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TITLE: Improving Treatment for Patellar Instability to Reduce Recurrence and Cartilage Degradation

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14. ABSTRACT
A lateral patellar dislocation is a traumatic event associated with cartilage degradation and a high risk of progression to patellofemoral osteoarthritis. The study focuses on identification of patients likely to progress to recurrent dislocations, characterization of cartilage degradation due to delaying surgical intervention until after recurrent dislocations, and evaluation of reconstruction of the medial patellofemoral ligament (MPFL) as a surgical tool to restore patellar stability.

15. SUBJECT TERMS
patellar instability, osteoarthritis, medial patellofemoral ligament reconstruction, cartilage properties, computational simulation, statistical shape model

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1. **INTRODUCTION**

A lateral patellar dislocation is a traumatic event associated with cartilage degradation and a high risk of progression to patellofemoral osteoarthritis. The standard of care for an initial dislocation is physical therapy, although approximately 40% of patients experience additional dislocations that are associated with an even greater risk of osteoarthritis. Continued dislocations, or recurrent patellar instability, is commonly addressed with surgical stabilization, with reconstruction of the medial patellofemoral ligament (MPFL) the most common approach. The investigators hypothesize that selective early surgical intervention for patellar instability will improve knee function and long term outcomes. The study focuses on characterization of cartilage degradation due to delaying surgical intervention until after recurrent instability, identification of patients likely to progress to recurrent instability based on anatomy and alignment, and establishment of the anatomical parameters for which MPFL reconstruction can successfully restore patellar stability. For the first aim of the study, MRI-based T1ρ and T2 relaxation time mapping of patellofemoral cartilage is being used to characterize cartilage degradation for a group of patients being treated for an initial patellar dislocation, a group of patients being treated for recurrent instability, and a group of control subjects. For the second aim, a statistical shape model is being developed based on the knees imaged for Aim 1 to characterize modes of variation in knee anatomy and alignment associated with recurrent patellar instability. For the third aim, a model for multibody dynamic simulation of knee function is being developed from the statistical shape model to simulate an activity that causes a patellar dislocation and subsequent MPFL reconstruction. The simulation model is being used to optimize parameters of MPFL reconstruction for the modes of variation associated with recurrent patellar instability. The proposed aims are designed to create a paradigm shift for treatment of patellar instability. Patients at high risk for post-traumatic osteoarthritis will be identified for early surgical intervention to preserve cartilage. Optimal treatment approaches will be designed to provide stability with limited risk of complications. Achieving the aims will result in improved short-term and long-term function for patients.

2. **KEYWORDS:** patellar instability, osteoarthritis, medial patellofemoral ligament reconstruction, cartilage properties, computational simulation, statistical shape model

3. **ACCOMPLISHMENTS:**

- **What were the major goals of the project?**

Specific Aim 1 (MRI characterization of cartilage)	**Timeline**	**Completion**
Initiate Enrollment	Months	
Amend IRB approval used for preliminary study	1-2	100%
Initiate enrollment for control group	1	100%
Initiate enrollment for initial instability group	2	100%
Initiate enrollment for recurrent instability group	2	100%
Imaging		
Finalize imaging protocols	1	100%
Imaging of control group	1-12	100%
Imaging of initial instability group	2-20	95%
Imaging of recurrent instability group	2-20	100%
Evaluation of cartilage properties		
T1ρ/T2 sub-region analysis		
Reconstruction of cartilage surfaces	2-20	95%
Create T1ρ/T2 relaxation time maps	3-22	95%
Statistical analysis between 3 groups	23-24	90%
T1ρ/T2 VBR analysis		
Select reference image	18-20	50%
Create T1ρ/T2 relaxation time maps	21-23	0%
Statistical analysis between 3 groups	23-24	0%
Specific Aim 2 (Statistical shape modeling)		
Statistical shape models of bones		
Reconstruct computational models from MRI	2-22	50%
Create template mesh	12-14	75%

