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© Portland Pivot Kick Study: Can a novel physical exam maneuver for medial meniscus tears predict improvement after partial medial meniscectomy?



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Samuel Moulton¹, Sean Sterrenberg¹, Kenneth R Gundle¹, Mark Berkson²

¹Oregon Health Sciences University; ²Portland Veterans Affairs Medical Center



Sean Sterrenberg

Oregon Health Sciences University

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We use this protocol and it's working

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Abstract

Specific Aims/Purpose

This study aims to evaluate patients with symptomatic medial meniscus tear verified by MRI using a novel physical exam maneuver, the Portland Pivot Kick (PPK). The goal is to assess whether patients with symptomatic medical meniscus tears have a change in the PPK before and after arthroscopic partial medial meniscectomy. This physical exam maneuver may help predict the potential benefit of arthroscopic partial medial meniscectomy in treating mechanical symptoms, even in the setting of degenerative joint disease.

Hypothesis: Patients with a positive preoperative PPK will have improvement of mechanical symptoms and significantly improved subjective outcomes scores following arthroscopic partial medial meniscectomy.

Scientific Rationale and Significance

Medial meniscal tears are common and they are often associated with osteoarthritis in elderly patients presenting with knee pain. One study reported a prevalence of 86% of medial meniscal tears in patients with symptomatic osteoarthritis. Management of medial meniscal tears include structured physical therapy and arthroscopic partial meniscectomy, with 700,000 partial meniscectomies performed annually in the United States. Multiple randomized control trials have evaluated the efficacy of partial meniscectomies in patients with osteoarthritis by comparing surgery to physical therapy. Three of the 4 studies found no benefit to partial meniscectomy, while one study found a significant benefit to surgical treatment. However, up to one third of patients in the randomized control trials crossed over from physical therapy to arthroscopic partial meniscectomy. A follow up analysis found that patients who crossed over to surgery after starting a course of physical therapy had a higher acute level of pain and similar outcome scores to patients who initially underwent surgery. These findings suggest that a subset of patients with meniscal tears and osteoarthritis elect for surgery even after physical therapy, leading to an improvement in symptoms.

Mechanical symptoms of catching or locking are often attributed to meniscal tears and used as evidence to recommend partial meniscectomy. However, there is no consensus on what exactly are mechanical symptoms specific to meniscal tears. Prior studies have evaluated mechanical symptoms solely based on subjective patient reports of knee catching and/or locking. There is a paucity of objective measures of mechanical symptoms of meniscal tears. This study will investigate the efficacy of the PPK in identifying medial meniscal tears that may improve with surgical intervention. Medial meniscal tears are a common finding amongst the veteran population with knee pain, with a prevalence approaching 50% in older patients. This study will help provide a more objective measurement of symptomatic medial meniscal tears for both veterans and the general population.



Guidelines

Guidance to Performing the Study

Study Population

A total of 75 patients will be included in the prospective part of the study. All adult veteran patients who are seen the Sports Orthopaedic clinic at VAMC with a medial meniscal tear proven on MRI will be offered inclusion in this study. Recruitment will occur only through a staff orthopedic surgeon after the patient has been clinically determined to have a medial meniscal tear. Non-veteran patients will not be included in the study. Exclusion criteria include any patients with prior surgery on the index knee, an intraarticular loose body on MRI, an anterior cruciate ligament (ACL), posterior cruciate ligament (PCL) tear, or a bucket handle tear or meniscal tear deemed amenable to repair rather than partial meniscectomy. No inclusion or exclusion criteria included are based on age, gender, racial/ethnic origin, pregnancy or childbearing potential. An a priori power analysis was performed assuming a power of 0.8 and an alpha of 0.8 which predicted a sample size (n) between 50-64 patients. We anticipate around a 10% drop out rate due to loss of follow up after surgery. We plan to enroll 75 patients over the course of a 24 month period, which provides a sufficient number of patients. No materials or advertisements will be implemented to recruit subjects. No payments or rewards will be offered for inclusion into this study. Medial meniscal tears do not disproportionately affect women or specific minority groups, so it is not necessary to select for a specific demographic of patients.

