Research Square

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Quadriceps Muscle Strength Recovery With the Use of High Tone Power Therapy After ACL Reconstruction: a Randomized Controlled Trial

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Abstract

Background

A relatively new method of electrotherapy is High Tone Power Therapy. It directly affects cell metabolism, improving metabolic processes in tissues, and pain relief. It can also be used to obtain stimulating effects of the current, in this case also for electro stimulation of the quadriceps.

The aim was to assess the effectiveness of electro stimulation of the quadriceps muscle in patients after ACL reconstruction, with the use of High Tone Power Therapy.

Methods

In pre post treatment randomized controlled trial took part thirty-five patients after anterior cruciate ligament reconstruction.

The tests were carried prior to and 6 months following the ACL reconstruction. After the surgery, the patients were randomly divided into two research groups – experimental group (17 patients) had the High Tone Power Therapy included in rehabilitation, while the control group (18 patients) was without the High Tone Power Therapy. All patients were subjected to 6-month rehabilitation. Research tools included the measurement of muscle strength torque, ROM, knee and thigh circumference measurements, the Lysholm and the VAS scale

Results

The analysis showed that there were no statistically significant differences in the measurement of maximum muscle torque of knee extensors between groups and measurements. The analysis did not show any statistically significant differences in other analyzed variables.

Conclusions

High Tone Power Therapy used in the rehabilitation of patients after ACL reconstruction does not significantly affect the strength of the quadriceps muscle and the function of the knee joint.

Trail Registration

This study was registered retrospectively in the Australian New Zealand Clinical Trials Registry (ANZCTR). Registration number: ACTRN12616001416482.

Introduction

An injury to the anterior cruciate ligament (ACL) causes gradual weakness of the quadriceps strength by 5%-40%. The biggest weakness occurs in the first few months following the reconstruction and it most

commonly affects the medial head of the quadriceps muscle. Restoration of muscle strength determines patient's return to activity after reconstruction [1,2,3].

For many years neuromuscular electrical stimulation (NMES) has been applied in order to prevent muscular atrophy and restore their strength. The primary effect of the NMES after anterior cruciate ligament tear is restoration and improvement of the quadriceps function. This kind of therapy helps to activate the muscle which activity is inhibited mostly by pain or effusion. In the literature there are a lot of contradictions regarding the effectiveness and benefits of using NMES in patients after ACL reconstruction (ACLr) [4,5,6,7].

A relatively new method of electrotherapy is High Tone Power Therapy (HiToP). Its undoubted advantage is the ability to influence the whole body. It directly affects cell metabolism, improving metabolic processes in tissues, and pain relief. It can also be used to obtain stimulating effects of the current, in this case also for electro stimulation of the quadriceps [8,9,10].

The therapy is based on bi-directional currents of average frequency (4096-32768 Hz). Such currents cause stimulating effects (they trigger off action potential for example in muscles, nerves or receptors) and unstimulating effects, namely influence on metabolism. Unlike other methods employed in electrotherapy, in the HiToP therapy there is a simultaneous change in amplitude and frequency. This allows to get unstimulating effects by applying high doses. In spite of this, the therapy alone does not cause bigger sensations in the patient. What is more, side effects in the form of irritation or burning are reduced [8,9,10].

There are two modes of operation in the HiToP:

- "Simul FAMi"
- "Simul FAM X".

"Simul FAMi" is based on non-stimulant effects, that is a high-frequency current which causes the formation of electric field in tissues which later vibrates different molecules, for example, dipoles or ions. It works in the tissues as a biocatalyst improving the diffusion of ions and affecting the distribution of substances such as mediators of pain or products of metabolism, which results in the reduction of pain. In addition to analgesia, medium frequency currents cause the acceleration of chemical reactions and metabolism which stimulates tissue regeneration. Researchers also highlight the influence of the medium frequency currents on resorption of hematoma and effusions by increasing circulation (both venous and lymphatic) and greater permeability of cell membranes [8,9,10].

The "Simul FAM X" mode, depending on the frequency, allows the use of stimulant effects (e.g. nerve or muscle stimulation). It involves triggering an action potential (nerves, muscles, or receptors). The range of stimulant frequencies which are most commonly used in the HiToP is from 3 Hz to 100 Hz [8,9,19].

Studies have shown wide application of HiToP. Both stimulant and non-stimulant effects are used. Non-stimulant effects are mainly used in conditions where there is a need to accelerate tissue regeneration or improve metabolic processes, ie. in chronic diseases such as rheumatism or arthritis or in overload or after soft tissue injuries. HiToP is also used in internal diseases such as diabetes and its consequences (polyneuropathy) as well as chronic venous insufficiency. What is more, HiToP is applicable to stimulation of weakened muscles. Both- the stimulant and non-stimulant action can be used [8,9,10,11].

