

Persistent Quadriceps Weakness with Femoral Nerve Block

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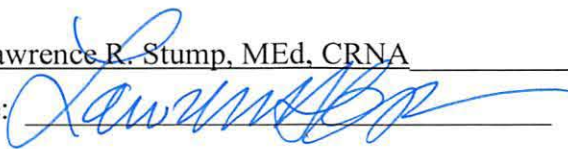
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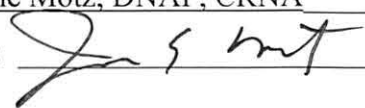
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Abstract

Purpose: Femoral nerve blocks (FNB) for anterior cruciate ligament reconstruction (ACLR) can effectively reduce post-operative pain, though this is tempered with the potential for quadriceps weakness, and subsequent concerns regarding impeded rehabilitation. The purpose of this retrospective study was to assess post-ACLR differences in International Knee Documentation Committee Subjective Knee Form (IKDC) scores in patients who did not (NB) and did (FB) receive perioperative FNB.

Methods: A retrospective review was performed to identify all adults undergoing ACLR at Tripler Army Medical Center between January 2013 and August 2016, with International Knee Documentation Committee (IKDC) outcome scores from pre-surgery to 6-12 months post-surgery. Patients were then divided into two groups, with the FB group being patients who received femoral nerve blocks (FNBs), and NB group patients not receiving a block. Demographics included age, sex, BMI, and ASA category. IKDC scores were converted to normative values. Variables were analyzed using Mann-Whitney-U, ANCOVA, and Chi-square tests.

Results: A total of 123 ACLR patients were identified with complete IKDC scores, of which 41 did not receive a femoral nerve block. Preoperatively, IKDC scores were statistically similar between NB (Mean=40.82,SD=15.82) and FB groups (Mean=40.03,SD=15.36), ($p=.79$). There were no significant group differences in time-to-follow-up ($p=.30$), age ($p=.74$), or BMI ($p=.11$), gender ($p=.27$) or ASA category ($p=.26$). A repeated measures ANCOVA examined whether the treatment groups differed in IKDC score changes from pre-surgery to follow-up. Both groups had a significant increase in IKDC score from pre-surgery to follow-up ($p<0.008$). However, there was no significant difference between groups ($p<0.8$) (Figure 2).

Conclusion: This retrospective review of outcomes after ACLR surgery indicate knee functioning improvements after ACLR did not differ between patients who did and did not receive FNB. Future rigorous studies are needed to fully examine FNB effects on other patient-reported and clinical outcomes after ACLR.

Data Sources: PubMed, Cochrane Library, CINAHL, and Google Search

Keywords: International Knee Documentation Committee, IKDC, anterior cruciate ligament, ACL, reconstruction, repair, surgery, femoral nerve block, nerve block, quadriceps

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Introduction

Anterior cruciate ligament reconstruction (ACLR) surgery is a common orthopedic procedure most often performed in an outpatient setting.¹ Patient satisfaction and outcomes are dependent on adequate pain control making pain management an important aspect of patient care. Femoral nerve blocks (FNBs) are an effective treatment for postoperative pain control in these patients as part of an anesthesia provider's multimodal pain management plan.⁴⁰ Peripheral nerve blocks may be avoided by surgeons, due to potential complications, or perceived inefficiency from potential delays related to block placement, onset, or failure.¹

Anterior cruciate ligament reconstruction is a painful surgical procedure. Femoral nerve blocks have been proven to be an effective pain management technique for ACLR surgery.⁶ Peripheral nerve blocks have been shown to offer many benefits postoperatively to include: improved analgesia with decreased narcotic consumption, earlier ambulation, increased patient satisfaction, decreased length of stay, and a decrease in narcotic associated side effects.⁷ As with all modes of anesthesia, there are associated risks with peripheral nerve blocks including: infection, nerve injury and an increased fall risk due to quadriceps weakness.⁷

ACL injuries and surgery can lead to deficits in motor function, muscular strength, muscle control, and range of motion.³ The International Knee Documentation Committee (IKDC) form is a patient self-reporting tool, used to measure quadriceps strength symmetry after ACLR.³ This tool was developed to standardize orthopedic assessment of postoperative outcomes.⁴ Literature shows the IKDC form to be a valid and reliable tool that has been adopted by the American Orthopaedic Society for Sports Medicine (AOSSM) for assessing function and mobility after ACLR.^{4,5}

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Gaps in current literature exist. There are studies that investigate muscle function after surgery with peripheral nerve blocks. However, there currently are no studies which investigate the relationship of FNB with long-term quadriceps muscle function using the IKDC form. The orthopedic department at Tripler Army Medical Center (TAMC) uses the IKDC form to evaluate quadriceps function in patients after ACLR surgery.

Deficits in muscle function, strength, control, and range of motion are common after ACLR.³ It is critical for military personnel to return to pre-injury function quickly in order to return to duty. The patient population in this study consists primarily of soldiers who are required to function at full capacity in order to be able to carry out their military duties and return to the field. For this reason, it is imperative to provide the most optimal anesthesia care with the least amount of recovery or impact on long-term function.

This study investigates the relationship of FNBs to persistent quadriceps muscle weakness using the International Knee Documentation Committee (IKDC) form. Information gained from this project will offer a foundation for future prospective studies involving nerve blocks and muscle function with the goal of optimizing return to function based on the IKDC form. The purpose of this project is to answer the question: Do patients undergoing anterior cruciate ligament reconstruction (ACLR) with a femoral nerve block (FNB), have persistent quadriceps muscle weakness, according to the International Knee Documentation Committee (IKDC) at six to twelve months postoperatively?

Literature Review

Transient quadriceps weakness is common after ACLR. Quadriceps impairment can affect gait, and may lead to pain, and fatigue. Many factors may contribute to weakness, and decreased motion including: type of procedure, length of time to surgery after injury,

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preoperative motion, delayed or inadequate rehabilitation.³¹ ACL injuries and surgical procedures for repair, lead to deficiencies in function, muscular strength and control, and range of motion.³ In the first 12 months following surgery, only half of patients are able to return to a pre-injury level of function, and approximately 25% will reinjure their ACL.³

Peripheral nerve blocks are an effective tool for post-operative pain management.³² Opioids are not always sufficient in the immediate postoperative period. Significant pain may lead to a patient's reluctance to move the extremity, which results in decreased participation in therapy.³³ There is some controversy over whether or not femoral nerve blocks lead to long term quadriceps weakness, prolonging the return to a preoperative level of functioning. There is very little data regarding regional anesthesia and its long-term effect on muscle function postoperatively after ACLR surgery.

ACL Reconstruction

ACL injury is one of the most commonly treated knee disorders with an estimated 250,000 ACL injuries each year in the United States. Surgical intervention of ACL injuries is on the rise.^{3,20} For patients with anterior cruciate ligament deficiency and functional instability, ACL reconstruction surgery is the standard treatment.²⁴ The goal of surgery is to restore functional stability of the knee to a preinjury level of function, and provide an expedient return to duty or sports activity.³⁴

Less than 50% of patients are able to return to their preinjury level of functioning within the first 12 months, 20-30% will develop a second ACL injury, and within 10 years over 50% will develop osteoarthritis.³ Patients undergoing subsequent ACL repair or revision have reported lower clinical outcome scores when compared to primary ACL reconstruction.²¹ Younger patients, and athletes have an increased risk for ACL revision after a previous

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injury.^{17,20} It is necessary for anesthesia practitioners to maximize patient recovery, while minimizing further complications, and risk for subsequent injury.³

