The Effectiveness of Supplementing a Standard Rehabilitation Program With Superimposed Neuromuscular Electrical Stimulation After Anterior Cruciate Ligament Reconstruction : A Prospective, Randomized, Single-Blind Study

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The Effectiveness of Supplementing a Standard Rehabilitation Program With Superimposed Neuromuscular Electrical Stimulation After Anterior Cruciate Ligament Reconstruction

A Prospective, Randomized, Single-Blind Study

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Background: Rehabilitation after anterior cruciate ligament reconstruction is a key determinant affecting patient return to usual activity levels. Neuromuscular electrical stimulation is a treatment that can counteract strength loss and serve as an adjunct to conventional therapy.

Purpose: To compare the effect of adding traditional neuromuscular electrical stimulation (Polystim) or a novel garment-integrated neuromuscular electrical stimulation (Kneehab) to a standard postoperative rehabilitation program (control).

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: Ninety-six patients, of a total enrolled cohort of 131 patients randomized to 1 of 3 intervention groups, completed a standard rehabilitation program. In addition, the 2 neuromuscular electrical stimulation groups underwent 20-minute sessions of neuromuscular electrical stimulation 3 times a day, 5 days a week, for 12 weeks, in which stimulation was superimposed on isometric volitional contractions. Outcome measures including isokinetic strength of the knee extensors of the injured and uninjured leg at 90 and 180 deg/s, along with functional tests of proprioception, were assessed at baseline and at 6 weeks, 12 weeks, and 6 months postoperatively.

Results: The Kneehab group achieved significantly better results at each time point compared with the Polystim and control groups ($P < .001$). Extensor strength of the Kneehab group at speeds of 90 and 180 deg/s increased by 30.2% and 27.8%, respectively, between the preoperative measurements and the 6-month follow-up point in the injured leg. The corresponding changes for Polystim were 5.1% and 5%, whereas for the control group they were 6.6% and 6.7%, respectively. The mean single-legged hop test hop score of the Kneehab group improved by 50% between the 6-week and 6-month follow-up, whereas the corresponding changes for the Polystim and control groups were 26.3% and 26.2%, respectively. Although there was no significant difference between the groups with respect to the Tegner score and the International Knee Documentation Committee 2000 knee examination score, the Kneehab group showed a significant difference in mean improvement for the baseline corrected Lysholm score compared with the control group ($P = .01$; 95% confidence interval, 1.12-8.59) and with the Polystim group ($P < .001$; 95% confidence interval, 1.34-9.09) with no significant difference evident between Polystim and control groups ($P = .97$; 95% confidence interval, −4.23 to 3.51).

Conclusion: Intensive garment-integrated stimulation combined with standard rehabilitation is effective at accelerating recovery after knee surgery.

Keywords: knee pathology; anterior cruciate ligament (ACL); strength gains; functional recovery; neuromuscular electrical stimulation (NMES)

Neuromuscular electrical stimulation (NMES) can be a beneficial supplement to traditional forms of therapy in the period after knee surgery. Previously, it has been reported that after knee joint replacement, a patient group who engaged in highly intensive activation of the quadriceps muscle using electrical stimulation produced better results for strength and muscle activation compared with a control group.[29] Comparable studies conducted after anterior cruciate ligament (ACL) reconstruction produced

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similar results with improved strength of the quadriceps muscle and better knee function being reported.[10,27,28] In contrast, there are also studies in which minimal or no differences were found between electrical stimulation and volitional strength training of the muscles affected.[17,18,25] The intensity of NMES-induced muscle activation and the extent of training are important factors affecting treatment outcomes, and consequently patient compliance at high levels of stimulation is required.[15,19,21] A recent study of patients who underwent total knee arthroplasty has shown that the addition of NMES to a program of progressive volitional exercise provided no additional benefit; however, the tolerance of the subjects to the NMES modality used was poor, leading to a high dropout rate in the NMES group.[26] The intervention was also delayed until 3 weeks after surgery.

The primary objectives of rehabilitation after ACL reconstruction are to reduce inflammation, regain neuromuscular strength and functional performance, recover normal range of motion, and reintegrate the patient to everyday activities. Studies have shown that the activation pattern of the quadriceps and hamstring muscles as well as restoration of proprioception play an important role in rehabilitation after ACL surgery.[4,5,16] A recent review concluded that rehabilitation training with NMES superimposed on voluntary contraction was better than either NMES or voluntary contraction practiced separately.[23] In a further review of NMES combined with but not directly superimposed on voluntary contraction, results showed that the combination therapy induced greater muscle adaptation than did voluntary contraction alone.[24]

Conventional lead-wired NMES devices such as Polystim (PS) (Biomedical Research Ltd, Neurotech, Galway, Ireland) can be effective; however, setup can be inconvenient because each of the 4 electrodes has to be attached to a lead wire, which then must be correctly located by the patient on the skin for each treatment. These drawbacks potentially restrict patient compliance. The Kneehab (KH) (Biomedical Research Ltd) device used in this study integrates the electrodes and wiring into a garment that can be applied and removed in seconds and would therefore be expected to lead to improved compliance. In addition, this device uses unconventionally large electrode surface areas, which reduces current density at the skin, leading to reduced discomfort for a given current level. This in turn allows the user to tolerate higher currents and thereby higher induced torque. The purpose of the present prospective, randomized, controlled, single-blind study was to assess the effectiveness of combining each of 2 forms of NMES therapy superimposed on volitional contractions with a standard postoperative rehabilitation program of volitional exercises. In this way, the study sought to bring together a number of elements that the literature has indicated are important in optimizing rehabilitation outcomes, namely, the superimposition of high-intensity NMES on volitional contractions, improved patient compliance with NMES treatment programs, and combination of NMES with a standard volitional exercise program.