Local or global application can be used in the HiToP. The device is usually equipped with 4 channels running independently of each other. The duration of treatment varies from 20 minutes to 60. It is recommended to perform 10 treatments daily or every other day [8].

Up to date, to the best of our knowledge, there are no scientific reports unambiguously describing the effectiveness of the HiToP therapy in patients after ACLr. This caused that in own research an attempt was made to present the possibilities of using the selected method of electrical stimulation in the treatment of an orthopaedic patient.

The aim of the research was to assess the effectiveness of the quadriceps muscle electro stimulation in patients after reconstruction of anterior cruciate ligament, with the use of HiToP therapy and above all answering the following questions:

1. What impact on the analyzed variables in patients after ACLr had the use of HiToP compared to the control group?
2. How were pain and functional level assessed in both groups?

Based on the above questions, the following hypotheses were adopted:

1. The use of HiToP in patients after ACL reconstruction will have a beneficial effect on the selected variables in both groups included in the study.
2. Pain and functional level of patients enrolled in the study, who received HiToP, will improve compared to patients included in the control group.

Materials And Methods

Design

This pre post treatment trial was reported according to the recommendations of the Consolidated Standards of Reporting Trials (CONSORT) statement [12].

The first author enrolled patients from a list of patients for ACLr. The qualification for research was based on the simple randomisation of research group. Allocation of patients to the research group was decided upon the coin-tossing. Heads – patient is participating in the research, tails – patient does not take part in the research. Patients qualified for the research were patients of the Trauma and Orthopaedics Clinical Department, University Hospital in Krakow, who underwent ACLr.

After the surgery, patients were randomly divided into two groups. Before starting the intervention, patients were randomly allocated to the Experimental or Control group by an independent researcher using the sealed envelopes method. The first group had the HiToP included in rehabilitation (Experimental group), while the second group, had been treated without the HiToP (Control group).

Eligibility criteria for the research were:

- The form of surgery prescribed by a physician – ACL reconstruction by an autogenic method – ST tendon graft
- Ability to move independently before and after the surgery (without the use of orthopaedic supports)
- No other injuries or illnesses that may affect the outcome of the measurements e.g. damage to the menisci, degenerative changes in the joints (tests performed by an orthopedist).
- A voluntary consent of the patient to participate in the study (written consent).
- The patients had not taken medications affecting motor coordination.

Criteria for exemption from the surgery and rehabilitation program:

- More than two absence in the rehabilitation program,
- Interruption of continuity of the graft.

Measurements were carried out between 2017 and 2019 at the University of Physical Education in Laboratory of the Diagnostics of the Motor System, Laboratory of the Motion Analysis, in collaboration with the Trauma and Orthopaedics Clinical Department, University Hospital in Krakow.

Intervention

The study included measurements of maximum muscle torque of the quadriceps and ROM, evaluation of knee function and pain assessment. The examination was carried out twice. The first examination session took place two days prior to the surgery.

In the period from 1 to 10 day after the surgery the patients complied with the physician's recommendations: the knee was blocked in the orthosis in full extension, cooled the joint with ice cubes (twice a day for 15 min.), weight-bearing as tolerated and quadriceps contraction. Post-operative restrictions were put in place to provide protection to the repaired ligament.

Next patients from both groups started intensive physiotherapy. Both groups had an identical exercise program. During the first 3 months physiotherapy was carried out 3 times a week, while between 4th and 6th month – twice a week. Physiotherapy included general rehabilitation and exercises focused on the knee function. The exercise protocol included exercises improving the ROM, strengthening the muscles of the operated limb, proprioception and coordination exercises with the use of accessories, i.e. TheraBand strip. (Figure 1.)

Figure 1. The goals of the individual stages of physiotherapy.

Patients from Experimental group were also applied HiToP. HiToP treatment involved electro stimulation of the quadriceps muscle at a frequency of 20 Hz (two electrodes set in the place of transition of the belly of the muscle into a tendon) and vitalisation: electrodes were arranged on the feet, forearms and the cervical spine using simultaneous frequency and amplitude sweep (in the range from 4096 to 32768 Hz) which purpose was to trigger and use in the therapy non stimulating effects of the currents.

HiToP was performed after each physiotherapy sessions and the duration of administration was 1 hour. 1 hour of HiToP session took place after the completion of 1 hour of physiotherapy. The total duration of intervention in patients from the HiToP Group was 2 hours.