Several intrinsic and extrinsic risk factors for ACL injury have been identified including individual anatomy, genetic predisposition, and body mass index (BMI).²¹ Based on IKDC scores, studies have demonstrated positive outcomes for ACLR in children, adolescents, and adults over 40 years of age.²¹ There has been no significant difference in clinical outcomes associated with gender after ACLR.²¹ An increased baseline BMI is associated with decreased functional mobility, and increased complications after surgery, compared to patients with a normal BMI.²¹ There are no statistically significant differences in patient outcomes with early surgical intervention versus late intervention (<3 weeks post injury vs. >6 weeks post injury).²¹

Surgical intervention is associated with better patient outcomes than medical management alone, however, IKDC scores do not show a statistically significant difference.²¹ Clinical outcomes after ACLR, including rehabilitation compliance, knee pain and function, and return to sports time are improved if patients are optimistic, self-motivated, self-confident, have low stress, and have an adequate social support system.²¹ At five years postoperative ACLR, health-related quality of life is not associated with patient gender, age, or time from injury to surgery, however, health-related quality of life scores are reduced in patients who have severe osteoarthritis, have any injuries after ACLR, or require ACL revision surgery.²¹ Studies report that after ACLR, reductions in bone density did not normalize and were most substantial with decreased weight bearing, and immobility.²¹ There was no significant difference in bone density between patients treated surgically and those treated nonoperatively.²¹ Knee joint proprioception was decreased in individuals with ACL injuries, however, proprioception was improved after ACLR when compared to patients treated medically.²¹

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Quadriceps Muscle Weakness

One of the most common persistent neuromuscular deficiencies correlated with ACLR is quadriceps muscle weakness, with strength deficits continuing to be greater than 20% at 6 months postoperatively.^{8,22} Quadriceps impairment can affect gait, and may lead to pain, and fatigue. Many factors may contribute to weakness, and decreased motion including: type of procedure, length of time to surgery after injury, preoperative motion, and delayed or inadequate rehabilitation.³¹

Transient quadriceps weakness is common after ACLR. The main goal of surgery is to return knee function to the preinjury level. ACL injuries and surgery lead to deficiencies in function, muscular strength and control, and range of motion.³ In the first 12 months following surgery, only half of patients are able to return to a pre-injury level of function, and approximately 25% will reinjure their ACL.³ Quadriceps muscle strength is a key variable for assessing clinical outcomes after ACL surgery and risks for re-injury of the affected knee.³ Muscle weakness is more profound in ACL deficient knees than in reconstructed knees.²¹

In the past, it was hypothesized that exercise of the affected limb postoperatively could cause excessive strain on the ligament graft.²² Current evidence based practice recommends aggressive exercise and strengthening of the quadriceps muscle early in the postoperative period in order to facilitate recovery and optimize functional outcomes.²² Quadriceps weakness can be attributed to surgical site pain.³⁷ Pain reduces mobility in the postoperative period, slowing recovery, and increasing complications associated with immobility, making pain management important for optimal recovery.

Loss of extension is common after ACL surgery, which may cause a patient to walk with a bent knee gait, placing pressure on the joint and strain on the quadriceps muscle, leading

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to pain and muscle fatigue.³¹ Some common predictors of postoperative loss of extension are preoperative range of motion, surgical factors, and delayed rehabilitation.³¹ One study used the IKDC form to evaluate loss of extension (LOE) in patients four weeks after ACLR. Of the patients that had LOE at four weeks, 49% required arthroscopic debridement to recover motion in the affected knee.³¹ Preoperative knee extension and time to surgery were the major contributing factors to reduced range of motion after surgery. Patients with time to surgery after injury of 60 (median) days were more likely to experience LOE than patients at 93.5 (median) days, indicating that it is important to restore knee extension as much as possible prior to surgery.³¹

Quadriceps muscle weakness is correlated with poor functional outcomes postoperatively, and is associated with early development of osteoarthritis.^{8,22} Research suggests that muscular deficiencies may persist for years after surgery, and that weakness is often present in the contralateral limb following reconstruction.²² It is of great interest to the orthopedic specialty to identify factors which may contribute postoperative muscle weakness, and ways to facilitate the recovery process.²² For this reason it is important to research the long-term effect of peripheral nerve blocks on muscle function and recovery.

IKDC Form

Knee injuries often result in a necessity for surgical intervention, rehabilitation, and prevention of participation in sports or military duty, and are associated with an increased incidence of recurrent injury after a previous injury.¹⁷ The goal of treatment is to facilitate the return to duty or sports activity as quickly as possible. There are several instruments for evaluating knee function, but a standardized method of assessment is necessary for comparison of treatment outcomes and effectiveness.^{15,17} Evidence based practice requires measurement

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tools to be well designed, well documented, high quality, reliable, valid and appropriate for the patient population being assessed.^{5,17,19}

In the 1980's, due to the advent of new surgical procedures for anterior cruciate ligament (ACL) injuries, and the numerous mechanisms for evaluation of knee function, it was recognized that there was no standard method for assessing knee conditions.¹⁵ Empiric assessment often led to inaccurate interpretation of variables, and was generally subject to bias.¹⁵ Differences in assessment methods prohibited the ability to use the results of one scale to predict the outcomes on an alternate scale.¹⁵ An international committee of knee experts was formed in 1987 to create a standardized tool for evaluation of knee conditions, function and treatment outcomes.^{5,14,15} The International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form (Appendix A), was developed to standardize a method for measuring knee function in a variety of conditions.^{5,15} It has been adopted and endorsed by many orthopedic associations including the American Orthopaedic Society for Sports Medicine (AOSSM).^{4,5,14}

Patient-oriented questionnaires are a meaningful mechanism for measuring clinical outcomes.¹⁹ These clinical outcome measures are designed to evaluate pain, function, and health status, and are useful in directing patient care.²³ They have been shown to be beneficial for comparative effectiveness research, as well as, the comparison of institutional or provider quality.²³ Patient-reported outcomes questionnaires specific to knee conditions focus on the major objectives of treatment, such as pain and other symptoms, function and activity level.²³ The validity, reliability and responsiveness of these instruments must be thoroughly and systematically evaluated.¹⁹ Responsiveness is a significant psychometric property of a clinical outcomes test, which offers the ability to detect a statistically significant change in the status of a patient.¹⁸ If a patient's condition improves or deteriorates it will be reflected in a responsive

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outcome measure.¹⁸ The IKDC is a patient-reported data collection instrument which has been extensively tested and proven to be a reliable, effective tool for assessing clinical outcomes.

The International Knee Documentation Committee (IKDC) form is a self-administered questionnaire which uses simple language, appropriate for a general patient population, and measures symptoms (pain, edema, stiffness, catching, locking, and giving way), knee function, and sports activity.^{14,17} It is simple to administer in almost any clinical setting, and it functions similarly in both genders, various age groups, and patients with different diagnoses.^{3,19} The IKDC has been proven to be valid and reliable, and is associated with increased patient satisfaction scores.^{5,15} Studies have shown that the instrument has high convergent and divergent construct validity, as well as, content and structural validity.^{14,17} It is reported to have high test-retest reliability, responsiveness, internal consistency, and interpretability with no ceiling or floor effects.^{4,14,17,18} The proven validity and reliability of this standardized patient-oriented outcome assessment tool, and the ease of its use, makes the IKDC form perfect for studies comparing treatment outcomes and effectiveness.