The primary outcome measures of effectiveness were knee extensor strength and performance of a single-legged hop and shuttle-run tests. In comparison with isokinetic strength measurements, functional jump and walk tests bear relation to everyday movements. Jumping from the 1-legged stance is generally used as a clinical test of knee function in patients with a missing ACL or in the case of ACL reconstruction.[9,13,20] Hopping tests are regarded as a valid instrument for recording knee joint function, including neuromuscular function[11] and the strength of the extensor mechanism.[1,2] Some studies on the comparability of various function tests show that there is a positive correlation between muscle strength and the hopping test.[9,14]

The hypothesis was that the addition of the electrotherapy modalities to the standard rehabilitation program would accelerate recovery as indicated by repeated measures of these primary outcome measures during the postoperative period.

MATERIALS AND METHODS

Patients

One hundred thirty-one patients, from a single clinical rehabilitation site, who met the inclusion/exclusion criteria were enrolled into the study. All patients were candidates for minimally invasive, endoscopically assisted reconstruction of the ACL.[22] Only patients receiving a graft from the semitendinosus and gracilis tendons were included in the study. Inclusion criteria were as follows: (1) isolated rupture of the ACL, (2) patients between the ages of 18 and 55 years, and (3) no additional injury in the knee joint. Exclusion criteria were as follows: (1) ACL tear more than 6 months before surgery, (2) previous injury or surgery of the injured knee, (3) tears of the menisci, and (4) articular cartilage defects larger than International Cartilage Repair Society grade 2. Of 170 patients assessed for inclusion, 39 were excluded from enrollment (Figure 1).

Patients were randomly assigned by drawing lots to 1 of 3 treatment groups. The investigator, coinvestigator, and statistician were blinded. Randomization was delegated to an assistant physician who also instructed patients on the application of the NMES devices and the volitional

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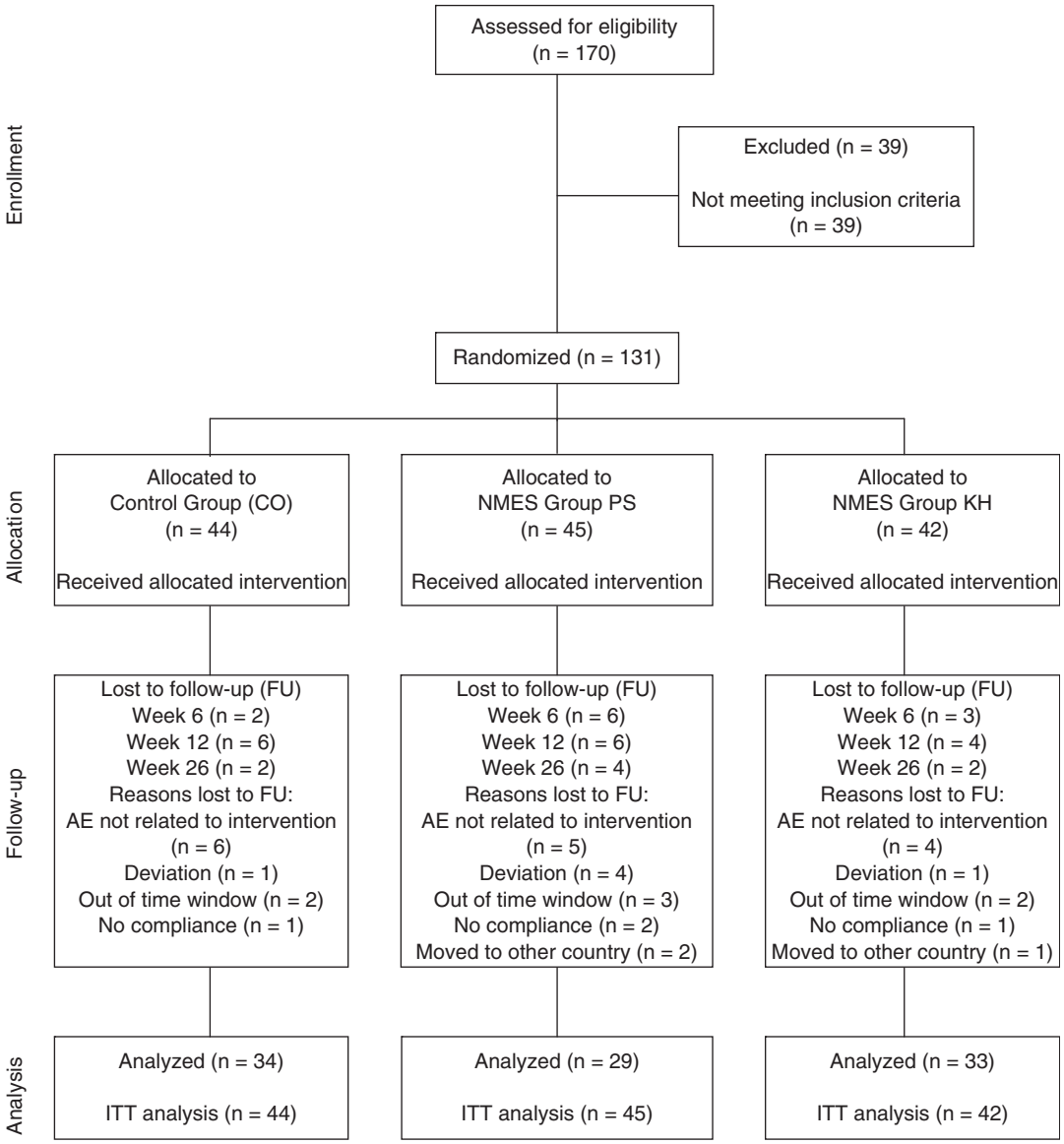

