2nd Clinical Trials Results

Efficiency of Functional Electrical Stimulation, using the FISIOTRON-02 medical device, in the rehabilitation of paralyzed CVA patients

Paper

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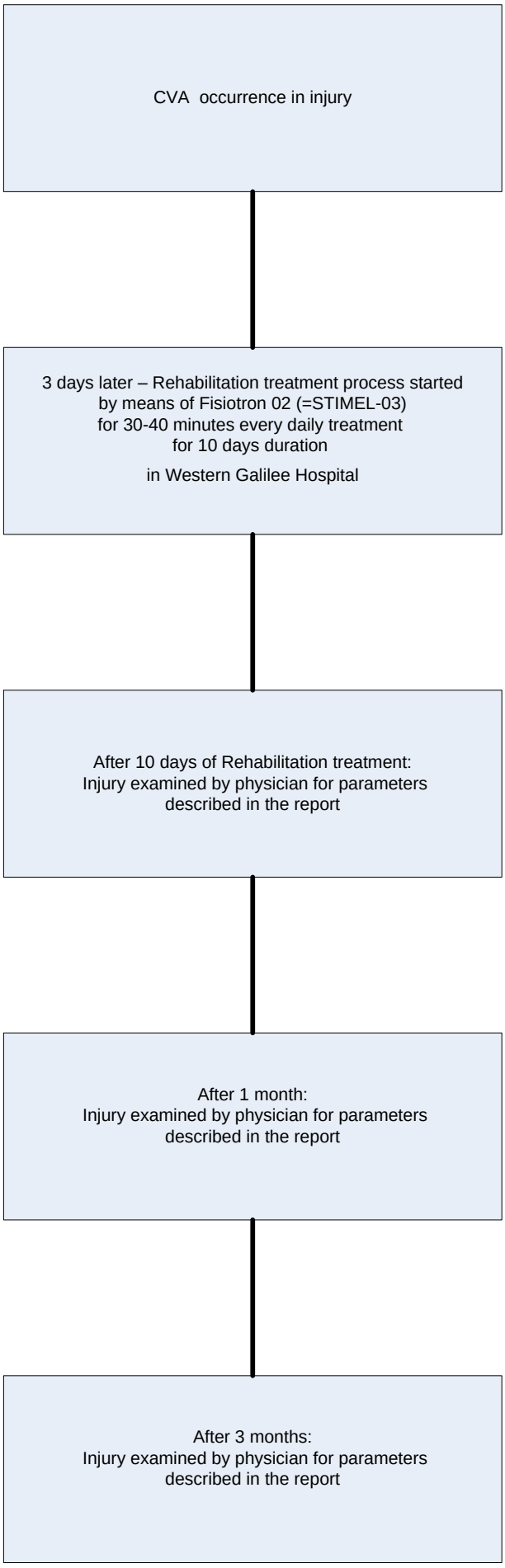
Fisiotron – 02 (=STIMEL-03) Clinical Trials Process



Introduction:

CVA is the most common disease which caused handicap in the world.
In Israel, according to the information obtained from the Health department, around 10000 patients were hospitalized in 1994 with a preliminary diagnosis of CVA, 90% over the age of 65.
CVA is the 3rd most common cause of death in the world, after heart disease and cancer.
1/3rd of the patients who suffered from a CVA, passed away. 2/3rds of the patients were left with a permanent handicap, and 1/3rd suffered from a deterioration of daily function. (TOO MANY 1/3RDS)
CVA leads to a huge financial burden, and there should be a rehabilitation system in place which would improve condition of the patients and reduce their long hospitalizations (1).
Rehabilitation treatment following a stroke includes physical therapy, occupational therapy and speech therapy.
In addition, there are non conventional methods (non physical therapy) of therapy including treatment using FUNCTIONAL ELECTRICAL STIMULATION (FES). Using this method, functional movement of the limb appears using electrical stimulation of the muscles and nerves.
The first time that this technique was used was in 1950. In the last few years, compact and convenient medical devices have been developed, which implement the biofeedback mechanism.
Many papers have been written on the efficiency of this method concerning lower motor neurons or peripheral nerves.
There is an understanding that an improvement in motor function in the upper limbs in the chronic stage following CVA, is less effective than the improvement following an acute event.
In KRAFTs (2) paper, it is written that EMG biofeedback alone is less effective in a chronic CVA case compared to an acute CVA case, but it is useful and effective in combination with physical therapy.
The FES method was used for many years to rehabilitate patients with damage to lower motor neurons.
Improvement in limb function was achieved by increasing the muscle contraction as a result of the direct stimulation of the lower motor neuron (2).
As a result of this electrical stimulation, there is also a decrease in muscle degeneration, and the demineralization process of the bones stops.
Stimulation of antagonistic muscles contributes to the improvement of muscle tone.
This is a combined informative affect on the joints, skin sensation, muscle contraction and visual perception, stimulating movement in the paralyzed limb, and providing information about this stimulation (1,2).
The influence of the FES method on the TIBIALIS ANTERIOS muscles can strengthen the dorsiflextion and improve the disruptive walking patters.
KRAFT (2) compared the influence of 3 different methods, on the function of the upper limb in the chronic stage after CVA.

The methods included:

1. EMG Initiated Electrical Stimulation of Wrist Extensors-EMG Stimulation.
2. (BB) LOW-INTENSITY Electrical Stimulation of Wrist Extensors.
3. (PNF) Proprioceptive Neuromuscular Facilitation Exercises.

In his work, KRAFT reached a conclusion, that EMG-Stim improved motoric function by 42%, compared to a 25% improvement with BB treatment, and 18% improvement with PNF. The estimation was carried out by FUGL-MEYER Test (2).
BOWMAN BR (3) used the Positional Feedback and Electrical Stimulation in his work, in the therapy of paralyzed hands, and stated that this method can increase Isometric Writs Extension and Range of Motion (ROM) in the wrist, in comparison with conventional treatment (3).
A number of clinical trials have indicated an efficiency of Transcutaneous Neuromuscular Stimulation in patients with a reduced rough force, who experienced in improvement in joint movement.
Patients with shoulder subluxation, who underwent treatment using electrical stimulation, had improved shoulder function in comparison to patients who were treated conventionally (5).

In another study, in which the different treatment methods were compared in 3 groups of patients with chronic hemiplegia, the patients treated with electrical stimulation, improved the function of the paralyzed hand more prominently that the control group.
In some of the patients, this improvement occurred immediately, with the onset of treatment. The rest of the patients improved within a few months.
Based on this information, it has been agreed that patients who have suffered a CVA, with a reduction in rough force and a reduction in function, undergo a quicker and more efficient rehabilitation, when incorporating the conventional therapy with FES (4,6,7).
The two complete indications for FES use are: after a CVA and after injury to the spinal chord.
Paralysis of half of the body limbs was the first case in which the FES method was used (8).
The effectiveness of electrical stimulation was observed with patients suffering from an injury to distal muscles- DROP FOOT, as a result of a CVA.
Recently there have been reports, that beginning the rehabilitation process early, following an acute CVA, improves the function of the paralyzed limb (9).

Aims of the study:

To examine the efficiency of the electrical stimulation on rough force, muscle tone, and pain relief on the paralyzed arm and leg, following a CVA.
Comparison of functional rehabilitation of the upper and lower limb in the conventional method (physical therapy), as opposed to the conventional method (physical therapy) + FES in patients who have been completely or partially paralyzed following a CVA.

