the menisci was severed such that sensors

could be placed in both the medial and lateral hemijoints under the menisci on the articulating surface of the tibia. Polyethylene threads were passed through the joint space and used to pull sensors into place. Sensors were positioned such that the anterior medial aspect of each of the two prongs aligned with the anterior attachments of the menisci. Tekscan sensors remained within the joint during testing of each condition but were realigned between angles and removed and realigned between conditions. No additional sutures or adhesive were used to maintain sensor position.

2.5. Testing Conditions

All limbs were subjected to a total of 5 conditions: intact, medial meniscectomy, suture reattachment of the native excised medial meniscus, medial meniscus allograft transplant, and an implantation of our novel 3D TPE meniscal construct (Figure 2). Given the nature of the conditions all tests were performed sequentially and each condition took approximately 15 minutes and the limbs were hydrated with 1x phosphate buffered saline solution between conditions to maintain hydration. All testing was concluded on a limb typically within 2 hours. For the meniscectomy condition, a scalpel blade was used to sever the native entheses as close to the insertion site as possible. Additional cuts were made to free the medial meniscus from the medial collateral ligament (MCL) while keeping the MCL fully intact. Following the meniscectomy testing condition, two bone tunnels 6 mm in diameter were created originating as near the native attachment sites as possible and exiting in the anteromedial aspect of the tibia. All treatment conditions were pulled around the femoral condyles from the posterior aspect between the MCL and joint space; the sutures were passed through the bone tunnels, and secured via suture knots on the anteromedial aspect of the tibia.

Two sutures were passed through the anterior and posterior horns of the native excised medial meniscus for the suture reattachment condition. This condition represented the best case scenario as it is a perfect match for both geometry and size. The fourth condition, an allograft transplant was implanted using similar bone block methods to previous work^{30,38}. Allografts with 5.9 mm in diameter bone blocks were harvested from separate ovine limbs. Three sizes categorized by overall length and width (small, medium, and large) were available for size matching to the native meniscus. Sutures were passed through the bone blocks and used for securing the allograft within the joint. The allograft transplant represents the “gold standard” for meniscal replacement treatments and represents a replacement that is generally sized and geometry matched. The final condition, TPE hydrogel construct, also followed the concepts of the bone block methods. TPE hydrogel constructs with tabs extending from the main body were created using negative molding and 3D printing techniques. Molds were designed from a μ CT image of a single ovine medial meniscus. Tabs of 5 mm in diameter were added to the solid meniscal body at 90° and 45° from the anterior and posterior horns respectively which allowed for insertion into the bone tunnels created for the other treatment conditions. Tabs were swollen into 6mm diameter plugs of polylactic acid (PLA) that were 3D printed hollow cylinders which provided a solid body for sutures to pass through and together these PLA plugs containing the TPE tabs acted as bone plugs (Figure 3). Similar to the allograft condition, the TPE constructs were created in small,

medium and large sizes for a general size and geometry matched to be made after the native tissue was excised.

2.6. Analysis

Tekscan raw value readings were converted to pressures using the custom calibration curve previously described. Sensel raw values beyond the calibration curve were capped at the maximum of 13.79MPa to avoid inaccuracies of interpolation beyond the curve. Contact area, mean pressure, and max pressure were only calculated from the total number of sensels detecting pressure rather than the total number of sensels which make up the sensor. Since assessments were only made within a single angle and load, a repeated measures analysis of variance (ANOVA) with post hoc Tukey's test was used to determine if there were differences across conditions. This approach paired the data from a single limb whereby reducing errors that could arise from limb to limb variability.

3. Results

In the intact native condition, all limbs were able to be loaded to the max 181kg at all flexion angles (Figure 4). Contact areas were seen to increase in both the medial and lateral hemijoints between 0 and 45kg but reached a plateau around 68kg and little change was seen at higher loading regimes. A greater contact area was observed in the medial hemijoint compared to the lateral across all angles, and the medial hemijoint had a consistent contact area across flexion angles while the lateral hemijoint had a reduced contact area with increased flexion angle. On average, across all angles, for applied loads greater than 68kg, the medial hemijoint recorded a contact area $31 \pm 8\%$ greater than the lateral hemijoint. As expected there was an increase in both maximum and mean contact pressures with increased loading. A multiregression analysis of the impact of angle and load was performed on the data obtained from the native joints. All measures including contact area, max pressure, and mean pressure for both the medial and lateral hemijoints, were found to be affected more by load compared to angle; however, angle still significantly affected all measures except medial contact area and medial mean pressure. Generally pressures were observed to shift from a higher lateral reading at lower flexion angles to greater medial readings at increased flexion angles. Medial vs lateral mean pressure readings were most similar at 60° flexion with only a 10% difference between the two compared to a 74% and 54% difference at flexion angles of 45° and 75° respectively.

