2015

Does Neuromuscular Electrical Stimulation as an Adjunct to Traditional Physical Therapy Improve Post-Operative Mobility After Total Knee Arthroplasty in Comparison to Traditional PT Alone in Patients 50-85 Years Old?

Kelsey L. Welsh
Philadelphia College of Osteopathic Medicine, Kelseywe@pcom.edu

Does neuromuscular electrical stimulation as an adjunct to traditional physical therapy improve post-operative mobility after total knee arthroplasty in comparison to traditional PT alone in patients 50-85 years old?

Kelsey L. Welsh, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

December 19, 2014

ABSTRACT

OBJECTIVE: The objective of this selective Evidence Based Medicine (EBM) review is to determine whether or not neuromuscular electrical stimulation (NMES) as an adjunct to traditional physical therapy (PT) improves post-operative mobility including walking and stair-climbing ability following total knee arthroplasty (TKA) in comparison to traditional PT alone in patients 50-85 years old.

STUDY DESIGN: Review of three English language primary studies published after 1999.

DATA SOURCES: Three randomized controlled trials comparing traditional PT with PT and adjuvant NMES following TKA in patients 50-85 years old found using PubMed and EBSCOhost Web.

OUTCOMES MEASURED: Clinical outcome was measured in each of the three studies through various assessments of post-operative mobility including a six-minute walk test (6MWT), stair-climbing test (SCT), tug up-and-go test (TUG), and walking distance. Each study assessed post-operative improvement from baseline after the respective intervention was introduced.

RESULTS: The study by Petterson et al. revealed no statistically significant difference between interventional and control groups of the RCT cohort, but significant improvements were noted between the RCT and standard of care cohorts. Both RCTs completed by Avramidis et al. and Stevens-Lapsley demonstrated that adjunctive NMES was an effective means to minimize deficits in quadriceps muscle strength and muscle atrophy thereby increasing functional recovery following TKA surgery.

CONCLUSION: The results of the RCTs reviewed suggest NMES is an effective adjunct to traditional PT regimens and permits greater gains in muscle strength and attenuates quadriceps muscle atrophy which allows for more significant functional gains in walking and stair-climbing ability following TKA. Further research needs to be completed to assess appropriate duration and intensity of NMES as well as the potential benefit of pre-operative use ofs NMES.

KEY WORDS: TKA, NMES, PT, quadriceps strength

INTRODUCTION

Total knee arthroplasty (TKA) is a surgical orthopedic procedure done to eliminate persistent pain due to osteoarthritis (OA), age related "wear and tear" that results in degenerative changes in the cartilage cushioning the joint space, which leads to functional limitations, most notably decreased mobility and inability to carry out activities of daily living.[1] TKA alleviates joint-related pain and helps restore mobility, but following this procedure, patients continue to exhibit marked deficits in quadriceps strength and atrophy of periarticular knee muscles.[3,5] Early deficits in quadriceps strength following TKA has shown to lead to significant functional consequences including limitations in walking and stair-climbing ability.[6] This paper evaluates three randomized control trials (RCT) comparing the efficacy of traditional physical therapy (PT) with and without adjunctive neuromuscular electrical stimulation (NMES) of the quadriceps muscle at improving a patient's mobility following surgery. NMES is a non-invasive device that delivers electrical impulses to targeted muscle groups in direct proximity to overlying electrodes placed on the surface of the skin.[4] Elicitation of muscle contraction using NMES has been implemented in numerous areas of rehabilitation and has shown to effectively increase voluntary activation of the quadriceps muscles as well as limit reductions in quadriceps strength by preventing early muscle atrophy following TKA.[3,5,6] Additionally, shortfalls in activation of the quadriceps muscle demonstrate the potential to limit improvements in muscle strength garnered through traditional PT regimens indicating the potential of NMES to augment recovery from TKA surgery when combined with a traditional PT regimen.[5]

Consideration of a patient's post-operative recovery following TKA is becoming an increasingly important component of TKA surgery to discuss due to the increased frequency of TKA surgeries in the United States. Annually, more than 600,000 TKA surgeries are performed

and the demand for knee replacement surgery is expected to exceed three million by the year 2030.[2] Moreover, due to increasing concern regarding medical expenditure, TKA can provide a savings of approximately $12 billion from the more than 600,000 TKA surgeries performed each year.[2] Osteoarthritis (OA) reduces the quality of life of more than 50 million Americans by placing limitations on mobility and activities of daily living.[6] While TKA assists in eliminating the joint-associated pain, the average patient experiences a 60% reduction in quadriceps strength and a 20-25% decline in functional performance following TKA surgery.[5] The previously noted deficits in quadriceps strength and functional performance are of concern because both are associated with decreased balance, stair-climbing ability, ability to rise from a seated position, and increased risk of falls.[6] Thus, it is important to consider methods to attenuate these deficits to avoid further reduction in quality of life following TKA surgery.

