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Emerging Techniques in Orthopedics: Advances in Neuromuscular Electrical Stimulation

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Abstract

Neuromuscular electrical stimulation (NMES) is defined as the application of an electric current to neuromuscular tissue to elicit a muscle contraction. It is typically applied in a clinical setting to strengthen muscle, particularly the quadriceps femoris, through repetitive contractions. Most studies to date involving NMES have been conducted using conventional lead-wired, or "single path" devices, and while effective, these devices have inherent limitations around comfort and incomplete muscle recruitment. In a prospective, randomized, controlled, single-blind trial, investigators found that using a novel "Multipath" device was effective when combined with standard rehabilitation in accelerating recovery after anterior cruciate ligament reconstruction. Additional research is warranted to explore whether this effect also occurs after other types of knee surgery.

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Neuromuscular electrical stimulation (NMES) involves the delivery of pulsed electrical current to the peripheral nervous system via pads placed on the surface of the skin. It is used to strengthen muscle groups, particularly the quadriceps femoris, by eliciting repetitive muscle contractions, which, when applied over a sustained intervention period, produce an inherent training adaption. Unlike other forms of electrical stimulation, including transcutaneous electrical nerve stimulation and functional electrical stimulation, NMES is generally delivered in static isometric conditions at sufficiently high current intensities to evoke visible muscle contractions.[1]

NMES has been shown to be a beneficial supplement to conventional physical therapy following total knee arthroplasty (TKA)[2,3] and anterior cruciate ligament (ACL) reconstruction.[4,5] In 2003, Fitzgerald and colleagues[4] observed that NMES, when combined with conventional rehabilitation following ACL reconstruction, resulted in an increase in quadriceps strength and self-reported knee function, compared with NMES or ACL rehabilitation alone. In a similar study, Snyder-

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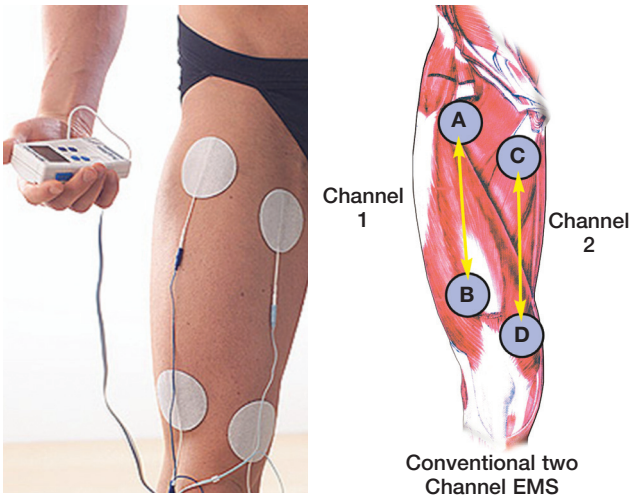

Figure 1. Single path device: Electrode positioning and stimulation patterns of the conventional single path neuromuscular electrical stimulation.

Mackler and colleagues[5] found a clinical and statistically significant difference in the recovery of the quadriceps strength ($P < .05$). Delitto and colleagues[6] also reported that the administration of NMES alone after ACL surgery achieved significant improvements in thigh musculature strength, compared with voluntary exercise alone ($P < .05$). Other studies however, have found the addition of NMES to be of minimal or no benefit after ACL surgery.[7-9]

The lack of a general consensus in the scientific community about the main physiological and methodological features of NMES has contributed to confusion regarding its usage and effectiveness.[1] In spite of this, NMES has received an increasing amount of attention not only as a strength-training tool in healthy individuals and athletes, but also as a rehabilitation and preventive tool in partially- or totally-immobilized patients, a testing tool to evaluate neural and/or muscle function in vivo, and a post-exercise tool in atheletes.[1]

The need for a general consensus on standardization of NMES terminology, including current and contraction characteristics, to allow a more uniform use of the modality in clinical settings and to assist in conducting and evaluating research, is highlighted in an editorial review by Maffiuletti and colleagues[1] in October 2011. The authors conclude that further efforts are needed to identify the most relevant applications of NMES and to discern its efficacy and the appropriate time-course of neuromuscular adaptations in specific patient populations.

Using NMES Alone or as an Adjunct

While individual studies have yielded conflicting results, results from systematic reviews have suggested that NMES can be beneficial, compared with no exercises,[10] and when combined with voluntary muscle contraction.[11]

In a systematic review of 35 randomized controlled trials, Bax and colleagues[10] underscored the importance for researchers to use clinically applicable, commonly used and validated outcome measures, and to move toward standardizing an approach to NMES research. Despite the abundance of methodological and descriptive weaknesses in many of the included studies, Bax and colleagues concluded that NMES is useful in both unimpaired and impaired quadriceps femoris muscles, compared with no exercise. It may be especially useful for within-cast muscle training where volitional training does not receive sufficient patient compliance.