Removal of the meniscus and subsequent treatments resulted in increased instability of the joint in part due to the level of dissection necessary for sensor insertion. For this reason, there was an inability to consistently obtain results from all 9 loading conditions at all 3 loading angles in the meniscectomy and treatment conditions. Limbs were tested at each condition/angle/load until either all combinations were achieved or a combination was attempted three times without success. As a result, the total number of testing combinations varied across conditions and limbs. Results were grouped based on angle and load and samples were reduced such that within angle and load each individual limb had an equal sample size for all conditions. This effectively reduced the sample size of limbs tested to $n =$

5 at 45° and loading conditions up to 113kg, n=7 at 60° and up to 159kg, and n=8 at 70° and up to 181kg.

All limbs had similar trends when comparing the meniscectomy and treatment conditions back to the native condition. Likewise, changes seen at lower loads were generally consistent but amplified with increased applied load (Figure 6). All results and significant differences can be seen in Tables 7-1-7-6. The greatest number of significant differences were observed at 60° and 75° (111 out of 480 comparisons and 132 out of 540 comparisons respectively), but these angles also represent the flexion angles where the greatest number of measurements were possible. There were a number of instances where the maximum pressure was at or exceeded the capacity of the sensors, and this was more frequently observed at higher applied loads and higher flexion angles.

Due to limitations with stability and readings obtained within the range of the sensors, the best angle/load combination to compare conditions across angles is 91kg (Figure 7). This loading regime represents 1-1.5x body weight which is physiologically relevant. Overall, test all conditions (meniscectomy, suture reattachment, allograft, and the TPE hydrogel construct) resulted in a reduced contact area and increased maximum and mean pressures within the joint compared to the native intact condition. As expected, the greatest changes were observed in the medial compartment; however, there were a number of significant changes to the lateral hemijoint as well particularly in the meniscectomy condition.

All conditions had a significantly lower medial contact area compared to the native condition at all loading regimes and at all flexion angles. At 75° flexion and at loads above 68kg the suture reattachment was able to significantly increase medial contact area compared to the meniscectomy condition but was still on average 50% lower than the native intact condition. At 60° and 75° flexion the suture reattachment was significantly better at maintaining contact area compared to the TPE construct, and at 75° and loads beyond 136kg, the allograft also outperformed the TPE construct with regards to maintaining medial contact area. The only contact area differences seen in the lateral hemijoint were between the meniscectomy condition and intact condition at 45° and 68–113kg.

Significant differences in medial maximum and mean pressures were identified at lower applied loads as flexion angle increased. At 45° the maximum and mean pressures were significantly increased in all conditions compared to the native at 113kg. Maximum pressure was significantly different in all conditions compared to the native at 91kg for 60° and 45kg at 75°. Mean pressure was generally significantly increased for all but the allograft condition at 60° and beyond 45kg, while at 75° both the suture reattachment and allograft prevented significant increases in mean pressure beyond 45kg. The suture reattachment and allograft conditions were also able to significantly lower medial mean pressures compared to the meniscectomy case at 75° beyond 68kg. The suture reattachment and allografts were also able to reduce mean pressures at 75° and beyond 91kg compared to the TPE construct.

The biggest improvements the treatment conditions offered compared to the meniscectomy condition were seen at the higher angles of 60° and 75° in the lateral hemijoint where maximum and mean pressures were reduced. At these angles, the TPE construct generally

performed superior to the other treatments for maximum and mean pressure. While all treatment conditions were not significantly different from the intact condition, mean and max pressures were still elevated. These elevated readings resulted in the treatments generally not being significantly different from the meniscectomy condition, although the TPE construct was most frequently significantly better than a meniscectomy suggesting it is both better than a meniscectomy and not statistically different from the intact condition.

4. Discussion

This study provided a more complete collection of pressure distribution data for an ovine model, as numerous angles and applied loads were reported as well as a broader comparison to multiple treatment options for meniscal injury including a novel 3D TPE hydrogel construct replacement. To the author's knowledge this the first study to report medial and lateral results following a complete meniscectomy and multiple treatment techniques. Results clearly indicate that a medial meniscectomy significantly alters the contact area and mean and maximum pressures not only within the medial hemijoint but also the lateral. None of the treatment conditions were able to fully restore the joints pressure distribution to the native condition, however, depending on the flexion angle and the applied load the treatment conditions were frequently better than the meniscectomy condition particularly at improving the lateral pressure distributions.