TKA is typically regarded as an effective surgical intervention for the treatment of severe OA refractory to conservative, non-surgical methods of treatment including oral analgesia, corticosteroid or hyaluronic acid injections, assistive devices, and lifestyle modification.[1] However, surgery alone is not sufficient enough to address the complications that frequently accompany OA including reduced muscle mass and strength. The combined effect of improving quadriceps strength and limiting muscle atrophy leads to a beneficial outcome for the patient including increased mobility and improved functional performance including walking and stair-climbing ability.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not NMES as an adjunct to traditional PT improves post-operative mobility including walking and stair-climbing ability after TKA in comparison to traditional PT alone in patients 50-85 years old.

METHODS

Randomized controlled trials were selected based on inclusion criteria that encompassed a population of individuals undergoing unilateral TKA between the ages of 50 and 85 years of age. Studies that compared the use of adjunctive NMES with a traditional PT regimen to a control group that received exclusively a traditional PT regimen were identified and considered for this review. The outcome measured in the included studies was improvement in post-operative mobility demonstrated via various tests evaluating walking and stair-climbing ability, which were used respectively to determine the effectiveness of intervention with NMES following TKA surgery. Based on the aforementioned criteria, three randomized controlled trials were chosen for this selective EBM review.

A detailed search was carried out by the author via PubMed and EBSCOhost using keywords including TKA, NMES, PT, and quadriceps strength in order to find relevant studies published in English after 1999. Demographics and characteristics of each study included in this review are outlined in Table 1. All articles included in this study were published in peer-reviewed journals and were selected based on relevance to the chosen review topic and on the importance of outcomes that matter to the patient (POEMs). Studies excluded from this review included those with OA involvement or instability of other lower extremity joints unrelated to the knee considered for TKA, uncontrolled cardiac and metabolic conditions, neurologic impairment, or pathologic skin conditions overlying the area designated for NMES application (see Table 1). The summary of statistics reported in the studies included in this review include change from baseline, analysis of covariance ANCOVA), p-values and 95% confidence intervals (CI).

Table 1: Demographics & Characteristics of Included Studies

Study	Type	# Pts	Age (years)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Avramidis[3], 2003	RCT	30	EMS group: 68.20 ± 10.59 Control group: 71.20 ± 7.83	Patients admitted for elective primary TKA.	Patients with symptomatic OA of hip or ankle joints, history of epilepsy, cardiac pacemaker, poor understanding of NMES use, or pathologic conditions of skin over the vastus medialis and lateral thigh.	3	PT v. PT with EMS of vastus medialis for 4 hours daily for 6 weeks
Petterson[5], 2009	RCT	200	50-85	Patients 50-85 yo scheduled to undergo TKA by 3 orthopedic surgeons.	Patients with uncontrolled hypertension, diabetes, body mass index (BMI) >40 kg/m^2, symptomatic OA in contralateral knee, other lower-extremity orthopedic problems, neurologic impairment, residence outside 20 mile radius of clinic. 12 Patients of a referring surgeon who met criteria but could not do RCT agreed to do testing 12 mo post-TKA to represent standard of care group as a comparison to RCT cohort.	51	PT 2-3 times per week for 6 weeks v. PT with 10 electrically elicited contractions to the quadriceps femoris muscle
Stevens-Lapsley[6], 2012	RCT	66	50-85	Patients 50-85 yo who underwent TKA by 3 orthopedic surgeons at University of Colorado Hospital between June 2006 and June 2010.	Patients with uncontrolled hypertension, uncontrolled diabetes, BMI > 35 kg/m^2, significant neurologic impairment, contralateral knee OA, or other unstable lower-extremity orthopedic conditions.	11	Home PT v. home PT with NMES intervention using a portable Empi 300PV stimulator