Create shape model and modes of variation	12-22	50%
Relate modes of variation to anatomy	23-24	50%
Statistical analysis between 3 groups	23-24	50%
Add alignment to shape model		
Reconstruct models from loaded MRI	6-22	10%
Represent aligned knees with shape model	14-22	0%
Add alignment to principal component analysis	22-24	25%
Statistical analysis between 3 groups	24	0%
Specific Aim 3 (multibody dynamic simulation)		
Create simulation model from shape model	16-22	0%
Create instability loading condition	18-22	100%
Evaluate MPFL reconstruction		
Run instability and MPFL reconstruction cases	20-24	75%
Statistical analysis of modes of variation	23-24	25%
Run alternative MPFL reconstruction cases	23-24	50%

- **What was accomplished under these goals?**

The primary components of Specific Aim #1 are enrollment, imaging, and evaluation of cartilage properties. To date, enrollment with acquired imaging has increased to 21 patients following an initial patellar dislocation, with 13 of those returning for imaging at 6 months. Enrollment of patients being treated for recurrent instability has increased to 15, and 17 subjects have been enrolled as controls. The acquired imaging includes a dual echo steady state (DESS) fat saturated sequence for reconstruction of cartilage surfaces for relaxation time mapping, a T1ρ sequence scan for characterization of relaxation times, and a non-fat saturated Sampling Perfection with Application optimized Contrasts using different flip angle Evolution (SPACE) sequence to highlight bones and soft tissues for reconstruction of computational models. The procedures for automated segmentation and registration have been completed to allow image processing to catch up with enrollment. The algorithms for voxel based relaxometry to reduce the variations in cartilage mapping between subjects and identify local differences between groups are still under development.

Relaxation times have been characterized within lateral, medial and central regions of the patellar and trochlear groove cartilage, along with medial and lateral regions of the tibiofemoral joint. To date, T1ρ-based cartilage properties have been quantified for all but one of the enrolled subjects (Fig. 1). The dislocation group shows trends for elevated T1ρ relaxation times (reduced proteoglycan content) throughout the knee (Fig. 2). For comparison between healthy knees and knees following a first dislocation, T1ρ relaxation times are significantly ($p < 0.05$, t-tests) different at the medial patella, lateral femoral condyle, and lateral tibia. At the medial patella, the T1ρ values tended to decrease with days from the injury ($r^2 = 0.20$, $p = 0.04$), but not to the values noted for healthy knees. Re-evaluation at five to ten months showed a wide variation in cartilage properties. Average T1ρ relaxation times increased by 9% for the central patella. Large variations were noted, such as T1ρ relaxation times for the three regions of patellar cartilage decreasing by approximately 50% for one patient and doubling for another.

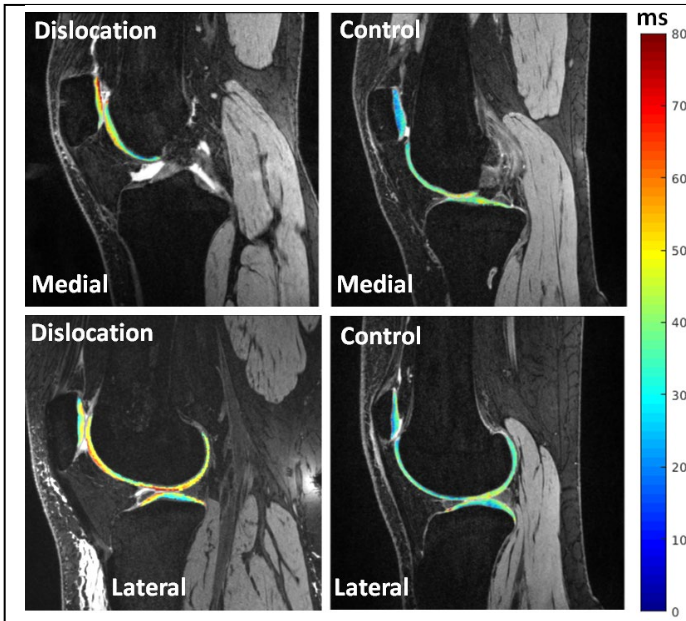

Figure 1: T1ρ maps showing elevated relaxation times for injured knees at the medial patella (top) and lateral tibiofemoral joint (bottom).

