

The effectiveness of supplementing a standard rehabilitation program with super-imposed neuromuscular electrical stimulation, following anterior cruciate ligament reconstruction

5 A prospective, randomised, single-blind study

KEYWORDS: NEUROMUSCULAR ELECTRICAL STIMULATION (NMES), ANTERIOR CRUCIATE LIGAMENT (ACL), ATROPHY PREVENTION, ACCELERATED RECOVERY

10 Abstract

Background: Rehabilitation interventions following surgical repair of the anterior cruciate ligament (ACL) are key determinants affecting patient return to usual activity levels. Studies show that neuromuscular electrical stimulation (NMES) can counteract loss of strength in the quadriceps and is a beneficial enhancement to traditional forms of therapy. This study compared the effect of adding traditional NMES or garment-integrated NMES to a standard post-surgery rehabilitation program. In both cases the NMES was superimposed on isometric voluntary contractions.

Study Design: Prospective, randomised, controlled, single-blind study in patients undergoing rehabilitation following anterior cruciate ligament reconstruction.

20 Methods: Ninety-six patients who underwent surgical reconstruction of the anterior cruciate ligament were randomly assigned to one of three post-surgery rehabilitation treatment groups. All patients followed a standard rehabilitation program of voluntary exercises. Additionally,

the PS group, (n=29), trained with a traditional NMES device and the KH group (n=33) trained with a garment integrated NMES device with multipath activation. The additional training for the PS and KH groups consisted of twenty-minute quadriceps muscle stimulation sessions, three times per day, five days per week for twelve weeks. The control group CO, (n=34) performed only volitional maximum quadriceps muscle contraction according to the same timed training session. Strength of the extensors and the flexors of the injured and uninjured legs at 90°/sec and 180°/sec, along with functional tests of proprioception, were assessed at baseline and at 6 weeks, 12 weeks and 6 months post operatively.

Results: There was convincing evidence ($p < 0.001$ in all cases) of a significant Treatment and Time effect, with no Treatment by Time interaction, for all physical responses. With respect to the primary outcome measures, (knee extensor strength, single leg hop and shuttle run tests) the KH group achieved significantly ($P < 0.001$) better results at each time point compared to the PS and CO groups. Extensor strength of the KH group at speeds of 90°/sec and 180°/sec increased by 30.2% and 27.8% respectively between pre-operative and 6 month follow-up points. The corresponding changes for PS were 5.1% and 5% while for CO they were 6.6% and 6.7% respectively. The mean single leg hop score of the KH group improved by 50% between the 6-week and 6 month follow up visits, while the corresponding changes for the PS and CO groups were 26.3% and 26.2% respectively. In nearly all tests, the KH group demonstrated a clear advantage at the 6-week follow up point, which was maintained, but not increased, for the remainder of the study.

Conclusions and Clinical Relevance: This study suggests that intensive NMES superimposed on voluntary contractions, combined with a standard rehabilitation program is effective in accelerating recovery. The benefit of adding the EMS component appears to accrue in the first 6 weeks post-operatively.

Key Words: Anterior Cruciate Ligament • Neuromuscular Electrical Stimulation • Atrophy
Prevention • Accelerated Recovery • Economics • Compliance

BACKGROUND:

Neuromuscular electrical stimulation (NMES) can be a beneficial supplement to traditional forms of therapy in the post-operative period. Stevens et al. [49] reported in a case series study following knee joint replacement that highly intensive activation of the quadriceps muscle using electrical stimulation produced better results for strength and muscle activation compared with a control group. Comparable studies [16, 46, 47] following cruciate ligament reconstruction produced similar results. Improved strength of the quadriceps muscle and better knee function were some of the aspects reported. In contrast there are also studies [27, 28, 37] that found no or only a slight difference between electrical stimulation and volitional strength training of the muscles affected. The intensity of NMES induced muscle activation and extent of training are decisive factors in treatment outcomes [24, 32, 33], and consequently patient compliance at high levels of stimulation is required.

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The primary objectives of rehabilitation following ACL reconstruction are to reduce inflammation, regain neuromuscular strength and functional performance, recover normal range of movement 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 following ACL surgery. [4, 5, 26].

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Paillard et al [39] in a recent review concluded that rehabilitation training with NMES superimposed upon voluntary contraction (VC) was better than either NMES or VC practised separately. In a further review of NMES combined with, but not directly superimposed on VC, Paillard [38] showed that the combination therapy (CT) induced greater muscle adaptation than VC alone.

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Conventional lead-wired NMES devices can be effective however patient compliance may be reduced by discomfort and inconvenience. The garment-integrated NMES device used in this study is claimed to produce high levels of muscle activation with improved comfort in an easy-to-use thigh wrap. The purpose of the present, prospective, randomised, controlled study was to assess the effectiveness of combining each of two forms of NMES therapy superimposed on voluntary contractions, with a standard post-operative rehabilitation program of voluntary exercises. The primary measures of effectiveness were knee extensor strength and performance of a single-leg-hop and shuttle-run tests. In this way the study sought to bring together a number of elements which the literature had indicated were important in

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optimising rehabilitation outcomes, namely, high intensity EMS superimposed on voluntary contractions, improved compliance with NMES, and combination with a standard voluntary exercise program.

5 Materials and Methods

Patients and Randomisation:

One hundred, thirty-one patients, from a single clinical rehabilitation site, who were candidates for minimally invasive, endoscopically assisted reconstruction of the cruciate
10 ligament [4, 36], and who met the study inclusion/exclusion criteria, were enrolled into the study. Patients were randomly assigned by drawing lots to one of three treatment groups. A different member of the study staff was responsible for measurement and assessment of subjects. Thirty-one (26.7%) patients were later excluded from study participation for reasons that included: deviation from the course of rehabilitation or additional extensive surgical
15 treatment of meniscal tear or cartilage defect carried out on the involved knee. Of the remaining ninety-six patients available for analysis: twenty-two were female and seventy-four were male, ranging in age from eighteen to fifty-four. The three Groups were as follows: the KH group (n=33) trained with KneeHab®, (Biomedical Research, Ltd., neurotech®, Galway, Ireland) and the PS group (n=29) trained with Poly-Stim™, (Biomedical Research, Ltd.,
20 neurotech®, Galway, Ireland. Patients receiving either form of NMES treatment were instructed to isometrically contract the quadriceps muscle voluntarily with each electrical muscle stimulation. The Control CO group (n=34), which did not use muscle stimulation, performed voluntary isometric quadriceps muscle contractions.

25 NMES Protocols

KneeHab is a garment-integrated NMES device that wraps around the thigh and locates four large electrodes over the quadriceps muscle (Fig 1, (2), (3)). It is thought to improve muscle activation compared to traditional NMES devices because it can create current pathways between any combination of its electrodes thereby improving the spatial distribution of the
30 stimulation current. In traditional NMES devices, such as the Polystim, the spatial distribution of current is restricted to the region between electrodes of a pair (Fig 1, (1)). The stimulation parameters are shown in Table 1. Both devices provided a stimulation frequency of 50Hz and had an output current in the range 0 to 70mA. The KH device had a shorter contraction relaxation cycle than the PS device. Patients were instructed on the use of the NMES devices
35 during their stay in hospital.

Device	Frequency Hz	Contraction Seconds	Relaxation Seconds	Ramp Up Seconds	Ramp Down Seconds	Treatment Time minutes
PS	50	10	20	1.5	1	20
KH	50	5	10	2*	1	20

Table 1. PS (Traditional NMES) and KH (garment-integrated NMES) device training

5 parameters. *The KH device applies stimulation to the Vastus Medialis approximately 1 second prior to activating the rest of the muscle.