OUTCOMES MEASURED

The outcome measured was patient oriented evidence that matters (POEMs). Both Petterson et al. and Stevens-Lapsley et al. used the timed "up-and-go" test (TUG), the stair-

climbing test (SCT) and the six-minute walk test (6MWT) to measure post-operative mobility status. The 6MWT was a measurement of the distance walked in six minutes. SCT was a measurement of the time taken to ascend and descend a flight of stairs. TUG test was a measurement of time to rise from an arm chair, walk a specified distance or length of time, turn around, and return to a seated position in the same chair.[5,6] Walking distance was a measurement of the distance walked in three minutes.[3] The six-minute walk test has demonstrated exceptional test-retest reliability and has been used extensively in similar studies involving recovery following TKA. It has also been used respectively as a measure of endurance and validated as a measure of functional mobility following TKA.[6] Avramidis et al. evaluated post-operative mobility by assessing walking speed via a three-minute walking test in which distance covered in meters was recorded.[3]

RESULTS

The three randomized controlled trials chosen for this selective EBM review compare the efficacy of traditional PT in combination with NMES of the quadriceps muscles to a control intervention of exclusively a traditional PT regimen. Demographic data of participants in the intervention and control groups in each study were similar at the start of the study and were consistent with the inclusion criteria for this review.

Petterson et al. completed a study that included 200 patients scheduled for unilateral TKA between July 2000 and November 2005 by one of three local orthopedic surgeons. One hundred patients were randomized to a progressive volitional strength training program (exercise group) and the other 100 patients were randomized to a combination NMES and volitional strength training program intervention group (exercise-NMES group). Both groups received outpatient PT targeting the quadriceps muscles and other muscles proximal and distal to the knee joint 2-3

times a week for a total of six weeks. Those receiving NMES received 10 electrically elicited contractions of the quadriceps muscle (50 pulses per second with a 2-second ramp-up time and 80 second rest period between contractions) with the application of electrodes over the rectus femoris muscle belly proximally and vastus medialis muscle belly distally. This study also included a standard of care group, which included the patients of one referring surgeon who were unable to undergo evaluation as part of the RCT cohort, but met all of the aforementioned inclusion criteria. These individuals, respectively, received the standard of care for rehabilitation in the community following surgery and agreed to undergo testing 12 months following TKA and were used as a cohort comparison to those participating in the RCT cohort.[5]

Assessments of functional performance including TUG, SCT, and 6MWT were completed at baseline, 3 months, and 12 months following TKA for the RCT cohort and at 12 months for the standard of care group. Results of this study revealed parallel gains in the aforementioned assessments of functional performance from baseline to 3 months and from 3-12 months when the exercise and exercise-NMES groups from the RCT cohort were compared.

Table 2: Percent change from baseline in assessment scores in the RCT cohort[5]

	Exercise Group						**Exercise-NMES Group**					
Assessment	**0 mo**	**3 mo**	**12 mo**	**% change 0-3 mo**	**% change 3-12 mo**	**% change 0-12 mo**	**0 mo**	**3 mo**	**12 mo**	**% change 0-3 mo**	**% change 3-12 mo**	**% change 0-12 mo**
TUG (seconds)	12.04	8.02	7.68	-33	-4	-36	12.10	8.29	8.07	-31	-3	-33
SCT (seconds)	25.76	12.78	11.75	-50	-8	-54	27.51	14.28	13.62	-48	-5	-50
6MWT (meters)	401	535	554	33	4	38	401	530	545	32	3	36

*mo = months[5]

However, when the RCT cohort was compared with the standard of care cohort, the standard of care cohort took 24% longer on the TUG ($p = 0.004$), 44% longer on the SCT (p

<0.001), and walked a 15% shorter distance on the 6MWT (p = 0.003) than the RCT cohort. No significant difference was noted between the exercise group and NMES group regarding the number of treatment visits completed, but the standard of care cohort received more PT sessions than the RCT cohort. During the study, one patient reported dizziness and lightheadedness following the first treatment with NMES, and of the 16 patients who dropped out of the exercise-NMES group, 11 reported being unable to tolerate the NMES treatment. No other adverse events related to participation in this study were reported.[5]

In a similar study completed by Stevens-Lapsley et al. 66 patients similar in sex, age, and height and with similar baseline performance measures were randomized into a NMES group who received both NMES and PT and a control group who received a PT regimen only following unilateral TKA surgery. PT for both groups included a standardized rehabilitation protocol, which consisted of 3 days of inpatient PT following surgery, 6 PT visits at home for 2 weeks and a subsequent 10-12 outpatient PT sessions. Those receiving NMES demonstrated proper use and safety with the NMES device prior to beginning the study and subsequently received 15 electrically elicited contractions twice daily for 6 weeks (50 pulses per second for 15 seconds with a 3 second ramp-up time and 45 second rest time between contractions) with electrodes placed over the distal medial and proximal lateral regions of the anterior thigh.[6]