We plan to include up to 100 patient records in the retrospective part of the study. The retrospective series will consist of patients previously treated with a partial medial meniscectomy by the senior author. These patients have all completed the usual amount clinical follow up with the senior author.

Subject Identification/Recruitment

All adult veteran patients who are seen the Sports Orthopaedic clinic at VAMC with a medial meniscal tear proven on MRI will be offered inclusion in this study. Recruitment will occur only through a staff orthopedic surgeon after the patient has it has been clinically determined to have a medial meniscal tear. No materials or advertisements will be implemented to recruit subjects. No payments or rewards will be offered for inclusion into this study. The selection process will be just, fair and equitable because patients will only be selected from those who present to our Sports Medicine Orthopaedic clinic and have medial meniscal tears. No patient demographics such as gender, race or ethnicity will be used during the selection process. Furthermore, no outside advertisements will be used limiting the possibility of advertising to only specific patient populations.

For patients whose data we will retrospectively analyze, there will be no recruitment as we will not be interacting with these patients. We are requesting a waiver of process of informed consent and authorization for the retrospective data analysis component of this study.

Research Design and Methods

This is a single-institution study of orthopedic patients at the Portland Veterans Affairs Medical Center (VAMC). The study will evaluate the efficacy of a novel physical examination maneuver, the PPK in determining mechanical



knee pain symptoms from a medial meniscal tear. Patients are asked to apply pressure momentarily with inside of their foot of the injured leg against a 1 gallon container filled with water. The pressure against the container of water will place tension on the medial knee joint capsule recreating pain or discomfort patients with medial meniscal tears experience during daily activities. The pain or discomfort will be brief and not cause any last pain or damage to the patient. Prior to performing the maneuver, patients will be informed that it will cause brief pain or discomfort.

Orthopedic patients evaluated in the Sports Orthopaedic clinic on the 8th floor at the Portland VAMC with medial meniscal tears confirmed on MRI will be offered inclusion. The clinical evaluation including physical exam maneuvers as well as the surgical procedure are currently part of the usual care of the PI. No new physical exam maneuvers or operative interventions will be used in this study. The medical records of prior patients who received a partial meniscectomy will be retrospectively evaluated to see whether the PPK maneuver changed after surgery. There will be no direct patient interaction for the retrospective component of the study. A future cohort of patients will be followed to evaluate prospectively the efficacy of the PPK maneuver.

The prospective observational cohort study was designed and will be reported using the STROBE cohort quidelines. Patients will be evaluated by the PI using his standard physical examination including the PPK, McMurray test, and the presence or absence of medial sided knee tenderness. MRI will confirm the presence of a medial meniscal tear. Radiographs of the affected knee will be evaluated by two orthopaedic surgeons to determine the extent of osteoarthritis via the Kellegren Lawrence grading system. Questionnaires include subjective patient outcomes scores, specifically the Knee Injury and Osteoarthritis Outcome Score (KOOS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) outcome scores. These questionnaires are already used for clinical purposes in the Sports Medicine Orthopaedic clinic. Please see examples of the KOOS (Appendix I) and WOMAC (Appendix II) questionnaires in the appendix.

All patients included in the study will undergo a 4-week home exercise program, which is the standard of care prior to the date of surgery. Patients with a positive PPK who have not improved will be offered surgery consistent with current clinical practice of the Pl. Patients with negative PPK, and those improving with non-operative treatment, will continue with home exercises, consistent with current clinical practice of the PI. Endpoints for patients undergoing partial medial meniscectomy will be reexamined and fill out subjective patient outcomes scores at 6 weeks, 6 months and 1 year after surgery. Endpoints for nonoperative patients will fill out subjective outcomes scores at 6 months after the initial visit. Follow-up phone calls may occur after surgery to remind patients to schedule follow up appointments and to ask about how they are doing clinically. All procedures performed are for clinical purposes. The number of clinical visits and the timing of clinic visits are the additional research components.