Bax and colleagues[10] included 3 randomized trials evaluating NMES versus no exercises in adult patients with impaired quadriceps femoris muscle.[12-14] One study conducted by Hortobágyi and colleagues[12] reported significantly better results in the NMES group than the no-exercise group. The other 2 studies found no significant differences.[13,14] However, Bax and colleagues[10] noted that none of these trials used allocation concealment, blinding, or accounted for dropouts or noncompliance. Hortobágyi and colleagues[12] also favored NMES training over volitional exercises, while Singer and colleagues[13] found volitional isokinetic and isotonic exercises to be superior to NMES.[10] The dichotomy in the data, Bax and colleagues noted, may be explained by the fact that one study used a 6-week eccentric training protocol[12] and the other a 4-week concentric training protocol.[13]

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In another review, Paillard[11] examined data on the neuromuscular adaptations induced by volitional exercise alone, with those induced by NMES alone, and in combination with volitional exercise. The physiological effects of these different training programs were evaluated in healthy subjects and/or athletes, as well as postoperatively in patients with knee injuries. Combination therapy induced greater muscular adaptation than exercise alone in both groups. This is likely because NMES and voluntary contractions activate muscles differently and induce different effects on the neuromuscular system, the study author noted.[11] Combination therapy was particularly effective in accelerating recovery of muscle contractility and functional abilities following surgery. The author further concluded that addition of NMES to voluntary exercise in the early phase of rehabilitation elicits a strength increase that is necessary to perform voluntary training during later rehabilitation sessions.[11]

The Practicality of NMES

Most studies involving NMES have been conducted using conventional lead-wired, or "single path" devices (Figure 1) such as AvivaStim™ XP (Neurotech N.A., a division of Biomedical Research Ltd of Galway, Ireland), 300 PV Complete Electrotherapy System (Empi, St. Paul, Minnesota), and Bionicare Stimulator (RS Medical, Vancouver, Washington). These devices have been shown to be effective, although issues around discomfort and relatively incomplete muscle recruitment have been observed.[1]

Set-up of conventional lead-wired devices can be inconvenient because each of the 4 electrodes must be attached to a lead wire, which then has to be correctly located by the patient on the skin for each treatment. This drawback—which can lead to non-adherence to treatment—has prompted investigations of alternative techniques and strategies, including distributed NMES, magnetic stimulation, and Multipath stimulation with conductive gel pads.[1]

"Set-up of conventional lead-wired devices can be inconvenient because each of the 4 electrodes must be attached to a lead wire. This drawback has prompted investigations of alternative techniques and strategies, including multipath stimulation with conductive gel pads."

Kneehab® XP (Neurotech N.A., a division of Bio-Medical Research Ltd of Gateway, Ireland) is a conductive garment that delivers stimulation to the quadriceps using patented Multipath technology (Figure 2). It is cleared for marketing by the US Food and Drug Administration and indicated for muscle re-education of the quadriceps, maintaining or increasing range of motion of the knee joint, preventing or retarding disuse atrophy in the quadriceps for early postsurgical quadriceps strengthening, improving postsurgical knee stability secondary to quadriceps strengthening, and increasing local blood circulation. In addition, it can be programmed to deliver transcutaneous electrical nerve stimulation as an adjunctive therapy to reduce the level of pain and pain symptoms associated with osteoarthritis, provide symptomatic relief of chronic,