Paralleling the Petterson study, Stevens-Lapsley et al. also evaluated improvements in functional performance including the TUG, SCT, and 6MWT. Outcome measurements were gathered at baseline and 3.5, 6.5, 13, 26, and 52 weeks post-operatively. At 3.5 weeks, the NMES group revealed greater improvements in all assessments of functional performance (see Table 3). Significant attenuation in loss of quadriceps strength at 3.5 weeks post-TKA was noted in the NMES group (40% loss) in comparison to the control croup (67% loss). At 52 weeks

differences between the NMES and control groups were less significant but still favored the NMES group. No adverse events were reported related to participation in this study.[6]

Table 3: Mean change from baseline at 3.5 weeks[6]

Assessment	Change From Baseline to 3.5 Weeks $\bar{x}$ (SE)[a]	
	NMES Group	Control Group
6MWT (meters)	-34.7 (15.5)	-137 (18.3)
SCT (seconds)	-8.9 (2.8)	-22.2 (3.0)
TUG (seconds)	-1.5 (0.6)	-4.2 (0.7)

[a] values noted are means ± standard error of estimate. Negative values reflect a deficit from baseline; positive values reflect an improvement from baseline[6]

In the third study included in this review, Avramidis et al. conducted an RCT including 30 patients scheduled for prospective unilateral TKA. Patients were randomized into a control group receiving PT only and a electric muscle stimulation (EMS) group receiving both PT and EMS inventions. Both groups received the same amount of traditional PT and the EMS group received electrical stimulation of the vastus medialis muscle twice daily for 2 hours on each occasion for a total of 6 weeks postoperatively.[3]

This study evaluated functional performance via a measurement of walking distance. Walking distance was assessed by performing a 3-minute walking test and recording the distance walked in meters. Outcome measurements were completed at baseline and 6 and 12 weeks post-operatively and baseline-adjusted ANCOVA values were reported. Results gathered at both 6 and 12 weeks reveal a treatment effect of value to the patient demonstrating a statistically significant difference in distance walked between EMS and control groups favoring the EMS group, $P = 0.0002$ and $P = <0.0001$ respectively (see Table 4). Moreover, 95% confidence intervals at 6 and 12 weeks, 12.6 – 36.2m in 3 min and 20.9 – 43.9m in 3 min respectively, also demonstrate post-operative statistical significance in favor of adjunctive EMS to solely a

traditional PT regimen (see Table 4).[3] No adverse events were noted to have occurred in this study.

Table 4: Distance walked in 3-minute walking test[3]

	Walking Distance (m) (3-minute walk)		
Weeks Post-Op	0	6	12
Controls	140.6	151.7	155.9
EMS Group	135.5	176.1	188.2
Difference		24.4	32.3
95% CI		12.6 – 36.2	20.9 – 43.9
***P* Value**		0.0002	<0.0001

The exclusion criteria outlined in Table 1 was implemented in each of the three studies to avoid introduction of other confounding variables that may impair true measurements of mobility and physical performance following TKA surgery. However, unlike the studies completed by Petterson and Stevens-Lapsley, the study completed by Avramidis et al. did not exclude patients based on a past medical history including uncontrolled hypertension, diabetes mellitus or obesity.[3,5,6] Because of this, the post-operative assessments of mobility in this population may have been altered by other medical conditions known to directly or indirectly influence physical activity. Additionally, there were significantly more female participants in the Avramidis study in comparison to the Petterson et al. and Stevens-Lapsley studies.[3,5,6]

DISCUSSION

Electrically elicited contractions have proven to augment muscle hypertrophy leading to corresponding improvements in muscle strength, which parallel muscle gains observed following high-intensity voluntary muscle contractions. Prior studies have shown the use of NMES applied to the quadriceps muscle has also reduced the length of hospital stay following TKA and has demonstrated greater muscle gains in the electrically stimulated leg when applied unilaterally to patients who have undergone bilateral TKA.[6]

