Comparing Conventional Physical Therapy Rehabilitation With Neuromuscular Electrical Stimulation After TKA

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abstract

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Rehabilitation following total knee arthroplasty (TKA) is a costly, cumbersome, and often painful process. Physical therapy contributes to the successful outcome of TKA but can be expensive. Alternative methods of obtaining good functional results that help minimize costs are desirable. Neuromuscular electrical stimulation (NMES) is a potential option. Neuromuscular electrical stimulation has been shown to increase quadriceps muscle strength and activation following TKA. Functional scores also improve following TKA when NMES is added to conventional therapy protocols vs therapy alone. The authors hypothesized that rehabilitation managed by a physical therapist would not result in a functional advantage for patients undergoing TKA when compared with NMES and an unsupervised at-home range of motion exercise program and that patient satisfaction would not differ between the 2 groups. Seventy patients were randomized into a postoperative protocol of conventional physical therapy with a licensed therapist, including range of motion exercises and strengthening exercises, or into a program of NMES and range of motion exercises performed at home without therapist supervision. Noninferiority of the NMES program was obtained 6 weeks postoperatively (Knee Society pain/function scores, Western Ontario and McMaster Universities Osteoarthritis Index, flexion). Noninferiority was shown 6 months postoperatively for all parameters. The results suggest that rehabilitation managed by a physical therapist results in no functional advantage or difference in patient satisfaction when compared with NMES and an unsupervised at-home range of motion program. Neuromuscular electrical stimulation and unsupervised at-home range of motion exercises may provide an option for reducing the cost of the postoperative TKA recovery process without compromising quadriceps strength or patient satisfaction.
Total knee arthroplasty (TKA) is frequently performed in the United States. In 2005, more than 400,000 TKAs were performed; by 2008, the number reached 615,000.\textsuperscript{1,2} This number is expected to continue to increase as the Baby Boomer population ages.\textsuperscript{3} The surgical aspect of TKA is just one part of the total process. Physical therapy and rehabilitation play an integral role in successful TKA outcomes. A main concern of patients after TKA involves the physical therapy exercises and the related process (ie, pain involved, inconvenience, and cost). Patient perceptions of pain, time commitment during rehabilitation, cost, and inconvenience vary, which may affect outcomes.\textsuperscript{3} The physical therapy process is also costly.\textsuperscript{5}

The current standard of care after TKA involves a physical therapy program supervised by a licensed physical therapist during the hospital stay and for 6 to 12 weeks postoperatively. Usually, therapy occurs under the guidance of a physical therapist in the home for 2 weeks and is followed by therapy in an outpatient facility for another 4 to 8 weeks. It involves therapeutic modalities such as ice, heat, and massage in addition to exercise. The exercise protocol involves range of motion (ROM) and strengthening exercises. Occasionally, hands-on ROM maneuvers are performed by the therapist.

Therapy is necessary because of the significant weakness noted in the musculature after TKA, particularly in the quadriceps. Quadriceps muscle weakness can persist for 6 to 13 years postoperatively.\textsuperscript{6} Quadriceps strength has been shown to decrease by 62\% and voluntary activation of the quadriceps musculature by 17\% after TKA when compared with preoperative values.\textsuperscript{3} This significant impairment of quadriceps function is predominantly due to failure of voluntary muscle activation.\textsuperscript{7} Given that voluntary muscle activation is significantly decreased after TKA, rehabilitation is often difficult. Therefore, even with standard rehabilitation protocols, strength, function, and ROM are significantly worse at 1 month postoperatively and do not approach preoperative levels until 6 months postoperatively.\textsuperscript{8} It also appears that exercise protocols alone do not restore patients to the level of a nonarthritic peer.\textsuperscript{9} Thus, alternative methods of gaining muscle recovery after TKA should be considered.

Neuromuscular electrical stimulation (NMES) has been shown to increase quadriceps muscle strength and activation after TKA.\textsuperscript{9} Functional scores appear to improve after TKA when NMES is added to conventional therapy protocols as opposed to therapy alone.\textsuperscript{10} However, most studies to date have examined NMES as an adjunct to supervised therapy protocols and have not evaluated its benefit after TKA without formal therapy.\textsuperscript{9,10} The current authors hypothesized that rehabilitation managed by a physical therapist would not result in a functional advantage for patients undergoing TKA compared with NMES and an unsupervised at-home ROM exercise program, and that patient satisfaction would not differ between the 2 groups.

**MATERIALS AND METHODS**

This study was a balanced, 2-group, single-center, randomized, noninferiority trial comparing NMES with unsupervised at-home ROM exercises and therapist-managed physical therapy after TKA. Physical therapy was the standard of care. The study sought to determine whether any clinically meaningful difference existed between the NMES group and the physical therapy group. The study was approved by the institutional review board of the Western Pennsylvania Hospital and processed through the Singer Research Institute of the West Penn Allegheny Health System. All patients were required to provide informed consent specific to the study and to the surgical procedure.