More recently a pediatric version of the IKDC has been developed, with wording modified to be more suitable to a pediatric population.²³ It has been shown to be valid and reliable with psychometric properties adequate for pediatric ages ranging from 10 to 18 years.²³ However, in adolescent patients aged 13 to 17 years, there is no clinically significant difference between the scores on pediatric, and adult IKDC forms, allowing for the use of the form that is most practical for long-term tracking of patient treatment, and outcomes.²³ In this age group, the scores of both versions of the IKDC form can reliably be converted between the two, because they are highly correlated.²³ The International Knee Documentation Committee form is an effective tool for assessing quadriceps strength after ACLR and using the data to determine when

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a patient is ready to return to work, sports, or military duty. Clinicians can use the form to evaluate quadriceps strength and decide when they feel it is safe for patients to return to their previous level of physical activity.³⁴

Peripheral Nerve Blocks

Postoperative pain control is an important aspect of anesthetic management and patient care. Patient satisfaction and outcomes are heavily dependent on adequate pain control.¹ For patients receiving orthopedic surgery, a peripheral nerve block (PNB) can be an effective treatment for postoperative pain as part of a multimodal anesthetic plan. PNBs block the pain impulses along the nerves that supply the extremity which leads to a decrease in the use of narcotics and other anesthetics.¹³ This in turn leads to a reduction in the side effects associated with narcotics such as nausea and vomiting, prolonged sedation, or respiratory depression.³¹ Reduced anesthetic and narcotic consumption are associated with shorter hospital stays, quicker recovery, fewer hospital admissions, reduced healthcare costs, and increased patient satisfaction.¹

History

In 1853, Alexander Wood came up with the idea of producing nerve blockade by nerve injection. He attempted to treat neuralgia by injecting morphine close to the nerve of the affected area.³⁸ Carl Koller discovered the use of cocaine to numb the conjunctiva for eye surgery in 1884. By 1885, William Halsted and Richard Hall had demonstrated the effectiveness of blocking peripheral nerves with cocaine.³⁸ However, the use of cocaine for regional anesthesia was limited by its toxicity, difficulty to sterilize, brief duration and potential for addiction. In 1904, Einhorn developed procaine which was low in toxicity, and high in stability but it had a short duration of action and a potential to induce allergic reactions.³⁸ In 1943, Nils Lofgren developed lidocaine and from this, derivatives were developed. The advantage of local

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anesthetics is that they are potent, predictable, heat resistant, and rarely cause allergic reactions. It is lidocaine and the derivatives mepivacaine, prilocaine, bupivacaine and ropivacaine that are used today to provide safe and effective nerve blockade for postoperative surgical pain management.³⁸

Benefits

Peripheral nerve blocks (PNB) are used routinely in orthopedic surgery for perioperative pain management. They provide postoperative analgesia and reduce anesthetic requirements intraoperatively. PNBs can be safely administered using nerve stimulation, or ultrasound guidance, as a single shot injection, or continuously through a catheter. Improved perioperative pain control is associated with earlier mobilization of the extremity, quicker recovery, reduced length of hospital stay, decreased expense, and increased patient satisfaction.²⁵ It is important for postoperative orthopedic patients to begin ambulation, rehabilitation and physical therapy early.²⁴ Patients who begin ambulation and therapy early in the postoperative period experience less deep vein thrombosis formation, decreased length of hospital stays and a reduction in hospital costs.²⁶

Peripheral nerve blocks are associated with decreased PACU stay, decreased need for narcotics, and a decreased incidence of postoperative nausea and vomiting (PONV).²⁷ Reducing postoperative pain reduces morbidity, increases functional recovery, hastens discharge from the hospital, and may reduce the development of chronic postoperative pain.²⁷ Nerve blocks provide a superior level of analgesia as compared to using an opioid analgesic method alone.²⁴ PONV, hypotension, and apnea are associated with opiates and can potentially lead to increased morbidity and mortality, especially in older patients.²⁶ PNBs provide effective analgesia while significantly reducing opioid consumption, and the risk of apnea associated with opioid use.

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Complications

Peripheral nerve blocks are safe and effective for postoperative pain control as part of the anesthetic plan. As with any type of anesthetic, there are risks and benefits associated with PNBs. When preparing an anesthetic plan, the anesthesia provider must carefully weigh the risks and benefits of the types of anesthesia with the patient's comorbidities, in order to formulate the safest plan of care for each patient.

Complications associated with PNBs include hematoma from injury to adjacent blood vessels, nerve damage from inadvertent injection directly into the nerve, toxicity from intravascular injection of local anesthetic, and injury of adjacent structures.²⁸ Although, these complications are extremely rare they can potentially be very serious. Relatively large amounts of local anesthetic are used for PNB which can contribute to local anesthetic systemic toxicity. Preventive measures can be taken to reduce the risk of toxicity such as incremental injections with aspiration, test doses, dose limitation, and intravascular markers such as epinephrine which constricts nearby blood vessels reducing the amount of uptake into the vascular system.²⁹ Lack of motor and sensory function of the blocked extremity can also lead to inadvertent injuries to the limb or falls.

Technique

The electrical nerve stimulator has been the gold standard for placing peripheral nerve blocks for years but with developments in ultrasound (US) technology, US is becoming more popular.³⁶ The ability to visualize the nerves and the surrounding structures make it easier to avoid complications such as inadvertent intraneural or intravascular injection. Ultrasound guidance offers benefits such as faster onset times, prolonged analgesia, better block quality, and decreased need for rescue analgesia.²⁹ Less local anesthetic is required when ultrasound is

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utilized, which decreases the incidence of local anesthetic systemic toxicity that may occur with intravascular injection or absorption.²⁹ Ultrasound utilization allows the practitioner to visualize the needle trajectory to avoid nearby blood vessels and other sensitive surrounding tissues.³⁵ Ultrasound offers the ability to visualize the spread of local anesthetic around the nerve for a more successful nerve block. There is no statistically significant difference in the already low rates of neurological complications between techniques that use ultrasound or peripheral nerve stimulators to place blocks.³⁶

Femoral Nerve Block

Femoral nerve blocks have been the standard for regional anesthesia for postoperative pain management following knee surgery for decades.²⁴ They are commonly used with general anesthesia as part of a multimodal anesthetic plan of care, and are shown to effectively treat perioperative pain while decreasing anesthetic and narcotic requirements, reducing anesthesia associated side effects, and increasing patient satisfaction.¹ Femoral nerve blocks offer improved analgesia when compared to opioid analgesia.²⁴ The superior analgesia demonstrated by FNBs results in a decrease in narcotic consumption and narcotic associated side effects.²⁴ High narcotic requirements are associated with an increased incidence of nausea and vomiting, increased recovery times, unplanned admissions to the hospital and a resulting increase in healthcare costs.²⁴

One study looked at quadriceps strength and function at six months after ACLR in patients that received a continuous femoral nerve block.⁹ In this retrospective study, patients received femoral nerve blockade continuously for 48 hours postoperatively through a peripheral nerve catheter for pain management.⁹ Functional tests were administered by a physical therapist six months after surgery to evaluate quadriceps strength and function.⁹ Time to return to sport

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was determined by full clearance for return to activity by the surgeon.⁹ It was concluded that at six months there was inferior quadriceps strength and function in the nerve block group, but there was no significant difference in time to return to sports, bringing into question the clinical significance of the decreased muscle strength.⁹

Another study investigated strength deficits in adolescent patients at six months after ACLR with FNBs.¹⁰ At six months postoperatively, patients under the age of 18 underwent strength and functional testing at which time the surgeon made the decision for clearance for return to sports activity.¹⁰ The study concluded that the adolescent patients in the FNB group had significant deficiencies in knee extension and flexion strength when compared to the control group, and that patients who did not receive a block were on average five times more likely to meet criteria to be cleared for sports.¹⁰

A study using the IKDC form to evaluate loss of extension (LOE), in patients four weeks after ACLR, investigated FNB for analgesia as a possible contributing factor of LOE. Loss of extension is a common knee motion deficit after ACLR surgery, which may produce a bent knee gait, placing pressure on the joint and strain on the quadriceps muscle, leading to pain and muscle fatigue.³¹ Researchers found no correlation between FNB and LOE in this study, or a subsequent study using single-shot and continuous FNB when compared to placebo.³¹ It was discovered that preoperative knee extension and time to surgery were the major contributing factors of decreased range of motion after ACLR, and that it is most important to restore as much knee extension as possible prior to surgery.³¹

Saphenous Nerve Block

Femoral nerve blocks are an effective part of the multimodal anesthetic plan, with patients demonstrating a decrease in opioid consumption, and decreased visual analog scale

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(VAS) pain scores in the first 24 hours of the postoperative period.⁶ However, a postoperative decrease in quadriceps muscle strength associated with FNBs, may create an increased risk for falls or other injuries in the first 24 hours after surgery.⁶ This risk has led to a search for a treatment that is as effective at treating postoperative pain as an FNB, while maintaining quadriceps strength and function.