Patients and method examined:

In this experiment we used a medical device called ELECTRO-STIMULATION type 02 FISIOTRON (=STIMEL-03) created by the STIMEL company.
This medical device creates bipolar electrical currents, having special characterization in the two channels simultaneously or alternately.
The frequency of these currents in a series of impulses lies in the range of 30-80 Hertz, and in between 0.1 to 75 milliamps in the amplitude range.
The stimulation is controlled according to sensitivity threshold units.
The medical device is intended for patients with central or peripheral paralyses. The medical device transfers the electro- stimulatory stimulus to the muscle via a couple of stimulation and sensing electrodes
The electrodes are attached to the muscles which undergoing rehabilitation.
The system uses the potential strength recorded from the muscle by the medical device, and stimulates the muscle with a general amplitude, of the same force.
CVA injuries inclusion in this Fisiotron-02 (=STIMEL-03) Clinical Trials:
We examined 42 patients who were hospitalized in the internal medicine and geriatrics departments, and which suffered from a recent paralysis of half their body following an acute CVA.
The diagnosis was verified by clinical findings and brain CT.
16 of the patients examined were male and 26 female.
The age of the patients ranged between 53-89 years. The average age was 74 years.
Four patients did not complete the study; 3 of them due to medical conditions, and one of them did not complete the study protocol.

The study did not include patients who had:

Malignant diseases.
Blood diseases.
Blood clotting diseases.
Acute heart insufficiency.
Acute infectious diseases.
Pacemaker
Epilepsy

The patients included in this study were divided randomly into two groups:
19 patients: 13 women and 6 men, received conventional therapy only: physical therapy and occupational therapy, and they formed the control group. 9 patients suffered from paralysis on the right side, and 10 patients suffered from paralysis on the left side.
In this group the medical device was attached to the injured muscle, but did not give an electrical impulse.
19 patients: 12 women and 7 men, received physical therapy, occupational therapy and FES using the FISIOTRON 02 medical device developed by the STIMEL company. The formed the treatment group. 7 suffered from paralysis on the right side and 12 suffered from paralysis on the left side. 12 of the patients from this group regulated the electrical response using the biofeedback mechanism.
With the admission to the department, all the patients were evaluated according to the severity of their CVA, using the NIH scale as described below:
Score 4 and below- mild CVA
Score 5-15- moderate CVA
Score 16 and above- severe CVA

The rough force of the muscles stimulated was also measured, and was determined using a scale from 0-5.

ADL function was determined using FIM, which was scored from 18-126.
Hand function was determined using FUGL-MEYER TEST, which was scored from 0 to 60.
Pain estimation was determined by the VISUAL ANALOG SCALE from 0 to 10.
Spastic estimation was determined using the ASHWORTH SCALE from 0 to 4.

3 days following the incident, daily therapy was carried out on the patients: 30-40 minutes each day, for a period of 10 days. Electrical stimulation were carried out on the following hand muscles:
EXTENSOR DIGITORUM COMMUNIS
FLEXOR CARPI ULNARIS
FLEXOR DIGITORUM SUPERFICIALIS
In the foot muscles:
TIBIALIS ANTERIOR
The patients were examined after 10 days, 1 month, and 3 months of therapy.
Blinding: An additional functional evaluation was carried out, using the same scales. By an occupational therapist who did not know what treatment the patient received.
All the patients signed a form agreeing to the experiment.

Methods of statistical investigations:

The characteristics of the groups were described using scattered and central index. Quantitative characteristics (for example age) were described using averages, standard deviation, medians, range.
Qualitative characteristics such as: risk factors, were described using whole numbers and percentages.
Functional Index: FIM, NIH, FUGL-MEYER index, rough strength of hand muscles according to the NIH scale, were described in each group using averaged and standard deviations.
The score and the range of measurements: rough strength of hand/foot muscles and hand/foot tone, were described using percentages, after they were divided up into categories.

Comparison of the measurements as well as changes in the measurement values was carried out between the groups, continuously, using the Mann-Whitney test, and when possible, with the T-test.
Comparison of the measurements through time, was done using the Wicoxon signed and the Fridman test.
Graphs have been created to display the results.

Results:
42 patients with clinical findings of an acute CVA, verified using brain CT, underwent therapy and evaluation between May 2002 and November 2002, in the internal medicine and neurology departments in the West Gallile Hospital.
No side effects were observed in the participants of this Clinical Trial.
Two groups of patients participated in the study.

Patient characteristics, according to their respective groups are shown in table 1

Total number of patients	42
Patients who did not complete the study	4
Patients who continued in the study	38
Patients who received conventional treatment only	19
Patients who received conventional treatment + FES	19

Table number 1

First Group- The control group consisted of 20 patients, who received conventional therapy only: physical and occupational therapy. **One person from the control group was removed from the study** due to acute heart insufficiency/failure (table number 2).
Second Group- The treatment group consisted of 22 patients, who received conventional therapy + treatment with FES. **Three people from the treatment group were removed from the study**. One patient developed a cardiac muscle infarct, another patient suffered a pulmonary embolism and the third patient did not complete the study protocol as he moved to the centre of Israel (table number 2).

Control Group	Therapy Group	Reason
	1	Pulmonary Embolism
	1	Cardiac Muscle Infarct
1		Heart Insufficiency
	1	not complete the study proto
1	3	Total

Table number 2: Patients who did not complete the study

Patient characteristics according to group presented in table number 3:

PV sided -2	Name of test	Control group N=19	Control group N=19	Value/measurement	charecteristic
1	Chi-square test	7 36.8%	6 31.6%	Male - Number %	sex
		12 63.2%	13 68.4%	Female - Number %	
0.88	Mann-Wi\hitney	57-88	53-89	Ages Range	age
		74.8 (10.6)	73.89 (10.7)	Ages Average (Standard Deviation)	
0.714	Chi-square test	6 31.6%	4 21.1%	קורטיקלי	infarct
		13 68.4%	15 78.9%	לקונרי	
0.66	Fisher Exact test	4 21.1%	2 10.5%	מחלת לב איסכמית	Risk factor
0.079	Chi-square test	16 84.2%	10 52.6%	High Blood Pressure	
0.495	Chi-square test	5 26.3%	8 42.1%	Diabetes	
1	Fisher Exact test	3 15.8%	2 10.5%	Smoking	
0.743	Chi-square test	7 36.8%	9 47.4%	Right Side paralysis	diagnosis
		12 63.2%	10 52.6%	Left Side paralysis	

Table number 3- patient characteristics according to group

There was no variation between the groups: in distribution of sex, age, type of infarct, area affected and risk factors.

Table number 4a- Comparison of the values of the 2 groups, at time 0, upon admission to the department.