Patients were voluntarily recruited from the daily operations of the medical practice of the principal investigator (M.L.), with no form of advertisement or financial remuneration. All surgical procedures were performed at Forbes Regional Hospital, Monroeville, Pennsylvania, by the principal investigator using the posterior-stabilized Optetrak Knee (Exactech, Inc, Gainesville, Florida). Patients were included if they were older than 18 years, scheduled for an elective TKA for osteoarthritis, and able to consent for themselves. Exclusion criteria included age younger than 18 years, revision surgery, inflammatory arthritis, admission to an extended care facility, pacemaker or defibrillator, epilepsy, lower-limb ischemia, abdominal or inguinal hernia, cutaneous lesions, acute trauma or fracture, inability to undergo extended physical therapy, and diminished mental capabilities. Patients randomized to the physical therapy group were not allowed to undergo NMES as part of their physical therapy during the study period.

Preliminary evaluations for study inclusion were performed at the principal investigator’s office. After eligibility was confirmed, patients were evaluated by the physical therapists (K.M., V.S.) 14 days preoperatively, at which time preoperative assessments were performed and instructions on the treatment protocol and the devices used in the protocol were initiated. Randomization was performed by the physical therapists at the initial evaluation 14 days preoperatively by drawing 1 paper from a hat that contained 35 papers for each group. A sample size of 70 patients was used, with 35 patients randomized to each group.

Patients in the physical therapy group were instructed in a formal physical therapy program consisting of 5 packets of exercises that included different combinations of ROM and progressive resistive exercises done while hospitalized and after discharge under the direct supervision of a physical therapist. Packets 1 and 2 contained ROM exercises only, and packets 3 to 5 included strengthening.
Patients in the NMES group were given the same first 2 packets of exercises as the physical therapy group, but only included ROM exercises. After discharge from the hospital, the patients had no direct contact with a physical therapist postoperatively except for during study evaluations. In addition, 14 days preoperatively, the NMES group was instructed to begin use of the Compex Neuromuscular Electrical Stimulator (DJO Global, Vista, California). Preoperative use continued until 1 day before surgery, was reintitated on postoperative day 1, and was continued for 60 days postoperatively. Postoperative pain management was standard to both groups. Surgery was performed under spinal anesthesia unless contraindicated or the anesthesiologist was unable to perform spinal anesthesia and the patient had to undergo general anesthesia. A long-acting morphine supplement was added to the spinal anesthesia. An oral analgesic protocol consisting of extended- and short-release oxycodone or tramadol was then used.

During the initial preoperative visit, patients underwent evaluations including the Knee Society score (KSS), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, ROM assessment, and Get-Up-and-Go (GUG) testing by a licensed physical therapist (K.M., V.S.). The WOMAC and KSS scores were calculated at Orthoscores.com using their modifications. Similar examinations occurred at 6 weeks and 6 months postoperatively. A daily log was maintained by each patient to confirm compliance with daily study protocol participation. The primary endpoint of the investigation was the 6-month postoperative evaluation.

Noninferiority was assessed for flexion, extension, KSS pain score, KSS function score, WOMAC score, and GUG test by examining the absolute 6-week and 6-month differences between groups and the change from baseline to 6 weeks and 6 months. A 95% confidence interval was used. All tests had a 2.5% type I error rate and a power of 80%; no adjustment was made for attrition.

Margins for each parameter were established by the principal investigator.12-15 Tests for superiority were performed to determine a margin for noninferiority testing for the 6-week and 6-month outcomes. This was necessary because no widely accepted preestablished margin of inferiority exists in the clinical literature for the parameters evaluated in this study. The margin was set at roughly 10% of the most extreme value (Table 1). This percentage, although arbitrary, seemed reasonable based on the authors’ calculations.

**RESULTS**

Seventy patients were initially recruited into the study. Thirty-five patients were randomized into the physical therapy and NMES groups, respectively. All patients were diagnosed with osteoarthritis and underwent TKA with a posterior-stabilized implant. Mean age was 65.1 years in the physical therapy group and 68.1 years in the NMES group ($P = .16$). The physical therapy group comprised 21 (62%) women and 13 (38%) men, and the NMES group comprised 25 (76%) women and 7 (21%) men ($P = .19$). Mean body mass index was $31.9 \text{ kg/m}^2$ in the physical therapy group and $30.6 \text{ kg/m}^2$ in the NMES group ($P = .35$). Baseline comparison of the physical and functional outcomes showed no significant differences between groups (Table 2).

