KERLAN-JOBE INSTITUTE

PROJECT TITLE	Pain outcomes after posterior capsular injection during Anterior Cruciate Ligament (ACL) reconstruction: A prospective, randomized trial.
BACKGROUND and RELEVENT REFERENCES	Post-operative pain control following elective anterior cruciate ligament reconstruction continues to be a hurdle for orthopaedic surgeons. This obstacle becomes particularly problematic during the first 36 hours after the operation, when the patient is experiencing pain at its peak intensity. Good control of pain leads to better patient comfort, confidence to place weight on the operative limb and improved ability to perform critical exercises in this period to improve joint range of motion. (Rev Bras Ortop. 2015 Jun 16;50(3):300-4) A variety of anesthetic techniques have been employed to reduce pain including: cryotherapy, systemic analgesic and anti-inflammatory drugs, intrathecal, regional blockade of peripheral nerves and frequently intra-articular injections. Each technique has been studied at length with mixed but overall favorable results. However, in the authors' experience, after femoral nerve blockade, patients continue to complain of posterior knee pain in the Post-Anesthesia Care Unit (PACU) and peri-operative period. Intra-articular injections comprised of morphine and other Na-channel blocker analgesics may curb some of this pain by bathing the posterior capsule in anesthetic. However, there is still a large concern amongst orthopaedic surgeons about the potential harm these agents may have on the knee's healthy articular cartilage surfaces. The long term effects, including chondrolysis have been documented in the shoulder and while in the short term this effect is diminished there is still hesitation among surgeons to use this form of pain blockade. This has led the authors to adapt a technique of isolated posterior capsular injections after total knee replacements from the joint arthroplasty literature, which has shown favorable results with low complication risk. (Orthop Clin North Am. 2015 Jan;46(1):1-8). We plan to study the effectiveness of this technique during ACL reconstruction in an attempt to curb the amount of posterior knee pain and decrease the overall narcotic use postoperatively while limiting the exposure of the native cartilage to harmful agents. References: See Attached Sheet
OBJECTIVE	To determine if there is a significant difference in post-operative pain visual analog pain (VAS) scores, a decrease in time before first narcotic and total decrease in peri-operative narcotic use after ACL bone-patellar-bone reconstruction after a posterior capsular injection with 20cc of 0.5% marcaine.

SITE/RESOURCES **Please list location where study will be carried out and any staffing resources that will be needed. Indicate if site/staff have committed to project or if they have been approached**	Kerlan Jobe Orthopaedic Clinic Post-Anesthesia Care Unit Nursing staff: if the fellow is unavailable they will deliver the visual analog pain scale survey to patients at specific time points. – Staff has been instructed on how to administer the surveys appropriately. Anesthesia- We have discussed with the anesthesia staff that the femoral nerve blocks will be standardized for all patients in the study. Statistician – Cedars STATs department has been contacted
METHODOLOGY **To include:** **-hypothesis** **- variables** **- methods** **-statistical analysis plan** **- power analysis**	**Hypothesis:** Patients who receive a posterior capsular injection with Marcaine 0.5% during ACLR will report less pain and have less total narcotic use immediately post-op and up 4 days postoperatively compared to those that did not receive this injection. **Variables** 1) Injection Group a. VAS Scores @ 15min/1 hour/POD1- 4 b. Time to first narcotic c. Total narcotic use d. 3 month Post-op visit assessment ((rule out chondrolysis) 2) Non-Injection Group a. VAS Scores @ 15min/1 hour/POD 1-4 b. Time to first narcotic c. Total narcotic use d. 3 month Post-op visit assessment (rule out chondrolysis) **Methods** A prospective series of consecutive patients undergoing primary ACLR will be recruited from a preoperative log of patients seeing one of four sports medicine fellowship trained surgeons within our group. Patients undergoing primary unilateral anterior cruciate ligament reconstruction (ACLR) either with bone-patellar bone autograft or Achilles tendon allograft will be included by surgeons using similar techniques and fixation options. *Inclusion Criteria* – Adult individuals (ages 18-60), both sexes, submitted to elective ACL reconstructions with or without partial menisectomies of the medial or lateral meniscus. *Exclusion Criteria* – 1) Multiligamentous injury or revision surgery 2) Known narcotic/substance abuse or regular opiate use 3) Known allergy to any medication or anesthetic being used in this study 4) Patients with pre-existing diabetic or femoral neropathy 5) INTRAOPERATIVELY- if chrondral microfractures, inside-out or outside-in meniscal repairs were performed (***Since these additional surgeries within the joint may increase the perceived level of pain post-op***) After consenting to participate, subjects will be randomized into one of two groups. Using a random number generator,

