Effects of Transcutaneous Electrical Nerve Stimulation (TENS) on Postoperative Pain and Function Following Arthroscopic Knee Surgery: A Prospective Randomized Clinical Trial Pilot Study

Study Protocol
NCT01528228

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1.0 Abstract

Introduction

Transcutaneous Electrical Nerve Stimulation (TENS) therapy has been used for the control of postoperative pain with variable results.[1-9] TENS therapy is also considered an appropriate non-pharmacologic adjunct to patient care in the setting of symptomatic knee arthritis.[10-28] Recently, orthopaedic surgeons have begun to utilize TENS therapy about the operative site in the early post-operative period because of several proposed benefits including pain relief with decreased analgesic requirements, increased quadriceps strength with decreased postoperative muscle atrophy. To our knowledge, the use of TENS as an adjunct to post-operative analgesia in the setting of outpatient knee arthroscopy has not been extensively studied. We propose a pilot study to determine the effectiveness of TENS therapy in the early post-operative period following knee arthroscopy for meniscectomy, synovectomy, or chondroplasty.

Methods

Consecutive patients meeting inclusion criteria will be randomized to one of two treatment groups: 1) structured TENS therapy (n=10) or 2) sham TENS therapy (n=10). Patients and the surgeon will be blinded to the TENS treatment group. Patients will complete preoperative assessments of pain and function using standardized outcomes instruments, then complete daily pain assessments and reports of analgesic consumption in the early post-operative period (two weeks). TENS will be discontinued at two weeks post-operatively. The surgeon will complete the IKDC Surgical Document Form with information from the surgical procedure. Patients will be followed for a total of six months post-operatively with clinical measurements of quadriceps strength, knee range of motion, presence of effusion, and quadriceps circumfrence (measure of atrophy). Functional outcomes will be measured with KOOS, Marx, Lysholm, IKDC, and SF-12 for up to six

months post-operatively. Statistical analysis will be performed using computer software and significance defined as $p<0.05$.

The results of the pilot study will be used to design a multi-center prospective randomized clinical trial.

Conclusion

TENS therapy in the early post-operative period following outpatient knee arthrscopy has not been extensively studied. This pilot study will provide initial information for the effectiveness of this widely-used clinical device.

2.0 Specific Aims

Transcutaneous Electrical Nerve Stimulation (TENS) therapy has been used for control of knee pain with good results. Documented benefits of non-pharmacologic post-surgical pain control using TENS include decreased opioid analgesic usage, increased muscle strength, with a relative lack of side-effects.[1-9] Additionally, TENS therapy has been studied extensively for the nonoperative treatment of knee arthritic conditions with somewhat mixed results.

Knee arthroscopy in the outpatient setting often requires a patient's pain to be well controlled in order to ensure day of surgery discharge. In the early post-operative period, pain is primarily controlled with a combination of modalities including cryotherapy, narcotic and non-steroidal analgesia. To our knowledge, the use of TENS as an adjunct to post-operative analgesia in the setting of outpatient knee arthroscopy has not been studied extensively. To this end, we propose the following hypothesis:

Hypothesis: Following standard of care procedures for arthroscopy knee surgery it is anticipated that Transcutaneous Electrical Nerve Stimulation (TENS) will provide improved pain relieve and improve functional outcomes.

Specific Aim 1: Determine patient's perception of pain in the early post-operative period while utilizing structure TENS therapy.

Specific Aim 2: Determine the short-term (6 months) outcomes following knee arthroscopy while using TENS in the early post-operative period.

Specific Aim 3: Determine effect of early TENS use on quadriceps strength and tone in the early and intermediate post-operative periods.