With the current use of ultrasound technology for peripheral nerve blocks, it is easier to block the saphenous nerve in the anteromedial thigh safely and successfully.⁶ It is difficult to achieve complete pain relief with one nerve block, due to the many branches of nerves innervating the knee.⁶ Patient satisfaction scores favor FNB, however, there is no difference in the occurrence of adverse effects.⁶ The femoral nerve block provides superior postoperative analgesia, however, the saphenous nerve block causes less quadriceps muscle blockade in the immediate postoperative period.⁶ The initial ACL injury is more likely to cause quadriceps muscle weakness than the peripheral nerve block.⁶ There are no studies comparing the long-term effects of saphenous nerve blocks versus femoral, on quadriceps function.

Adductor Canal Block

Ambulating patients early after surgery is important for decreasing postoperative morbidity, and hastening the recovery process, to include function and mobility. Pain and muscle weakness are the two main limiting factors for early ambulation, however, improving one factor generally diminishes the other.²⁴ Femoral nerve block is a standard treatment for postoperative pain control after ACLR. Studies show that femoral nerve blocks provide superior analgesia compared to only opioids, but with fewer side effects.²⁴ However, quadriceps weakness postoperatively places patients at higher risks for falls.^{11,12,13} Studies have investigated adductor canal blocks (ACBs) as an alternative to FNBs for postoperative pain management, due to the

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potential for quadriceps muscle sparing, and a reduction of the risks associated with decreased motor function. This is accomplished by blocking the distal branches of the femoral nerve in the mid-thigh.³⁷ Compared to the FNB, the ACB primarily affects sensory nerves.

One study compared FNB to ACB for management of pain after ACL reconstruction.²⁴ Visual analog scale (VAS), morphine consumption, and muscle strength were assessed postoperatively and every six hours for 24 hours.²⁴ Patients that received FNB had lower VAS scores, less morphine requirements, but more quadriceps muscle weakness than the ACB group.²⁴ Two studies compared quadriceps strength of healthy volunteers without surgery after FNB and ACB.^{11,12} Both studies demonstrated a greater reduction in quadriceps strength in the FNB group compared to the ACB group. In one of the two studies, the ACB group exhibited only an 8% reduction in muscle strength from baseline, and may be related to the effect of the anesthetic on the vastus medialis muscle which traverses the adductor canal.¹¹ The FNB group averaged a 49% decrease compared to baseline.¹¹ However, these studies were unable to compare analgesic effect between the two groups since the study populations were healthy volunteers and not surgical patients. There is muscle sparing with an adductor block when compared to FNB in the immediate postoperative period, but there are no long-term studies investigating muscle function with adductor block.^{11,12}

Systematic Review

A systematic review of six studies, compared outcomes of patients that received FNB with outcomes of patients that did not receive FNB for ACLR.⁴¹ Two studies examined the early postoperative period (within 12 weeks), and found no significant difference between patients who received FNBs and those that did not.⁴¹ One study found significant deficits in the nerve block group at 6 weeks postoperatively, which were no longer apparent at 6 months.⁴¹ The other

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three studies examined patient outcomes at 6 months with conflicting results, none of which appear to have any clinical significance. None of the six studies used IKDC scores to measure functional outcomes.

Conclusion

Anterior cruciate ligament reconstruction is a common surgical procedure for repair of ACL rupture. ACL injury and surgery result in decreased knee function and quadriceps muscle weakness. The IKDC form is a patient self-reporting tool, which was developed to standardize orthopedic assessment of postoperative outcomes. It is a reliable, validated tool that has been adopted by many orthopedic associations for assessing function and mobility after ACLR. Literature demonstrates that FNBs effectively treat perioperative pain while decreasing anesthetic and narcotic requirements, reducing anesthesia associated side effects, and increasing patient satisfaction, with minimal risk of complications. There is some controversy over the contribution of femoral nerve blocks on to quadriceps weakness. There are studies that investigate muscle function after surgery with peripheral nerve blocks. However, there currently are no studies which investigate the relationship of FNB with long-term quadriceps muscle function using the IKDC form.

The purpose of this study was to investigate the relationship of FNBs to persistent quadriceps muscle weakness, using the (IKDC) form. Research of this nature will provide a basis for future studies utilizing the IKDC form to explore the relationship between nerve blocks and muscle function, with the goal of optimizing the return to a preoperative level of function. This retrospective study was intended to answer the question: Do patients undergoing anterior cruciate ligament reconstruction (ACLR) with a femoral nerve block (FNB), have persistent quadriceps

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muscle weakness, according to the International Knee Documentation Committee (IKDC) from six to twelve months postoperatively?

Methods and Materials

An extensive literature review was performed for this study. Current literature agrees that FNBs are effective for perioperative pain control while reducing narcotic consumption and associated risks. There is limited data regarding long term effects associated with FNBs, and available data is inconclusive. There are no studies using the IKDC form to evaluate effects of FNB on muscle function after ACLR at 6 to 12 months postoperatively.

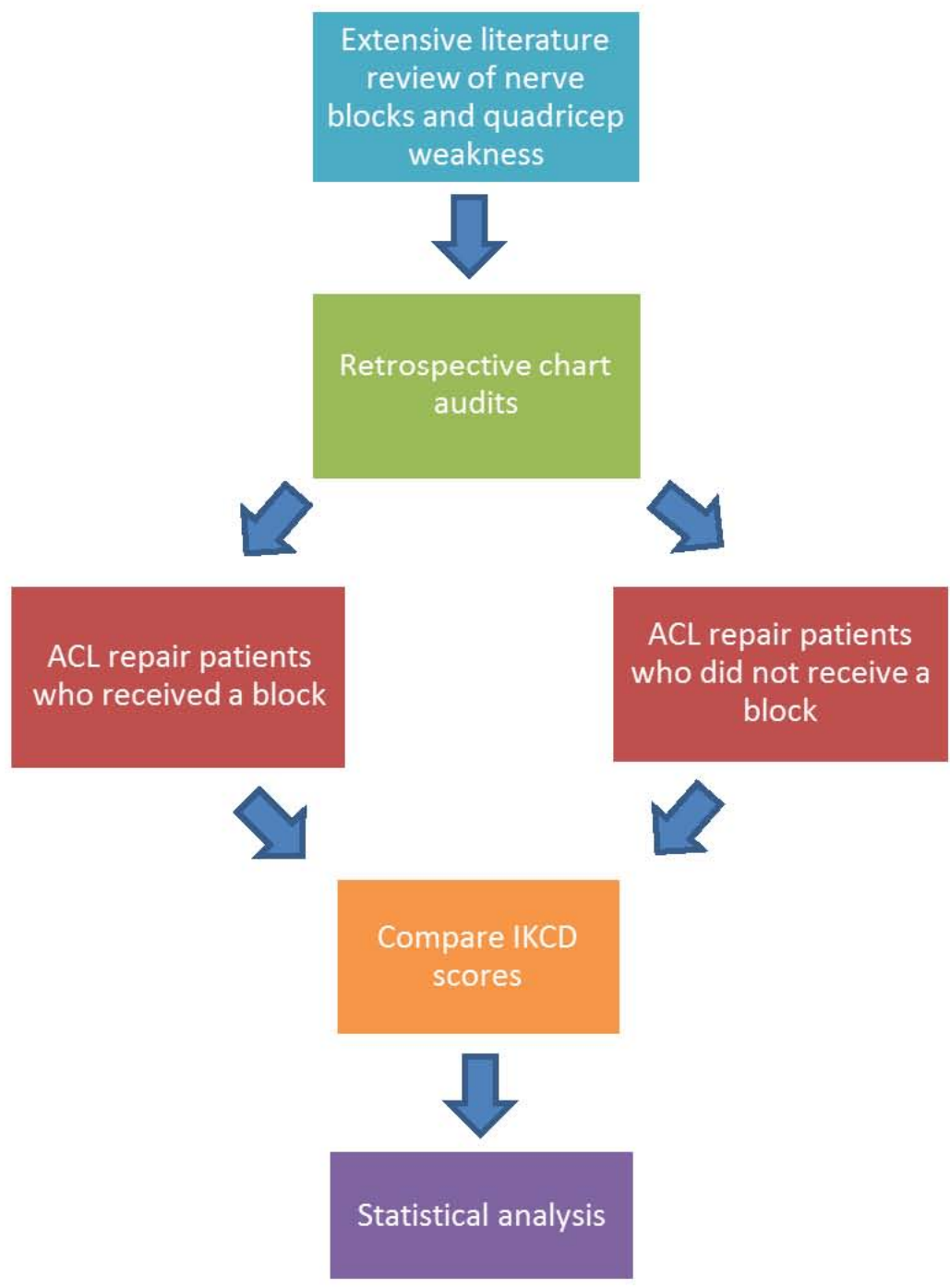
This study was performed, as illustrated in figure 1, at Tripler Army Medical Center (TAMC) with cooperation from the orthopedic and anesthetic departments. IKDC data was collected from the orthopedic department to identify patients for the study. The anesthetic records for the identified patients were recovered from the archives to identify the patients who received an ultrasound guided FNB, and which patients did not. The study participants were then divided into two groups. Group FB are patients who received an FNB and group NB are patients who did not receive a block. The two groups were compared to determine if there is a relationship between FNB and persistent quadriceps weakness.