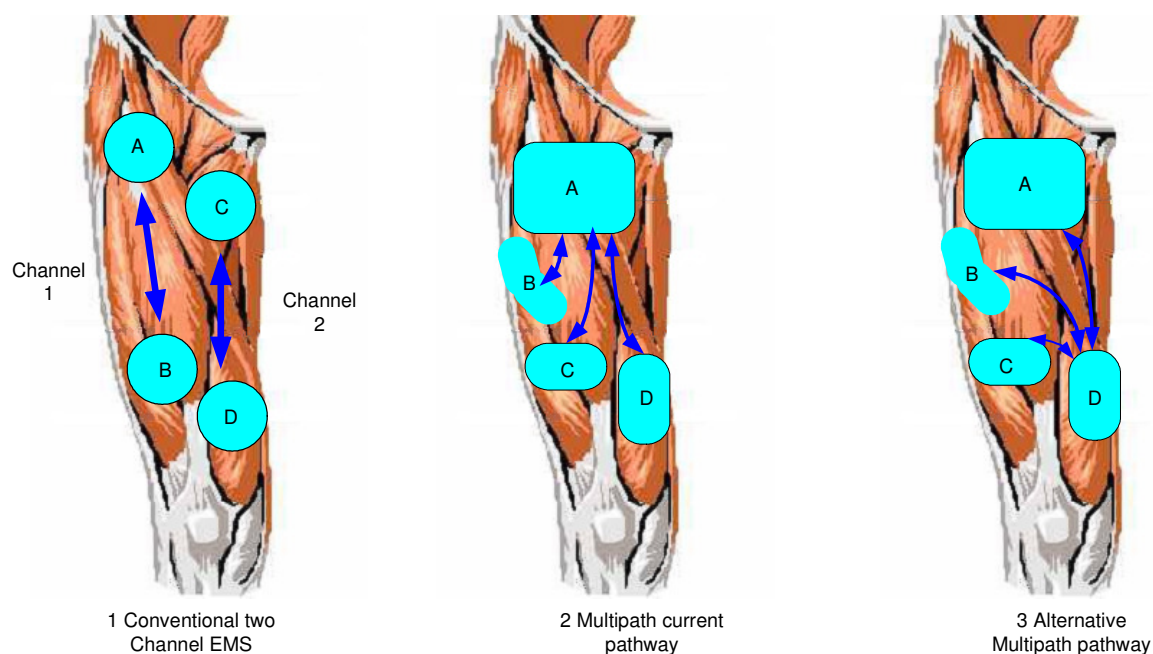


Fig 1. (1) PS stimulation using 4 x 70 mm round electrodes. (2), (3) example KH stimulation using multiple current pathways between 4 electrodes, A=10x20cm, B= 3x18cm , C=10x7.5cm, D=7x14cm

Rehabilitation protocol

15 In the first and second day following surgery, all patients began physiotherapy and received lymph drainage. Active and passive movement of the injured leg in the pain-free range (tense the flexors and extensors for a count of 10 and slowly relax) until a range of movement of 0 - 90° was achieved. In the first three weeks patients used walking aids, with partial weight

bearing of 15 kg. When patients achieved normal, non-limping gait, the walking aid was discarded.

During the third to fifth day following surgery, and once pain had eased, patients commenced a program of muscle strength exercises with the injured and uninjured leg by flexing and
5 tensing the thigh muscles in turn. Patients in the PS and KH groups trained with their respective NMES devices, for three, twenty-minute sessions per day, five days per week. The CO group performed voluntary isometric quadriceps muscle training for the same time schedule as the PS and KS groups, but without stimulation. The stimulation and voluntary
10 muscle contractions continued during the entire twelve-week study period. Patients conducted training sessions at home.

All subjects followed the same physiotherapy program, with the exception of the group-specific electrotherapy intervention. During the sixth to the tenth day following surgery, physiotherapy exercises were increased and training therapy commenced with the addition of
15 practice on the bicycle ergometer, rowing machine, knee bends and active flexion and extension exercises on a sling table. Strengthening exercises for the whole thigh musculature, in particular the Vastus Medialis, including adductors and hip flexors and extensors were performed with rubber bands (Thera-Band). Wearing waterproof, protective dressings, patients performed aqua-jogging by walking slowly backwards and forwards against the water
20 resistance in hip-high water.

The objectives by the tenth day following surgery were full, active extension, active flexion at a limit of 90° and a decrease in swelling. Ten to twelve days following surgery, sutures were removed at the study clinic. Swimming, using the crawl and backstroke only, was recommended. During the third to sixth week following surgery, patients performed
25 progressively increasing exercises of strength, flexion and proprioception. Additionally, from the fourth week onwards, simultaneous, conscious tensing of the flexors and extensors was combined with stair climbing and leg presses, including ¼ to ½ knee-bends. When needed,

patients trained to achieve normal gait pattern. Twelve weeks following surgery, sport or activity specific training, including jogging, commenced.

5 *Testing Procedure*

The key pre-defined target criteria of this study were the strength of the knee extensors, the ability to jump on one leg (single leg hop) and the time to complete the shuttle run. Secondary target criteria included the strength of the knee flexors test and five other functional tests of coordination and proprioception. Subjective and objective questionnaires were used to collect data to support key measurements of proprioception and the individual patient knee situation.

The three patient groups KH, PS and CO were examined and interviewed preoperatively, 1-2 days before the operation and at 6 weeks (± 3.1 days); 12 weeks (± 4.3 days) and 6 months (± 14.7 days) postoperatively.

15 *Test Measurements*

The objective measurements included isokinetic strength tests of extension and flexion of the knee joint using the Isomed 2000 (D&R Ferstl GmbH®), as well as functional hopping and walk tests to measure coordination and proprioception.

Measurement of the extensors and flexors 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° flexion to 45° extension [5, 8, 18, 27, 30]. A set of ten 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 five submaximal practice movements. During this time it was possible to fit the “Isomed 2000” optimally to the patient (adjust fixings etc.). Strength was measured isokinetically at two speeds; 180°/sec and 90°/sec, on both the injured and uninjured legs. [15, 17, 21]

The relative maximum strength of the extensors and the flexors was calculated in relation to body weight and the strength ratio of the injured leg to the uninjured leg. The relative value is

stated in Nm/kg body weight and the strength ratios in %.

In comparison to isokinetic strength measurements, functional jump and walk tests bear relation to everyday movements. Jumping from the one-leg stance is generally used as a clinical test of knee function in patients with a missing anterior cruciate ligament or in the case of anterior cruciate ligament reconstruction [13, 19, 31, 31, 42]. Hopping tests are regarded as a valid instrument for recording knee joint function, including neuromuscular function [17] and the strength of the extensor mechanism [1, 2, 14]. Some studies on the comparability of various function tests show that there is a positive correlation between muscle strength and the hopping test [15, 21, 40, 44].

In conjunction with hopping tests, walk tests are also often performed [18, 22, 23, 33, 55], which make correspondingly heavy demands on the patient. The walk tests, like the jump tests, were performed in three sets and the average result was calculated.

Functional measurements of coordination and proprioception:

The single or one-leg hop test is a one-legged jump, in which the landing is on the same leg as that from which the jump was made. In a standardized form the one-legged jump is done with the arms are crossed behind the back. The result is a distance of jump achieved, averaged over three 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 triple hop is a one-legged jump, in which takeoff and landing likewise involve the same leg. However, in this jump three jumps are performed directly after one another on the same leg. Analysis was performed in the same way as in the one-leg hop.

The shuttle run is a walk/sprint test, where patients have to cover a fixed distance (6.3 m) four times with changes of direction. The measurement reading is the time required to cover this distance. The final result was the average value from three attempts.

The side-step was carried out over the same fixed distance as the shuttle run and is also performed four times. The movement is a sideways movement, whereby one leg is moved to follow the other. Analysis was performed in the same way as in the shuttle run.