One patient in the physical therapy group withdrew from the study in postoperative week 2 because she was unable to travel to the study site for postoperative evaluation. Two patients in the NMES group were withdrawn because they developed confusion postoperatively, which required inpatient skilled nursing. Another patient was withdrawn from the NMES group after it was identified that workman’s compensation was involved. Four patients in the NMES group and 9 patients in the physical therapy group were lost to follow-up at 6 months. Attempts were made to contact each of these patients by telephone, and those reached reported satisfactory progress but did not wish to continue being evaluated.

The 6-week and 6-month data were assessed for noninferiority on each of the functional outcomes. Extreme values of each outcome were used to choose the margins of noninferiority. The maximum values were as follows: flexion, 134°; extension, 14°; KSS pain score, 95 points; KSS function score, 100 points; WOMAC score, 100 points; Get-Up-and-Go test, 23 seconds; and change from preop to wk 6, −36° to 49°; extension, −10° to 24°; KSS pain score, −42° to 64°; KSS function score, −45° to 90°; WOMAC score, −30° to 67°; Get-Up-and-Go test, −14° to 8°.

### Table 1

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Maximum (Margin)</th>
<th>Change From Preop to Wk 6/ Mo 6 Postop, Range (Margin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion, deg</td>
<td>134 (10)</td>
<td>−36 to 49 (5)</td>
</tr>
<tr>
<td>Extension, deg</td>
<td>33 (3)</td>
<td>−10 to 24 (2)</td>
</tr>
<tr>
<td>Knee Society score, points</td>
<td>95 (10)</td>
<td>−42 to 64 (5)</td>
</tr>
<tr>
<td>Function</td>
<td>100 (10)</td>
<td>−45 to 90 (10)</td>
</tr>
<tr>
<td>WOMAC score, points</td>
<td>100 (10)</td>
<td>−30 to 67 (5)</td>
</tr>
<tr>
<td>Get-Up-and-Go test, s</td>
<td>23 (3)</td>
<td>−14 to 8 (2)</td>
</tr>
</tbody>
</table>

**Abbreviations:** deg, degrees; Postop, postoperative; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.
## Table 2

### Preoperative Data

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Mean ± SD</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NMES Group</td>
<td>Physical Therapy Group</td>
</tr>
<tr>
<td><strong>Flexion, deg</strong></td>
<td>109.1±16.2</td>
<td>108.9±14.8</td>
</tr>
<tr>
<td><strong>Extension, deg</strong></td>
<td>4.5±4.9</td>
<td>4.1±4.1</td>
</tr>
<tr>
<td><strong>KSS score, points</strong></td>
<td>52.7±13.4</td>
<td>50.2±20.7</td>
</tr>
<tr>
<td><strong>Pain</strong></td>
<td>49.6±13.9</td>
<td>48.1±12.5</td>
</tr>
<tr>
<td><strong>Function</strong></td>
<td>50.7±12.6</td>
<td>46.8±16.9</td>
</tr>
<tr>
<td><strong>WOMAC score, points</strong></td>
<td>13.1±3.8</td>
<td>13.1±3.6</td>
</tr>
</tbody>
</table>

Abbreviations: KSS, Knee Society score; NMES, neuromuscular electrical stimulation; s, seconds; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

## Table 3

### Statistics for Each Outcome by Treatment Group

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Mean ± SD (n)</th>
<th>95% CI for Δ: NMES – PT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NMES Group</td>
<td>PT Group</td>
</tr>
<tr>
<td><strong>Flexion, deg</strong></td>
<td>104.4±10.37 (30)</td>
<td>107.6±11.18 (33)</td>
</tr>
<tr>
<td><strong>Extension, deg</strong></td>
<td>114.5±13.01 (26)</td>
<td>112.2±10.56 (24)</td>
</tr>
<tr>
<td><strong>KSS pain, points</strong></td>
<td>4.8±4.38 (30)</td>
<td>4.15±6.27 (33)</td>
</tr>
<tr>
<td><strong>KSS function, points</strong></td>
<td>2.58±2.86 (26)</td>
<td>3.54±6.05 (24)</td>
</tr>
<tr>
<td><strong>WOMAC score, points</strong></td>
<td>63.97±15.15 (30)</td>
<td>61.21±18.98 (33)</td>
</tr>
<tr>
<td><strong>Get-Up-and-Go test, s</strong></td>
<td>79.08±10.97 (26)</td>
<td>75.5±14.77 (24)</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; deg, degrees; KSS, Knee Society score; NMES, neuromuscular electrical stimulation; PT, physical therapy; s, seconds; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

*Noninferiority attained.

Confidence interval per the unequal variance Satterthwaite method.

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with a margin of 10°; extension, 33° with a margin of 3°; KSS pain score, 95 points with a margin of 10 points; KSS function score, 100 points with a margin of 10 points; WOMAC score, 100 points with a margin of 10 points; GUG test, 23 seconds with a margin of 3 seconds.