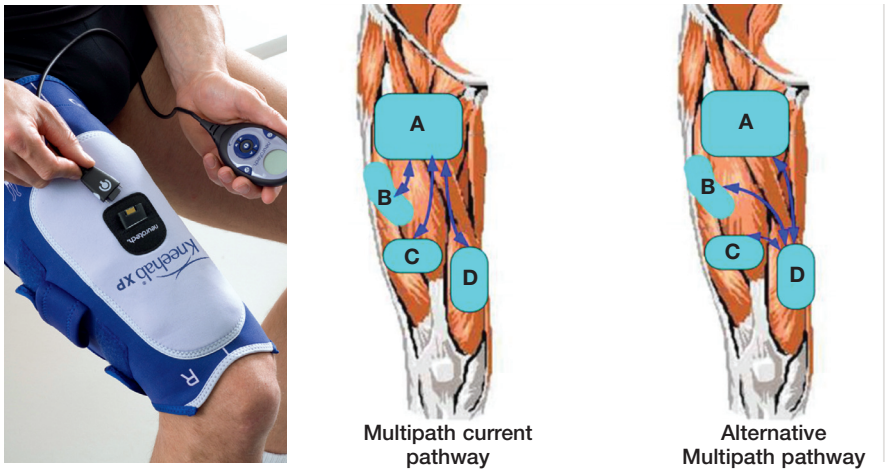
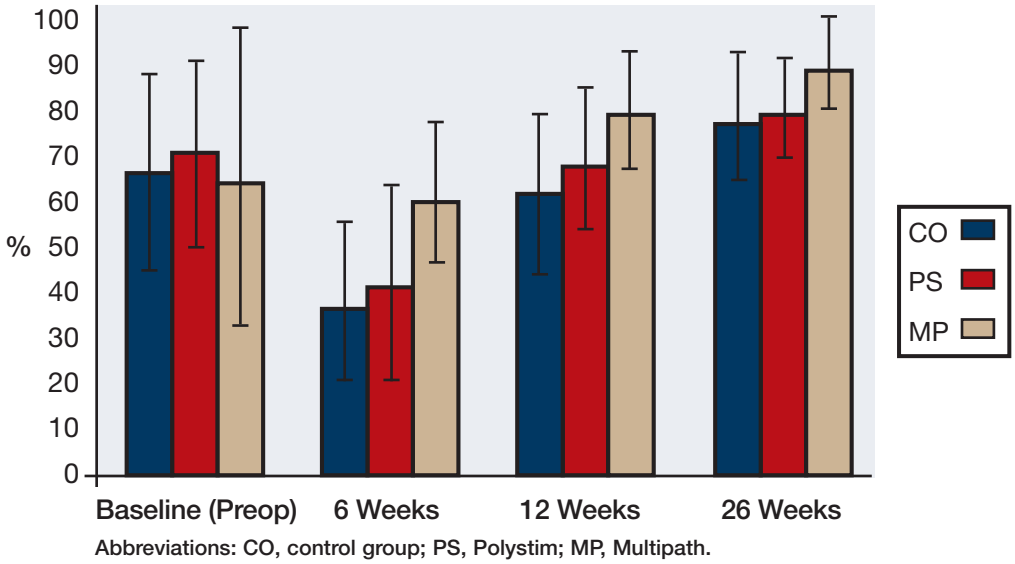


Figure 2. Multipath device: Neuromuscular electrical stimulation delivered via medial and lateral current pathways with Multipath device.

intractable pain and as adjunctive treatment in the management of acute, postsurgical or posttraumatic knee pain. The device is available only by prescription in the US.

Kneehab® XP is widely used as an adjunctive therapy for patients with atrophy of the quadriceps muscles due to sports injuries, including the ACL, lateral collateral ligament (LCL), medial collateral ligament (MCL), or posterior cruciate ligament (PCL). It has also been used in degenerative conditions including osteoarthritis, knee joint conditions including patella femoral pain syndrome, and to strengthen the quadriceps pre- and post-surgery for ligament repair and knee replacement.



Abbreviations: CO, control group; PS, Polystim; MP, Multipath.

Figure 3. Mean Single-legged hop test scores: Quotient of injured and uninjured leg in percentages; mean single-legged hop test scores for all groups at all time points.

This novel device integrates the electrodes and wiring into a garment that can be quickly and conveniently applied and removed. It also uses unconventionally large conductive surface areas, reducing current density at the skin and allowing users to more comfortably tolerate higher currents and the resultant higher induced torque.

> **"The hypothesis was that the addition of NMES to the standard rehabilitation program would accelerate recovery."**

A Pivotal Trial

In June 2011, Feil and colleagues[15] reported the findings of a prospective, randomized, controlled, single-blind study designed to assess the effectiveness of supplementing a standard rehabilitation program of volitional exercises after ACL reconstruction with superimposed NMES delivered by the novel device (Kneehab® XP), compared with a conventional device for NMES and a control group with no device.

The study sought to combine several elements that have emerged in the literature as important in optimizing rehabilitation outcomes when applying NMES, either on its own or superimposed on volitional contractions. These include improved patient adherence to NMES treatment regimens, and combining NMES with a standard, volitional exercise program. The hypothesis was that the addition of NMES to the standard rehabilitation program would accelerate recovery. The primary outcome measures of effectiveness were knee extensor strength, performance of a single-legged hop, and time to complete the shuttle-run. Secondary measures included objective assessment on the International Knee Documentation Committee (IKDC) 2000 evaluation form.[15]

All study participants were from a single clinical rehabilitation site and were candidates for minimally invasive, endoscope-assisted ACL reconstruction. Patients between the ages of 18 and 55 years who had an isolated rupture of the ACL and no additional injury to the knee joint were eligible for inclusion.