The treatments options presented in this study represent those necessary in more severe cases of meniscal injury including complex tearing extending to more than 50% of the tissue, full radial tears, root avulsions, or uni-compartmental meniscal degradation. In less severe injuries it is not likely that a total meniscal replacement would be clinically suggested, rather a partial meniscectomy would likely be performed. In contrast if overall degradation of the knee joint was observed, particularly if cartilage degradation was also indicated, it would be more likely for patients to receive a total knee replacement rather than a meniscal allograft or replacement construct. The treatments tested within this study represent total repair/replacement options compared to a total meniscectomy which represents a worst case scenario.

Two ovine studies, one at 91kg and 60° and one at 130kg and 6.5°, have previously accessed the native contact areas and peak pressures of both the medial and lateral hemijoints^{17,22}. Both of these reported larger contact areas in the medial hemijoint which is consistent with the findings of this study's intact native condition. Directly comparing results from 60° and 91kg, the current study found average contact areas of 275mm² and 171mm² for the medial and lateral hemijoints respectively compared to the previously reported 252 mm² and 240 mm². The two studies, however, have conflicting reports on maximum pressures as one reports the lateral hemijoint having a higher max pressure while the other reports the medial hemijoint. A gait study by Taylor et. al. concluded load was primarily distributed through the medial compartment which aligns with our findings as well as those by Lee Shee et. al. who found the medial hemijoint had a 42% greater contact area and 12% higher peak pressure^{22,35}.

Although only medial findings were reported, numerous studies have compared contact area, mean pressure, and maximum pressure for the ovine joint in the native intact condition and medial meniscectomy condition, but at limited flexion angles and low loading conditions (10–51kg)^{5,11,23}. On average these reports observed a meniscectomy decreases medial contact area by 65±18% compared to the 70±2% seen in this current study for similar loads. The average increase in mean and maximum pressures found within this study are also comparable to those previously reported, with maximum pressure increasing 290±170% and mean pressure increasing 310±140% at an applied load of 45kg^{6,11,23}.

Overall, the decrease in contact area and increase in maximum and mean pressures seen with the meniscectomy condition were as expected. However, none of the treatment conditions restored these measures. At the higher flexion angles of 60°, the treatment conditions were beginning to outperform the meniscectomy condition but still showed significant increased medial contact area and pressures compared to the native intact condition. One exception to this was that no significant difference was found between the medial mean pressures of the native condition and the allograft. Similarly, while the medial contact area and maximum pressures of the treatment conditions were significantly different than the native intact condition both the suture reattachment and allograft prevented a significant increase in medial mean pressure at 75°. Many of the differences seen between the meniscectomy condition and the treatment conditions were observed in the lateral hemijoint by way of restoring lateral maximum and mean pressures.

The suture reattachment and allografts were specifically chosen to assess the role of geometry and size. The suture reattachment represented a perfect match for both geometry and size, with the allograft size matched only on a scale of small, medium, and large and since it was donor tissue only a general match to the geometry of the excised native meniscus was achieved. Few significant differences were seen between these two conditions. In fact, the allograft had fewer significant differences across the board than the suture reattachment when compared to the native intact conditions. Suggesting that exact size and geometry may not play as significant a role as once thought, and that future replacements could perhaps proceed with a more general meniscus shape in a limited number of sizes (small, medium, large).

A large area of concern which is not addressed in this study is the role of attachment and specifically the attachment method. Although the allograft and TPE construct had bone blocks and solid cylindrical plugs respectively that were used for insertion compared to only sutures for the suture reattachment, all three conditions were limited in the degree to which they could be tensioned and pulled into the joint. The allograft also retained the soft to hard tissue gradient while the suture reattachment condition relied solely on the sutures pulled through the tissue to maintain its position relative the bone tunnels. This could account for the inability of any of the treatment conditions to restore contact area or pressures to the native condition. Clinically there is no consensus on the best fixation method for allografts²⁸, and further work is necessary to determine if using sutures pulled through bone tunnels is sufficient in anchoring meniscal replacements, or if screw fixation is preferable or necessary. Furthermore, additional investigation is necessary to determine the extent to which the fixation method affected the current study.