Muscle strength and ROM measurements, assessment of pain and knee function were repeated after 6 months.

Outcome measures

Primary outcome: For each patient measurements of the maximum muscle torque were performed in standard positions for the measurement of the knee extensors strength (angles between the trunk, hip joint and knee joint were 90°). The examination was conducted by means of the isometric muscle force measurement and analysis program, 2001 Metitur Ltd. The value of maximum muscle force (Fmax) was measured and on its basis the values of maximum muscle torque (τmax) and relative muscle torque (τr) for a selected group of muscles were calculated according to:

$$\tau max = Fmax \times d \ [Nm]$$

$$\tau r = \tau max/m \ [Nm/kg]$$

where: d-the value of the external force arm- the distance from the axis of joint rotation to the line of action of the dynamometer, m-weight of the subject [13].

Secondary outcome: measurements of the range of motion were carried out using a goniometer, measurement of the circumferences of the thigh (10 cm from the base of the patella) and the knee and Lysholm scale were performed, as well as the visual-analog pain assessment scale (VAS) [14,15,16].

Data analysis

Methods of descriptive statistics were used to present the results in the form of tables containing arithmetic means, standard deviation, minimum and maximum values.

All analyzes were performed using the Statistica V.12 package. In order to select the optimal test tool to investigate the significance of differences between the values observed in both groups, the distribution of observed values was tested in the sample using the Shapiro-Wilk test. In both groups, all observed

variables had a normal distribution. This is evidenced by the probability level obtained in the test, which in no case was less than the assumed level of significance (0.05).

The significance of changes in static stabilographic parameters was determined using the two-way ANOVA (ANOVA group × time). The Bonferroni correction was used for multiple comparisons. The analyzes also concerned the verification of whether there were significant differences between the effects of therapy between groups. For this purpose, the non-parametric Mann-Whitney U test was used. A significance level of $p < 0.05$ was assumed for all analyzes. The effect size was calculated using Cohen's *d*, analyzed and discussed in accordance with the previous studies [17,18,19]. The paired *t*-test power analysis of exercise influence determined that at least 30 subjects were required to obtain a power of 0.8 at the two-sided level of 0.05 with the effect size of $d = 0.6$.

Results

40 patients were recruited but 36 were eligible to be included in the study. In Control group 18 patients were followed up to analysis and in Experimental group 18 participants were allocated to intervention but one of them lost to follow-up up (95% follow-up). Finally research material comprised a group of 35 men, aged 21-50 (mean age 28.4±7.83). Figure 2. presents the qualification process for research. Characteristics of patients divided into two groups are displayed in Table 1.

Figure 2. Flow diagram

Table 1. Anthropometric data.

Variable	Experimental				Control				*p*
	X	SD	Min	Max	X	SD	Min	Max	
Age [yrs]	30	7.35	22	47	30	10.42	21	50	0.88
Body height [cm]	175.74	3.52	169.00	181.00	177.74	8.01	165.00	193.00	0.41
BMI	25.53	3.47	20.12	31.54	24.42	3.54	19.23	31.56	0.43

Experimental – patients with HiToP in physiotherapy.

Control – patients without HiToP in physiotherapy.

The conducted analysis showed that there were no statistically significant differences in torque measurement of the knee extensors strength between Groups and measurements.

The analysis showed no statistically significant differences in the measurements of the knee circumference between Groups and measurements.

The analysis showed that in the Control group thigh circumference of the injured leg statistically increased. However, in the Experimental group the thigh circumference increased but the difference was statistically insignificant.

The analyses showed no statistically significant differences between Groups of the range of extension in both measurements. The analyses showed that the difference between measurement of the range of extension was statistically significant only in the Control group. (Table 2.)

Table 2. Comparsion of outcome variables characterizing the knee indicators at baseline and after physiotherapy.

		Baseline	Post	X difference	p^a	ES[a]
		X±SD	X±SD	(95% CI)		
Knee extensorsstrength [N/kg]	**Experimental**	20.49 ± 0.8	20.28 ± 0.7	-0.21 (1.11 to 1.25)	0.051	0.28
	Control	20.30 ± 0.6	20.19 ± 0.6	-0.11 (1.04 to 1.15)	0.316	0.18
	p^b	0.505				
	ES[b]	0.27				
Knee circumference [cm]	**Experimental**	39.00±2.90	37.00±1.80	-2 (1 to 2)	0.168	0.82
	Control	39.00±1.84	38.00±2.18	-1 (2 to 3)	0.662	0.50
	p^b	0.647				
	ES[b]	0.65				
Thigh circumference [cm]	**Experimental**	44.00±4.02	46.00±3.86	2 (2 to 3)	0.059	0.61
	Control	42.00±3.80	44.00±3.11	2 (1 to 2)	0.032	0.66
	p^b	0.643				
	ES[b]	0.51				
Knee extension [°]	**Experimental**	1.00± 3.20	0.00 ± 0.00	-1 (1 to 2)	0.222	0.44
	Control	4.00 ± 6.65	1.00 ± 0.99	-3 (1 to 3)	<0.001	0.63
	p^b	0.815				
	ES[b]	0.68				