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Figure 1.

Conceptual Map

Persistent Quadriceps Weakness with Peripheral Nerve Blocks



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Socrates[®] (Standardised Orthopaedic Clinical Research and Treatment Evaluation Software) is a computer software program, which has been approved for use at TAMC for data collection/storage, tracking patient outcomes, conducting research, and quality assurance/performance improvement. It is a patient reported outcome database registry that houses information regarding outcome measures, to include IKDC data. The registry is a HIPAA compliant, password protected software program which is installed within the TAMC firewall on TAMC servers. The orthopedic department at TAMC has been collecting data using this electronic platform since 2013. The contract with Socrates[®] includes the use of the IKDC form (Appendix A) and the IKDC is a validated outcome score approved for use within the TAMC system. Essentris[®] is a password protected medical database which stores medical records, including anesthetic records. It is also installed on the TAMC servers and within the firewall.

Study Design

A retrospective review of existing data from the orthopedic registry was performed to identify all patients who had an ACLR between January 1, 2013 and August 31, 2016, and have IKDC outcome scores with a 6-12 month follow-up. The electronic medical records were then reviewed for the type of anesthetics administered, and the patients were then divided into two groups: group FB (patients who received FNBs) and group NB (patients who did not receive FNBs). Each patient record was identified, reviewed, and compiled individually by hand due to the lack of a computer program or database available for identification of types of anesthesia received by patients. All data was combined onto one excel spreadsheet and de-identified at the time of analysis. Any links to patient identifiers were destroyed. Only the study team had access to the data, and the data collection sheet was kept on a password-protected spreadsheet, with access via Common Access Card[®] (CAC) enabled computers. The CAC[®] is a smart card used by

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the military to protect the security of sensitive and confidential information on military computers and servers.

The retrospective design of this study was similar to that of Krych et al,⁹ in which they observed quadriceps strength and function at six months after ACLR in patients that received femoral nerve blockade continuously for 48 hours postoperatively, through a peripheral nerve catheter.⁹ Functional tests were administered at six months postoperatively to evaluate quadriceps strength and function.⁹ It was concluded that at six months there was inferior quadriceps strength in the nerve block group, but the results were not clinically significant.⁹ The IKDC form was not used in this study for the assessment of muscle strength and function.

Setting

This study was performed at Tripler Army Medical Center (TAMC) with cooperation from the orthopedic and anesthetic departments. Orthopedic and anesthetic data had previously been collected and stored routinely as necessary for documentation of patient care. The appropriate population was identified, and the data was reviewed, compiled, and analyzed. The only cost associated with this study was consistent with lost wages associated with cost of the researchers' time.

Ethics

Data was kept on a password-protected spreadsheet accessed via CAC[®] enabled computers and only available to investigators. Identifying information collected included name and date of surgery. This was kept on a separate spreadsheet and each patient assigned a unique, non-identifying alphanumeric code. The main datasheet contained only the alphanumeric code, and did not include personally identifiable information. Once all data had been collected, the link between the names and alphanumeric code was deleted. IRB approval was obtained through

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the University of Michigan Flint (Appendix B). As a retrospective review of existing data, this study qualified as a performance improvement (PI) project (Appendix C) through TAMC, and was exempt from IRB submission.

Population

A retrospective chart audit was performed to identify all patients, 18 years and older, at TAMC who underwent ACLR between January 1, 2013 and August 31, 2016, and have IKDC outcome scores in the Socrates[®] database, with follow-up 6-12 months postoperatively. This convenience sample consisted of a total sample size of 123 patients, 82 who received a FNB for surgery, and 41 who did not receive FNB. Demographics included age, sex, body mass index (BMI), American Society of Anesthesiology (ASA) physical status, and tobacco use. Inclusion criteria were: unilateral ACLR, preoperative and 6-12 month postoperative IKDC scores, and 18 years of age and older.

Subjects were excluded from the analysis if they had bilateral ACL injuries/reconstructions, multiple ligament reconstructions, no preoperative or 6-12 month postoperative IKDC scores, or under age 18 at the time of surgery. Concomitant meniscus or cartilage surgery at the time of ACLR were not grounds for exclusion. IKDC scores were converted to normative values. Variables were analyzed using Mann-Whitney-U, ANCOVA, and Chi-square tests (Table 1).

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Table 1. Demographic and Clinical Differences Between Patients who did not (NB) and did (FB+) Receive Femoral Nerve Blocks

	NB (n=40)	FB+ (n=82)	Difference Test Statistic (p)
Male, n (%)	35 (85%)	63 (64%)	Pearson Chi-Square = 1.23 (p=.27)
Current tobacco use, n (%)	10 (24%)	25 (31%)	Pearson Chi-Square = .00 (p=1.00)
Age, median years [IQR]	28 [25, 35]	29 [24, 35]	Mann-Whitney U=1618 (p=.74)
ACLR Revision, n (%)	4 (10%)	10 (12%)	Pearson Chi-Square = .16 (p=.69)
Other perioperative block, n (%)	3 (7%)	36 (44%)	Pearson Chi-Square = 16.87 (p<.001)
Autograft, n (%)	18 (45%)	26 (32%)	Pearson Chi-Square = 2.06 (p=.15)
ASA Physical Status 1, n (%)	14 (34%)	33 (40%)	Pearson Chi-Square = .43 (p=.51)
BMI [IQR]	28.18 [25.76, 31.33]	26.71 [24.85, 29.93]	Mann-Whitney U=1347 (p=.11)

Note: All patients had an ASA Physical Status of 1 or 2, except one patient had an ASA 3.

Implementation

After the study was approved by TAMC and the University of Michigan Flint (UMF), patients who had undergone ACLR between January 1, 2013 and August 31, 2016 were identified from the surgical scheduling database. Once these patients were identified, the IKDC data was obtained from the orthopedic department using the Socrates[®] database. Once this list of patients was finalized, the anesthetic records were accessed using Essentris,[®] to identify which patients received FNBs and which did not.