The carioca test was also carried out over a fixed distance (6.3 m) and performed four times. The movement is a sideways movement carried out by crossing the legs in front of and behind each other. Analysis was performed in the same way as in the shuttle run.

For the timed hop the patient has to cover a distance of 6m hopping on one leg as quickly as possible. The result is the time measured in seconds. The overall result was calculated from three attempts and is shown using a side comparison as a quotient, injured/uninjured, in percent.

The cross-over hop is a series of three jumps on one leg, which is performed as in the triple hop. It differs from the triple hop in that the jumps are performed crossing over a line. The aim is to cover as great a distance as possible while performing sideways movements. The overall result is calculated as above and is likewise shown as a side comparison in percent.

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 or operated structures. For reasons of safety and weight-bearing capacity, the triple hop, the cross-over hop and the timed hop were not performed in the first follow-up examination at 6 weeks postoperatively.

Questionnaire data

The Tegner Activity Score, Lysholm Score and IKDC Knee Examination Form were used to standardize comparative assessment of the treatment methods as reported by the patient and investigator. Additionally, a VAS score was used to determine pain, function and satisfaction with the knee joint. Patients kept a diary to document training at home, (number of physiotherapy treatment units, lymph drainage exercises and muscle development training) pain, intake of analgesics, function and satisfaction, date of full weight-bearing capability and return to the daily work activities

Statistical Techniques

Statistical analysis was blinded to the meaning of the different treatment codes. Given the Within-Subjects design employed, the response variables were calculated as the change from baseline measurements in order to account for baseline variability between subjects. Linear Mixed Modelling techniques were used which included a random effect associated with the intercept for each subject, a Between Subject Factor Treatment (with levels CO, KH, PS; subject nested within Treatment) and Within Subject Factor Time Post Baseline (with levels 6, 12 and 24 weeks), and Age as a covariate. The significance of the Between and Within Subject factors on the response variables was determined at the $\alpha=0.05$ significance level. Follow up Tukey multiple comparisons were used to identify which levels of the Between Subject Factor Treatment had significantly different mean responses - as and when appropriate. The final model for each response was justified based on suitable model diagnostics i.e. examination of relevant residual plots, tests for homogeneity of variance and compound symmetry.

The IKDC categorisation was available for each individual at Baseline, and 6, 12 and 24 weeks post baseline. In order to compare the Treatments, Ordinal Logistic Regression was used to model the probability of being in a particular IKDC categorisation (or one of less severity) while adjusting for Time.

The study was powered to detect a difference of 10% in the primary response variables. Minitab 14 and *R* were used for all statistical analyses.

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Results

Summary statistics and plots of the mean Baseline Adjusted Responses by Treatment and Time are presented for each variable (Table 2, and Fig 2). In each plot the longitudinal benefit of KH is evident as the sample mean improvement from baseline is larger than the mean for 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.

5 On the basis of the models fitted, there was convincing evidence ($p < 0.001$ in all cases) of a significant Treatment and Time effect, with no Treatment by Time interaction, for all responses. Interval estimates of the difference in the mean baseline adjusted response are given for all pairwise comparisons of factors identified as significant. (Table 3) Where the confidence interval for the difference does not include zero it follows that the difference is significant at the $p < 0.05$ level.

10 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 group with the other two were significant (at the $\alpha = 0.05$ significance level).

Expressed in terms of percentage change compared to pre-operative values, the extensor strength gain of the KH group at speeds of $90^\circ/\text{sec}$ and $180^\circ/\text{sec}$ increased by 30.2% and 15 27.8% respectively. The corresponding changes for PS were 5.1% and 5% while for the CO they were 6.6% and 6.7% respectively. The mean single leg hop score of the KH group improved by 50% between the 6-week and 6 month follow up visits, while the corresponding changes for the PS and CO groups were 26.3% and 26.2% respectively.

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Fig 1. Plots of mean baseline corrected responses, by treatment group, by time.

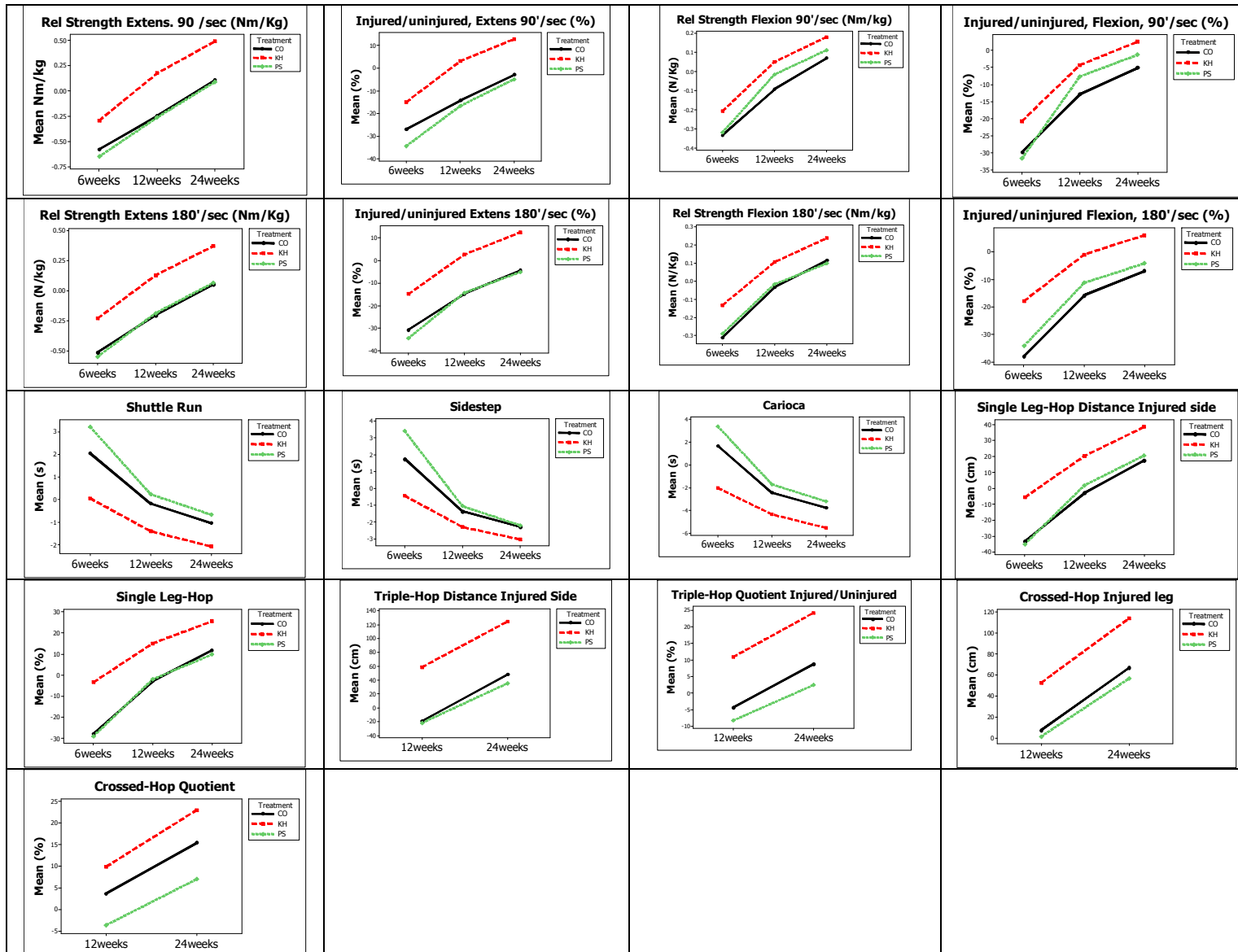


Table 2. Mean and Standard Deviation for Each Baseline Adjusted Response Variable at 6, 12 and 24 weeks post Baseline by Treatment