Baseline – the measurement before physiotherapy; **Post -** the measurement after physiotherapy

p^a – p-value between baseline and post-physiotherapy within each group; p^b – p-value between study groups; ES^a – effect size (Cohen d) within each group; ES^b – effect size (Cohen d) between study groups; ***p*** <0,05; **CI** – confidence interval

The analysis showed that within the groups the Lysholm scale results increased after physiotherapy and these differences were statistically significant. However, there were no statistically significant differences between groups.

Comparison of results of pain level according to the VAS scale in I and II measurement in the Experimental group and the Control group showed no statistically significant differences. The results of the pain scale in both I and II measurement showed that the patients from the Experimental group determined the degree of pain according to the VAS scale at a lower level than the patients in the Control group. The differences, however, were statistically insignificant. (Table 3.)

Table 3. Statistical analysis of the results of the Lysholm and VAS scales in both Groups at baseline and after physiotherapy.

		Baseline	Post	X difference	p^a	ES^a
		X±SD	X±SD	(95% CI)		
Lysholm scale [pts]	**Experimental**	65±4.20	94±7.01	29 (2 to 4)	<0.001	0.74
	Control	66±6.33	97±8.71	31 (1 to 2)	<0.001	0.79
	p^b	0.325				
	ES^b	0.67				
VAS scale [pts]	**Experimental**	2±0.2	3±0.8	1 (1 to 2)	0.469	0.74
	Control	1±0.5	2±0.4	1 (1 to 2)	0.416	0.68
	p^b	0.428				
	ES^b	0.69				

Discussion

The aim of the research was to assess the effectiveness of the quadriceps muscle electro stimulation in patients after reconstruction of anterior cruciate ligament, with the use of HiToP therapy. The obtained results indicate the overall low effectiveness of HiToP, however, the results of the selected outcome measures allow to assess the use of HiToP as an effective.

Injury of the ACL mostly concern young and active people who get injured during recreational or professional physical activity. Comprehensive physiotherapy covering both kinesitherapy and physical

therapy is aimed at restoring motor skills in patients after ACL reconstruction. The mobility depends on the adequate level of knee muscles strength, range of motion, proprioception. Immediately after the reconstruction the range of motion in the knee joint is limited by pain and swelling. Such a limitation does not have a positive influence on muscle strength, particularly knee extensors. Researchers agree that after rehabilitation the values of muscle strength should be similar to those from before the surgery [20,21,22]

One of the elements of therapy of patients after ACL reconstruction can be electrostimulation of the quadriceps muscle, which helps to rebuild muscle strength. Currently, in the rehabilitation of patients after ACL reconstruction HiToP is used, which in addition to muscle stimulation supports cell metabolism, thereby reducing pain [8].

In the available literature there is, however, lack of reports on the effectiveness of the use of the HiToP in patients after ACL reconstruction. There are also no publications including the analysis of the results of knee extensors strength measurements in patients after ACL reconstruction in whom the HiToP was used.

One of the few authors who undertook the evaluation of the effectiveness of HiToP in rehabilitation of patients with soft tissue injuries was Wilk et al. They indicate the improvement in muscle strength of knee extensors after including the HiToP therapy into rehabilitation [9].

Also in the studies of Janiszewski et al., who analyzed the use of HiToP in patients with pain in the lumbar spine, after using the therapy, the strength of the muscles stabilizing the spine improved [23].

Kulis et al. also confirm the effectiveness of HiToP in the therapy of patients with cervical spine pain [24]. The authors conducted a study on a group of 40 people who used HiToP twice a week for 30 minutes for a period of 3 weeks. Test results show an improvement in the mobility of the cervical spine and a reduction in back pain.

Czamara et al. present the study which shows the results suggesting that after ACL reconstruction there is always a decline in muscle strength torque in the operated limb resulting from, inter alia, a reduced activity following the surgery [21]. The authors studied the effect of physiotherapy on extensors and flexors strength in a group of men where each of them had an individual therapeutic program with a similar therapeutic procedure as the patients in this research, also complemented by electrical stimulation of the quadriceps. The authors conclude that the therapy aimed at restoring muscle strength of the knee allows to achieve results similar to the non-operated limb.