	http://stattrek.com/statistics/random-number-generator.aspx 60 consecutively enrolled patients will be placed in their appropriate study arm. (Odd numbers = Control Group) (Even numbers = Experimental Group). Only the patient will be blinded to which arm of the study they belong. Group 1(Control) patients will undergo routine arthroscopically assisted ACLR surgery with a standardized postoperative protocol. Group 2 (Experimental) patients will undergo the same procedure with the same postoperative protocols as Group 1, with the addition of the posterior capsular injection of 20 cc of Marcaine 0.5%. There are no placebo treatments being offered and the surgeons and operating room staff are not blinded to the subjects group. Injecting marcaine in this study will be performed in accordance with its standard use according to the FDA labeling/guidelines. The physicians will use their discretion as to the appropriate location for the injection into the posterior capsule of the knee which should bring no additional risks than expected for a knee injection. At the conclusion of the case, each patient will receive a dry sterile dressing, followed by a compressive wrap and a hinged knee brace locked in extension. No drains, pain pumps or nerve stimulators will be used. The nurses in the recovery room who will be administering the VAS assessment and recording time and frequency of pain medication dosing will be blinded to the patients' Group number. The nurses will provide pain medications and the visual analog assessment for their duties in the post-op anesthesia unit, and are not administering drugs or procedures specifically for research purposes. *Post-operative Care* All patients will be discharged home from the surgery center on the same day (within 2-3 hours) postoperatively. Patients will be made weight bearing as tolerated with crutches and a brace. While in the PACU, at time points 15min and 1 hour, a standardized and previously validated visual analog scale (VAS) for pain assessment will be delivered to the patient by the recovery room nurse. In addition, during this time, the extent of postoperative motor block will be assessed using the Bromage scale as follows: 0 = free movement of the leg/foot, 1 = Free foot movement with only knee flexion 2 = Free foot movement with inability to flex knee and 3 = complete motor blockade of knee and foot. Patients after discharge will then be asked to rate their most severe pain each morning and night for 4 consecutive postoperative days using this VAS pain scale. A standardized pain medication regimen will be given including: one or two tabs of Percocet 7.5/325mg to be taken every 4 to 6 hours as needed. A log of the time and amount of medication taken each POD will be kept and recorded by the patients. Patients will also be instructed to use cryotherapy for 20 min intervals 3 times per day. Patients will also begin on POD 0 the use of continuous passive motion machines starting at a comfortable range of motion and progressing 5 degrees/day as tolerated. Patients will return for their first post-operative visit between 7-10 days where diaries will be collected and the patient clinically assessed. Patient's will also be seen at their three month post-operative visit and be clinically assessed for the presence of chondrolysis (a frequently measured

	outcome during knee pain medication injection studies). **Statistical Analysis** Based on previous studies, the Mann-Whitney U test will check differences between numeric variables. Nonparametric Kruskal-Wallis tests can compare the analgesia level in the two groups and if possible ANOVA test can compare the analgesia duration. Chi-square tests will be utilized for any potential complications which will also be recorded. (J Inj Violence Res. 2013 Jun; 5(2): 84-88.) (Acta Ortop Bras. 2012;20(5); 285-90) **Power Analysis** ***Prelim Power Analysis*** per STATS department @ Cedars: sample sizes of **26** for **each group** (N1=N2=26) = **Total 52 patients to achieve 80% power** to reject the null hypothesis of equal means when the population mean difference is 2 with a standard deviation for both groups of 2.5 and with a significance level (alpha) of 0.050 using a two-sided two-sample equal-variance t-test. A total of 60 patients will be enrolled to ensure we achieve adequate power for the study.
CLINICAL RELEVANCE IMPACT	Despite the addition of selective regional blockade by the anesthesia team including femoral and saphenous nerve blocks, a portion of patients are still experiencing post-operative knee pain within the first few hours to days after the procedure. Pain may be a result of the femoral tunnel drilling which theoretically may be relieved by a posterior capsular injection. Eliminating this painful period will improve the patient's subjective experience undergoing surgery, and may also allow for earlier range of motion and participation in rehabilitation strengthening exercises performed by the patient in the peri-operative period.
APPROX BUDGET **Include comprehensive and detailed budget.** **Do NOT include any overhead expenses**	Marcaine 0.5% with epi & 20 cc, syringe = Pending Paper VAS forms = Pending (< $100) Envelopes for randomization process = Pending ($<50) Statistician = Pending
AUTHORS **indicate areas of involvement**	1._Michael Birns, M.D – Primary Researcher [1,2,3,4,5] 2._Michael Banffy, M.D – Principle Investigator [1,2,4] 3._Orr Limpisvasti, M.D.[1,2,4] 4._Aneet Toor, M.D. [1,2,3,4,5] 1= idea development/project design; 2=data collection; 3=data analysis; 4=data interpretation; 5=manuscript preparation/revisions
TIMELINE **State approximate**	Stage 1 – Data Collection – 10 months Stage 2 – Data Analysis – 1 month

duration of time to completion of data collection as well as ultimate completion of project	Stage 3 – Presentation/Publication – 1 month Projected Start Date – August 2015 Projected End Date – June 2016
DISCLOSURES OF FACULTY AND FUNDING	KJOC
TARGET JOURNAL	Arthroscopy, AJSM, OJSM, JBJS
TARGET MEETINGS	AOSSM, AANA