Figure 1. CONSORT flow chart, including intention-to-treat (ITT) analysis.

exercise program. Thirty-five (26.7%) patients were later excluded from study participation for reasons that included deviation from the course of rehabilitation or additional extensive surgical treatment of meniscal tears or cartilage defects carried out on the involved knee. The 3 groups were as follows: the KH group (n = 33 at completion) trained with Kneehab (Biomedical Research Ltd), the PS group (n = 29 at completion) trained with Polystim (Biomedical Research Ltd), and the CO group (n = 34 at completion) as controls who performed volitional isometric quadriceps muscle contractions but did not use NMES. Patients receiving either form of NMES treatment were instructed to isometrically contract the quadriceps muscle voluntarily with each electrical muscle stimulation. All groups carried out these interventions as a supplement to a standard rehabilitation protocol.

Standardized Rehabilitation Protocol

All patients of the 3 groups completed the same standardized rehabilitation program (see the Appendix, available online at http://ajs.sagepub.com/supplemental/) that emphasized restoration of full extension and quadriceps function as soon as possible. Immediately after the operation, an accelerated rehabilitation program was initiated. Partial weightbearing of 10 to 20 kg was required for the first 3 weeks. An Aircast Cryo Cuff (Ormed, Freiburg, Germany) cooling and compression system was applied from the first day until swelling was reduced significantly. A brace allowing full hyperflexion (Hypex Light, Albrecht, Neubeuren, Germany) was used for the first 6 weeks. Quadriceps strengthening was restricted to closed kinetic chain exercises for the first 6 weeks. Proprioceptive

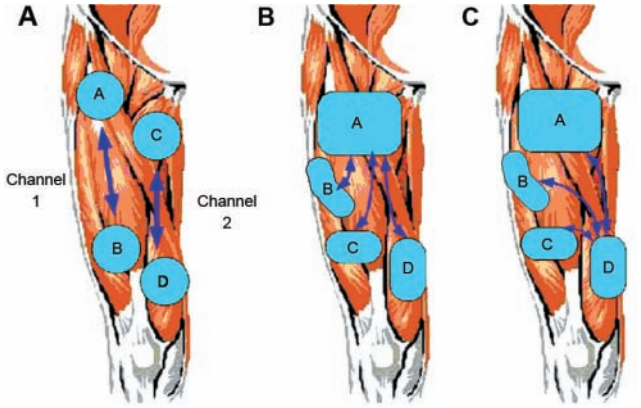

Figure 2. Electrode positioning and stimulation patterns of neuromuscular electrical stimulation groups. A, Polystim current pathway for channels 1 and 2; B, Kneehab current pathway for lateral channel; C, Kneehab current pathway for medial channel.

training, exercise bicycle riding, and aqua jogging were initiated after 3 weeks and continued for 3 months. Jogging was allowed 3 months postoperatively at the earliest. A minimum period of 6 months was recommended to return to unrestricted athletic activity, including pivotal sports like football or skiing.

Additional Electrical Stimulation Protocols

Kneehab is a garment-integrated NMES device that wraps around the thigh and locates an array of 4 large electrodes over the quadriceps muscle. It is claimed to improve muscle activation compared with traditional NMES devices because it dynamically changes the current pathways between the electrodes of the array during the treatment session, thereby improving the spatial distribution of the stimulation current (Figures 2b and 2c). Polystim is a traditional 2-channel NMES device in which the spatial distribution of current is restricted to the region between electrodes of a pair (Figure 2a). The stimulation parameters for the KH and PS groups are shown in Table 1. Both devices provided a stimulation frequency of 50 Hz and had an output current in the range 0 to 70 mA. The KH device had a shorter contraction relaxation cycle than did the PS device, although the contraction-relaxation ratio was the same (1:2). Patients were instructed on the use of the NMES devices during their stay in hospital.