CO Group (Controls)	6 Weeks		12 Weeks		24 Weeks	
	mean	sd	mean	sd	mean	sd
Response Variable						
Relative Strength Extens. 90°/sec (Nm/Kg)	-0.58	0.35	-0.25	0.42	0.11	0.35
Injured/uninjured, Extens 90°/sec (%)	-26.94	17.12	-14.26	19.83	-2.85	15.86
Relative Strength Flexn. 90°/sec (Nm/Kg)	-0.33	0.25	-0.09	0.26	0.07	0.27
Injured/uninjured Flexn 90°/sec (%)	-29.88	16.54	-12.91	17.21	-5.15	15.29
Rel. Strength Extens. 180°/sec (Nm/Kg)	-0.51	0.36	-0.20	0.38	0.05	0.31
Injured/uninjured, Extens 180°/sec (%)	-30.65	18.10	-14.67	18.28	-4.31	14.45
Rel. Strength Flexn. 180°/sec (Nm/Kg)	-0.31	0.29	-0.03	0.25	0.12	0.22
Injured/uninjured Flexn 180°/sec (%)	-37.83	25.90	-15.80	24.09	-6.89	23.31
Shuttle Run (s)	2.04	1.92	-0.17	1.35	-1.03	1.49
Sidestep (s)	1.76	3.48	-1.36	3.10	-2.28	3.48
Carioca (s)	1.69	3.58	-2.44	3.35	-3.73	4.10
Single Hop (cm)	-33.25	27.87	-2.91	29.08	17.59	29.51
Single Hop Injured/Uninjured (%)	-27.77	21.52	-2.68	23.07	11.91	23.39
Triple Hop (cm)	-	-	-19.04	98.80	48.26	111.53
Triple Hop Injured/Uninjured (%)	-	-	-4.36	24.09	8.81	27.69
Crossed Hop (cm)	-	-	7.55	116.86	66.90	125.45
Crossed Hop Injured/Uninjured (%)	-	-	3.72	30.95	15.49	34.50

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PS Group (Polystim)	6 Weeks		12 Weeks		24 Weeks	
	mean	sd	mean	sd	mean	sd
Response Variable						
Relative Strength Extens. 90°/sec (Nm/Kg)	-0.65	0.38	-0.26	0.38	0.09	0.40
Injured/uninjured, Extens 90°/sec (%)	-34.32	17.93	-16.67	19.30	-4.83	16.45
Relative Strength Flexn. 90°/sec (Nm/Kg)	-0.32	0.19	-0.01	0.19	0.11	0.19
Injured/uninjured Flexn 90°/sec (%)	-31.61	15.28	-7.69	15.11	-1.32	13.79
Rel. Strength Extens. 180°/sec (Nm/Kg)	-0.55	0.31	-0.19	0.31	0.07	0.27
Injured/uninjured, Extens 180°/sec (%)	-34.41	20.47	-14.21	19.27	-5.03	16.01
Rel. Strength Flexn. 180°/sec (Nm/Kg)	-0.29	0.20	-0.01	0.19	0.10	0.18
Injured/uninjured Flexn 180°/sec (%)	-34.06	18.97	-11.24	16.78	-4.20	15.72
Shuttle Run (s)	3.21	2.60	0.24	1.76	-0.66	1.27
Sidestep (s)	3.43	5.17	-1.06	3.40	-2.20	3.19
Carioca (s)	3.39	5.86	-1.70	4.14	-3.19	3.83
Single Hop (cm)	-34.99	27.19	1.93	26.72	20.63	26.17
Single Hop Injured/Uninjured (%)	-28.92	25.03	-1.85	21.75	9.93	20.64
Triple Hop (cm)	-	-	-21.60	67.66	35.51	105.09
Triple Hop Injured/Uninjured (%)	-	-	-8.26	17.15	2.46	21.06
Crossed Hop (cm)	-	-	1.50	77.50	56.55	107.35
Crossed Hop Injured/Uninjured (%)	-	-	-3.56	22.01	7.07	27.99

KH group (Kneehab)	6 Weeks		12 Weeks		24 Weeks	
	mean	sd	mean	sd	mean	sd
Response Variable						
Relative Strength Extens. 90°/sec (Nm/Kg)	-0.29	0.57	0.17	0.62	0.49	0.68
Injured/uninjured, Extens 90°/sec (%)	-14.98	26.11	3.07	27.75	12.82	28.04
Relative Strength Flexn. 90°/sec (Nm/Kg)	-0.21	0.29	0.05	0.25	0.18	0.29
Injured/uninjured Flexn 90°/sec (%)	-20.71	24.42	-4.32	20.63	2.54	22.20
Rel. Strength Extens. 180°/sec (Nm/Kg)	-0.23	0.43	0.13	0.46	0.37	0.53
Injured/uninjured, Extens 180°/sec (%)	-14.81	24.19	2.70	25.10	12.60	25.21
Rel. Strength Flexn. 180°/sec (Nm/Kg)	-0.13	0.24	0.11	0.23	0.24	0.26
Injured/uninjured Flexn 180°/sec (%)	-17.84	24.78	-1.00	22.25	6.02	21.48
Shuttle Run (s)	0.06	3.11	-1.39	3.02	-2.06	3.06
Sidestep (s)	-0.43	3.70	-2.30	3.58	-3.03	3.76
Carioca (s)	-2.01	8.97	-4.33	8.85	-5.51	8.79
Single Hop (cm)	-5.68	41.21	20.32	38.52	38.57	40.67
Single Hop Injured/Uninjured (%)	-3.29	32.31	15.17	30.40	25.67	33.50
Triple Hop (cm)	-	-	58.82	150.16	124.68	147.89
Triple Hop Injured/Uninjured (%)	-	-	10.90	35.59	24.22	35.77
Crossed Hop (cm)	-	-	52.61	140.90	113.88	143.00
Crossed Hop Injured/Uninjured (%)	-	-	9.97	36.59	23.05	37.32