PV 2 – Sided	Name of test	Control Group N=19	Control Group N=19	Statistical Index	Clinical Index
					time 0:
0.456	Mann-Whitney	66.2 (19.5) [62] 36-110	59.95 (20.05) [58] 29-93	Mean (S.D) [Median] Range	Fim0
0.181	Mann-Whitney	28.2 (18.4) [33] 4-55	20 (17.4) [14] 4-59	Mean (S.D) [Median] Range	Fug0
0.039	Mann-Whitney	7.8 (3.1) [8] 2-16	10.05 (3.13) [10] 4-15	Mean (S.D) [Median] Range	NIH0
0.134	Mann-Whitney	2.2 (1.08) [2] 1-4	2.79 (1.1) [3] 1-4	Mean (S.D) [Median] Range	NIH hand 0
0.375	Mann-Whitney	15 78.90% 4 21%	16 84.20% 3 15.80%	Value till 3 %(included 4-5	hand muschle stregnth 0
0.027	Mann-Whitney	15 78.90% 4 21.10%	17 89.50% 2 10.60%	Value till 3 %(included) 4-5	foot muscle stregnth 0
		13 68.40%	15 78.90%	0	hand tone 0
		3 15.80%	2 10.50%	-1	
		2 10.55%	2 10.50%	+1	
		1 5.30%	0	2	
		15 78.90%	14 73.70%	0	feet tone 0
		1 5.30%	1 5.30%	-1	
		1 5.30%	4 21.10%	+1	
		2 10.50%	0	1	
0.479	Mann-Whitney	6.3 (1.5) [0] 0-5	0.21 '(0.92) [0] '0-4	'1-10	PAIN0

Table 4b: Comparison of the values of the 2 groups after 10 days:

PV 2 – Sided	Name of test	Treatment Group N=19	Control Group N=19	Statistical Index	Clinical Index
					time 10:
0.011	Mann-Whitney	83.1	63.37	Mean (s.d) [Median] Range	Fim10
		(21.7)	(19.4)		
		[77]	[58]		
		51-120	31-97		
0.007	Mann-Whitney	38.6	21.47	Mean (s.d) [Median] Range	Fug10
		(17-98)	(18.7)		
		[43]	[14]		
		4-60	4-59		
0.002	Mann-Whitney	5.5	9.05	Mean (s.d) [Median] Range	NIH10
		(2.97)	(3.13)		
		[6]	[10]		
		0-12	4-14		
0.017	Mann-Whitney	1.47	2.4	Mean (s.d) [Median] Range	NIH10 hand
		(1.12)	(1.0)		
		[1]	[2]		
		0-4	1-4		
0.015	Mann-Whitney	8	15%	Till Vlue 3%	Muscle strength hand 10
		42.1%	78.9%		
		11	4	4-5	
		57.90%	21%		
0.001	Mann-Whitney	6	14	Till Vlue 3%	Muscle strength feet 10
		31.60%	73.70%		
		13	5	4-5	
		68.40%	26.40%		
0.479	Mann-Whitney	3.2	0.11	1-10	PAIN10
		(0.8)	(0.46)		
		[0]	[0]		
		'0-3	0-2		

The data from table 4b demonstrate a significant improvement in the therapy group in comparison to the control group after 10 days of treatment using the electrical stimulation in the evaluation indexes: NIH, FUGL-MEYER FIM, rough strength of hand and

Table 4c: Comparison of the different values, of the different groups, after one month

PV 2 – Sided	Statistical Test	Therapy group N=19	Control Group N=19	Statistical Index	Clinical Index
					Time 30:
0.006	Mann-Whitney	93.2	68.6	Mean	Fim30
		(20.6)	(24.2)	(s.d)	
		[87]	[67]	[Median]	
		66-126	31-105	Range	
0.004	Mann-Whitney	44.11	25.9	Mean	Fug30
		(14.6)	(18.9)	(s.d)	
		[48]	[20]	[Median]	
		7-60	4-59	Range	
0.004	Mann-Whitney	4.58	7.89	Mean	NIH30
		(2.65)	(3.5)	(s.d)	
		[5]	[8]	[Median]	
		0-10	2-14	Range	
0.018	Mann-Whitney	1.3	2.11	Mean	NIH hand 30
		(1.1)	(0.875)	(s.d)	
		[1]	[2]	[Median]	
		0-4	1-4	Range	
0.001	Mann-Whitney	6	14	Till value of 3%	Muscle strength hand 30
		31.60%	73.70%		
		13	5		
		68.40%	26.30%		
<0.001	Mann-Whitney	1	11	Till value of 3%	Muscle strength feet 30
		5.30%	57.90%		
		18	8	4-5	
		94.70%	42.20%		

The values in this table show an increase in all values of the therapy group in comparison to the control group.

Table number 4d: Comparison of the different Groups Index values after 3 months:

PV 2 – Sided	Statistical Test	Therapy Group N=19	Control Group N=19	Statistical Index	Clinical Index
					time 90:
0.001	Mann-Whitney	99.7 (19.6) [90] 66-126	72.37 (24.795) [77] 31-112	Mean (s.d) [Median] Range	Fim90
0.003	Mann-Whitney	47.2 (14.03) [51] 7-60	26.95 (19.5) [20] 4-59	Mean (s.d) [Median] Range	Fug90
0.002	Mann-Whitney	4 (2.2) [4] 0-8	7.42 (3.5) [8] 2-14	Mean (s.d) [Median] Range	NIH90
<0.001	Mann-Whitney	1 0.8% [1] 0-3	2 (0.82) [2] 1-4	Mean (s.d) [Median] Range	NIH90 hand
<0.001	Mann-Whitney	5 26.30% 14 73.7	14 73.70% 5 26.30%	Till Value 3%(including) Till Value 3%(including)	Muscle strength hand 90
<0.001	Mann-Whitney	1 5.30% 18 94.7	11 57.90% 8 42.20%	Till Value 3%(including) Till Value 3%(including)	Muscle strength feet 90

The values in this table show an increase in all values of the therapy group in comparison to the control group.

Table number 5a: Comparison of the values through time in the control group:

Indexes	time 0	time 10	time 30	time 90	Whole process
Mean Fim (S.D) Range PV	59.5 (20.05) 29.93	63.37 (19.4) 31-97 0.001 (**)	68.6 (24.2) 31-105 0.02 (**)	72.37 (24.795) 31-112 0.045 (**)	(*)P<0.001
Mean Fug (S.D) Range PV	20 (17.4) 4-59	21.47 (18.7) 4-59	25.9 (18.9) 4-59 0.021	26.95 (19.5) 4-59 0.14	(*)P<0.001
Mean NIH (S.D) Range PV	10.05 (3.13) 4-5	9.05 (3.13) 4-14 (**)0.001	7.89 (3.5) 2-14 (**)0.011	7.42 (3.5) 2-14 (**)0.055	(*)P<0.001
Mean hand NIH (S.D) Range PV	2.79 (1.1) 1-4	2.4 (1) 1-4 (**) 0.004	2.11 (0.875) 1-4 (**) 0.063	2 (0.82) 1-4 (**) 0.25	(*)P<0.001
Muscle strength hand until 3 including	16 84.20%	15 78.90%	14 73.70%	14 73.70%	(*)P<0.001
Above 3	3 15.80%	4 21%	5 26.30%	5 26.30%	
PV		(**)0.063	(**) 0.102	(**) 0.75	
Muscle strength feet until 3 including	17 89.50%	14 73.70%	11 57.90%	11 57.90%	(*)P<0.001
Above 3	2 10.60%	5 26.40%	8 42.20%	8 42.20%	
PV		(**) 0.004	(**) 0.008	(**) 0.281	
Mean Pain (S.D) Range PV	0.21 (0.92) 0-4	0.11 (0.46) 0-2 (**) 0.5	0.05 (0.23) 0-1 (**) 0.5	0 (0) 0-0 (**) 0.5	(*) 0.007

Friedman test (*) . Wilcoxon signed rank test (**).
The detailed analysis in the table shows that comparison of each two consecutive time points in the table points to an improvement of values:
NIH, FIM, FUGL-MEYER in each point in time. There is an improvement in the values of rough strength in the feet muscles, between 0 to 10 days, and 10 to 30 days, with no improvement between days 30 to 90.
There is a limited improvements in the values of rough strength of the hand muscles between 0 to 10 days, with no improvement between 10 to 30 days, and 30 to 90 days.