After reviewing the results of several studies comparing a traditional PT regimen with and without adjunctive NMES, the application of NMES has further shown to be a successful adjunct to traditional PT regarding post-operative functional improvements in walking and stair-climbing ability following TKA surgery in patients 50-85 years old.[3,5,6] While the Petterson et al. study revealed no statistically significant difference between interventional and control groups of the RCT cohort, significant improvements in quadriceps muscle strength and functional outcomes were noted between the RCT and standard of care cohorts suggesting the benefit of a structured rehabilitation program including NMES and traditional PT in comparison to the standard of care for rehabilitation in the community. The other two studies by Stevens-Lapsley et al. and Avramidis et al. revealed NMES is an effective adjunct to traditional PT in the post-operative recovery of the quadriceps muscles by attenuating muscle atrophy and augmenting functional gains acquired via a PT regimen following TKA. However, the study completed by Avramidis et al. could have potentially demonstrated even greater gains in quadriceps strength had NMES been applied to a larger region of the quadriceps muscles like the other two studies in this review, rather than solely the vastus medialis muscle.

CONCLUSION

NMES is an effective adjunct to traditional PT following unilateral TKA in patients 50-85 years old. The three RCTs discussed in this review reveal evidence that support the use of NMES to strengthen the quadriceps muscle and attenuate quadriceps atrophy leading to post-operative improvements in function which matter to the patient including walking and stair-climbing ability. While post-surgical PT is an effective method to assist in restoring a patient's mobility by strengthening the musculature surrounding the knee joint, this intervention alone does not address the pre- and post-operative atrophy of the quadriceps. The addition of NMES to

a traditional PT regimen aids in minimizing quadriceps muscle atrophy while the muscles surrounding the joint are effectively strengthened via a combined effort of both interventions.

Though all of the studies in this review initially provided the patients with proper instruction on the use of the NMES device, patients were subsequently expected to independently use the NMES device to their maximum tolerance. Observation of patient use of the NMES device has shown a reluctance to initiate uncomfortable doses of electrical stimulation. Because of this, it is difficult to determine the maximum potential benefit of NMES application. Therefore, it is critical during the initial device training to encourage stimulation with the maximum tolerated dose.[6] Thus, though these studies reveal a significant benefit of adjunctive NMES to PT, it is difficult to determine the maximum benefit that could potentially be achieved by initiation of both interventions following TKA.

Moreover, the studies included in this review did not place limitations or restrictions on engagement in other means of exercise other than the assigned PT exercises which may have contributed to further functional gains for particular individuals included in the studies. Therefore, exercise independent of the respective study's intervention may have been introduced which may have subsequently augmented respective outcomes. Thus, future studies should place strict limitations on other forms of exercise that are not part of the NMES and PT intervention. Additionally, further research needs to be done to determine specific duration of NMES use and intensity of electrical stimulation that lead to the best functional outcomes for the patient. The benefit of the application of NMES both pre- and post-operatively should also be considered to see if pre-operative strengthening of the quadriceps may lead to greater and faster functional recovery following TKA.

REFERENCES

1. American Academy of Orthopaedic Surgeons. Arthritis of the knee. OrthoInfo: Your connection to expert orthopedic information Web site. http://orthoinfo.aaos.org/topic.cfm?topic=a00212. Updated 2014. Accessed October 4, 2014.

2. American Academy of Orthopaedic Surgeons. Beyond surgery day: The full impact of knee replacement. A Nation in Motion Web site. http://anationinmotion.org/value/knee/. Updated 2014. Accessed October 4, 2014.

3. Avramidis K, Strike PW, Taylor PN, Swain ID. Effectiveness of electric stimulation of the vastus medialis muscle in the rehabilitation of patients after total knee arthroplasty. *Arch Phys Med Rehabil*. 2003;84(12):1850-1853.

4. NMES. DJO Global Web site. http://www.djoglobal.com/our-brands/empi/information/healthcare-professionals/nmes. Published 2014. Updated 2014. Accessed December 3, 2014.

5. Petterson SC, Mizner RL, Stevens JE, et al. Improved function from progressive strengthening interventions after total knee arthroplasty: A randomized clinical trial with an imbedded prospective cohort. *Arthritis Rheum*. 2009;61(2):174-183. doi: 10.1002/art.24167; 10.1002/art.24167.

6. Stevens-Lapsley JE, Balter JE, Wolfe P, Eckhoff DG, Kohrt WM. Early neuromuscular electrical stimulation to improve quadriceps muscle strength after total knee arthroplasty: A randomized controlled trial. *Phys Ther*. 2012;92(2):210-226. doi: 10.2522/ptj.20110124; 10.2522/ptj.20110124.