Patients were randomly assigned to 1 of 3 treatment groups: control (CO), PolyStim (PS), or Multipath (MP). Patients in all 3 groups completed the same standardized accelerated rehabilitation protocol after ACL reconstruction, plus a home training schedule of 20 minutes training 3 times daily, 5 days a week, for 12 weeks. Patients in the

CO group trained using only voluntary quadriceps contractions; patients in the PS group trained with a conventional 2-channel NMES device (AvivaStim™ XP); and patients in the MP group trained with the novel device (Kneehab® XP).

In the PS and MP groups, patients began training with their respective devices on the third or fourth day postoperatively and were instructed to co-contract their quadriceps muscles in synchronism with the electrically–elicited contractions. Patients in the CO group performed volitional isometric quadriceps muscle training without stimulation for the same time schedule.

Both NMES devices provided a stimulation frequency of 50 Hz and had an output current in the range 0 to 70 mA. Kneehab® XP differs from conventional devices in that it wraps around the thigh and locates an array of 4 large conductive gel pads over the quadriceps muscle (Figure 2). It dynamically changes the current pathways between gel pads during treatment, improving the spatial distribution of the stimulation current. Spatial distribution of current with a traditional 2-channel device is limited to the region of electrodes of a pair (Figure 1). The PS device used in this study has four 70-mm round electrodes, while the MP device has 4 different-sized conductive gel pads (10 cm × 20 cm, 3 cm × 18 cm, 10 cm × 7.5 cm, and 7 cm × 14 cm) with current pathways activated by both the lateral and medial pathways.

Patients were examined and interviewed by a surgeon (investigator) blinded to the intervention, as well as a co-investigator, preoperatively, and at 6 weeks, 12 weeks, and 6 months postoperatively. Objective measurements included isokinetic strength tests of the knee extensors, as well as functional hopping and walking tests to measure coordination and proprioception. Strength measurements of the knee extensors were performed in a seated open kinetic chain position with active extension and flexion at a limited range of movement (90° of flexion to 45°of extension). A set of 10 repetitions each was measured on both the injured and uninjured leg. Strength was measured at 90°/s and 180°/s on both legs.

The single-legged hop test was measured as the distance of jump achieved, averaged over 3 attempts. Three sets were performed on each leg, with the uninjured leg tested first, and the injured/uninjured quotient of the averages calculated. The shuttle run is a walk/sprint test in which patients have to cover a fixed distance of 6.3 m four times with changing direction. The measurement reading is the average time for 3 attempts.

"Kneehab® XP differs from conventional devices in that it wraps around the thigh and locates an array of 4 large conductive gel pads over the quadriceps muscle."

Table. Change in Extensor Strength Gain Across All Treatment Groups[a]

Extension	Multipath Group	Polystim Group	Control Group
90°/s	+30.2%	+5.1%	+6.6%
180°/s	+27.8%	+5%	+6.7%

[a]Data represented as percentage change, compared with preoperative values.

Objective and subjective outcomes were evaluated by the Tegner score, Lysholm score, IKDC Knee Examination Form, and KT-1000 arthrometer (Med-Metric Corp, San Diego, California) measurement. In addition, patients kept a diary to document training at home and report on various aspects of their rehabilitation, including the date of their return to normal work activities.

Results of the multiple comparisons reflect improvement in the MP (Kneehab® XP) group for all responses, as nearly all comparisons with the other 2 groups were significant ($P < .05$). Extensor strength gain at speeds of 90°/s and 180°/s (expressed in percentage change compared with preoperative values) increased by 30.2% and 27.8%, respectively, in the MP group, compared with 5.1% and 5%, respectively, in the SP group, and 6.6% and 6.7%, respectively, in the CO group (Table).

The mean single-legged hop test score of the MP group improved by 50% between the 6-week and 6-month follow-up visits, compared with 26.3% in the PS group and 26.2% in the CO group (Figure 3). The MP group attained preoperative speed in the shuttle run by the sixth week, whereas the other groups did not attain preoperative speed until 12 weeks or later.

Patient diaries showed a higher rate of adherence to training in the MP group than in the PS group, as verified by inspection of the stimulator data readouts. The time taken to return to daily working life showed a positive trend in favor of the MP group, whose members returned to work a full week faster than the other groups. Return-to-work time was 2.7 weeks for the MP group, 3.9 weeks in the PS group, and 3.7 weeks in the CO group.