Table number 5b: Comparison of the values through time, therapy group:

Indexes	time 0	time 10	time 30	time 90	Whole process
Mean Fim (S.D) Range	66.2 (19.5) 36-110	83.1 -21.7 51-120 (**)0.001	93.2 (20.6) 66-126 (**)0.001	99.7 (19.6) 66-126 (**)0.001	P<0.001(*)
Mean Fug (S.D) Range	28.2 (18.4) 4-55	38.6 (17.98) 4-60 (**) 0.001	44.11 (14.6) 7-60 (**) 0.001	47.2 (14.03) 7-60 (**) 0.001	P<0.001(*)
Mean NIH (S.D) Range	7.8 (3.1) 2-16	1.47 (1.12) 0-4 (**) 0.001	1.3 (1.1) 0-4 (**) 0.002	1.00 (0.8) 0-3 (**) 0.031	P<0.001(*)
Mean hand NIH (S.D) Range PV	2.2 (1.08) 1-4	1.47 (1.12) 0-4) (**) 0.001	1.3 (1.1) 0-4 (**) 0.125	1.00 (0.8) 0-3 (**) 0.031	P<0.001(*)
Muscle hand strength 3 and below	15 78.90%	8 42.10%	6 31.60%	5 26.30%	P<0.001(*)
above 3	4 21%	11 57.90%	13 68.40%	14 73.70%	
PV		(**) 0.001	(**) 0.001	(**) 0.004	
Muscle leg strength 3 and below	15 78.90%	6 31.60%	1 5.30%	1 5.30%	P<0.001(*)
above 3	4 21.10%	13 68.40%	18 94.70%	18 94.70%	
PV		(**) 0.001	(**) 0.001	(**) 0.008	
Mean Pain (S.D) Range PV	6.3 (1.5) 0-5	3.2 (0.8) 0-3 (**) 0.25	0.11 (0.3) 0-1 (**) 0.25	0.11 (0.3) 0-1 (**) 0.25	0.007(*)

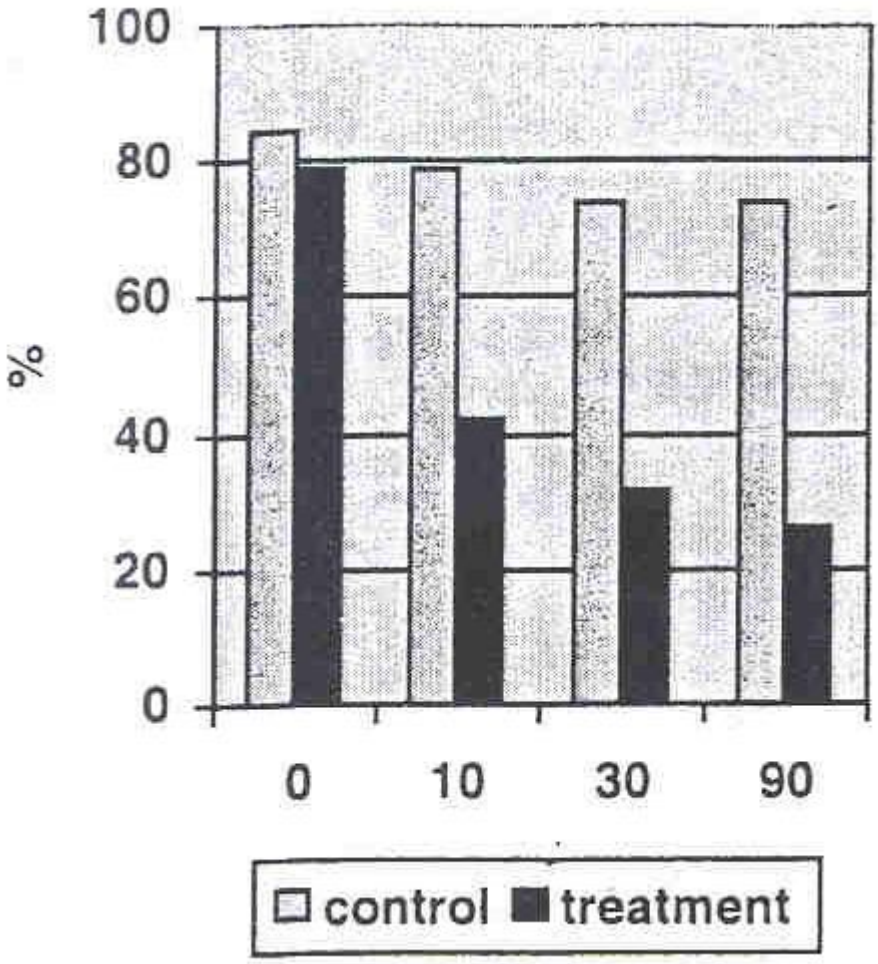
Friedman test (*)
Wilcoxon signed rank test (**).
The values from this table show that there is an improvement in all values, between all 2 consecutive points in time.

Discussion:

A brain stroke is the main reason for long term functional disabilities in most of the industrialized countries. The age of patient at the time of the CVA is a significant risk factor, especially since the chance of suffering a CVA injury is doubled every decade after the age of 55.
Every year, 2-4 people per thousand, suffer a CVA. Out of them, 75% suffered from paralysis and motor limitations, which lead to a reduction in quality of life, and the patients, become a burden on society and their close environment.
In the last few years there have been reports which indicate and improvement in limb function, in patients who have suffered an acute CVA and were treated with physiotherapy and occupational therapy in combination with FES (9,13,14) . This method of therapy now defined as ELECTRICAL FUNCTIONAL THERAPY (15).
A number of studies have been published which support the notion that treatment with FES leads to an improvement in motor function of the paralyzed hand, with patients who have suffered a chronic CVA (2,10).
In our study, we have found that therapy which combines FES, physiotherapy and occupational therapy during the acute stage of the CVA, accelerates the clinical improvement of the damaged hand and feet function in any point in time.
This improvement continues at a quicker rate, even after one and three months. This is in comparison with the control group which received only conventional therapy consisting of occupational therapy and physiotherapy.
This improvement was found in all values examined: FUGL-MEYER, FIM, NIH.
It should be noted that electrical stimulation improved/lessened the feeling of pain in a small group of people who experienced pain in the limb, as measured according to the VISUAL ANALOG SCALE on a scale of 0-10.
The suffering from the pain lessened to 0-1.
In our study, we did not find a statistical improvement in muscle tone in the injured hand and foot, in contrast to POPOVIC (15) which demonstrated that FES led to a decrease in spasticity.
Patients, who received treatment of electrical stimulation, did not report feeling uncomfortable of in pain. This is in contrast to reports from CHAE (9).
In our study we found that electrical stimulation improves motor function in the upper and lower limbs in patients, who suffered from an acute CVA, and this improvement was significant and continued 3 months after the treatment ended.
Our study found that in addition to motor improvement, there was also functional improvement.
Beginning the rehabilitation process early, using a combination of treatments including: electrical stimulation, occupational and physiotherapy leads to a quicker and more qualitative recovery.