Analysis also showed that cartilage degradation following patellar dislocation is primarily a concern for young patients (Fig. 3). Adolescent patients (< 20 years old) make up 13 of the knees with a single dislocation, 10 of the knees with multiple dislocations, and 10 of the healthy knees, with follow up data obtained for 9 of the injured knees. Knees with a single dislocation and multiple dislocations both had significantly higher T1ρ relaxation times than controls for all three regions of patellar cartilage.

The data indicates that patellar dislocations are associated with patellofemoral and tibiofemoral cartilage degradation. Traumatic injury plays a role, especially related to impact of the medial patella against the lateral femoral condyle. Partial recovery of cartilage at the medial patella is possible with time from injury. Systemic factors also contribute to loss of cartilage integrity in the absence of direct traumatic injury. Progression of cartilage degradation following injury is common, but varies dramatically between patients and regions of the knee. At present, cartilage degradation does not seem to be worse following multiple dislocations than for a single dislocation. Overloading cartilage and post-injury inflammation are both potential contributors to cartilage degradation, especially for young subjects.

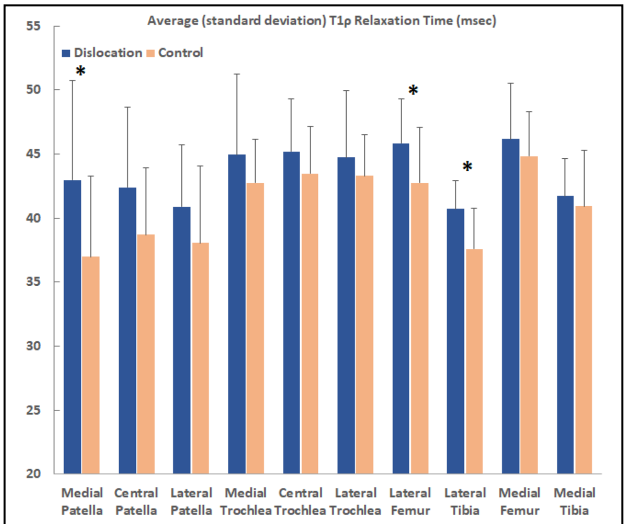

Fig. 2. Elevated T1ρ relaxation times for patellar dislocations for all patients (* = $p < 0.05$).

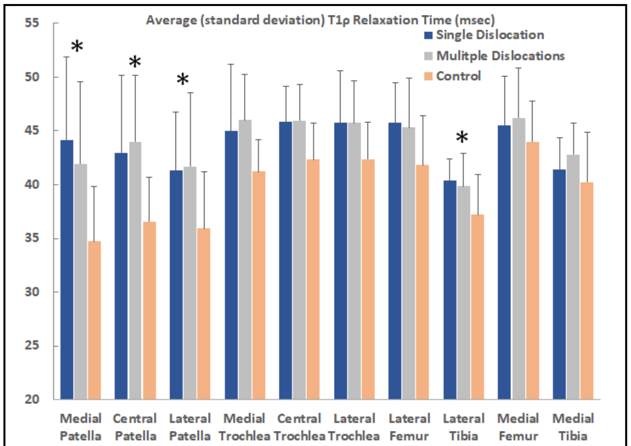

Fig. 3. Elevated T1ρ relaxation times for patellar dislocations for young patients (* = $p < 0.05$).