3.0 Background and Significance

Outpatient knee arthroscopy is considered a common procedure in the United States with more than 500,000 surgeries performed on an outpatient basis yearly.[29] Immediate post-operative pain has multiple etiologic factors including the type of surgery performed, operative time, and time from surgery among others.[30] Unfortunately, these factors are non-modifiable. Therefore, post-operative pain in the ambulatory setting is inevitable.[31-33] Limiting narcotic analgesic

usage has several advantages and thus strategies to accomplish this goal have been proposed for major orthopaedic surgery.[31]

TENS has been offered as an adjunct to analgesic use in the early post-operative period in a variety of settings. In a prospective, randomized study, Briet and Van der Wall compared narcotic analgesic usage following total knee arthroplasty with and without the use of TENS therapy. The authors were unable to demonstrate significant reductions in post-operative analgesic requirements with the use of TENS therapy following total knee arthroplasty.[1] In a prospective randomized clinical trial following abdominal surgery however, Cooperman and colleagues found that 77% of patients receiving TENS therapy in the immediate post-operative period reported good or excellent results, while 33% of patients reported good to excellent pain control without TENS.[9]

For the non-operative treatment of knee osteoarthritis, TENS therapy has seen mixed results. When compared to intraarticular hyaluronic acid, TENS therapy has shown no statistically significant difference in pain and functional outcome at 6 months following treatment.[15] Law et al. demonstrated significant improvements in self-reported pain and ROM in first two weeks following initiation of a TENS therapy program for patients with osteoarthritis. They were unable to detect differences in patient-oriented outcomes.[18] Cheing et al. found that four weeks of TENS therapy for knee osteoarthritis resulted in improved pain measures, but the treatment was not statistically different than placebo ore exercise alone.[24] In a Cochrane Review of 6 trials, Osiri et al concluded that TENS is more effective than placebo for the treatment of knee osteoarthritis.[25] In the setting of rheumatoid arthritis, Casamiro and colleagues in a Cochrane Review found that TENS was effective for pain control, but a formal recommendation for its use was precluded by the poor design of the studies included.[17]

4.0 Preliminary Studies

Preliminary data is pending.

5.0 Research Design and Methods

5.1 Rationale for use of hand-held dynamometer

The reliability and validity of hand-held dynamometry has been extensively studied and adopted as a means of efficiently determining quadriceps strength in the outpatient setting.[34-45]

5.2 Rationale for use of outcomes instruments

Outcomes measures have been extensively used in orthopaedic research.[46] The KOOS (Knee Injury and Osteoarthritis Outcomes Score) evaluates five diminsions and is specific to kneerelated pathology: pain, symptoms, ADLs, sports and recreation function, and knee-related quality of life. The Marx Activity Level Scale consists of four questions and was designed to be a short, patientreported activity assessment that can be used in addition to knee rating scales and general health outcomes measures. The The Lysholm knee scale was developed for the followup evaluation of knee ligament surgery, with an emphasis on symptoms of instability. It consists of eight items (limp, support, stair climbing, squatting, instability, locking and catching, pain,

swelling). It is included for historical comparison and perspective. The IKDC (International Knee Documentation Committee) scale is a subjective form consisting of 18 questions. This form is considered to be specific to the knee and widely used in outcomes research. The SF-12 is a shortened version of the SF-36 and is a general health quality of life instrument.

6.0 Inclusion/Exclusion Criteria

- Age 18-60
- BMI ≤50
- No significant joint malalignment ○ Neutral to 5° valgus alignment as measured on standing weight-bearing PA radiographs of the knee or standing extremity alignment radiographs.
- No significant ligamentous instability.
  - ○ Normal Lachman, pivot shift, varus and valgus stress tests.
- No significant radiographic joint space narrowing ○ Joint space measurement within 10% in each compartment as measured by digital radiography in standing weight-bearing view.
- No prior significant knee surgery ○ No prior ligamentous or osteotomy surgery ○ Prior partial meniscectomy is acceptable
- Unilateral knee surgery
- Not Worker's Compensation
- Planned knee arthroscopy for meniscectomy, chondroplasty, or synovectomy

7.0 Randomization Procedure

Patients will be randomized using a block randomization scheme generated by the statistician. Sealed envelopes will be used to conceal the random assignments of patients to one of two treatment groups in the immediate post-operative period.