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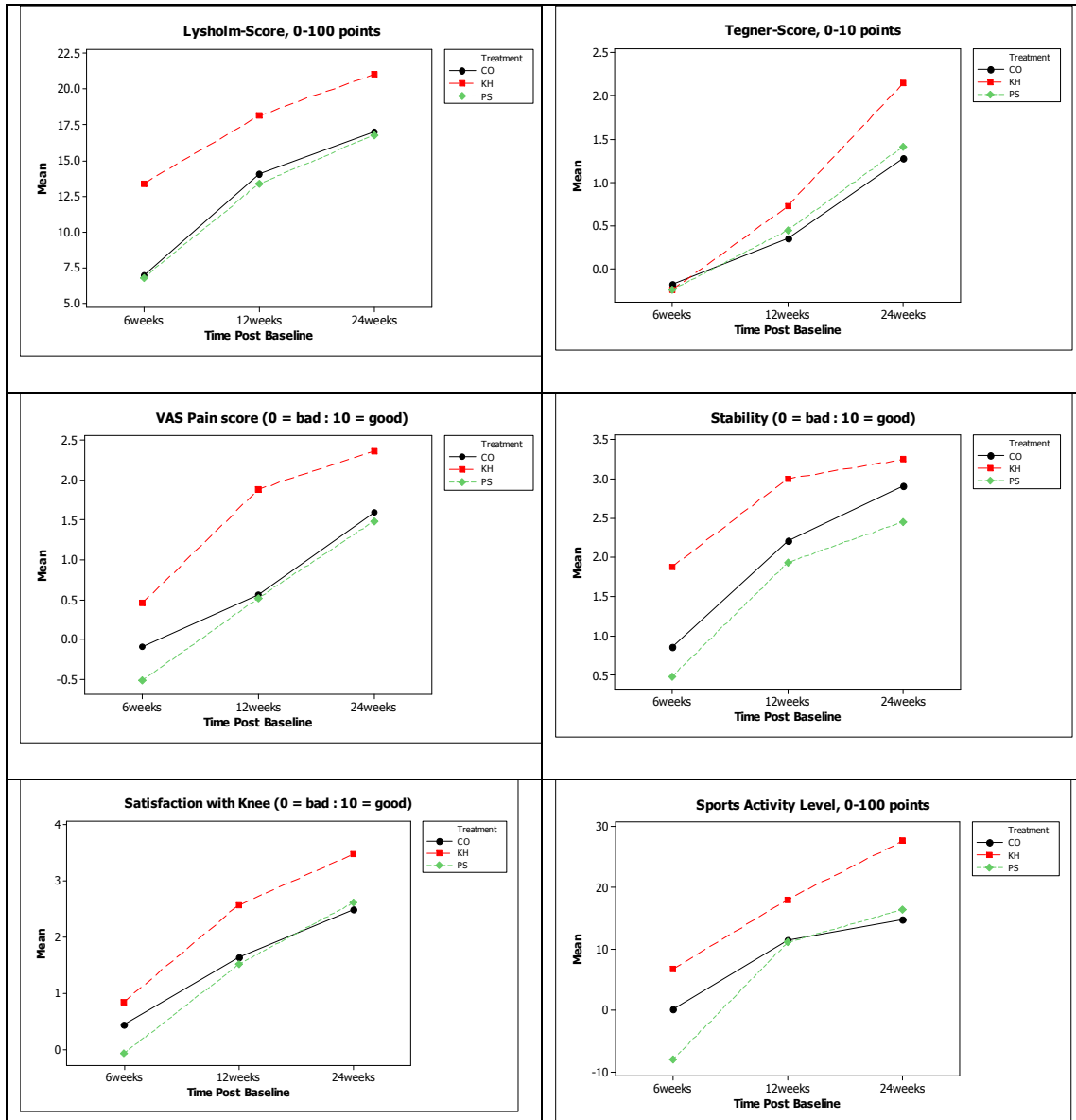
Table 3. Sample Mean Difference, 95% CI and p-value for each Baseline Adjusted Response Variable Treatment Level Comparison

Relative Strength Extens 90°/sec (Nm/Kg)	Mean Difference	Lower	Upper	p-value
PS-CO	-0.03	-0.20	0.13	0.87
KH-CO	0.36	0.21	0.52	<0.001
KH-PS	0.40	0.23	0.57	<0.001
Inj/Uninj Extensor 90°/sec (%)				
PS-CO	-3.94	-11.36	3.47	0.42
KH-CO	14.97	7.80	22.14	<0.001
KH-PS	18.91	11.48	26.35	<0.001
Relative Strength Flexn 90°/sec (Nm/Kg)				
PS-CO	0.04	-0.04	0.13	0.44
KH-CO	0.13	0.04	0.21	<0.001
KH-PS	0.08	-0.01	0.17	0.07
Inj/Uninj Flexn 90°/sec (%)				
PS-CO	2.44	-3.86	8.74	0.63
KH-CO	8.48	2.39	14.57	<0.001
KH-PS	6.04	-0.27	12.35	0.06
Rel Strength Extens. 180°/sec (Nm/Kg)				
PS-CO	0.00	-0.13	0.13	1.00
KH-CO	0.31	0.18	0.44	<0.001
KH-PS	0.31	0.18	0.45	<0.001

Inj/Uninj Extens 180°/sec (%)				
PS-CO	-1.34	-8.39	5.70	0.89
KH-CO	16.70	9.88	23.52	<0.001
KH-PS	18.05	10.98	25.11	<0.001
Rel Strength Flexn. 180°/sec (Nm/Kg)				
PS-CO	0.01	-0.07	0.09	0.97
KH-CO	0.15	0.07	0.23	<0.001
KH-PS	0.14	0.06	0.22	<0.001
Inj/Uninj Flexn 180°/sec (%)				
PS-CO	3.70	-3.84	11.24	0.48
KH-CO	15.93	8.64	23.22	<0.001
KH-PS	12.22	4.67	19.78	<0.001
Shuttle Run (s)				
PS-CO	0.65	-0.15	1.45	0.14
KH-CO	-1.41	-2.18	-0.64	<0.001
KH-PS	-2.06	-2.86	-1.26	<0.001
Sidestep (s)				
PS-CO	0.68	-0.59	1.96	0.42
KH-CO	-1.29	-2.53	-0.06	0.04
KH-PS	-1.98	-3.26	-0.70	<0.001
Carioca (s)				
PS-CO	0.99	-1.15	3.14	0.52
KH-CO	-2.46	-4.53	-0.38	0.02
KH-PS	-3.45	-5.60	-1.30	<0.001
Single Hop (cm)				
PS-CO	2.06	-9.16	13.28	0.90
KH-CO	23.94	13.09	34.79	<0.001
KH-PS	21.88	10.63	33.13	<0.001
Single Hop Injured/Uninjured (%)				
PS-CO	-0.72	-9.77	8.32	0.98
KH-CO	18.74	9.99	27.49	<0.001
KH-PS	19.46	10.40	28.53	<0.001
Triple Hop (cm)				
PS-CO	-7.59	-57.55	42.37	0.93
KH-CO	77.20	28.88	125.52	<0.001
KH-PS	84.79	34.83	134.75	<0.001
Triple Hop Injured/Uninjured (%)				
PS-CO	-5.11	-16.99	6.77	0.57
KH-CO	15.35	3.86	26.83	0.01
KH-PS	20.46	8.58	32.33	<0.001
Crossed Hop (cm)				
PS-CO	-8.19	-59.61	43.23	0.92
KH-CO	46.03	-3.70	95.76	0.08
KH-PS	54.22	2.81	105.64	0.04
Crossed Hop Injured/Uninjured (%)				
PS-CO	-7.85	-21.49	5.79	0.36
KH-CO	6.91	-6.29	20.10	0.43
KH-PS	14.76	1.11	28.40	0.03

4.4 Questionnaires and VAS score

5 The baseline-adjusted values for 6 responses are summarised in Fig 3 and tables 4 and 5. With the exception of the Tegner score, there is evidence of a significant Treatment and Time effect, with no interaction. A similar pattern to the physical responses emerges as the KH group appears to have an advantage at the 6 week point which is largely preserved for the remainder of the study.



10 Fig 3. Baseline adjusted plots of questionnaire and VAS scores.

15 Table 4 Baseline adjusted values of six subjective response variables

Control Group	6 Weeks		12 Weeks		24 Weeks	
Response Variable	mean	sd	mean	sd	mean	sd
PS Group	6.94	2.14	14.09	11.56	17.05	17.48
Lysholm	6.79	12.05	13.38	10.43	16.59	10.22
Tegner	-0.24	0.85	0.45	1.09	1.41	0.93
Pain	0.44	1.79	0.55	1.64	1.48	1.49
Stability	0.48	31.96	11.32	20.75	24.45	20.94
Satisfaction with knee	-0.07	2.07	1.52	1.70	2.62	1.57
Activity	-8.10	27.30	11.03	22.73	16.38	21.46

KH Group	6 Weeks		12 Weeks		24 Weeks	
Response Variable	mean	sd	mean	sd	mean	sd
Lysholm	13.39	10.63	18.15	10.78	21.06	11.71
Tegner	-0.24	1.20	0.73	1.23	2.15	1.84
Pain	0.45	2.02	1.88	2.10	2.36	2.06
Stability	1.88	1.76	3.00	2.19	3.24	1.87
Satisfaction with knee	0.85	1.86	2.58	2.02	3.48	1.72
Activity	6.67	31.42	18.03	25.40	27.58	27.90