The electrode arrangements and current pathways illustrated in Figure 2 were the PS device (2a) using 4 × 70-mm round electrodes and the KH device with current pathways activated by the lateral (2b) and medial (2c) channels using 4 electrodes: A, 10 × 20 cm; B, 3 × 18 cm; C, 10 × 7.5 cm; D, 7 × 14 cm.

Patients in the PS and KH groups trained with their respective NMES devices, beginning on the third or fourth day postoperatively, for three 20-minute sessions per day, 5 days per week. Both the KH and PS groups were instructed to co-contract their quadriceps muscles in synchronism with the stimulators. The CO group performed volitional isometric quadriceps muscle training for the same time schedule as that of the PS and KS groups but without stimulation. The stimulation and volitional muscle contractions continued during the entire 12-week study period. Patients conducted training sessions at home.

Assessments

The primary outcome measures of this study were the strength of the knee extensors, the ability to jump on 1 leg (single-legged jump), and the time to complete the shuttle run. Secondary measures included objective assessment on the International Knee Documentation Committee (IKDC) 2000 evaluation form. The 3 patient groups, KH, PS, and CO, were examined and interviewed by a blinded surgeon (investigator) and a coinvestigator preoperatively, 1 to 2 days before the operation, and at 6 weeks ± 3.1 days, 12 weeks ± 4.3 days, and 6 months ± 14.7 days postoperatively.

Objective measurements included isokinetic strength tests of the knee extensors using the Isomed 2000 (D&R Ferstl GmbH, Hemau, Germany), as well as functional hopping and walk tests to measure coordination and proprioception. Measurement of the knee extensors was performed in a seated position, in the open kinetic system with active extension and flexion (concentric muscle activity), at a limited range of movement of 90° of flexion to 45° of extension.[5,7,12] A set of 10 repetitions each was measured on the injured and uninjured side. The patient had the opportunity to get used to the load, being allowed to perform up to 5 submaximal practice movements. Strength was measured isokinetically at 2 speeds, 180 and 90 deg/s, on both the injured and uninjured legs similar to previous studies.[10,11]

The relative maximum strength of the extensors was calculated by dividing the measured torque by the subject's body weight (N·m/kg). The strength ratio of the injured leg to the uninjured leg was also calculated, expressed as percentage.

The single-legged hop test was measured with the distance of jump achieved, averaged over 3 attempts. Three sets were performed on each leg, with the uninjured leg being tested first. The injured/uninjured quotient of the averages was calculated. The shuttle run is a walk/sprint test in which patients have to cover a fixed distance (6.3 m) 4 times with changes of direction. The measurement reading is the time required to cover this distance. The final result is the mean value from 3 attempts.

All functional tests were performed by the patients during each of the test sessions in such a way that they were not exposed to any additional risk to the injured structures or those recently operated on.

Objective and subjective outcomes were evaluated by using the Tegner score, Lysholm score, the IKDC Knee Examination Form, and the KT-1000 arthrometer (MedMetric Corp, San Diego, California) measurement.

In addition, patients kept a diary to document training at home in which they also reported on aspects of their

TABLE 1
Electrical Stimulation Parameters for Neuromuscular Electrical Stimulation Groups

Device	Frequency, Hz	Contraction, s	Relaxation, s	Ramp Up, s	Ramp Down, s	Treatment Time, min
Polystim	50	10	20	1.5	1	20
Kneehab	50	5	10	2[a]	1	20

[a]The Kneehab device applies stimulation to the vastus medialis approximately 1 second before activating the rest of the muscle.

TABLE 2
Baseline Demographic Data[a]

	Group		
	Control	Polystim	Kneehab
Age, y (range)	31.6 ± 1.36 (18-51)	34.8 ± 1.49 (18-54)	31.1 ± 1.52 (18-47)
Body mass index, kg/m^2	25.1 ± 3.97 (18.3-30.8)	24.6 ± 3.45 (19.6-31.7)	24.9 ± 3.15 (19.7-31.4)
Activity level	64.32 ± 19.00	63.33 ± 21.19	59.52 ± 24.04
Pain	7.5 ± 1.89	7.5 ± 1.34	7.07 ± 1.84
Baseline strength involved leg 90 deg/s, N·m/kg	1.66 ± 0.69	1.76 ± 0.37	1.62 ± 0.62
Gender, female:male	8:25	7:22	7:27

[a]Data are means ± SD.

rehabilitation, including the date of their return to normal work activities.

Statistical Analysis

The continuous response variables of interest are longitudinal as each is measured at baseline and then at 6, 12, and 24 weeks after baseline. Such longitudinal data are useful in addressing questions about the change in a response variable over time and changes in a response relating to subject characteristics. Longitudinal data are typically modeled using a repeated-measures analysis of variance (ANOVA) with time as a within-subject factor. One of the restrictive assumptions underlying this approach, however, is that all measurements on the same subject have equal correlations with each other measurement on that subject; that is, the pairwise correlation for each same individual is the same at the fixed time points. If this assumption is false, the inference from a repeated-measures ANOVA will be wrong.