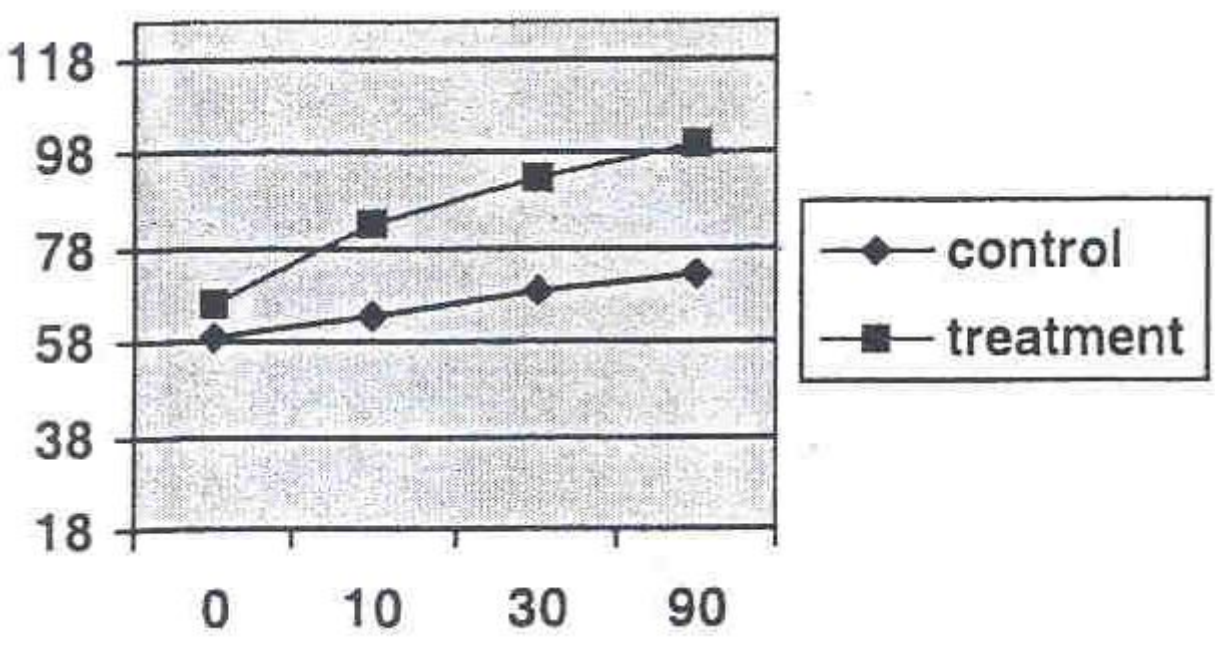
Percentage of patients with hand muscle strength 3 and below

Graph 1: Indicates the decrease in the percentage of patients which were left with rough strength 3 and below, During 90 days.

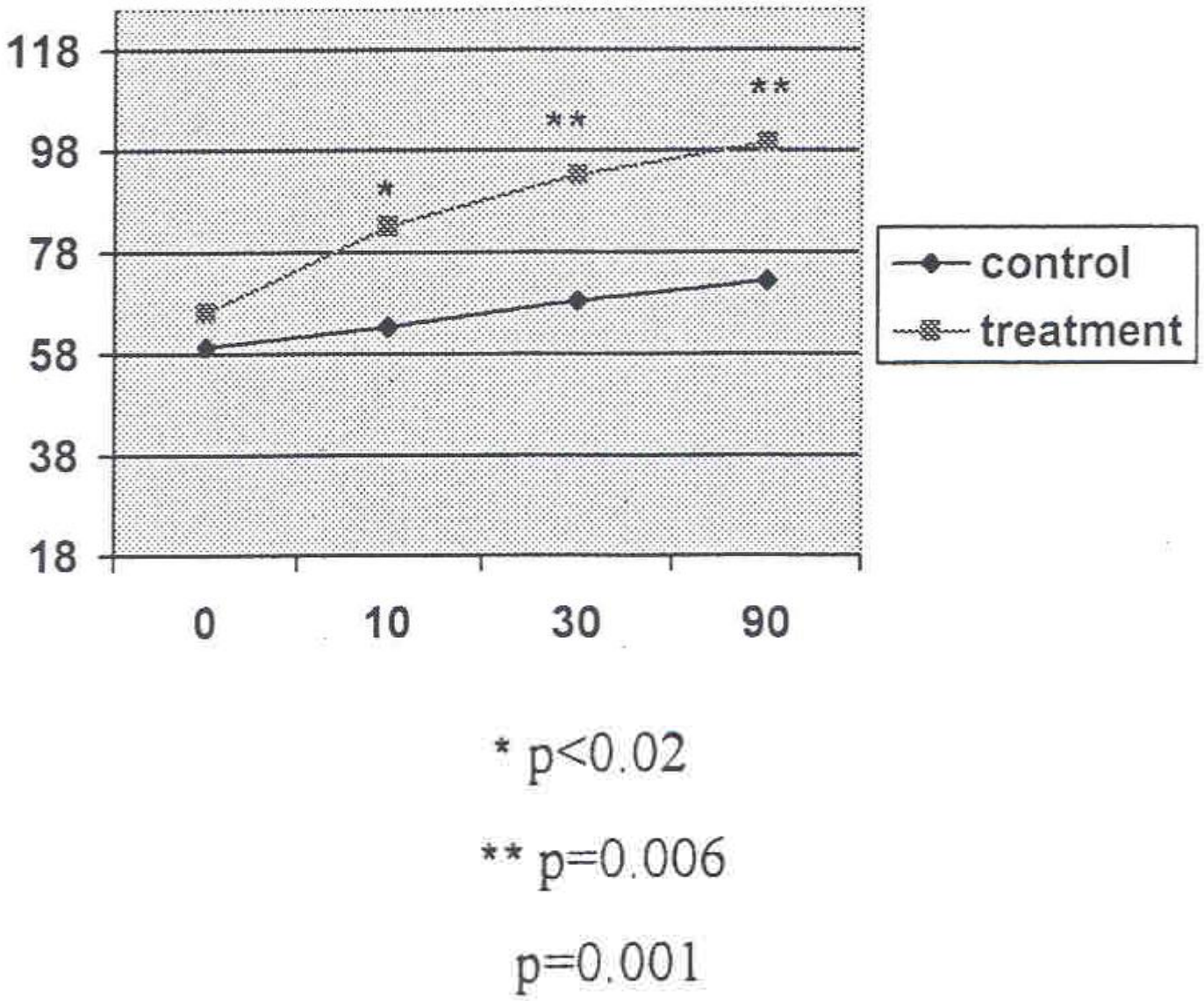


Change in FIM values according to time.

Graph 2: Indicates the improvement in functional abilities according to the FIM index throughout 90 days.