5

Table 5 Pairwise comparison of mean difference between groups

Lysholm	Mean Difference	Lower	Upper	p-value
PS-CO	-0.36	-4.23	3.51	0.97
KH-CO	4.85	1.12	8.59	0.01
KH-PS	5.21	1.34	9.09	0.00
Tegner*				
PS-CO	0.14	-0.26	0.54	0.68
KH-CO	0.37	-0.02	0.76	0.07
KH-PS	0.23	-0.18	0.63	0.38
Pain				
PS-CO	-0.19	-0.88	0.49	0.78
KH-CO	0.88	0.21	1.54	0.01
KH-PS	1.07	0.38	1.76	0.00
Stability				
PS-CO	-0.36	-1.01	0.28	0.38
KH-CO	0.72	0.10	1.35	0.02
KH-PS	1.09	0.44	1.73	0.00
Satisfaction with Knee				
PS-CO	-0.18	-0.83	0.48	0.80
KH-CO	0.77	0.14	1.40	0.01
KH-PS	0.95	0.29	1.60	0.00
Activity				
PS-CO	-2.34	-11.19	6.52	0.81
KH-CO	8.65	0.09	17.21	0.05
KH-PS	10.99	2.12	19.86	0.01

* Treatment effect p-value=0.06. Time effect p-value=<0.001

10

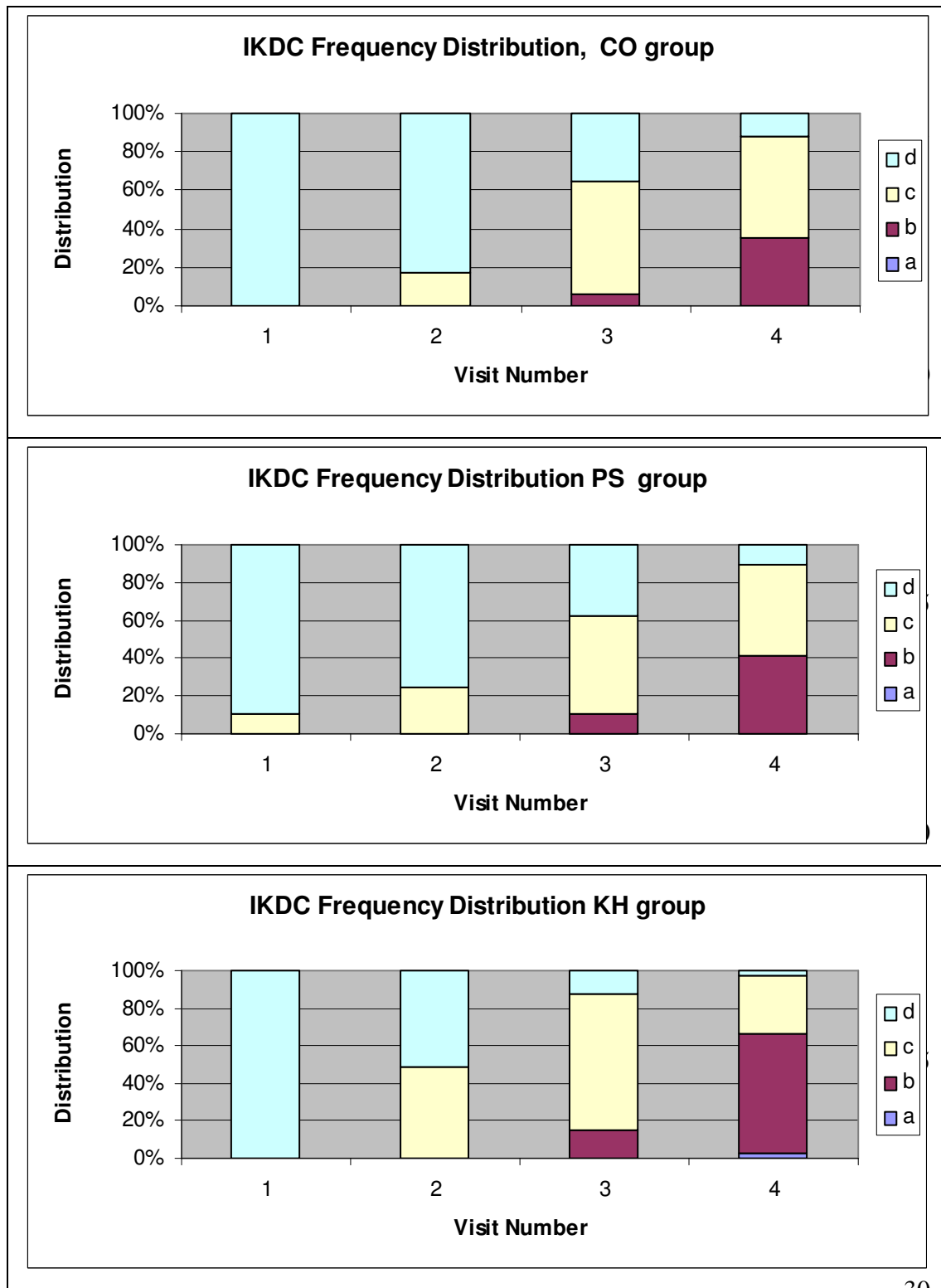


Fig 4. Distribution of IKDC grades by group, over time. Visit 1 is the pre-operative visit. a=normal, b=nearly normal, b=abnormal, d=severely abnormal

Fig 4 shows the progression of the frequency distribution of the IKDC Knee examination rating during the course of the study. There was evidence of a change in IKDC categorisation across Time ($p < 0.001$) and between Treatments ($p < 0.001$). There was no evidence of a significant Time Treatment interaction. There was evidence of a significantly higher probability of improvement (i.e. an improving IKDC classification across Time) for the KH group compared to the Controls ($p < 0.001$) with an estimated Odds Ratio of 3.53 (95% CI [1.98, 6.30]) and compared to the PS group ($p = 0.002$) with an estimated Odds Ratio of 2.50 (95% CI [1.39, 4.48]). There was no evidence of a significant difference in classification probability across time when comparing the Controls to the PS group ($p = 0.254$)

10

4.5 Patient diaries

The frequency of training over the period of 12 weeks reveals differences in group compliance. The target was 20 minutes training three times daily, five times per week, which amounts to a total target training time of 60 hours over a period of 12 weeks. The actual compliance was as follows;

15

- Control group: 48 hours and 48 minutes
- Poly-Stim group: 39 hours and 18 minutes
- Kneehab group: 45 hours and 20 minutes

20

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

The period for which the patients had to **use the walking aids** was set at 3 weeks postoperatively. This period is standard in the rehabilitation programme used here and was not set in the light of the study design. Here there were also differences between the groups although without achieving statistical significance:

25

- Control group: 3.21 weeks
- Poly-Stim group: 3.24 weeks
- Kneehab group: 2.83 weeks

30

The **return to everyday working life** gave similar values as in the full weight-bearing:

- Control group: 3.67 weeks
- Poly-Stim group: 3.88 weeks
- Kneehab group: 2.7 weeks

5

DISCUSSION:

10 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 EMS with a programme of voluntary 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
15 study was the inclusion of a group (KH) who used a garment-integrated stimulator 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
20 in the plots of Fig 1. For all groups, there is apparently a loss of performance with respect to pre-surgical baseline at the 6-week follow-up point. Thereafter, there is a general recovery in performance that restores or exceeds the pre-surgical performance level. Within this general picture there are differences between the groups. The KH group demonstrates less of a deficit compared to the other groups at the 6-week point, and generally preserves, but does not
25 increase, this advantage at the subsequent time points. Such a scenario would appear to bear out the conclusion of Paillard [38] that NMES in the early stages of rehabilitation helps to build capacity which is required in the later stages. 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.