- Group 1: structured TENS therapy (n=10)
- Group 2: sham TENS therapy (n=10)

8.0 Patient Form (Week 1 and 2 post-operative)

Patients will complete a pain and analgesic usage diary. Additionally, patients will complete VAS pain questions daily and pre- and post-TENS treatment. See Appendix D. TENS treatment will be standardized and will consist of 20 minute sessions three times per day at the manufacturer's recommended settings.

9.0 Proposed Timeline

- Pre-study: Patient questionnaire and database constructed.
- 0-3 months: Patient enrollment begins.
- 3-9 months: Data collection. Initial data analysis of immediate post-operative pain logs.
- 9-12 months: Data analysis.
- 12-14 months: Pilot study completion and preparation for multi-center study. Power analysis will be performed to determine the number of patients needed to enroll.

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Appendix A. Enrollment Screening

NAME _____ Participant ID #_____

Question	Yes	NO
Is patient age less than 18 or greater than 60?	☐	☐
Did patient **refuse** to sign informed consent?	☐	☐
Is patient BMI > 50?	☐	☐
Is the patient receiving simultaneous bilateral surgical treatment?	☐	☐
Is any knee joint malalignment present?	☐	☐
Is there any significant joint space narrowing present?	☐	☐
Has the patient had prior significant knee surgery?	☐	☐
Does this surgery involve a worker's compensation claim?	☐	☐

Are there reasons the patient will not be able to keep postoperative appointments?		

If any question is answered with "YES", the patient should not be included in this study.

Appendix B. Physician-entered Data at each evaluation

Participant ID # _____

Time	ROM (R/L)	Effusion (R/L)	Strength (R/L)	Quad Circ (R/L)	Other
Pre-op					
I week					
2 weeks					
6 weeks					
12 weeks					

6 months					

- ROM (“3-0-135”)
- Effusion (none, 1+, 2+, 3+)
- Strength (lbs) using hand-held dynamometer
- Thigh circumfrence (cm) measured 10 cm proximal to superior pole of the patella Other comments

Appendix C. Preoperative Patient Form

Participant ID # _____

Thank you for agreeing to participate in this important study about the pain control after knee arthroscopy surgery. Please answer the following questions.

1. Are you currently taking pain medication for your knee?

   □ Yes

   □ No

2. If yes, what medication are you taking for your knee pain?
   □ Over the counter (Tylenol, Aleve, Motrin, etc…)

   □ Prescribed anti-inflammatory medication (Celebrex, Ibuprofen, etc…)

   □ Narcotic medication (Vicodin, Percocet, Codeine, etc…)

   □ Steroid medication (Cortisone, Prednisone, etc….)

   □ Other _____
3. During the past week, how often have you taken these medications?
   □ Three or more times a day

   □ Once or twice a day

□ Once every couple of days

□ Once a week

□ Have not taken in the past week 4.

How much pain are you having today?

Please mark on the line where your current pain level is.

No Pain **0 1 2 3 4 5 6 7 8 9 10** **Severe Pain**

Pain

Thank you. Please complete the surveys on the following pages.

Appendix D. Patient Pain Diary

Participant ID #: _____

Find your pain level number from the scale below. Enter the number that best represents your pain level for each time listed.