Mixed-effects models have become very popular in the analysis of longitudinal data as they can take account of the structured patterns of correlation that longitudinal studies induce, that is, the within-subject correlation. In addition, mixed models handle missing data more efficiently than does a repeated-measures ANOVA. In this article, linear mixed-effects models were used to model the change from baseline (ie, subtracting the baseline from each individual response) to compare the 3 treatments (CO, KH, and PS) across time. An explanatory variable was deemed significant at the $\alpha = .05$ significance level, and follow-up Tukey multiple comparisons were used to identify which levels of the treatment had significantly different mean responses, when appropriate.

The choice of the best model for each response variable was made on the basis of the Akaike information criterion. The validity of each model was justified based on suitable model diagnostics and residual plots.

As there were some missing data, an intention-to-treat analysis was carried out in which all data of enrolled subjects were analyzed. Multiple imputation was performed using a predictive model-based method in which each missing value was replaced by 5 imputed values. Continuous and ordinal responses were imputed using ordinal least squares regression. The multiple imputations were generated using a regression model of the imputation variable using the complete baseline variables and age as covariates.

A power calculation was made on the basis of single-legged hop test data available from a pilot study that estimated the baseline mean and SD at 115 and 20 cm, respectively. The power calculation was based on detecting a difference of 10% between the 3 groups at 24 weeks, where it was assumed that the SD of the difference in single-legged hop test scores over this time period is 15 for each group. On the basis of a 1-way ANOVA for the comparison of mean differences between the groups, a sample size of 32 per group was needed to achieve 80% power at a significance level of .05.

RESULTS

Descriptive statistics of demographic variables at baseline are provided in Table 2. An ANOVA revealed no significant difference between the groups across any of these variables.

Objective Measurements

Summary statistics and plots of the mean baseline-adjusted responses by treatment and time are presented for each variable (Table 3 and Figure 3). In each plot, the longitudinal benefit of KH is evident as the sample mean improvement from baseline is larger than is the mean for