Although patients in all groups showed improvement in this study, those in the MP group achieved consistently better results for strength and functional performance measures at all time points during the rehabilitation period. Of the 2 groups that used NMES devices, patients in the MP group achieved higher compliance rates than those in the conventional PS group and were able to return to their usual work activities a week earlier than did patients in both of the other groups. These findings highlight both the functional benefits of supplementing a standard rehabilitation program with NMES and the health economic implications.

Looking Towards the Future

Recent research by Feil and colleagues[15] adds to a growing body of evidence suggesting that the addition of NMES protocols to a standard rehabilitation program accelerates recovery after surgery. It differs from other studies that combined NMES with a program of volitional exercises in that subjects in the 2 NMES groups contracted their muscles simultaneously during each electrically stimulated contraction. This is the same type of superimposition technique evaluated by Bax and colleagues[10] in their review, which demonstrated favorable results for NMES in impaired patients. The main difference in the Feil study[15] is that it included the MP group that used garment-integrated stimulation, which delivers the pulsed electrical currents across multiple stimulation pathways and uses large surface conductive gel pads to minimize comfort and muscle recruitment concerns.

With regard to strength and performance measures, an apparent reduction in performance was observed in all groups at the 6-week follow-up point, compared with pre-surgical baseline performance. This was followed by a recovery that exceeded or restored pre-surgical performance in all groups. Patients in the MP group exhibited less of a deficit at 6 weeks than patients in the other groups, and maintained, but did not increase this advantage in subsequent time points. This is consistent with the observation that the addition of NMES in the early phase of rehabilitation produces a strength increase that is necessary to perform volitional exercises in later phases.[11] Further research is warranted to explore whether this effect also occurs after other types of knee surgery.

"The study conducted by Feil and colleagues[15] adds to a growing body of evidence suggesting that the addition of NMES protocols to a standard rehabilitation program accelerates recovery after surgery."

Findings from a randomized controlled trial published in November 2011 by Stevens-Lapsley and colleagues[3] provide additional evidence that early addition of NMES treatment to the quadriceps muscles effectively attenuates loss of muscle strength and improves functional performance following TKA. Sixty-six patients, aged 50 to 85 years, were enrolled as part of a prospective longitudinal study and randomized to receive either standard rehabilitation (control) or standard rehabilitation plus NMES initiated 48 hours after surgery. Patients were assessed preoperatively and at 3.5, 6.5, 13, 26, and 52 weeks. At 3.5 weeks after TKA, NMES application substantially attenuated loss of quadriceps muscle strength (67% loss in the control group vs 40% loss in the NMES group). As in previous studies, the effects of NMES were most pronounced during the early phase of rehabilitation. Benefits persisted through 1 year, with improvements in quadriceps and hamstring muscle strength, functional performance, and some self-performance measures.[3]

Furthermore, findings from a pilot study of 17 patients published in 2010 suggest that preoperative NMES may improve recovery of quadriceps muscle strength and hasten functional recovery in patients undergoing TKA for osteoarthritis.[16] NMES was provided by a portable, battery powered, garment-based stimulator as described above in the study by Feil and colleagues[15] (Kneehab XP by Neurotech N.A., a division of Bio-Medical Research Ltd. of Galway, Ireland). In this study, which was the first to assess the use of NMES as a prehabilitation modality (i.e., supervised preoperative muscle training), adherence to an 8-week preoperative NMES program was excellent and the intervention group showed a trend towards an increase in quadriceps muscle strength and significant improvements in functional performance prior to surgery. Postoperatively, these effects translated into earlier strength and functional recovery in the NMES group from week 6 to the final postoperative assessment at week 12. The authors concluded that further study is warranted in a larger cohort as part of a cost–effectiveness analysis and efficacy study.

Additional studies and clinical experience will be needed to determine optimal uses for Multipath delivery of NMES. Kneehab® XP is currently being used at the ATOS Clinic in Heidelberg, Germany, for conservative or preoperative treatment of patella femoral pain syndrome, osteoarthritis of the knee and patella femoral joint, and acute tears of the ACL, PCL, and MCL. Postoperatively, it is used in cartilage repair procedures of the knee, meniscus repair or therapy, TKA, ACL and PCL reconstruction, medial patellar femoral ligament reconstruction, high tibial osteotomy, and osteosynthesis of the lower leg.

Author's Disclosure Statement

The authors report no actual or potential conflict of interest in relation to this article.

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