The following demographic information was recorded: age, sex, gender, American Society of Anesthesiology (ASA) physical status, body mass index (BMI), and tobacco use (table 1). Other data collected included allograft versus autograft, if the patient received another perioperative block with the FNB, and whether the ACLR was a primary surgery or a revision (table 1). The data was then de-identified, the patients were assigned alpha-numeric codes, and

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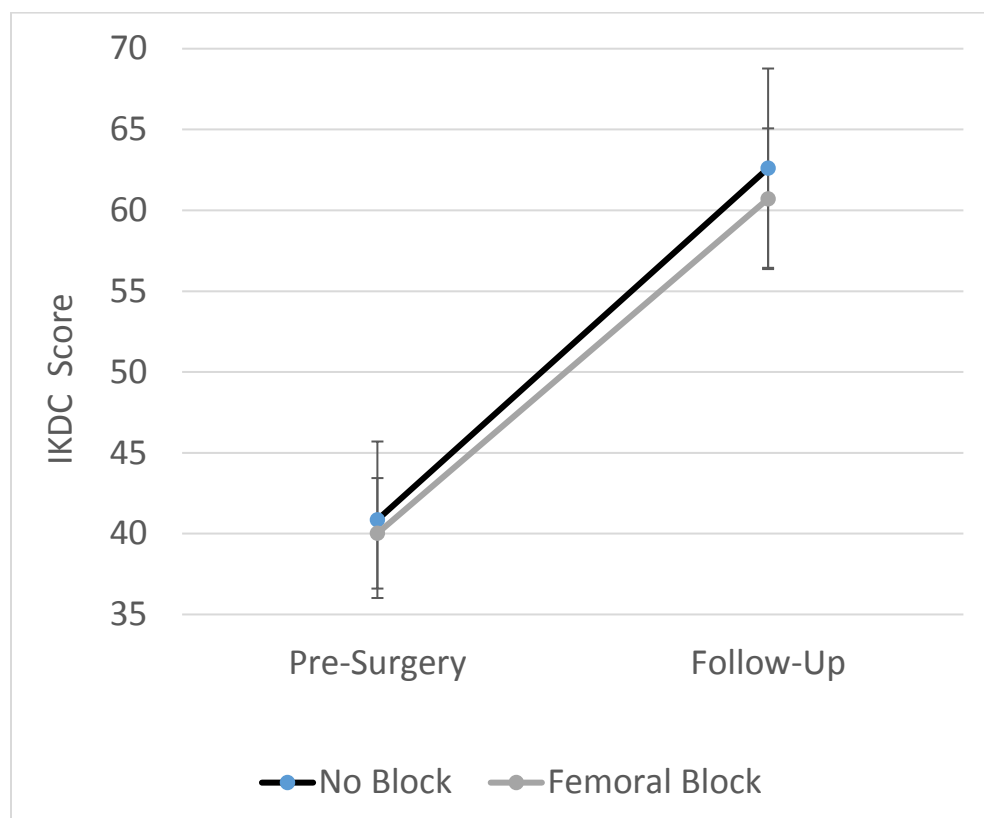
all patient identifiers were destroyed. All data was accessed and stored on a computer at TAMC which is encrypted and password protected. Any data which contained patient identifiers incorporated a second level of encryption and password protection. All standards were maintained per TAMC policy to protect patient data.

Results

In this retrospective study, 123 ACLR patients with completed IKDC scores were identified, of which 82 received a femoral nerve block and 41 did not. Preoperatively, IKDC scores were statistically similar between NB (Mean=40.82, SD=15.82) and FB groups (Mean=40.03, SD=15.36), ($p=.79$). There were no significant group differences in time-to-follow-up ($p=.30$), age ($p=.74$), or BMI ($p=.11$) by means of Independent Samples Mann-Whitney U tests. Chi-square tests indicate there were no significant distribution differences between groups for gender ($p=.27$) or ASA category ($p=.26$).

Outlier tests indicated two patients had BMI values that were extreme and these values were substituted using Tukey's Hinges ($1.5 \times$ Tukey Hinge range + 75th percentile value). A repeated measures ANCOVA examined whether the treatment groups differed in IKDC score changes from pre-surgery to follow-up. To control for any variance in IKDC score changes attributed to time-to-follow-up, it was included as a covariate in the model. There was a significant effect of time ($p<0.008$), such that both groups had a significant increase in IKDC score from pre-surgery to follow-up. However, the treatment group x time interaction was not significant ($p<.80$), indicating that both groups had similar IKDC score improvements from pre-surgery to follow-up (Figure 2).

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Figure 2. Change in IKDC Scores from Baseline to 6-12 mos. Postoperatively.

Both groups were similar across all clinical and demographic characteristics. After controlling for graft type, additional type of regional block, current tobacco use, and pre-surgical IKDC, covariate-adjusted generalized linear model (GLM) results indicated no significant difference between NB (M=21.13, SE= 3.05) and FB+ (M=21.18, SE=2.07) IKDC change scores [B=-.05 (95%CI -7.53, 7.43), p=.99].

IKDC Scores

The IKDC form is a validated instrument used for patients with knee disorders to assess function, symptoms, and sports activity.⁵ The form is endorsed by the American Academy of Orthopaedic Surgeons (AAOS) as a patient reported outcome measures instrument specifically for ACL related assessment.⁴² The IKDC form is administered preoperatively and postoperatively to measure progress in knee function, and compared to published data.⁵ The

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results of the form (Appendix A) are scored by summing the scores for each item. An ordinal method is used to score the response to each item. A score of 0 is given to responses representing the lowest level of function, or the highest level of symptoms. The scores for each item are summed and divided by the maximum score which is 87. The total score is then transformed to a scale that ranges from 0 to 100.

$$\text{IKDC Score} = \left[\frac{\text{Sum of Items}}{\text{Maximum Possible Score}} \right] \times 100$$

The transformed score represents a measure of function. Higher scores indicate higher levels of function and lower levels of symptoms. For example, a score of 100 would be interpreted to mean no limitation with activities, and the absence of symptoms. The scores in figure 2 indicate the improvement in scores from preoperatively to 6 to 12 months postoperatively. The lower preoperative scores indicate the level of function and symptoms with the ACL injury prior to surgery, and the higher postoperative scores indicate the improvement in function after surgery (Figure 2). The scores in figure 2 are normalized for age and gender using the normative data produced by Anderson et al⁵ for the International Knee Documentation Committee.

Discussion

Femoral nerve blocks for ACLR can effectively reduce post-operative pain, though this is tempered with the potential for quadriceps weakness, and subsequent concerns regarding impeded rehabilitation. The goal of the present retrospective study was to assess post-ACLR differences in IKDC scores in patients who did, or did not receive perioperative FNB. Both groups showed similar improvements in IKDC scores from pre-surgery to follow-up, indicating no statistical difference between the groups. There were no differences in scores with regards to age, gender, BMI, ASA physical status, tobacco use, time to follow-up, graft type, or the addition

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of a second nerve block. The implications of this study serve to give piece of mind to anesthesia providers and surgeons alike, that postoperative pain for patients undergoing ACLR can be safely, and effectively managed with FNBs. This is this first study of this type that utilizes the IKDC score to investigate patient outcomes associated with the use of FNB for postoperative pain management associated with ACLR.

Study Limitations

This study was performed at a single military medical center, and the results may not be generalizable. The patient population predominately consisted of young, healthy, males, ASA physical status 1 and 2, active duty military members. Pediatric patients were not represented in this sample. The retrospective design of this study allows for the influence of other potential variables due the lack of randomization.