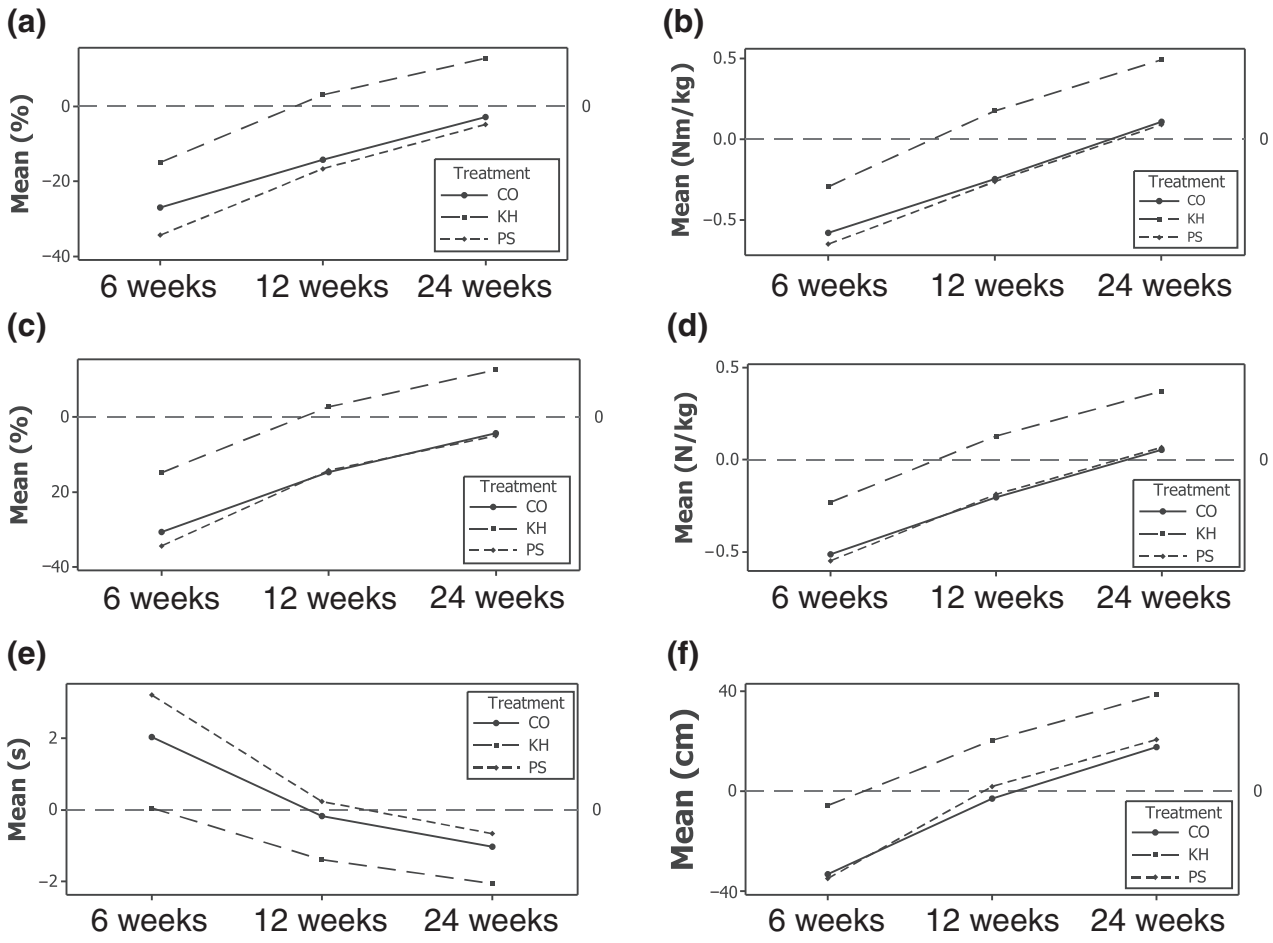

Figure 3. Plots of mean baseline-corrected responses, by treatment group, by time of (a) isokinetic relative strength of the quadriceps at 90 deg/s, (b) isokinetic strength of the quadriceps side-to-side difference at 90 deg/s, (c) isokinetic relative strength of the quadriceps at 180 deg/s, (d) isokinetic strength of the quadriceps side-to-side difference at 180 deg/s, (e) shuttle run, and (f) single-legged hop injured side. CO, control; KH, Kneehab; PS, Polystim.

the other treatments. The mean improvement appears additive as the difference between the groups is comparable at each level of time. Note that for some responses, for example the shuttle run, improvement is represented by a negative trend.

On the basis of the models fitted, there was convincing evidence ($P < .001$ in all cases) of a significant treatment and time effect, with no treatment-by-time interaction, for all responses; that is, the mean effect of treatment was the same across time. Interval estimates of the difference in the mean baseline-adjusted response are given for all treatment pairwise comparisons identified as significant (Table 4). Where the confidence interval for the difference does not include 0, it follows that the difference is significant at the $P < .05$ level. The results of the multiple comparisons are reflective of an improvement in the KH group for all (baseline-adjusted) responses, as nearly all comparisons involving this treatment with the other 2 were significant (Table 4). Expressed in terms of percentage change compared with preoperative values, the extensor strength gain of the KH group at speeds of 90 and 180 deg/s increased by 30.2% and 27.8%, respectively. The corresponding changes for PS were 5.1% and 5%, whereas for the CO they were 6.6% and 6.7%, respectively. The mean single-legged hop test score of the KH group improved by 50% between the 6-week and 6-month follow-up visits, whereas the corresponding changes for the PS and CO groups were 26.3% and 26.2%, respectively.

An intention-to-treat analysis was performed to compare the estimated treatment effect (pairwise comparison between KH and CO group only), using imputing values for all missing data, with the results obtained when analyzing the data while removing subjects with missing data. The estimated coefficients (mean differences), SEs, and P values, using the Barnard-Rubin adjustment method,[3] for the KH to CO comparison from the original and imputed analyses were compared for each of the primary and secondary responses. In each and every case, the inference relating to treatment effect was unchanged between the actual and imputation model, providing evidence that the missing data have no influence on the overall results.

TABLE 3
Summary Statistics of Baseline-Adjusted Response Variable at 6, 12, and 24 Weeks After Baseline by Treatment[a]

Response Variable	Control	Polystim	Kneehab
6 weeks – baseline			
Relative strength extension 90 deg/s, N·m/kg	−0.58 ± 0.35	−0.65 ± 0.38	−0.29 ± 0.57
Injured/uninjured extension 90 deg/s, %	−26.94 ± 17.12	−34.32 ± 17.93	−14.98 ± 26.11
Relative strength extension 180 deg/s, N·m/kg	−0.51 ± 0.36	−0.55 ± 0.31	−0.23 ± 0.43
Injured/uninjured extension 180 deg/s, %	−30.65 ± 18.10	−34.41 ± 20.47	−14.81 ± 24.19
Shuttle run, s	2.04 ± 1.92	3.21 ± 2.60	0.06 ± 3.11
Single-legged hop, cm	−33.25 ± 27.87	−34.99 ± 27.19	−5.68 ± 41.21
12 weeks – baseline			
Relative strength extension 90 deg/s, N·m/kg	−0.25 ± 0.42	−0.26 ± 0.38	0.17 ± 0.62
Injured/uninjured extension 90 deg/s, %	−14.26 ± 19.83	−16.67 ± 19.30	3.07 ± 27.75
Relative strength extension 180 deg/s, N·m/kg	−0.20 ± 0.38	−0.19 ± 0.31	0.13 ± 0.46
Injured/uninjured extension 180 deg/s, %	−14.67 ± 18.28	−14.21 ± 19.27	2.70 ± 25.10
Shuttle run, s	−0.17 ± 1.35	0.24 ± 1.76	−1.39 ± 3.02
Single-legged hop, cm	−2.91 ± 29.08	1.93 ± 26.72	20.32 ± 38.52
24 weeks – baseline			
Relative strength extension 90 deg/s, N·m/kg	0.11 ± 0.35	0.09 ± 0.40	0.49 ± 0.68
Injured/uninjured extension 90 deg/s, %	−2.85 ± 15.86	−4.83 ± 16.45	12.82 ± 28.04
Relative strength extension 180 deg/s, N·m/kg	0.05 ± 0.31	0.07 ± 0.27	0.37 ± 0.53
Injured/uninjured extension 180 deg/s, %	−4.31 ± 14.45	−5.03 ± 16.01	12.60 ± 25.21
Shuttle run, s	−1.03 ± 1.49	−0.66 ± 1.27	−2.06 ± 3.06
Single-legged hop, cm	17.59 ± 29.51	20.63 ± 26.17	38.57 ± 40.67

[a]Data are mean ± SD.