No Pain **0 1 2 3 4 5 6 7 8 9 10** **Severe Pain**

Pain

Time	Pain Number (0-10)	Number of Pain Pills since last entry	To Do	Complete (X)
Surgery				
5:00 PM				

8:00 PM				
Day 1				
9:00 AM			TREATMENT	
9:30 AM				
12:00 PM				
3:00 PM			TREATMENT	
3:30 PM				
6:00 PM				
9:00 PM			TREATMENT	
9:30 PM				
Day 2				
9:00 AM			TREATMENT	
9:30 AM				
12:00 PM				
3:00 PM			TREATMENT	
3:30 PM				
6:00 PM				
9:00 PM			TREATMENT	
9:30 PM				
Day 3				
9:00 AM			TREATMENT	
9:30 AM				
12:00 PM				

3:00 PM			TREATMENT	
3:30 PM				

6:00 PM				
9:00 PM			TREATMENT	
9:30 PM				
Day 4				
9:00 AM			TREATMENT	
9:30 AM				
12:00 PM				
3:00 PM			TREATMENT	
3:30 PM				
6:00 PM				
9:00 PM			TREATMENT	
9:30 PM				
Day 5				
9:00 AM			TREATMENT	
9:30 AM				
12:00 PM				
3:00 PM			TREATMENT	
3:30 PM				
6:00 PM				
9:00 PM			TREATMENT	
9:30 PM				
Day 6				
9:00 AM			TREATMENT	
9:30 AM				
12:00 PM				

3:00 PM			TREATMENT	
3:30 PM				
6:00 PM				
9:00 PM			TREATMENT	
9:30 PM				
Day 7				
9:00 AM			TREATMENT	
9:30 AM				
12:00 PM				
3:00 PM			TREATMENT	
3:30 PM				
6:00 PM				
9:00 PM			TREATMENT	
9:30 PM				
Day 8				
9:00 AM			TREATMENT	
9:30 AM				
12:00 PM				
3:00 PM			TREATMENT	
3:30 PM				
6:00 PM				
9:00 PM			TREATMENT	
9:30 PM				
Day 9				
9:00 AM			TREATMENT	

9:30 AM				
12:00 PM				
3:00 PM			TREATMENT	
3:30 PM				
6:00 PM				
9:00 PM			TREATMENT	
9:30 PM				

Day 10				
9:00 AM			TREATMENT	
9:30 AM				

12:00 PM				
3:00 PM			TREATMENT	
3:30 PM				
6:00 PM				
9:00 PM			TREATMENT	
9:30 PM				
Day 11				
9:00 AM			TREATMENT	
9:30 AM				
12:00 PM				
3:00 PM			TREATMENT	
3:30 PM				
6:00 PM				
9:00 PM			TREATMENT	
9:30 PM				

Day 12				
9:00 AM			TREATMENT	
9:30 AM				
12:00 PM				
3:00 PM			TREATMENT	
3:30 PM				
6:00 PM				
9:00 PM			TREATMENT	
9:30 PM				
Day 13				
9:00 AM			TREATMENT	
9:30 AM				
12:00 PM				
3:00 PM			TREATMENT	
3:30 PM				
6:00 PM				
9:00 PM			TREATMENT	
9:30 PM				
Day 14				
9:00 AM			TREATMENT	
9:30 AM				
12:00 PM				
3:00 PM			TREATMENT	
3:30 PM				
6:00 PM				
9:00 PM			TREATMENT	

9:30 PM				

Appendix E. Timing of Data Collection

Time	Surveys	Clinical Data
Preoperative	SF-12 Marx KOOS Lysholm IKDC Pain VAS	ROM Effusion Strength Quad circ
Intraoperative	IKDC Surgical Document Form	Surgical Data
1 day-14 days	Pain VAS Medication Use	
1 week	See above	ROM Effusion Strength Quad circ
2 weeks	See above	ROM Effusion Strength Quad circ
6 weeks	SF-12 Marx KOOS Lysholm IKDC Pain VAS Medication Use	ROM Effusion Strength Quad circ

12 weeks	SF-12 Marx KOOS Lysholm IKDC Pain VAS Medication Use	ROM Effusion Strength Quad circ
6 months	SF-12 Marx KOOS Lysholm IKDC Pain VAS Medication Use	ROM Effusion Strength Quad circ

Appendix F. 2000 IKDC Surgical Documentation Form Appendix G. Outcomes Instruments (SF-12, KOOS, IKDC, Lysholm, Marx)