Data will include patient demographics, subjective patient outcome scores, physical examination findings, radiographic grading of osteoarthritis, and MRI presence of a medial meniscal tear. Patient data will be collected from CPRS, deidentified and stored in an Excel file on a restricted access network on a Research Drive folder within the VA computer system.

Patients evaluated in the PI's Orthopaedic Surgery clinic will be screened for inclusion in the study. The anticipated length of the study is 24 months, with 360 patients screened and 75 patients enrolled. Based on a prior power analysis, a sample size of 75 patients will be sufficient to evaluate an 80% change (or 80/100 proportion of patients with a change) the change of the PPK before and after partial meniscectomy. The expected study population includes all veterans seen in the PI's Orthopaedic Surgery clinic, which will be predominantly



older Caucasian male patients given the demographics of the veteran population in the surrounding Portland metro area. No new drugs or procedures will be used in the study.

Troubleshooting

1

The study timeline is as follows:

	Visit 1	Visit 2		Visit 4	Visit 5	Visit 6
	(The day surgery	(Preoperative	Visit 3	(6 weeks	(6 months	(1 year
	is decided)	appointment)	(Surgery)	Postop)	postop)	postop)
WOMAC Questionnaire	Х	х		Х	Х	Х
KOOS Questionnaire	Х	X		Х	Х	Х
Portland Pivot Kick Exam	Х	х		Х	Х	Х
Joint line tenderness	х	х		Х	Х	Х
McMurray test	Х	X		Х	Х	Х

- 2 **Initial visit:** The patient will be evaluated by physical examination including the PPK maneuver. Arthroscopic partial meniscectomy will be offered as a surgical option to the patient. The patient will fill out the WOMAC and KOOS questionnaire.
- 3 Preoperative visit: The patient will be evaluated by physical examination including the PPK maneuver. Arthroscopic partial meniscectomy will be offered as a surgical option to the patient. The patient will fill out the WOMAC and KOOS questionnaire.
- 4 **Surgery:** : Partial medial meniscectomy
- 5 6 week post operative follow up: The patient will be reevaluated by physical examination including the PPK maneuver. The patient will fill out the WOMAC and KOOS questionnaire.
- 6 6 month post operative follow up: The patient will be reevaluated by physical examination including the PPK maneuver. The patient will fill out the WOMAC and KOOS questionnaire.
- 7 1 year post operative follow up: The patient will be reevaluated by physical examination including the PPK maneuver. The patient will fill out the WOMAC and KOOS questionnaire.
- 8 The patient will perform the following home exercises during the postoperative period:

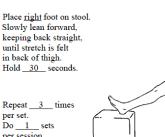
HIP / KNEE - 37 Stretching: Quadriceps (Standing)

Pull <u>right</u> heel toward buttock until stretch is felt in front of thigh. Hold 30 seconds.



Repeat 3 times per set. Do __1__ sets per session. Do __1__ sessions per day.

HIP / KNEE - 39 Stretching: Hamstring (Standing)



Repeat 3_ times per set. Do __1_ per session. Do __1_ sessions per day.





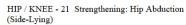
Tighten muscles on top of thighs by pushing knees down into

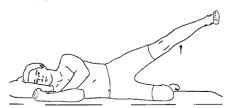
Repeat 10 times per set. Do 1 sets per session. Do 1 sessions per day.

HIP / KNEE - 11 Strengthening: Quadriceps Set

Tighten muscles on front of right thigh, then lift leg 18 inches from surface, keeping knee locked.

Repeat 10 times per set. Do 1 sets per session. Do __1_ sessions per day.





Tighten muscles on front of left thigh, then lift leg 18 inches from surface, keeping knee locked.

Repeat <u>10</u> times per set. Do <u>1</u> sets per session. Do <u>1</u> sessions per day.

HIP / KNEE - 22 Strengthening: Hip Adduction (Side-Lying)



Tighten muscles on front of right thigh, then lift leg 8 inches from surface, keeping knee locked.

Repeat <u>10</u> times per set. Do <u>1</u> sets per session. Do <u>1</u> sessions per day.