Recommendations for Future Research

Future research including a larger multicenter study within the military medical system is recommended, with a prospective randomized control design, or at a civilian hospital for generalizability. A patient population with a representative sample of ASA physical status 1-4, including elderly patients, and an equal gender pool should be included. This research provides a basis for future studies to utilize the IKDC form to explore the relationship between nerve blocks and muscle function, with the goal of optimizing the return to a preoperative level of function.

Dissemination

The results were shared as a lecture with approximately forty people at the weekly lecture series meeting including the Tripler Army Medical Center anesthesia department, the United States Army Graduate Program in Anesthesia Nursing/Northeastern University students, and Uniform Services University of Health Sciences medical students and residents. An abstract has

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been submitted, in collaboration with the orthopedic department, to the American Academy of Pain Medicine (AAPM) for a poster presentation at the AAPM 34th Annual Meeting in April 2018. An electronic manuscript will be prepared for submission to a peer reviewed journal, according to the journal guidelines. The results of this study are currently being used by the pain service at TAMC to support the use of FNBs for pain management for ACLR surgery.

Conclusion

Literature demonstrates that FNBs are effective in the management of perioperative pain. They decrease anesthetic and narcotic requirements, reduce anesthesia associated side effects, and increase patient satisfaction, with minimal risk of complications. However, there remains some controversy over the contribution of femoral nerve blocks on quadriceps weakness. The IKDC form is a patient self-reporting tool with proven reliability, and validity for assessing function and mobility after ACLR, making it the ideal tool for assessing patient outcomes associated with FNB.

The purpose of this study was to investigate the relationship of FNBs to persistent quadriceps muscle weakness, using the (IKDC) form, effectively answering the question: Do patients undergoing anterior cruciate ligament reconstruction (ACLR) with a femoral nerve block (FNB), have persistent quadriceps muscle weakness, according to the International Knee Documentation Committee (IKDC) from six to twelve months postoperatively?

This retrospective review of outcomes after ACLR surgery indicates knee functioning improvements after ACLR did not differ between patients who did and did not receive FNB. Future rigorous studies are needed to fully examine FNB effects on other patient-reported and clinical outcomes after ACLR.

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Appendix A

IKDC KNEE EVALUATION FORM

SYMPTOMS:

Grade symptoms at the highest activity level at which you think you could function without significant symptoms, even if you are not actually performing activities at this level.

1. What is the highest level of activity that you can perform without significant knee pain?

- Very strenuous activities like jumping or pivoting as in basketball or soccer
 Strenuous activities like heavy physical work, skiing or tennis
 Moderate activities like moderate physical work, running or jogging
 Light activities like walking, housework or yard work
 Unable to perform any of the above activities due to knee pain

2. During the past 4 weeks, or since your injury, how often have you had pain?

	0	1	2	3	4	5	6	7	8	9	10	
Never	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Constant

3. If you have pain, how severe is it?

	0	1	2	3	4	5	6	7	8	9	10	
No pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Worst pain

4. During the past 4 weeks, or since your injury, how stiff or swollen was your knee?

- Not at all
 Mildly
 Moderately
 Very
 Extremely

5. What is the highest level of activity you can perform without significant swelling in your knee?

- Very strenuous activities like jumping or pivoting as in basketball or soccer
 Strenuous activities like heavy physical work, skiing or tennis
 Moderate activities like moderate physical work, running or jogging
 Light activities like walking, housework, or yard work
 Unable to perform any of the above activities due to knee swelling

6. During the past 4 weeks, or since your injury, did your knee lock or catch?

- Yes No

7. What is the highest level of activity you can perform without significant giving way in your knee?

- Very strenuous activities like jumping or pivoting as in basketball or soccer
 Strenuous activities like heavy physical work, skiing or tennis
 Moderate activities like moderate physical work, running or jogging
 Light activities like walking, housework or yard work
 Unable to perform any of the above activities due to giving way of the knee

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SPORTS ACTIVITIES:

8. What is the highest level of activity you can participate in on a regular basis?
- Very strenuous activities like jumping or pivoting as in basketball or soccer
 - Strenuous activities like heavy physical work, skiing or tennis
 - Moderate activities like moderate physical work, running or jogging
 - Light activities like walking, housework or yard work
 - Unable to perform any of the above activities due to knee
9. How does your knee affect your ability to:

		Not difficult at all	Minimally difficult	Moderately Difficult	Extremely difficult	Unable to do
a.	Go up stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b.	Go down stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c.	Kneel on the front of your knee	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d.	Squat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e.	Sit with your knee bent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f.	Rise from a chair	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g.	Run straight ahead	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h.	Jump and land on your involved leg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i.	Stop and start quickly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

FUNCTION:

10. How would you rate the function of your knee on a scale of 0 to 10 with 10 being normal, excellent function and 0 being the inability to perform any of your usual daily activities which may include sports?

FUNCTION PRIOR TO YOUR KNEE INJURY:**Cannot perform daily activities**

0 1 2 3 4 5 6 7 8 9 10

No limitation daily activities**CURRENT FUNCTION OF YOUR KNEE:****Cannot perform daily activities**

0 1 2 3 4 5 6 7 8 9 10

No limitation daily activities

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Appendix B



Flint Institutional Review Board • 530 French Hall, 303 E. Kearsley St, Flint, MI 48502 • phone [\(810\) 762-3383](tel:810-762-3383) • fax [\(313\) 593-0526](tel:313-593-0526) • research@umflint.edu

To: Summer Scott

From:

Marianne McGrath

Cc:

Jane Motz
Summer Scott

Subject:Initial Study Approval for [HUM00125211]

SUBMISSION INFORMATION:

Study Title: Outcomes of Femoral Nerve Block in ACL Reconstruction

Full Study Title (if applicable): Outcomes of Femoral Nerve Block in ACL Reconstruction

Study eResearch ID: [HUM00125211](https://eresearch.umich.edu/HUM00125211)

Date of this Notification from IRB: 2/7/2017

Review: Expedited

Initial IRB Approval Date: 2/7/2017

Current IRB Approval Period: 2/7/2017 - 2/6/2018

Expiration Date: Approval for this expires at **11:59 p.m. on 2/6/2018**

UM Federalwide Assurance (FWA): FWA00004969 (For the current FWA expiration date, please visit the [UM HRPP Webpage](#))

OHRP IRB Registration Number(s): IRB00000248

Please check with the HIPAA officer of your institution to ensure all HIPAA regulations are followed for use of the data.

QUADRICEPS WEAKNESS WITH FNB**Approved Risk Level(s):**

Name	Risk Level
HUM00125211	No more than minimal risk

NOTICE OF IRB APPROVAL AND CONDITIONS:

The IRB Flint has reviewed and approved the study referenced above. The IRB determined that the proposed research conforms with applicable guidelines, State and federal regulations, and the University of Michigan's Federalwide Assurance (FWA) with the Department of Health and Human Services (HHS). You must conduct this study in accordance with the description and information provided in the approved application and associated documents.

APPROVAL PERIOD AND EXPIRATION:

The approval period for this study is listed above. Please note the expiration date. If the approval lapses, you may not conduct work on this study until appropriate approval has been re-established, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS**APPROVED STUDY DOCUMENTS:**

You must use any date-stamped versions of recruitment materials and informed consent documents available in the eResearch workspace (referenced above). Date-stamped materials are available in the "Currently Approved Documents" section on the "Documents" tab.

RENEWAL/TERMINATION:

At least two months prior to the expiration date, you should submit a continuing review application either to renew or terminate the study. Failure to allow sufficient time for IRB review may result in a lapse of approval that may also affect any funding associated with the study.

AMENDMENTS:

All proposed changes to the study (e.g., personnel, procedures, or documents), must be approved in advance by the IRB through the amendment process, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

AEs/ORIOs:

You must inform the IRB of all unanticipated events, adverse events (AEs), and other reportable information and occurrences (ORIOs). These include but are not limited to events and/or information that may have physical, psychological, social, legal, or economic impact on the research subjects or other.