The primary components of Specific Aim 2 are creating a statistical shape model of the knee and adding alignment of the bones to the shape model. The shape model is being used to identify variations in anatomy and alignment of the bones between the control, initial instability and recurrent instability groups to identify patients who should be considered surgical candidates following an initial patellar dislocation due to a high risk of recurrent instability. Statistical shape models have been created to represent the femur and patella from control knees, knees with an initial patellar dislocation, and knees with recurrent patellar dislocations. The current shape models represent each bone individually, creating a mean geometry plus orthonormal modes of variation, with the modes ranked based on the contribution to overall shape variations. Each bone included in the shape model is also being represented by a linear combination of the modes of variation of the shape model. The coefficients assigned to each mode characterize how an individual bone is represented by the combination of variations within the shape model. The coefficients are also being correlated with T1ρ relaxation times to identify anatomical characteristics that are associated with cartilage degradation. The shape models are continuously evolving as new knees are added to the analysis. The machine learning algorithms for creating statistical shape models are also being refined to improve automated reconstruction of the femur, patella and tibia.

The shape models developed to date represent the femur and patella based on control knees, patients being treated for an initial dislocation and patients being treated for recurrent dislocations. To improve the sample size, training sets were supplemented with knees from other studies. The current shape models are based on 25 healthy controls and 24 patients who experienced one or more patellar dislocations. The primary characteristic of the recurrent dislocation group is a shallow trochlear groove. The mean patella shapes for both dislocation patient groups displayed a more convex medial facet and a decreased medial-lateral width compared with the control group, with the recurrent dislocation group being the most extreme. The sample size needs to be increased to identify shape features specifically related to multiple patellar dislocations.

The shape models have also been used to relate anatomy to cartilage properties following patellar dislocation. The relationships were strongest when focusing specifically on young patients. For subjects being treated for an initial patellar dislocation, the primary relationships between T1ρ values and anatomy can be assessed by evaluating mode 4. For the knees that have been included in the statistical shape model to date, injured and contralateral knees were combined to reduce the influence of direct traumatic injury. At the baseline evaluation following injury, T1ρ values for all the cartilage on the patella and within the trochlear groove increased as mode 4 shifted toward a deep trochlear groove and valgus orientation ($n = 14$, $r^2 = 0.31$, $p = 0.037$ for patella; $r^2 = 0.40$, $p = 0.015$ for trochlear groove, Fig. 4). By the follow up time point, however, trends relating patellofemoral T1ρ values to this mode of variation reversed ($n = 11$, one contralateral knee missing, $r^2 = 0.56$, $p = 0.008$ for patella; $r^2 = 0.40$, $p = 0.038$ for trochlear groove).

The relationships between cartilage properties and anatomy for young patients being treated for a patellar dislocation show that some characteristic of the injury changes how cartilage responds to knee function. Constraint of the patella is related to cartilage degradation in the acute phase following patellar dislocation, when patients are limiting activities. A constrained patella may indicate high contact forces prior to injury or a high energy injury was required to dislocate the patella, resulting in direct trauma to medial cartilage and inflammation. On the contrary, by the follow up time point, when patients have generally returned to full activities, cartilage degradation seems to be related to lateral patellar maltracking, likely exacerbated by injury to medial soft tissue restraints during dislocation. Patellar maltracking could overload cartilage or create micro-traumas that perpetuate ongoing inflammation.