Comparing the performance of the TPE construct, the only significant difference across the remaining treatment conditions occurred at 45° and less than 113kg of load where the TPE construct had a significantly lower medial contact area compared to the suture reattachment. At both 60° and 75° the TPE construct had decreased contact area compared to the suture reattachment and at 75° the TPE construct also had a significantly lower contact area compared to the allograft. However, for the most part, the measured change in contact area only resulted in a significant change in pressure readings at 75° and above 91kg where the TPE construct had an increased mean medial pressure compared to the suture reattachment and allograft conditions. This suggests there may be some potential extrusion of the TPE construct at higher flexion angles and loads, or the TPE construct was offloading to areas outside the scope of the sensor. The TPE hydrogel material in its current form is a homogeneous isotropic material and may not be able to withstand the hoop stresses created within the knee joint. It is less stiff than the native tissue and would be more likely to deform in the radial direction. Altering the material to have some anisotropy in the circumferential direction by incorporation of fibers could improve its in situ load distribution ability by helping it maintain its position within the joint.

This study is not without limitations. One limitation was the size, shape, and capacity of the sensors used. Significant dissection was required to fit the sensors within the joint which in turn destabilized the knee resulting in incomplete data sets. Additionally, the max capacity of the sensors was 13.79MPa which unfortunately meant that some of the peak loads were not able to be recorded under certain high loading conditions. Bone tunnels were drilled as near to the original attachment locations as possible but had to be shifted slightly to avoid interfering with the anterior and posterior cruciate ligament tibial attachments. This not only reduced the footprint the sensors could occupy, but could also be a source of error when comparing all treatment conditions to the native intact condition. Furthermore, the use of sutures for the suture reattachment condition could have elongated or torn through the native tissue allowing them to extrude within the joint and altering results. Due to the nature of the 5 conditions, they were tested sequentially rather than in a randomized order, so the duration of testing time and order of testing could have impacted final results. Lastly, in the 3D TPE construct condition the TPE hydrogel material used did conform to the joint space to some degree, but was not measured. Understanding how and to what degree the construct material conforms to the joint space would be important for future work particularly with regards to how precise the dimensions of a potential replacement will need to be. A separate optimization study may be necessary to understand how much variance in construct size and shape will be necessary in more of a clinical setting. However, this replacement material and molding process does allow for creating a patient specific constructs so the number of dimensional variations is nearly limitless if such specificity is found necessary. The TPE hydrogel material used has yet to be approved by the FDA for use as a medical device and prior to any *in-vivo* testing it would be necessary to do a cytotoxicity study on the material.

In conclusion, a medial meniscectomy decreased contact area and increased the mean and maximum pressure reading for both the medial and lateral hemijoint. No treatment condition tested within this study was able to fully restore medial joint contact area and medial pressures to the native condition. To some degree, all reattachment and replacement conditions including a novel TPE hydrogel meniscal replacement were significantly better

than a meniscectomy as they typically repaired all increases in lateral pressures. Although the TPE construct did not restore contact area and pressure distribution in the medial compartment as well as hoped, it performed as well as, if not better, than the other reattachment and replacement options at restoring lateral pressures. At high flexion angles and high loads, improvements to the TPE construct are necessary if it is to match the performance of the suture reattachment and allograft. Further work is also necessary to determine the best anchoring and attachment methods.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

Custom testing fixture for Tekscan pressure distribution assessments with translation in the anterior-posterior and medial-lateral as well as universal joint left-side view with quad complex right - front view illustration without the quad complex

Figure 2.

Representative diagrams of the five testing conditions as seen looking down on tibial plateau (light grey) with Tekscan under the menisci (blue).

Figure 3.
Example of TPE hydrogel construct A) melt pressed dry TPE construct B) swollen TPE hydrogel construct with tabs swollen into PLA cylinders

Figure 4.

Results for the native condition contact area for both the medial and lateral hemijoints at all three flexion angles (45°, 60°, 75°) and all loads for n=8 joints

Figure 5.

Results for the native condition max pressure and mean pressure for both the medial and lateral hemijoints at all three flexion angles (45°, 60°, 75°) and all loads for n=8 joints

Figure 6.
Representative results from Tekscan pressure sensors of one joint at 60° medial and lateral hemijoint, data is presented for loading conditions of 45, 91, 136, and 181 kg

Figure 7.

Results for the contact area, max pressure, and mean pressure for both the medial and lateral hemijoints at all three flexion angles (45°, 60°, 75°) with an applied load of 91kg average $\pm$ std. ^N indicates significant difference from native, ^M indicates significant difference from meniscectomy, ^S indicates significant difference from suture reattachment, ^A indicates significant difference from allograft