Studies of other authors, however, demonstrate that not always balance in muscle strength occurs. Urabe et al. undertook research involving the analysis of the measurement of knee and hip strength in patients after ACL reconstruction [25]. They conclude that after 12 months of rehabilitation they did not obtain in the operated limb the improvement of muscle strength that would be similar to the results of the healthy limb.

Own research showed that there were no statistically significant differences between the results of I and II measurement of muscle strength in injured leg, separately for both groups and between the groups.

Measurement of thigh circumference, which is the determinant of the growth of muscle mass and strength, showed improvement after rehabilitation. In the Control group the result proved to be statistically significant, whereas in the Experimental group no statistically significant difference was noted, however, there was a trend towards significance of the result.

Another aspect addressed in this study was the influence of the HiToP on resorption of swelling in the knee.

Nowakowska et al. in their study observed increased blood flow in the microcirculation of the lower limbs after applying the HiToP [10]. It is possible that in the case of patients after ACL reconstruction in whom the HiToP was used a similar phenomenon occurred, which resulted in reduction of swelling and the lack of effusion after applied therapy.

The results of own research indicate a reduction in the knee circumference in both analysed Groups, suggesting a reduction of swelling, however, these differences were not statistically significant.

The impact of the HiToP on the range of motion was analyzed by Wilk et al. who, after the therapy, found improvement in the knee range of motion [9].

In own research the results of the measurements of the range of extension indicate that there were no differences that could significantly support the better recovery of patients treated with HiToP. Interesting results were also obtained by Janiszewski et al. where after using HiToP in patients with degenerative changes in the lumbar spine, the mobility of the spine improved [23].

One of the issues that were addressed in this study was the influence of the HiToP on pain. Wilk et al., on the grounds of their studies, conclude that pain is reduced in patients after the HiToP [9].

Analysis of subjective evaluation of pain in patients after ACL reconstruction showed reduction of pain in both tested Groups. Better results were obtained by patients whose rehabilitation included the HiToP therapy, but the differences between measurements and between Groups were statistically insignificant.

Study Limitations

Analysis of studies of other authors shows the positive impact of the HiToP on the strength and function of the knee in patients after ACL reconstruction. The results obtained in this study are, however, ambiguous. The cause of such results can be for example low frequency of treatments during the week – from 3 days a week for the first 3 months up to 2 times a week for the next 3 months. The best results of electrostimulation are obtained by applying the therapy every day, what was proved by, among others, Wilk et al. and Ziółkowska et al. [9,26].

Another aspect is the patients' approach to physiotherapy. Unfortunately, most people think that they do need to exercise too intensely or perform exercises at home once they have electro stimulation. Patients who did not have an additional therapy were more motivated to exercise. Such an attitude could result in

insignificant differences between the Groups. Rehabilitation in both Groups was identical, but the results were very similar and all patients achieved their goals. That is why, even rehabilitation and appropriate proceedings alone bring beneficial effects.

There are few scientific reports which would show that the inclusion of the HiToP therapy into the rehabilitation program gives better results. However, part of the results of this research, although statistically insignificant, from the therapeutic point of view is an important signal that the use of HiToP therapy in rehabilitation of patients after ACL reconstruction as well as after other surgeries or injuries brings effects. Therefore, it is worth to expand this issue in future by modifying the frequency and extending therapy.

Conclusions

In patients after ACLr, in whom HiToP therapy was used in rehabilitation, there were no beneficial effects on the analyzed variables compared to the control group. As regards the assessment of functional status and pain in patients included in the experimental group, no positive effect of HiToP therapy on the analyzed variables was found.

Abbreviations

ACL – anterior cruciate ligament

ACLr – anterior cruciate ligament reconstruction

HiToP therapy – High Tone Power therapy

NMES – neuromuscular electrical stimulation

Declarations

Authors' contributions

KOC – research idea, research plan development, data collection, data analysis, literature search, manuscript writing, manuscript approval; **GG** – research idea, development of research plan, literature search, manuscript writing, manuscript approval; **JŚ** – patient recruitment, data analysis, manuscript approval; **AG** – patient recruitment, research, manuscript approval.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The research project has obtained approval of the Ethical Committee of Regional Medical Chamber in Krakow (No. 19/KBL/OIL/2014) and participants provided written informed consent for participation in this study.

Consent for publication

Not applicable.

Competing interests

The author(s) declare no conflicts of interest with respect to the research, authorship, and/or publication of this article.

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