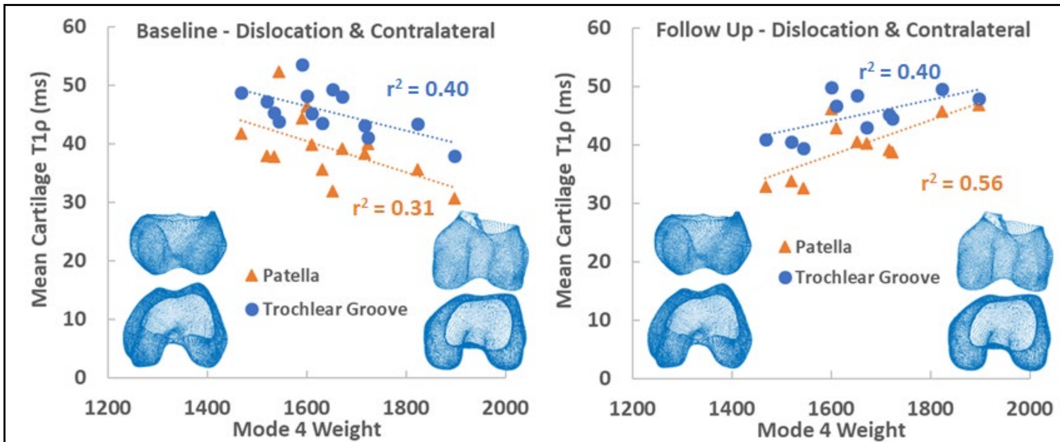

Fig. 4. Correlations relating high T1ρ values (cartilage degradation) to anatomical parameters from a femoral statistical shape model. Patellar and trochlear groove T1ρ values are plotted for dislocated and contralateral knees at baseline (left) and at follow up (right). Shapes representing ± 3 standard deviations from the mean along the modes are shown on the x-axis.

The primary goals of Aim 3 are to create a simulation model from the statistical shape model, simulate a dislocation event, and evaluate options for MPFL reconstruction. The approach is based on multibody dynamic simulation, with bones of the knee treated as rigid structures with reaction forces developed at articulating surfaces based on Hertzian contact (Fig. 5). Springs represent the relevant ligaments, tendons, and retinacular structures. Quadriceps and hamstrings muscle forces and body weight, combined with simulated hip and ankle joints, induce motion governed by the joint reaction forces and spring forces.

Dynamic simulation of knee function is being used to represent loading conditions that induce dislocations and routine functional activities with and without an MPFL graft. MPFL reconstruction is being simulated with springs representing a dual strand gracilis tendon graft, with a stiffness of 20 N/mm, applied to the standard attachment point on the femur, wrapping around the medial condyle, and attached at the medial edge of the patella. Patellar tracking is quantified based on clinically used parameters of bisect offset index and lateral patellar tilt, which express position of the patella with respect to the trochlear groove. Patellofemoral contact pressures are quantified for flexion angles with the patella constrained by the trochlear groove. The contact pressure distribution is quantified using a discrete element analysis approach that balances patellofemoral reaction forces and moments quantified from multibody dynamic simulation with joint reaction forces and moments quantified from overlap of the patellofemoral cartilage surfaces based on linear elastic theory. The overlap of the cartilage surfaces determines the contact pressure distribution.

To date, 13 computational models based on knees with recurrent patellar instability have been used to represent a pivoting maneuver that causes a patellar dislocation and a stable dual limb knee squat. The pivoting maneuver includes a total quadriceps force that increases from 180 N at contact to 1000 N with the knee at 90° of flexion, coupled with an external torque of 12 N-m applied to the distal tibia to represent an internal pivot with the foot set in the ground. The squatting motion is based on lower quadriceps and gravitational forces without torque applied to the tibia. The MPFL graft restored patellar stability during pivoting for 11 of the 13 models. Anatomical parameters related to patellar height, trochlear dysplasia and orientation of the patellar tendon were measured from the models to identify conditions that contribute to ongoing patellar instability following MPFL reconstruction. These parameters were correlated with lateral patellar tracking based on bisect offset index with the knee at 45° of flexion, representing a position at which the patella should be captured by the trochlear groove (Fig. 6). Bisect offset index at 45° was significantly correlated with both patellar height (Caton-Deschamps index, r^2 = 0.40, p = 0.02) and

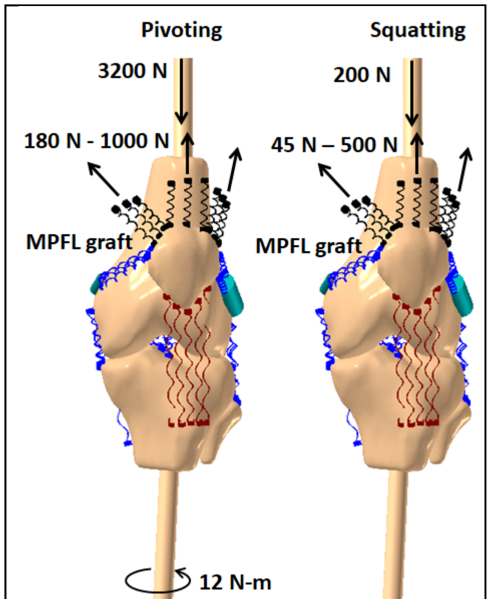

Figure 5: A computational model for dynamic simulation of knee function showing the loading conditions to represent a dislocation event (pivoting) and stable motion (squatting).