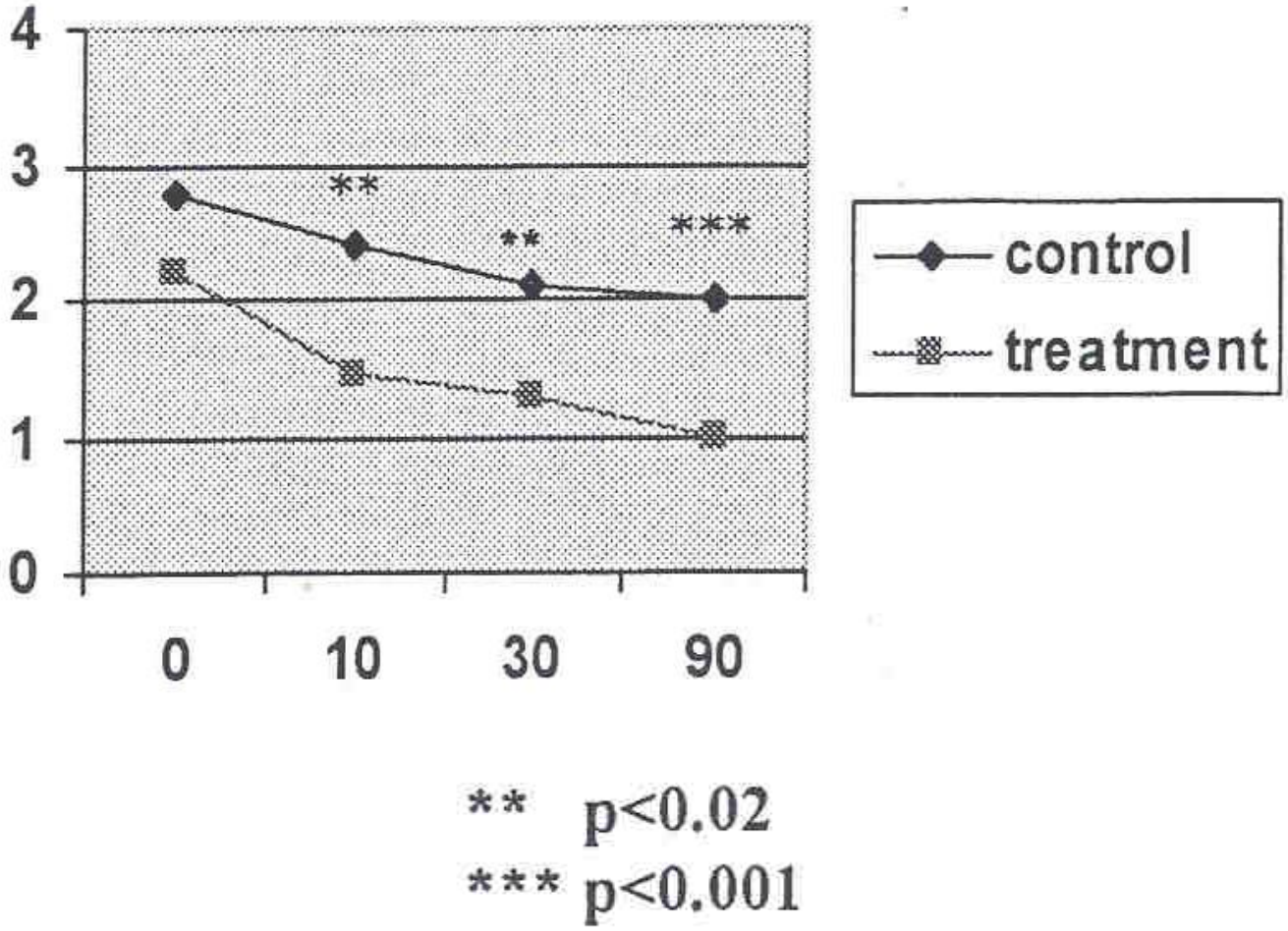


Changes in the FIM index according to time.



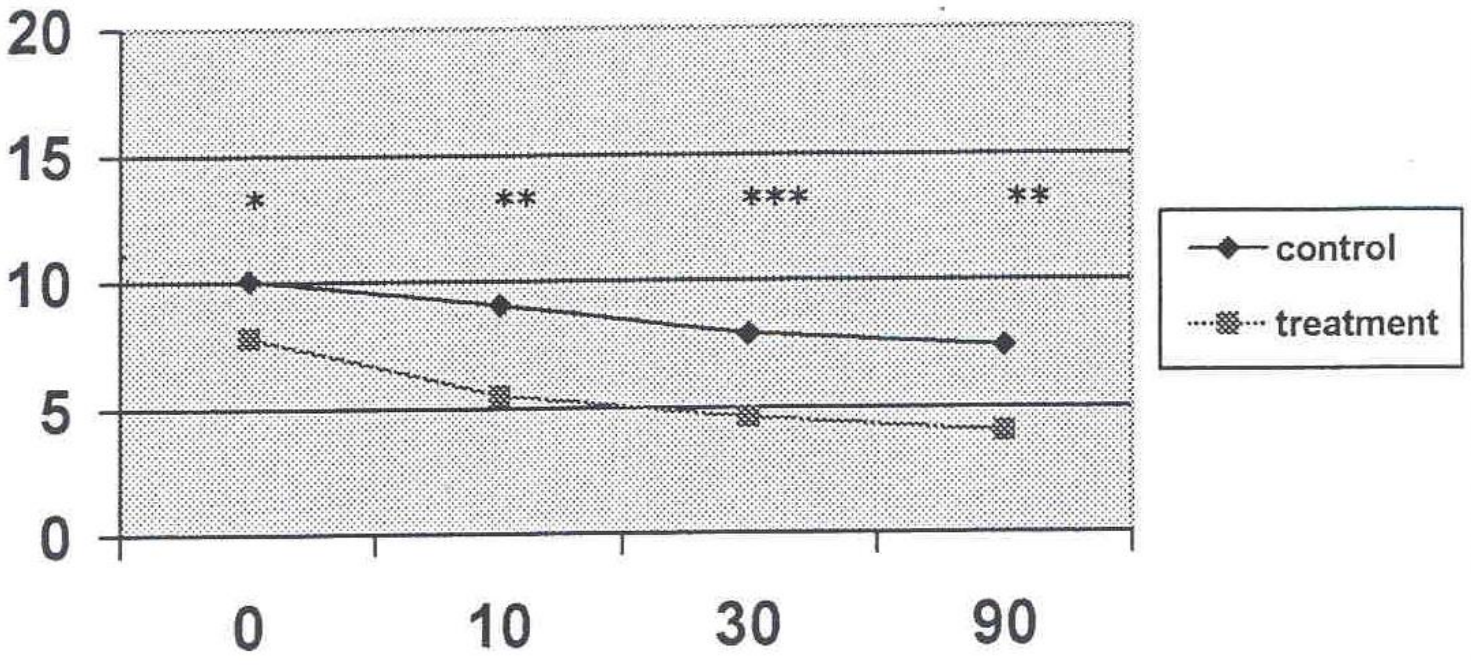
Graph 3- Changes in the FIM index according to time, in the 2 groups is represented in graph number 1. An improvement in daily function was seen in both groups, but in the treatment group there was a more significant improvement in comparison to the control group.

Changes in hand NIH according to time.



Graph 4: Change in the rough strength of hand muscles with time in both groups is represented in graph number 2. The estimation was carried out using the NIH scale (from 0 to 4). An improvement in rough hand strength was more significant in the therapy group in comparison to the control group.