This study may be compared with several others which reported a positive effect [9, 12, 16, 35, 46, 47, 48] of NMES on the quadriceps muscles, but there were also studies [27, 29, 37] that found no or only a slight difference between electrical stimulation and voluntary contraction of the affected musculature. The significantly better values for flexors in the KH group ($p=0.011$) over the entire period of the investigation have not been reported so far in any study.

Bax et al. [3] have systematically reviewed the evidence for quadriceps strengthening using NMES in both healthy and impaired subjects. For the latter group, comparing NMES with voluntary exercise, they point out that only one study of three acceptable studies showed clear results in favour of NMES, the remaining two being equivocal. Notably, that study, Delitto et al [10], also superimposed a voluntary co-contraction on the NMES exercise, possibly enhancing the training stimulus. Although both NMES groups in this study used the superimposed voluntary contraction technique, the KH group performed consistently better than PS across most response variables. Both NMES strategies used similar treatment parameters as indicated in table 1. The main distinctions between the systems were convenience of use of the KH device, which may account for the improved compliance, and an improved activation resulting from the multipath technique.

Paillard [38] has recently examined the evidence for the combined technique of adding NMES (not necessarily simultaneous) to a voluntary exercise programme in knee rehabilitation. He concluded that the combined therapy was better than voluntary exercise alone in reducing strength loss and atrophy, and moreover restored more functional abilities. He suggests that the complementary role of EMS may be in the early phase of rehabilitation, where it produces a strength increase that is necessary to perform voluntary exercises in the later phases of rehabilitation.

The second primary target criterion, the single leg hop test, also shows a clear significant difference between the KH and CO and PS groups. The KH group achieved significantly better values than the CO group at all three follow-up examinations. When the increase in distance hopped with the injured leg is considered, the KH group achieved a 50% increase, compared with the PS (26.3%) and CO (23.2%) groups. 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. Fitzgerald et al (16) and Snyder-Mackler et al (46) did however also study functional aspects of gait, coordination and walking speed and these studies also reported improvement in gait and knee function. The results of the Lysholm score and the IKDC score showed both subjectively (Lysholm) and subjectively/objectively (IKDC) that patients in the KH group achieved better results faster than the CO and PS groups. Evaluation of patient diaries reveals that patients in the KH group dispensed with crutches three days sooner (full weight bearing) and returned to work one week sooner than the PS and CO groups.

15

Conclusion

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

References

1. **Andersson, M. et al. (1991).** Knee function after surgical or nonsurgical treatment of acute rupture of the anterior cruciate ligament: a randomized study with a longterm follow-up period. In: *Clin. Orthop.*, Mar (264): 255-263.
2. **Barber, S.D. et al. (1990).** Quantitative assessment of functional limitations in normal and anterior cruciate ligament deficient knees. In: *Clin. Orthop.*, Jun (255): 204-14.
3. **Bax L, Staes F, Verhagen A.(2005).** Does neuromuscular electrical stimulation strengthen the quadriceps femoris? A systematic review of randomised controlled trials. *Sports Med.* 2005;35(3):191-212.
4. **Barrack, R.L. ; Skinner, H.B. ; Brunet, M.E. ; Buckley, S.L. (1989).** Proprioception in the anterior cruciate ligament deficient knee. In: *Am. J Sports Med.*, 17(1): 1-6.
5. **Barrett, D.S. (1991).** Proprioception and function after anterior cruciate reconstruction. In: *J Bone Joint Surg Br.*, 73(5): 833-7.
6. **Beynon, B.D. et al. (1995).** Anterior cruciate ligament strain behavior during rehabilitation exercises in vivo. In: *Am. J Sports Med.*, 23(1): 24-34.
7. **Bircan, C. et al. (2002).** Efficacy of two forms of electrical stimulation in increasing quadriceps strength: a randomized controlled trial. In: *Clin Rehabil.* 16(2): 194-9
8. **Carter, T.R.; Edinger, S. (1999).** Isokinetic evaluation of anterior cruciateligament reconstruction: hamstrings versus patellar tendon. In: *Arthroscopy*, 15(2): 169-72.
9. **Currier, D.P. et al. (1993).** Effects of electrical and electromagnetic stimulation after anterior cruciate ligament reconstruction.

In: J Orthop Sports Phys Ther. 17(4): 177-84

10. Delitto A, Rose SJ, McKowen JM, Lehman RC, Thomas JA, Shively RA. Electrical stimulation versus voluntary exercise in strengthening thigh musculature after anterior cruciate ligament surgery. *Phys Ther.* May 1988;68(5):660-663.
- 5
11. **Draganich, L.F.; Vahey, J.W. (1990).** An in vivo study of anterior cruciate ligament strain induced by quadriceps and hamstrings forces.
In: J. Orthop. Res., 8(1): 57-63.
- 10
12. **Draper, V.; Ballard, L. (1991).** Electrical stimulation versus electromyographic biofeedback in the recovery of quadriceps femoris muscle function following anterior cruciate ligament surgery. In: *Phys Ther.* 71(6): 455-61
- 15
13. **Eastlack, M.E.; Axe, M.J.; Snyder-Mackler, L. (1999).** Laxity, instability and functional outcome after ACL injury: copers versus noncopers.
In: *Med Sci Sports Exerc.* 31(2): 210-5.
14. **Engstrom, B. et al. (1993).** Knee function after anterior cruciate ligament ruptures treated conservatively. In: *Int. Orthop.*, 17(4): 208-13.
- 20
15. **Fitzgerald, G.K.; Lephart, S.M.; Hwang, J.H.; Wainner, R.S. (2001).**
Hop test as predictors of dynamic knee stability.
In: *J Orthop Sports Phys Ther.*, 31(10): 588-97.
- 25
16. **Fitzgerald, G.K.; Piva, S.R.; Irrgang, J.J. (2003).** A modified neuromuscular electrical stimulation protocol for quadriceps strength training following anterior cruciate ligament reconstruction. In: *J Orthop Sports Phys Ther.*, 33(9): 492-501.
- 30
17. **Gauffin, H. et al. (1990).** Function testing in patients with old rupture of the anterior cruciate ligament. In: *Int. J. Sports Med.*, 11(1): 37-7.
18. **Gobbi, A.; Tuy, B.; Mahajan, S.; Panuncialman, I. (2003).** Quadrupled bone-semitendinosus anterior cruciate ligament reconstruction: a clinical investigation in a group of athletes. In: *Arthroscopy*, 19(7): 691-9.
- 35

19. **Hefti, F. et al. (1993).** Evaluation of the knee ligament injuries with the IKDC form. In: Knee Surg Sports Traumatol Arthrosc., 1(3-4): 226-34.
- 5 20. **Hehl, G. et al. (1995).** Isokinetic muscle training with high motion speeds in the rehabilitation following surgical treatment of fresh anterior cruciate rupture. In: Z Orthop Ihre Grenzgeb., 133(4): 306-10.