trochlear dysplasia (lateral trochlear inclination angle, $r^2 = 0.48$, $p = 0.01$), but not with orientation of the patellar tendon (tibial tuberosity to trochlear groove distance, $p > 0.8$). The analysis indicates that excessive patellar height and a shallow trochlear groove place a knee at risk for patellar dislocation following MPFL reconstruction. Follow up analysis can examine alternatives to alter graft tension or attachment points to reduce the risk of patellar dislocation for at risk knees, while also determining if the changes adversely influence patellofemoral contact pressures during daily function (knee squatting). In some cases, alternative surgical approaches that require bone cuts might be needed to adequately stabilize the patella.

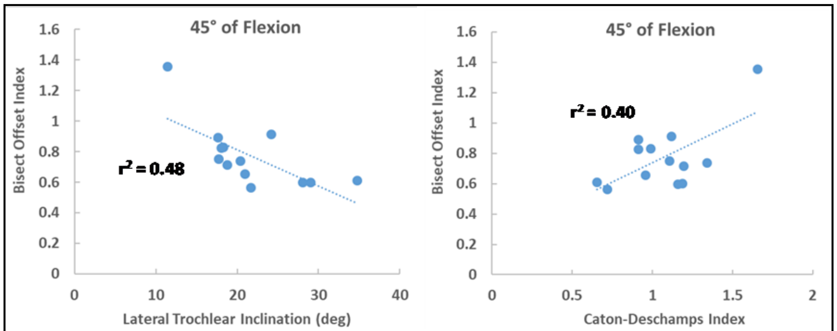

Figure 6: Correlations relating bisect offset index to lateral trochlear inclination and Caton-Deschamps index at 45° of flexion during simulated pivoting following MPFL reconstruction.

- **What opportunities for training and professional development has the project provided?**

Social distancing practices due to covid-19 limited personal interaction of the lead investigators with students, fellows, and residents throughout the project. Roles were identified for students, fellows and residents to participate in the study through a combination of onsite and remote work, and mentorship was provided through online lab and project meetings. Currently, two orthopedic residents are working on the project to measure anatomical parameters and quantify patient-reported outcomes. This data will be related to cartilage properties. Two post-doctoral fellows and one graduate student have worked on the project to produce T1ρ relaxation time maps. These students have been authors on conference presentations and one submitted manuscript.

- **How were the results disseminated to communities of interest?**

Nothing to Report

- **What do you plan to do during the next reporting period to accomplish the goals?**

The primary goal for Aim #1 for the next funding period is to finish enrolling new subjects and bringing back subjects for follow up evaluations for further evaluation of cartilage properties. Planned enrollment has been met for all groups. Four subjects will be due for six month follow up evaluations over the next few months. Some imaging funds remain to add a few subjects to each category, particularly to expand the sample size for young patients.

The primary goal for Aim #2 for the next funding period is to increase the number of models processed for statistical shape modeling from existing imaging and newly acquired imaging. Imaging is currently available from seven initial dislocation subjects, fifteen recurrent dislocation subjects, and six control subjects to add to the statistical shape model. The automated algorithms for reconstruction of bone models from the MRI scans to keep pace with the acquired imaging are nearly complete for the femur, but still under development for the patella and tibia. As new models are developed, statistical analyses to identify differences in the shape of the individual bones between the control, initial dislocation, and recurrent dislocation groups will continue. Regression analyses relating pathologic anatomy to cartilage degradation for healthy and injured knees will also continue.

The primary goal for Aim #3 for the next funding period is to further evaluate MPFL reconstruction to stabilize the patella during a potential dislocation event. The analysis to date has identified anatomical conditions that leave the knee at risk for patellar dislocation following MPFL reconstruction. Over the next six months, alterations in MPFL graft tension and attachment points will be explored to improve stability for these knees, with the consequences for patellofemoral contact pressures also evaluated.