Changes of NIH with time



* $p<0.04$

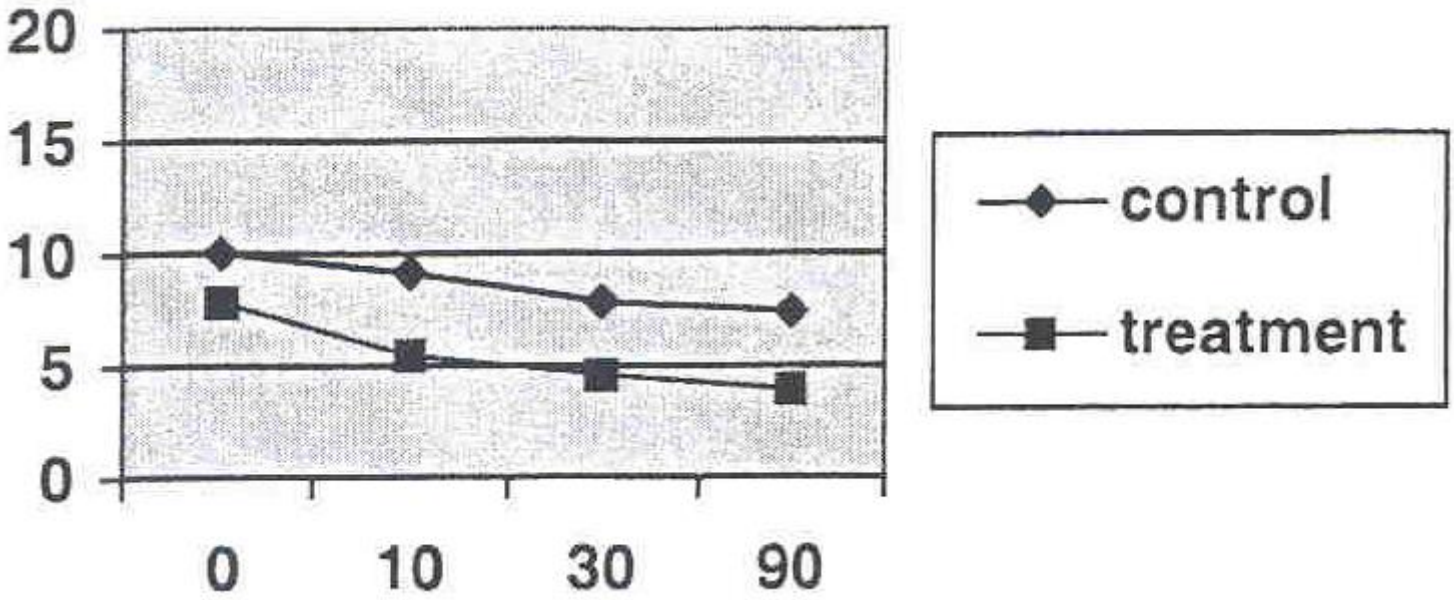
** $p=0.002$

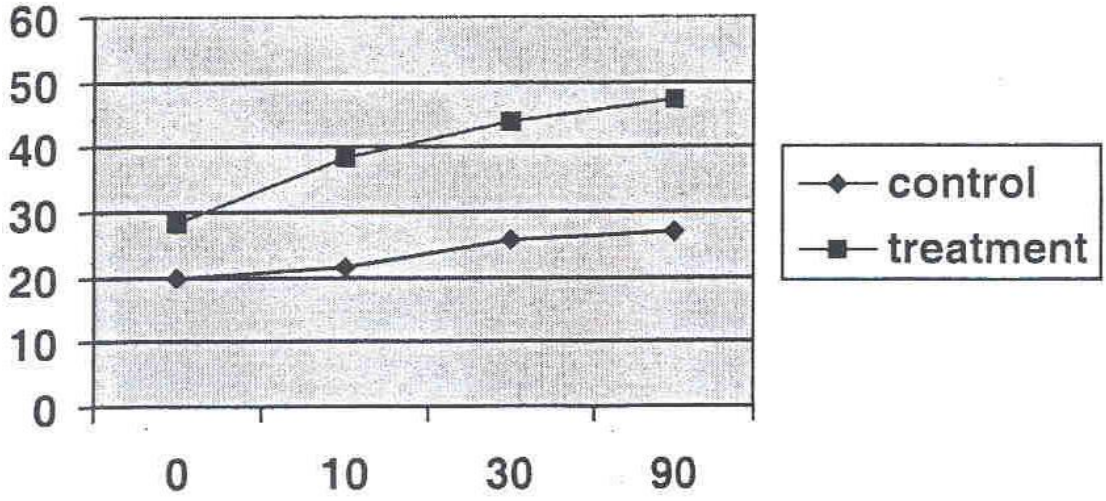
*** $p<0.004$

Graph 5: Changes of NIH (severity of the CVA) with time is displayed in graph number 5, and shows a more significant improvement in the therapy group in comparison with the control group.

Changes of NIH with time

Graph 6 shows the decrease in neurological deficit with time.