21. **Jarvela, T.; Kannus, P.; Latvala, K.; Jarvinen, M.; (2002).** Simple measurement in assessing muscle performance after an ACL reconstruction.
In: *Int J Sports Med.*, 23(3): 196-201.
- 5
22. **Keays, S.L. ; Bullock-Saxton, J.; Keays, A.C.; Newcombe, P. (2001).** Muscle strength and function before and after cruciate ligament reconstruction using semitendinosus and gracilis. In: *Knee.*, 8(3): 229-34
- 10 23. **Keays, S.L. ; Bullock-Saxton, J.E.; Newcombe, P.; Keays, A.C. (2003).** The relationship between knee strength and functional stability before and after cruciate ligament reconstruction. In: *J Orthop Res.*, 21(2): 231-7.
- 15 24. **Kramer, J. et al. (1993).** Knee flexor and extensor strength during concentric and eccentric muscle actions after anterior cruciate ligament reconstruction using the semitendinosus tendon and ligament augmentation device.
In: *Am J Sports Med.*, 21(2): 285-91.
- 20 25. **Kvist, J. et al. (2001).** Anterior tibial translation during different isokinetic quadriceps torque in anterior cruciate ligament deficient and nonimpaired individuals.
In: *J Orthop Sports Phys Ther.*, 31(1): 4-15.
- 25 26. **Lephart, S.M. et al. (1992).** Proprioception following anterior cruciate ligament reconstruction. In : *J Sports Rehab.*, 1: 188-196.
27. **Lieber, R.L.; Silva, P.D.; Daniel, D.M. (1996).** Equal effectiveness of electrical and volitional strength training for quadriceps femoris muscles after anterior cruciate ligament surgery. In: *j Orthop Res.*, 14(1): 131-8.
- 30 28. **Morrissey, M.C. et al. (2000).** Velocity specificity in early training of the knee extensors after anterior cruciate ligament reconstruction.
In: *Eur J Appl Physiol.*, 81(6): 493-6.

29. **Morrissey, M.C.; Brewster, C.E.; Shields, C.L. Jr.; Brown, M. (1985).** The effects of electrical stimulation on the quadriceps during postoperative knee immobilization. In: *Am J Sports Med.*, 13(1): 40-5.
- 5
30. **Negrete, R.; Brophy, J. (2000).** The relationship between isokinetic open and close chain lower extremity strength and functional performance. In: *J Sport Rehabil.*, 9: 46-61.
- 10 31. **Noyes, F.R. et al. (1983).** The symptomatic anterior cruciate deficient knee. Part I: the long term functional disability in athletically active individuals. In: *J Bone Joint Surg Am.*, 65(2): 154-62.
- 15 32. **Noyes, F.R. et al. (1983).** The symptomatic anterior cruciate deficient knee. Part II: the results of rehabilitation, activity modification and counseling on functional disability. In: *J Bone Joint Surg Am.*, 65(2): 163-74.
- 20 33. **Nyland, J.; Caborn, D.N.; Rothbauer, J.; Kocabey, Y.; Couch, J. (2003).** Two-year outcomes following ACL reconstruction with allograft tibialis anterior tendons: a retrospective study. In: *Knee Surg Sports Traumatol Arthrosc.*, 11(4): 212-8.
- 25 34. **Oshino, T.A.; Greene, T.A.; Jensen, G.M.; Lopopolo, R.B. (1983).** The effect of varied hip angles on the generation of internal tibial rotatory torque. In: *Med Sci Sports Exerc.* 15(6): 529-34
- 30 35. **Parker, M.G.; Bennett, M.J.; Hieb, M.A.; Hollar, A.C.; Roe, A.A. (2003).** Strength response in human femoris muscle during 2 neuromuscular electrical stimulation programs. In: *J Orthop Sports Phys Ther.*, 33(12): 719-26.
- 35 36. **Paessler, H.H.; Mastrokalos, D.S. (2003).** Anterior cruciate ligament reconstruction using semitendinosus and gracilis tendons, bone patellar tendon, or quadriceps tendon-graft with press-fit fixation without hardware. A new innovative procedure. In: *Orthop Clin North Am*, Jan 34(1): 49-64.

37. **Paternostro-Sluga, T. et al. (1999).** Neuromuscular electrical stimulation after anterior cruciate ligament surgery. In: *Clin Orthop.*, Nov; (386): 166-173.
38. Paillard T. Combined application of neuromuscular electrical stimulation and voluntary muscular contractions. *Sports Med.* 2008;38(2):161-177.
39. Paillard T, Noe F, Passelergue P, Dupui P. Electrical stimulation superimposed onto voluntary muscular contraction. *Sports Med.* 2005;35(11):951-966.
40. **Petschnig, R.; Baron, R.; Albrecht, M. (1998).** The relationship between isokinetic quadriceps strength test and hop tests for distance and one-legged vertical jump test following anterior cruciate ligament reconstruction.
In: *J Orthop Sports Phys Ther.*, 28(1): 23-31
41. **Renstrom, P. et al (1986).** Strain within the anterior cruciate ligament during hamstring and quadriceps activity. In: *Am J Sports Med.*, 14(1): 83-7.
42. **Rudolph, K.S.; Axe, M.J.; Snyder-Mackler, L. (2000).** Dynamic stability after ACL injury: who can hop? In: *Knee Surg Sports Traumatol Arthrosc.*, 8(5): 262-9.
43. **Segawa, H.; Omori, G.; Koga, Y.; Kameo, T.; Iida, S.; Tanaka, M. (2002).** Rotational muscle strength of the limb after anterior cruciate ligament reconstruction using semitendinosus and gracilis tendon.
In: *Arthroscopy*, 18 (2): 177-82
44. **Sekiya, I.; Muntea, T.; Ogiuchi, T.; Yagishita, K.; Yamamoto, H. (1998).** Significance of the single-legged hop test to the anterior cruciate ligament reconstructed knee in relation to muscle strength and anterior laxity.
In: *Am. J. Sports. Med.*, 26 (3): 384-8
45. **Shelburne, K.B.; Pandy M.G. (1997).** A musculoskeletal model of the knee for evaluating ligament forces during isometric contractions.
In: *J. Biomech.*, 30(2): 163-76.
46. **Snyder-Mackler, L.; Ladin, Z.; Schepsis, A.A.; Young, J.C. (1991).** Electrical

stimulation of the thigh muscles after reconstruction of the anterior cruciate ligament. Effects of electrically elicited contraction of the quadriceps femoris and hamstrings muscles on gait and on strength of the thigh muscles.
In: J Bone Joint Surg Am., 73(7): 1025-36.

5

47. **Snyder-Mackler, L.; Delitto, A.; Bailey, S.L.; Stralka, S.W. (1995a).** Strength of the quadriceps femoris muscle and functional recovery after reconstruction of the anterior cruciate ligament. A prospective, randomized clinical trial of electrical stimulation. In: J Bone Joint Surg Am., 77(8): 1166-73.

10 48. **Snyder-Mackler, L.; Delitto, A.; Stralka, S.W.; Bailey, S.L. (1995b).** Use of electrical stimulation to enhance recovery of quadriceps femoris muscle force production in patients following anterior cruciate ligament reconstruction.
In: Phys Ther., 75(3): 237-8.

15 49. **Stevens, J.E.; Minzer, R.L.; Snyder-Mackler, L. (2004).** Neuromuscular electrical stimulatory for quadriceps muscle strengthening after bilateral total knee arthroplasty: a case series. In: Orthop Sports Phys Ther., 34(1): 21-9.

50. **Tegner, Y.; Lysholm, J. (1985).** Rating systems in the evaluation of knee ligament
20 injuries. In: Clin Ortop., Sep;(198): 43-49.

51. **Toutoungi, D.E. et al. (2000).** Cruciate ligament forces in the human knee during rehabilitation exercises. In: Clin Biomech., 15(3): 176-87.

25 52. **Vanderthommen, M.; Crielaard, J.M. (2001).** Muscle electric stimulation in sports medicine. In: Rev Med Liege., 56(5): 391-5.

53. **Viola, R.W. et al. (2000).** Internal and external tibial rotation strength after anterior cruciate ligament reconstruction using ipsilateral semitendinosus and gracilis
30 tendon autografts. In: Am J Sports Med., 28(4): 552-55

54. **Wilk, K.E. et al (1994).** The relationship between subjective knee scores, isokinetic testing, and functional testing in the ACL-reconstructed knee.
In: Orthop Sports Phys Ther., 20(2): 60-73.

35

55. **Wilk, K.E. et al. (1997).** Kinetic chain exercise: implications for the anterior cruciate ligament patient. In: *J Sport Rehab.*, 6: 125-143.