4. IMPACT

- **What was the impact on the development of the principal discipline(s) of the project?**

The current data provides the first characterization of cartilage properties throughout the knee in the acute phase following a patellar dislocation. The data confirms that traumatic impact at the medial patella is the primary source of injury to cartilage. Cartilage at this site can partially recover, however. For young patients, patellofemoral cartilage degradation is also noted away from the site of traumatic impact. No other study has shown that young patients are more prone to early cartilage degradation following a patellar dislocation. A larger sample size could identify additional patellofemoral regions with cartilage degradation following patellar dislocation. The initial data on cartilage properties also indicates knees that experience a patellar dislocation are also at risk of degradation of cartilage within the tibiofemoral joint, which has not been previously described for this population. The initial comparison of anatomical features between control subjects, subjects experiencing a single dislocation and subjects experiencing multiple dislocations indicate there are specific features characteristic of multiple dislocations. The primary feature is a shallow trochlear groove, which has been identified in several previous publications. Other features related to shape of the patella and femoral condyles can also be identified, however. With a larger sample size, the combination of features that indicate risk of recurrent dislocations can be more accurately characterized to help clinicians identify subjects who should consider surgical treatment after an initial dislocation to prevent multiple dislocations. The data to date provides information on relationships between anatomical features of the femur and cartilage properties that have not been shown previously. Specifically, limited constraint of the patella leads to increased cartilage degradation from the time of injury to approximately six months later. The initial data on simulated knee function following reconstruction of the medial patellofemoral ligament (MPFL) indicates that the approach does not consistently stabilize the patella during activities such as landing and pivoting on one foot. In particular, a shallow trochlear groove and elevated patellar height are correlated with lateral patellar maltracking during pivoting, indicating standard MPFL reconstruction may not be suitable for patients with these characteristics. Prior to this study, MPFL reconstruction had not been evaluated while representing functional activities that place the patella at risk of dislocation.

- **What was the impact on other disciplines?**

Nothing to Report

- **What was the impact on technology transfer?**

Nothing to Report

- **What was the impact on society beyond science and technology?**

Nothing to Report

5. **CHANGES/PROBLEMS:**

- **Changes in approach and reasons for change**

Nothing to Report

- **Actual or anticipated problems or delays and actions or plans to resolve them**

The primary disruption for the initial study period was related to the covid-19 pandemic. The pandemic altered the work environment, access to students and ability to recruit subjects. The investigators have developed new processes to address all of these issues. Although there is a delay in the overall timeline for the study, the investigators expect to meet the targeted goals by the end of the one year no cost extension. One other source of a delay has been ongoing development of machine learning based algorithms for automated processing of imaging data that has limited the number of models included in the statistical shape model. Considering the extensive manpower requirements for manual tracing of bones from imaging and manual adjustments to semi-automated reconstruction, the decision was made to primarily focus on development of fully automated algorithms so that the remaining imaging data can be processed as efficiently as possible. Algorithms are nearly ready for automated reconstruction of the femur, which will then be adapted for the patella and tibia. Enhancements to the statistical shape model to evaluate alignment of the three bones to each other are also not ready at this time. To offset this, shape data from the individual bones is being supplemented with clinical measures from the imaging to characterize the superior-inferior and medial-lateral alignment of the patella and the medial-lateral alignment of the patellar tendon attachment on the tibia with respect to the femur. The shape features and alignment features are being correlated with the T1ρ relaxation times processed to date to evaluate the influence of anatomy on cartilage properties. This analysis will be expanded as images are processed for more subjects. Without the deformable statistical shape model including all three bones to incorporate into simulation, anatomical models with a wide range of pathological conditions were developed to represent the knee during a pivoting maneuver. The correlations between clinical measures of anatomy and simulated output are being used to address the aim related to features that influence the effectiveness of MPFL reconstruction while the statistical shape model is still being developed.