Noninferiority was shown at 6 weeks for flexion, KSS pain score, KSS function score, and WOMAC score. Noninferiority was not shown at 6 weeks for extension and GUG test. However, noninferiority was shown at 6 months for all parameters (Table 3).

Overall functional scores, such as KSS pain and function scores and WOMAC scores, were better in the NMES group, whereas ROM and GUG results were slightly better in the physical therapy group at 6 weeks. At 6 months, all parameters except GUG testing were slightly better in the NMES group. Patient satisfaction WOMAC scores were similar between the 2 groups.

## DISCUSSION

The hypothesis of this study was that a NMES protocol with self-performed ROM exercises administered for 2 weeks before and 60 days after TKA would provide similar outcomes regarding quadriceps strength and patient satisfaction at 6 weeks and 6 months compared with a traditional therapist-managed physical therapy program. This was confirmed using well-accepted outcome assessments for TKA.

Looking at the absolute values of the KSS pain and function scores and the WOMAC scores, patient satisfaction was somewhat better in the NMES group. Physical therapy is often a source of concern for patients after TKA; if it could be reduced or eliminated, anxiety over the procedure could also be reduced. Other potential advantages of reducing or eliminating physical therapy are its cost and inconvenience. Medicare reimbursements at local outpatient physical therapy facilities are approximately $100 to $125 per session; a cost ranging from $1200 to
$1500 for 12 sessions. This does not include the 2 weeks of home care, for which the actual cost of therapy is difficult to assess because of the Medicare bundled payment system. The cost of the NMES device in this study was $400, which resulted in a substantial cost savings over the therapist-managed physical therapy. Neuromuscular electrical stimulation and ROM exercises can be performed at home and at the patient’s convenience, not according to the schedule of a therapist. This lowers the burden on the patient with regard to scheduling home visits with a therapist or the need to visit a therapy facility, which involves making transportation arrangements.

Recently, unsupervised physical therapy, such as telerehabilitation, has been shown to provide results comparable with therapist-managed physical therapy.16 However, a role exists for active therapy. Certain patients will require a formal physical therapy program; extension was not shown to be noninferior at 6 weeks, and some individuals in the NMES study group may have benefited from physical therapy. However, by 6 months, noninferiority was observed. Prior studies have shown less improvement in knee extension after TKA when fewer physical therapy visits occurred on a home care basis.17 However, in the current study, extension in the NMES group was similar to that in the physical therapy group at 6-month follow-up.

Another area of concern was the GUG test, which was shown to be noninferior at 6 months but not at 6 weeks. The GUG test is a reliable assessment of function; however, it may not represent overall physical performance of the test can also affect results. Patient perceptions of function can differ from actual function,18 which may explain the WOMAC and KSS results differing from the GUG results at 6 weeks in the current study. Significant patient factors, including obesity, motivation, fatigue, and preoperative activity levels, in the performance of the test can also affect results. Stratification of patients at randomization based on their preoperative activity levels may be necessary to detect differences in groups based on the GUG test.

This study had some limitations. Although the physical therapy group was given a comprehensive protocol, the therapists differed for each patient, and the therapy protocol may not have been implemented identically for each patient. In the NMES group, the authors were able to monitor patient compliance with the protocol but not to objectively assess performance of the unsupervised ROM exercises. Finally, the power for the study was not adjusted to reflect the 13 patients lost to follow-up by 6 months; this may have skewed the results.

Another potential limitation of the study was the inherent design. When the study was initially designed, the hypothesis was to evaluate NMES with unsupervised, at-home ROM exercises versus a supervised physical therapy program. This evaluation produced no clear evidence that NMES with home exercise is superior to home ROM exercises alone or no therapy at all. For future investigations, the authors will consider a different study design. An appropriately sized study population could be divided into 4 groups, such as supervised physical therapy with NMES, supervised physical therapy without NMES, at-home ROM exercises with NMES, and at-home ROM exercises without NMES. This type of design represents a logical next step for study.

Patients can have impaired quadriceps function after TKA due to decreased voluntary muscle activation.7 Therefore, it is important to make the rehabilitation process after TKA as efficient as possible to encourage compliance. Neuromuscular electrical stimulation combined with self-administered ROM exercises may provide a more efficient and cost-effective alternative approach for improving short-term outcomes.

**CONCLUSION**

The hypothesis of this study was that physical therapist–managed rehabilitation would not result in a functional advantage for patients undergoing TKA compared with NMES and an unsupervised at-home ROM exercise program, and that patient satisfaction would not differ between the 2 groups. The results of the study support this hypothesis. Use of NMES and unsupervised at-home ROM exercises may provide an option for simplifying and reducing the cost of the postoperative TKA recovery process without compromising quadriceps strength or patient satisfaction.

**REFERENCES**

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