Objective and Subjective Outcomes

For the baseline-corrected Lysholm score, there was evidence of a significant difference between the groups, in particular for KH compared with CO ($P = .01$) and for KH compared with PS ($P < .001$) with no time-by-treatment interaction. For the IKDC 2000, Tegner, and KT-1000 arthrometer response variables, all groups improved over time with no significant difference between the groups. See summary data in Tables 5 and 6.

Patient Diaries

The frequency of training over the period of 12 weeks revealed differences in group compliance. The target was 20 minutes of training 3 times daily, 5 times per week, which amounts to a total target training time of 60 hours over a period of 12 weeks.

The average compliance was as follows:

CO group: 48 hours, 48 minutes;
PS group: 39 hours, 18 minutes;
KH group: 45 hours, 20 minutes.

The compliance of the KH and PS groups could be verified by inspection of the stimulator data readout, whereas the CO group times could not be verified.

The time taken to return to everyday working life showed a positive trend in favor of the KH group. The CO group returned to work after 3.67 ± 1.56 weeks ($P = .079$ vs KH), PS after 3.88 ± 1.28 weeks ($P = .061$ vs KH), and KH after 2.7 ± 1.36 weeks. The distribution of professions within each group was broadly similar, with approximately 70% being office based or sedentary. The proportion with jobs involving high physical loads for each group was 8.8% for CO, 3.4% for PS, and 15.1% for KH.

DISCUSSION

Our hypothesis was that the addition of the NMES protocols to the standard program of rehabilitation would accelerate recovery after surgery. This involved repeated measures at 3 time points: 6, 12, and 24 weeks after surgery. This study combined physiological tests of strength with tests more representative of functional ability in an attempt to better reflect the varied objectives of rehabilitation. In common with several others, this study combined NMES with a program of volitional exercises. However, it was unusual in that the NMES subjects activated their muscles voluntarily during each electrically induced contraction. A final point of difference in this study was the inclusion of a group (KH) that used a garment-integrated stimulation that incorporated a new form of electrode switching designed to improve levels of muscle activation.

Considering the strength and performance measures, there is a clear pattern as demonstrated in the plots of Figure 3. For all groups, there is an apparent reduction in performance with respect to the presurgical baseline at the 6-week follow-up point. Thereafter, there is a general recovery in performance that restores or exceeds the presurgical performance level. Within this general picture, there are differences between the groups. The KH group demonstrates less of a deficit compared with the other groups at the 6-week follow-up point and generally preserves but does not

TABLE 4
Sample Mean Difference, 95% Confidence Interval, and *P* Value for Each Baseline-Adjusted Response Variable Treatment-Level Comparison

Response Variable	Mean Difference[a]	95% Confidence Interval	*P*
Relative strength extension 90 deg/s, N·m/kg			
PS – CO	−0.03	−0.20 to 0.13	.87
KH – CO	0.36	0.21 to 0.52	<.001
KH – PS	0.40	0.23 to 0.57	<.001
Injured/uninjured extensor 90 deg/s, %			
PS – CO	−3.94	−11.36 to 3.47	.42
KH – CO	14.97	7.80 to 22.14	<.001
KH – PS	18.91	11.48 to 26.35	<.001
Relative strength extension 180 deg/s, N·m/kg			
PS – CO	0.00	−0.13 to 0.13	1.00
KH – CO	0.31	0.18 to 0.44	<.001
KH – PS	0.31	0.18 to 0.45	<.001
Injured/uninjured extension 180 deg/s, %			
PS – CO	−1.34	−8.39 to 5.70	.89
KH – CO	16.70	9.88 to 23.52	<.001
KH – PS	18.05	10.98 to 25.11	<.001
Shuttle run, s			
PS – CO	0.65	−0.15 to 1.45	.14
KH – CO	−1.41	−2.18 to −0.64	<.001
KH – PS	−2.06	−2.86 to −1.26	<.001
Single-legged hop, cm			
PS – CO	2.06	−9.16 to 13.28	.90
KH – CO	23.94	13.09 to 34.79	<.001
KH – PS	21.88	10.63 to 33.13	<.001

[a]Mean difference between the groups across time as no treatment-by-time interaction was identified. CO, control; KH, Kneehab; PS, Polystim.