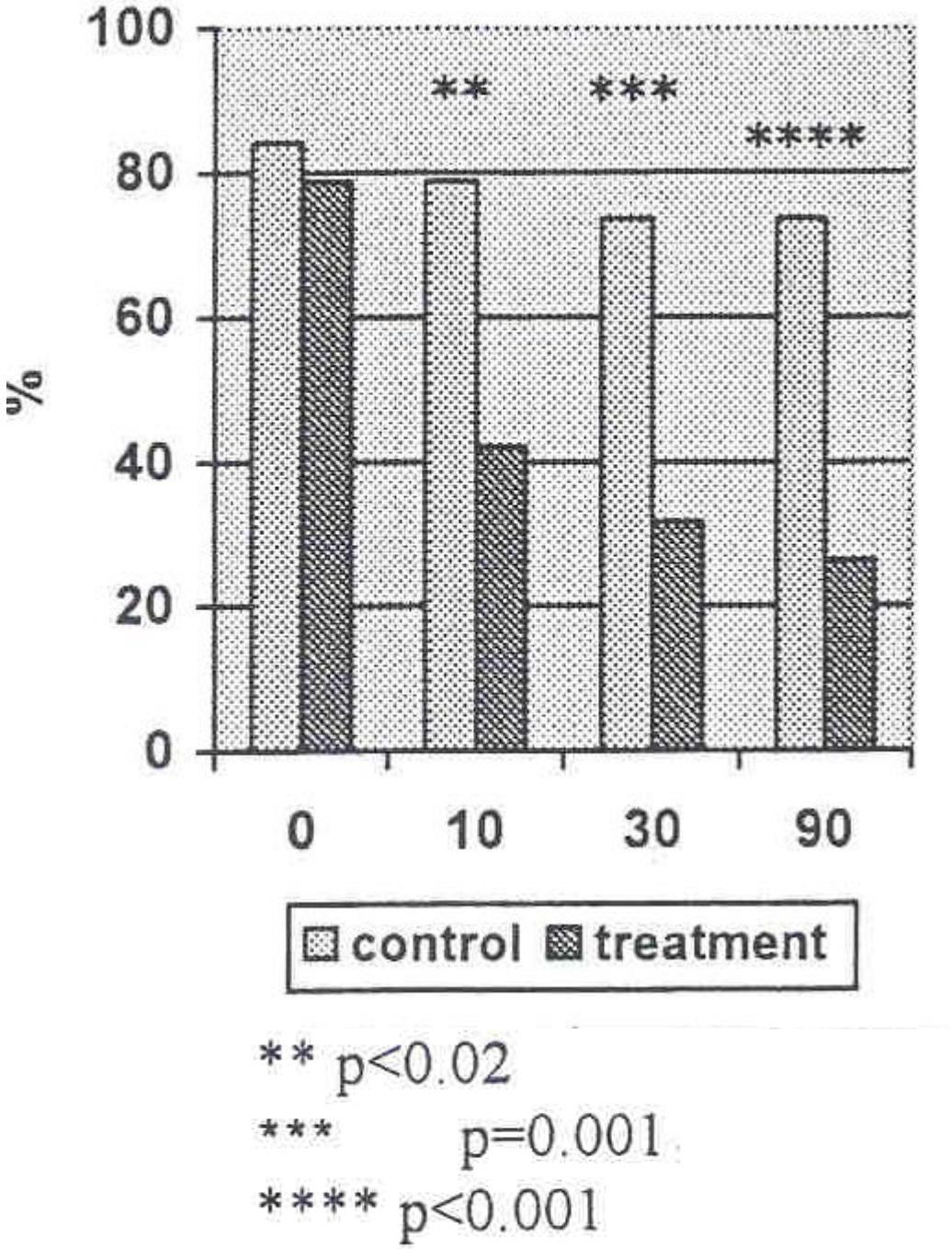




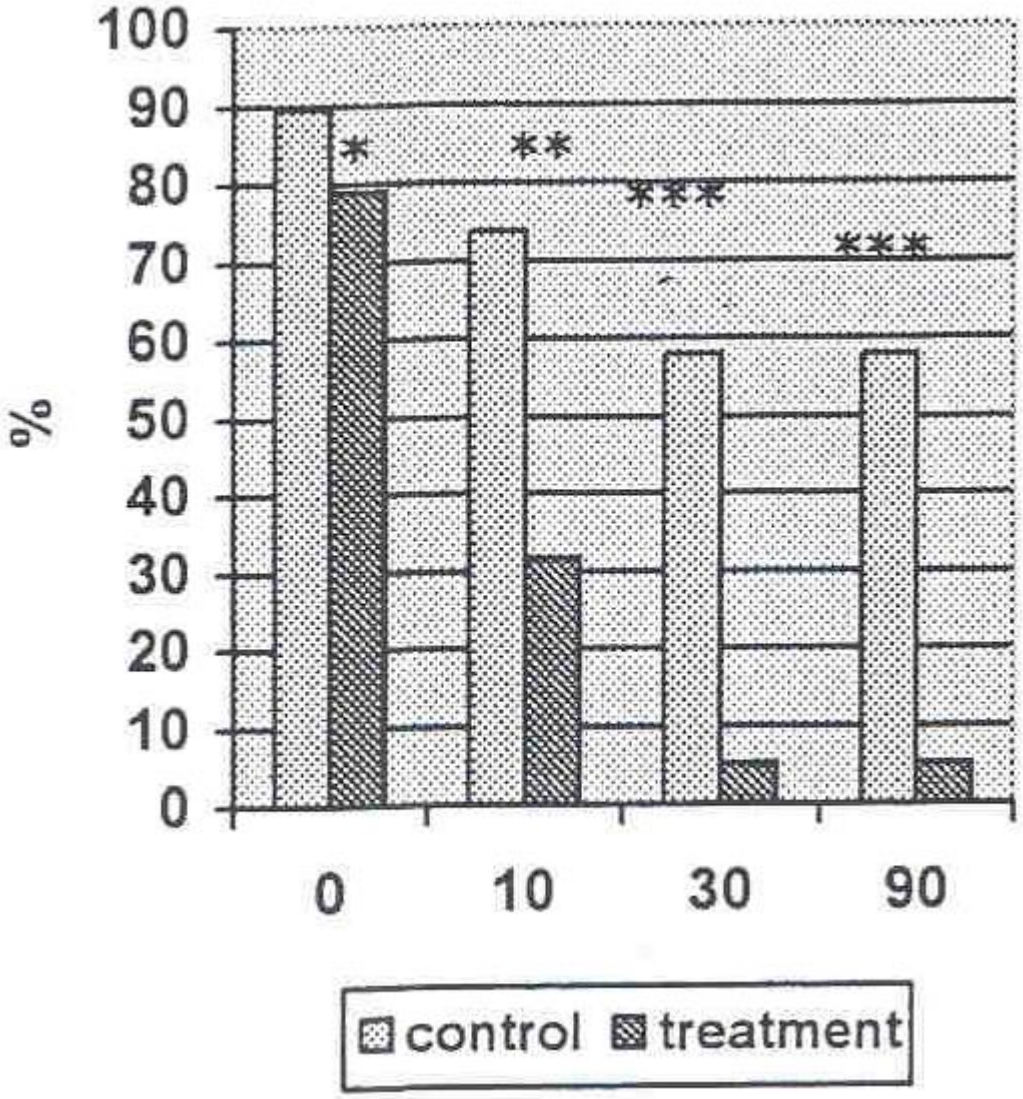
Graph 7: Indicates the improvement of motor ability according to the Fugel Meyer Assessment index.

Conclusions: In this study it has been found that electrical stimulation using FES improves motor recovery in upper and lower limbs following an acute CVA. This improvement in prominent and continues three months after concluding treatment with FES. In addition, it has been found that in addition to motor improvement, there is also functional improvement. Therefore, the use of treatment which combines electrical stimulation- FES, occupational and physiotherapy, in comparison to rehabilitation treatment without FES, brings to quicker and more qualitative motor and functional improvement, than rehabilitation treatment without FES.

Graph 8:.Percentage of patients with hand - muscle strength 3 and below.

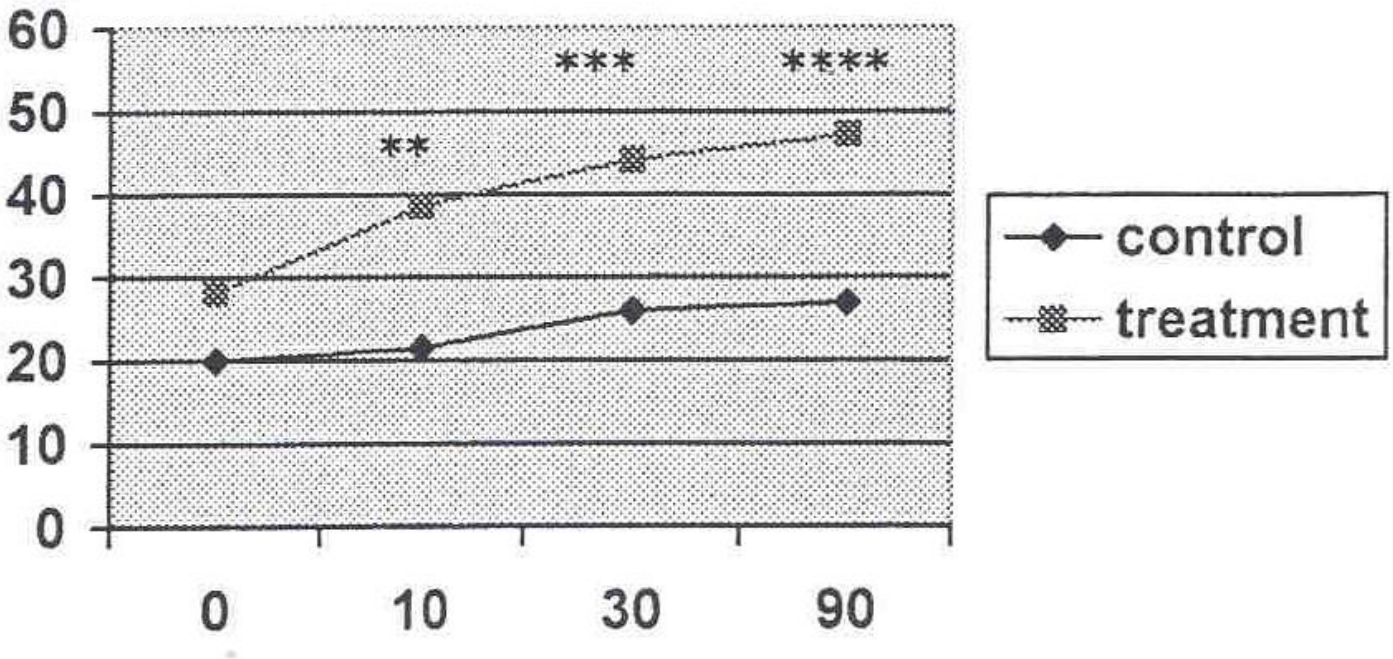


Graph 9: Percentage of patients with foot muscle strength 3 and below



Graph numbers 8 and 9: show the percentage of patients who experienced an improvement in rough strength in the limbs was significantly higher in the therapy group than in the control group.

Change in FUG –Meyer Test with Time



** p=0.007

*** p=0.004

**** p=0.003

Graph 10: shows a change in hand function which was determined using the FUGL-MEYER TEST. As can be seen, hand function improved in both groups, but the improvement was more significant in the therapy group.

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