- **Changes that had a significant impact on expenditures**

Expenses were limited in years 1 and 2 to allow a no cost extension to complete enrollment, imaging and analysis. Some cost savings for imaging have allowed a modest increase in the sample size.

- **Significant changes in use or care of human subjects**

After a temporary pause in recruiting due to covid-19, full enrollment has been allowed over the past eighteen months.

- **Significant changes in use or care of vertebrate animals.**

Nothing to report

- **Significant changes in use of biohazards and/or select agents**

Nothing to report

6. **PRODUCTS:**

- **Publications, conference papers, and presentations**

Conference presentations for the past year

Elias JJ, Yang M, Li M, Ma J, Lartey R, Gaj S, Colak C, Winalski C, Farrow L, Li X. Cartilage Degradation Related to Patellar Dislocations: Comparing T1ρ Relaxation Times to Anatomical Characteristics from Statistical Shape Models. OARSI Virtual World Congress, April 29 - May 1, 2021, poster 404. Federal funding acknowledged.

Elias JJ, Watts JC, Farrow LD. Anatomical Characteristics Contributing to Patellar Dislocations Following MPFL Reconstruction. American Society of Biomechanics Annual Meeting, August 10-13, 2021, virtual, poster 336. Federal funding acknowledged.

Watts JC, Elias JJ, Farrow LD. Anatomical Characteristics Contributing to Patellar Dislocations Following MPFL Reconstruction. American Society of Biomechanics Regional Meeting, September 16-17, 2021, Cleveland, OH, podium. Federal funding acknowledged.

Watts JC, Farrow LD, Jones TJ, Elias JJ. Computational Simulation of MPFL Reconstruction Stabilizing the Patella during a Pivot Landing. ISAKOS Congress 2021, paper Federal funding acknowledged.

Elias JJ, Yang M, Li M, Lartey R, Murray J, Farrow LD, Winalski CS, Li X. Patellar Dislocation Alters the Relationship between Cartilage T1ρ Relaxation Times and Femoral Shape. ORS Annual Meeting, Feb 4-8, 2022, Tampa, FL, poster 0583 Federal funding acknowledged.

Elias JJ, Yang M, Li M, Lartey R, Murray J, Farrow LD, Winalski CS, Li X. Elevated Patellofemoral and Tibiofemoral Cartilage T1ρ Relaxation Times Following an Initial Patellar Dislocation. ORS Annual Meeting, Feb 4-8, 2022, Tampa, FL, podium 0286 Federal funding acknowledged.

- **Website(s) or other Internet site(s)**

Nothing to Report

- **Technologies or techniques**

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**

Within the existing framework for MRI-based relaxation time mapping of cartilage properties, machine-learning algorithms for automated processing of imaging data, which were originally developed to focus on tibiofemoral osteoarthritis following ACL injury, have been expanded to include patellofemoral compartments. Initial automated algorithms to reconstruct bone models and add them to statistical shape models have also been developed. For development of a statistical shape model, algorithms have been developed to align a computational model representing a loaded knee with local coordinate systems for each bone and a global coordinate system to include the shape of each bone and the alignment within the modes of variation. Within the existing framework for dynamic simulation of knee function, loading and boundary conditions have been developed to consistently represent a pivoting maneuver causing a patellar dislocation. Models representing knees that are not adequately stabilized by MPFL reconstruction have been developed for evaluation of alternative surgical parameters to stabilize the patella. The data collected to date is being developed into a database including the subjects from all groups. The database contains demographic information for each subject, T1ρ relaxation times for the tibiofemoral and patellofemoral cartilage, weighting factors along each mode of variation from the statistical shape models, clinical measures of patellofemoral anatomy and alignment, and patient-reported outcome measures.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name:	John Elias – no change
Name:	Mingrui Yang
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	0000-0002-8902-6316
Nearest person month worked:	1.5
Contribution to Project:	Dr. Yang has been developing the statistical shape model.
Name:	Jennifer Turczyk – no change
Name:	Mei Li – no change

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Nothing to Report

- **What other organizations were involved as partners?**

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

Nothing to Report

9. APPENDICES