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Investigators and research staff are responsible for reporting information concerning the approved research to the IRB in a timely fashion, understanding and adhering to the reporting guidance (<http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/adverse-events-aes-other-reportable-information-and-occurrences-orios-and-other-required-reporting>), and not implementing any changes to the research without IRB approval of the change via an amendment submission. When changes are necessary to eliminate apparent immediate hazards to the subject, implement the change and report via an ORIO and/or amendment submission within 7 days after the action is taken. This includes all information with the potential to impact the risk or benefit assessments of the research.

SUBMITTING VIA eRESEARCH:

You can access the online forms for continuing review, amendments, and AEs/ORIOs in the eResearch workspace for this approved study (referenced above).

MORE INFORMATION:

You can find additional information about UM's Human Research Protection Program (HRPP) in the Operations Manual and other documents available at: <http://research-compliance.umich.edu/human-subjects>.

A handwritten signature in black ink, consisting of several overlapping loops and a long, sweeping tail that curves back towards the main body of the signature.


Marianne McGrath
Chair, IRB Flint

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Appendix C

Performance Improvement Request form (Please save form, complete required fields and submit to Mr. Don Kyle for approval at donald.m.kyle.civ@mail.mil)	
TYPE OF PROJECT: (Select one type)	<input type="checkbox"/> Quality Improvement (QI): To assess or improve an existing internal process, or local program / system OR to improve performance when compared to established or accepted standards. Implementation is based on existing knowledge. <input type="checkbox"/> Research: To test a hypothesis OR to establish clinical practice standards where none are already accepted. The primary goal is to create, establish generalizable knowledge. <input type="checkbox"/> Evidence Based Practice (EBP): To evaluate evidence along a continuum to identify the strongest, or best evidence, to guide clinical practice within an
Date:	12/9/2016
Project Title: (as you want to call it now)	Outcomes of Femoral Nerve Block in ACL Reconstruction
QI/EBP PROJECT TEAM LEADER: (Last, Name, Career)	MAJ Jeanne C. Patzkowski, MD, MC
POC Email Address:	jeanne.c.patzkowski.mil@mail.mil
POC Phone Number:	808-433-5978
Department:	Orthopedic Surgery Service
Additional Team Members: <small>Do you have other "collaborators" working on the project with you? If so, provide their Name, Title, Service or Department, and state their role on the project?</small>	Michael S. Patzkowski, MD, Summer Scott, CRNA (collaborators)
What department(s) or inpatient unit(s) will be involved or affected?	Orthopedic Surgery Service
PROJECT SUMMARY <small>The Project Summary section should be brief and concise. It should provide a summary of the following: Background, Question, Supporting Evidence or Accepted Practice, Plan, and Outcomes</small>	
Background: <small>What led to the development of the project?</small>	<small>Given the above number of ACL reconstruction performed on active duty personnel, and the potential long-term functional limitations due to femoral nerve dysfunction, such as chronic a contract to chronic pain, the sponsor justifies the post management course.</small>
Is this project a CAPSTONE or Requirement for an academic program? <small>(If yes, please provide brief summary of the requirement)</small>	Yes
Question: <small>Specifically identify the clinical problem or question to be investigated</small>	<p>For evidence based practice projects, develop your question in the PICO format (Patient population of interest, Intervention of interest, Comparison of interest, Outcome of interest). Below</p> <p>Do patients with femoral nerve block have worse functional outcomes after ACL reconstruction at 6 -12 months post-op than those that did not receive a femoral nerve block</p> <p>For QI projects develop your question in the PDCA format (Plan, Do, Check and Act). Describe your plan, how will you do it, how will you check (measure) it, and how will you act on it (i.e. if desired outcome is attained-how will it be sustained and if the desired outcome is not attained what is the next step.) Briefly Below</p>

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Date:	12/9/2016		
Supporting Evidence or Accepted Practice: Describe the supporting evidence or accepted practice for making the change (in change in Clinical Practice Guidelines or recommendations; change in internal process, SOPs, TIC standards, etc.)			
Plan: Describe detailed sequential steps for implementing your project. For instance, why/how the staff will be educated about the process or practice change, when/how the change will be implemented and why/how outcome metrics will be collected. Provide a timeline for this project.	A chart review will be conducted retrospectively using TAMC electronic medical record database for femoral nerve block in ACL reconstruction patients. The orthopedic data registry contains outcomes scores, i.e. IKDC to determine functional outcomes at 6 - 12months post op.		
Outcomes: Describe what you want to change and what you measure to determine the change was successful. (Examples might include chart audits, patient safety reports (PSRs), patient or provider satisfaction surveys, FY data, HEDIS measures, etc.). Provide a copy of your data collection form.	Based on the evidence supported by this research, orthopedic surgeons and anesthesia providers may change their anesthetic practice in perioperative anesthetic management for patients undergoing ACL reconstruction repair.		
Dissemination Plans: Describe if you have any plans to disseminate your findings to unit or department level leadership and staff members who participated in the project.	Report on findings and reassess current practices.		
Dissemination Plans: Describe if you have any plans to disseminate your findings to unit or department level leadership and staff members who participated in the project.	Findings will be reported to staff and residents in the orthopedic surgery service and anesthesia department.		
FUNDING			
Is this project funded? (If so, by whom?)	n/a		
REFERENCES	<ol style="list-style-type: none"> 1. Hoffman, Robert P. "The use of nerve blocks in arthroscopic ligament reconstruction surgery." <i>Reference: The Journal of Orthopaedic & Sports Physical Therapy</i>. 2015;45(12):844-848. Available online from doi:10.1519/JPT.0000000000000214. 2. Liu D, Anderson J, Smith D, Spangola M, Mendenhall M. Postarthroscopic a common wall procedure using arthroscopy and arthroscopy. <i>Journal of the American Academy of Orthopaedic Surgeons</i>. 2014;22(10):1942-1944. doi:10.1097/BPO.0000000000000002. 3. Zampieri G, Schifano G, Giamberini P, Tassinari S, Basso M. The influence of corticosteroids on postoperative function of knee arthroscopy in sports medicine. <i>The American Journal of Sports Medicine</i>. 2013;41(10):2288-2292. doi:10.1177/0363546513502224. 4. Manganari M, Ruffini F, Ruffini G. The International Knee Documentation Committee Subjective Outcome Form is a Prosthesis-Independent Measure. <i>The American Journal of Sports Medicine</i>. 2006;34(1):55-59. 5. Anderson J, Spangola M, Smith D, Mendenhall M. International Knee Documentation Committee Subjective Outcome Form. <i>The American Journal of Sports Medicine</i>. 2002;30(1):108-110. 6. Chhabra M, Singh A, Kulkarni S, et al. Postoperative Analgesia with Epidural Block versus Epidural Block in ACL Reconstruction. <i>PMID</i>. 2014; 25:285-291. 		
PUBLICATION POLICY:			
All publications/presentations that originate from this project will be identified as a QM/QI project and NOT as a research project. No identifying information for any of the volunteers in the project will be included in any presentation of data or photographs unless consent or release was obtained. Publications will be submitted for clearance as per Company policy.			
LEADERSHIP ACKNOWLEDGEMENT			
Signatures as indicated	Signature Block	Digital signature	Comments
*Project Leader Signature (REQUIRED) (Person requesting approval/support of project)	Jeanne Patzkowski, MD	PATZKOWSKI,JEANNE AMERON1241120934	
*Department Leadership Signature (REQUIRED) (Chief, COO, Deputy etc. indicating support of project)	Claude Anderson, Chief		
Stakeholder Signature (as indicated) (required by leadership of each department/division if project affects their operation in any way)			
Stakeholder Signature (as indicated) (required by leadership of each department/division if project affects their operation in any way)			

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References:

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