TABLE 5
Summary Data for Lysholm and Tegner Scores and KT-1000 Readings[a]

Response Variable	Baseline	6 Weeks	12 Weeks	24 Weeks
Lysholm score				
CO	81.26 ± 11.23	88.21 ± 7.61	95.35 ± 4.66	98.31 ± 2.82
KH	78.00 ± 11.53	91.39 ± 4.87	96.15 ± 3.46	99.06 ± 2.19
PS	80.66 ± 11.02	87.45 ± 8.06	94.03 ± 5.72	97.45 ± 3.20
Tegner score				
CO	3.47 ± 1.08	3.29 ± 0.52	3.82 ± 0.52	4.84 ± 0.85
KH	3.61 ± 1.37	3.36 ± 0.55	4.33 ± 0.85	5.76 ± 1.42
PS	3.45 ± 0.87	3.20 ± 0.68	3.90 ± 0.72	4.86 ± 0.60
KT-1000 arthrometer difference, mm				
CO	5.57 ± 1.61	0.12 ± 0.40	0.33 ± 0.59	0.38 ± 0.49
KH	5.71 ± 1.49	0.13 ± 0.41	0.31 ± 0.53	0.36 ± 0.49
PS	5.38 ± 1.40	0.13 ± 0.34	0.36 ± 0.60	0.38 ± 0.56

[a]Data are mean ± SD. CO, control; KH, Kneehab; PS, Polystim.

increase this advantage at the subsequent time points. Such a scenario would appear to underline the conclusions of reviews that claim NMES in the early stages of rehabilitation helps to build capacity required in the later stages.[23,24] It would appear from these graphs that the KH group consistently leads the other groups in reaching a given level of recovery performance and that this arises because the deficit was less at the 6-week point.

Others have systematically reviewed the evidence for quadriceps strengthening using NMES in both healthy and impaired subjects.[6] For the latter group, comparing NMES with volitional exercise, results show that only 1 of 3 acceptable studies showed clear results in favor of NMES, the remaining 2 being equivocal. Notably, that study also superimposed a volitional co-contraction on the NMES exercise, possibly enhancing the training stimulus.[8] Although both NMES groups in this study used the superimposed volitional contraction technique, the KH group performed consistently better than did the PS group across most response variables. Both NMES strategies

TABLE 6
Proportion (%) of Patients Classified as Normal in the IKDC 2000 Knee Examination Form[a]

Response Variable	Baseline	6 Weeks	12 Weeks	24 Weeks
IKDC 2000 score (proportion graded A)				
CO	0	14	81	100
KH	0	10	66	100
PS	0	13	67	97

[a]CO, control; IKDC, International Knee Documentation Committee; KH, Kneehab; PS, Polystim.

used similar treatment parameters as indicated in Table 1. The main distinctions between the systems were the convenience of use of the KH device, which may account for the improved compliance, and the multipath technique with large area electrodes, which is claimed to improve muscle activation levels. A recent review examining the evidence for the combined technique of adding NMES (not necessarily simultaneous) to a volitional exercise program in knee rehabilitation concluded that the combined therapy was better than was volitional exercise alone in reducing strength loss and atrophy, and moreover it restored more functional capacities.[23] Here, the complementary role of NMES may be in the early phase of rehabilitation, where it produces a strength increase that is necessary to perform volitional exercises in the later phases of rehabilitation. This alone could account for the results obtained in this study, with the difference between the 2 NMES protocols being due to differences in compliance and activation levels in the immediate weeks after surgery.

The single-legged hop test also shows a clear significant difference between the KH and CO and PS groups. The KH group achieved significantly better values than did the CO group at all 3 follow-up examinations. A direct comparison with other studies is not possible as the majority of studies only considered the effects of electrical stimulation on the musculature and the strength of the thigh muscles. Others did examine functional aspects of gait, coordination, and walking speed, and these studies also reported improvement in gait and knee function in an NMES intervention group.[10,28]

Evaluation of patient diaries revealed a tendency for patients in the KH group to return to work 1 week sooner than did the PS and CO groups. These findings not only illustrate the functional benefits of supplementing rehabilitation with NMES, but also highlight the potential health economic implications.

Limitations

Among the limitations of the present study were the inability to objectively measure the compliance of patients with the volitional exercises at home and, indeed, the inability to verify patient diaries. The NMES devices used differed in several ways, for example, electrode size, current pathways, contraction-relaxation timing, and ease of use, and consequently the apparent difference in effectiveness cannot be attributed to any single factor. The single-blind design is not ideal; however, realistic placebo controls in NMES studies are impractical because the use of sham devices is inevitably apparent to subjects. Strength measurements were done by open kinetic chain isokinetic testing, which may not transfer to closed kinetic chain activities. The isokinetic testing was done in a restrictive arc of motion (90°-45°) to protect the reconstructed ACL.[5,7,12] Finally, a follow-up of more than 24 weeks would have provided valuable information as to whether the gains made were sustained and whether there was any lasting effect on subjective outcome scores.

Future Research

The contribution of NMES in this study appears to have been in the immediate postoperative period. Apart from investigating whether this effect also occurs after other types of knee surgery, there is some merit in exploring whether treatment with NMES in the weeks preceding procedures such as knee arthroplasty would provide additional benefit.

CONCLUSION

In summary, the results of this study show that all patients improved; however, patients in the KH group achieved consistently better results for strength and functional performance measures at all time points in the rehabilitation period. In addition, the KH patients achieved higher rates of compliance than with conventional NMES, progressed faster, and were able to return to their usual work activities 7 days sooner than did both the CO and PS groups.

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